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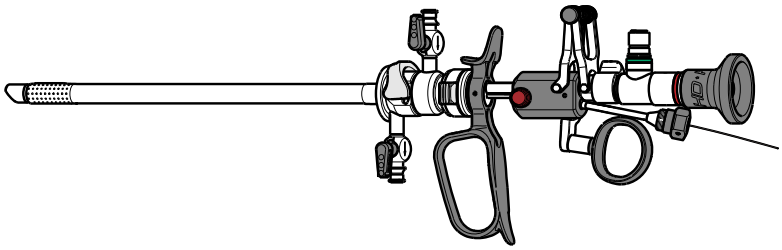
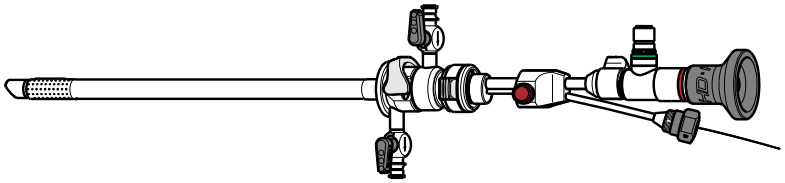
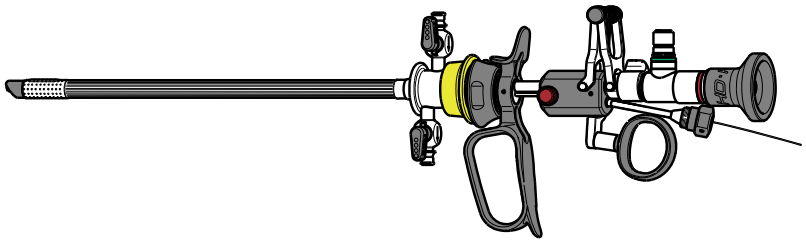
Instructions for use







Laser Resectoscopes

GA-D374 / en / US / V1.0 / 2024-03 /

Subject to technical changes!

Due to ongoing development, the product descriptions, figures, and technical data may deviate slightly from the current state.
For further information about our products, please contact Richard Wolf GmbH or a local representative.

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Contents

1 General information

1.1 Safety instructions and levels of danger

⚠ WARNING

This signal word is used to indicate a potentially dangerous situation. Not avoiding this situation can result in death or extremely serious injuries.

⚠ CAUTION

This signal word is used to indicate a potentially dangerous situation. Not avoiding this situation can result in minor or moderate injury.

ATTENTION

This signal word without warning sign is used to indicate a potential danger of material damage.

NOTICE

This signal word indicates additional useful information for the reader, such as hints for easier operation as well as cross references.

1.2 Symbols

Symbols	Designation
	Follow the manual
MD	Medical device
REF	Product number
SN	Serial Number
LOT	Lot code
	Manufacturer
	Manufacturing date
	Number, amount
	Data Matrix Code
Rx ONLY	Federal law restricts this device to sale by or on the order of a physician.
CE 0124	CE identification with code number of the competent authority in conformity with Directive 93/42/EEC on medical products or EU regulation 2017/745 on medical products. **Only valid** if the product and/or the packaging is marked with this identification. Products where a notified body is not involved in the conformity assessment procedure are marked with the CE-identification without the code number of the notified body. The CE identification on the title page of these instructions for use relates exclusively to the Richard Wolf main product or, if serveal identical products are described, to the Richard Wolf product with the highest classification. The CE identification of the other Richard Wolf products and, if applicable, of products made by other manufacturers, described in these instructions for use results exclusively from the identification on the product and/or packaging.

2 General safety instructions and guidance for use

The product must only be used as intended following the instruction manual by adequately trained and qualified medical personnel. Maintenance and repair must be carried out by authorized experts.

Use the product only in the combinations and with the accessories and spare parts specified in this instruction manual. Use other combinations, accessories and replacement parts only if they are expressly intended for the planned application and if the performance characteristics and safety requirements are met. The product must not be altered in any way.

Reprocess the products in accordance with the manual before every use and before return shipment to protect the patient, user and third parties.

This manual is an integral part of the product and must be stored in such a way that it is accessible at any time during its entire life cycle. This manual must be passed on to any subsequent owner or user.

Immediately on receipt, check the product and its accessories for completeness and possible damage. Should the shipment give rise to complaints, please inform the manufacturer or supplier immediately.

Any severe incident occurring in conjunction with this product must be reported to the manufacturer.

⚠ CAUTION

Federal law restricts this device to sale by or on the order of a physician.

3 Product description

For diagnosis and therapy via transurethral access in the lower urinary tract, e.g., TURP (transurethral resection of the prostate) or via percutaneous access for renal pelvic tumors or stenoses.

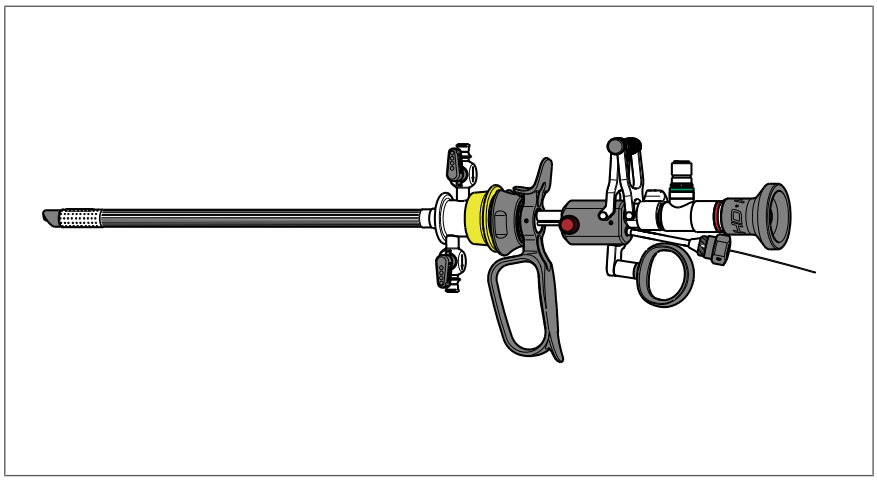
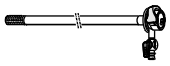
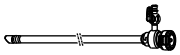
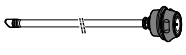


Fig. 1

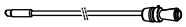
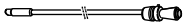
OUTER SHEATH

	8655314 OUTER SHEATH FOR LASER THERAPY 24.5 FR. Color code green, SL 191 mm, round, not rotatable, distal end straight, continuous irrigation, compatible with inner sheath 8655324, and telescopes Ø 4 mm, 12°/30°, with irrigation valve, E-Line quick-release mechanism, reusable
	8675426 OUTER SHEATH FOR RESECTOSCOPE 26 FR. SL 189 mm, round, rotatable, distal end straight, continuous irrigation, compatible with Shark inner sheath 8675324, and telescopes Ø 4 mm, 0°/12°/30°, snap-on lock, reusable

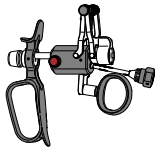
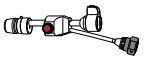
INNER SHEATH

	8655324 INNER SHEATH FOR LASER THERAPY 22 FR. Color code green, SL 206 mm, round, distal end oblique, stainless steel, continuous irrigation, compatible with outer sheath 8655314, and telescopes Ø 4 mm, 12°/30°, with irrigation valve, quick-release mechanism, reusable
	8675524 INNER SHEATH FOR LASER THERAPY 24 FR. Color code yellow, SL 203 mm, round, rotatable, distal end oblique, stainless steel, continuous irrigation, compatible with Shark outer sheath 8675426, and telescopes Ø 4 mm, 0°/12°/30°, snap-on lock, reusable

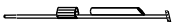
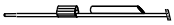
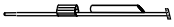
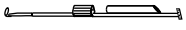
OBTURATOR

	865415 OBTURATOR FOR RESECTOSCOPE 22 FR. Color code green, WL 231 mm, round, distal end rounded, compatible with E-Line sheath 8655324, reusable
	8673324 OBTURATOR FOR RESECTOSCOPE 24 FR. Color code yellow, WL 232 mm, round, distal end rounded, compatible with Shark inner sheath 8675524, reusable

WORKING ELEMENT AND WORKING INSERT

	8654382 LASER WORKING ELEMENT, PASSIVE 12/30° Closed, with locking mechanism for laser fiber, compatible with telescopes Ø 4 mm, bayonet lock, reusable
	8654383 LASER WORKING INSERT 12/30° With locking mechanism for laser fiber, compatible with telescopes Ø 4 mm, bayonet lock, reusable

GUIDE TUBES

	8654990 GUIDE TUBE LASER THERAPY 1,000 µM 22 FR. With lateral guide, distal end straight, reusable
	8654991 GUIDE TUBE LASER THERAPY 1,000 µM 24 FR. With lateral guide, distal end straight, reusable
	8654992 GUIDE TUBE LASER THERAPY 600 µM 22 FR. With lateral guide, distal end straight, reusable
	8654993 GUIDE TUBE LASER THERAPY 600 µM 24 FR. With lateral guide, distal end straight, reusable
	8654994 GUIDE TUBE LASER THERAPY 600 µM 22 FR. With lateral guide, distal end oblique, reusable
	8654995 GUIDE TUBE LASER THERAPY 600 µM 24 FR. With lateral guide, distal end oblique, reusable
	8654996 GUIDE TUBE LASER THERAPY 600 µM 22 FR. With lateral guide, distal end with ring, reusable
	8654997 GUIDE TUBE LASER THERAPY 600 µM 24 FR. With lateral guide, distal end with ring, reusable

CURETTE

	8654998 CURETTE 22–24 FR. For continuous irrigation laser resectoscope, for prostate chips, reusable

4 Indications for use

4.1 Statement

Resectoscopes are used for endoscopically controlled ablation of tissue. They are used, in combination with endoscopic accessories, for examination, diagnosis, and/or therapy in vaious medical disciplines, such as urology and gynecology.

Application

TURP (Transurethral Resection of the Prostate), TURBT (Transurethreal Resection of Bladder Tumors), adenomas, myoma resection, soft tissue tumor, endometrium ablation, as well as slitting of the neck of the bladder and incision of the prostate.

4.2 Intended Use of the Resectoscope Parts

Laser resectoscope outer sheaths

The products are used for accessing the operating field, as well as for drainage or suction of irrigation fluid and resected tissue.

Laser resectoscope sheaths for blunt preparation – with irrigation connector

The products are used for the blunt preparation of tissue and for the supply of irrigation fluid.

Laser resectoscope sheaths for blunt preparation – without irrigation connector

The products are used for the blunt preparation of tissue and for receiving working elements.

Resectoscope sheaths – irrigation and drainage connections

The products are used for the supply of irrigation fluid and for suction of fluid and tissue.

Resectoscope obturators

The products are used for atraumatic insertion of resectoscope sheaths, which are used in combination with additional resectoscope components for endoscopically controlled tissue ablation.

Laser resectoscope working elements

The products are used for holding and attaching telescopes, laser fiber guide tubes, and auxiliary instruments as well as for guiding and inserting laser fibers, laser probes, and medical instruments into the operating field in a controlled manner.

Laser resectoscope working inserts

The products are used for holding and attaching telescopes and laser fiber guide tubes as well as for guiding and inserting laser fibers/laser probes into the operating field in a controlled manner.

Laser resectoscope guide tubes

The products are used for guiding laser fibers along a telescope.

Laser resectoscope guide tubes with bracket

The products are used for guiding laser fibers along a telescope and for keeping tissue away when inserting thinner laser fibers.

Laser resectoscope curettes

The products are used for removing any tissue remnants from the body cavity after morcellation.

4.3 User and Patient Population

User

These products are exclusively intended for use by specialized medical personnel and must only be used by medically qualified and adequately instructed persons.

Patient population

The product is intended for adult patients.

The patient population intended for the application of the medical product herein described is not limited with regard to ethnicity, gender, body height and weight. Before use, the attending physician must make sure that the product in view of its dimensions or settings can be used safely in the patient.

5 Contraindications and side effects

5.1 Contraindications

The following contraindications apply for resection in hysteroscopy:

Myomas that are not suitable for resection, i.e., no possibility to separate the myoma due to its size, such as intramural myomas with small submucosal parts.

If there are medical contraindications for hysteroscopy, such as pregnancy, use with the products concerned is excluded.

There are currently no known contraindications in urology directly related to the products. If there are medical contraindications for the interventions listed, use with the products concerned is excluded.

5.2 Side effects

No side effects directly related to the product are known if the system is used as intended.

6 Combination

⚠ CAUTION

Be careful not to combine products incorrectly!

Injuries of the patient, user or others as well as damage to the product are possible.

- The products must only be used jointly if the intended use and the relevant technical data such as working length, diameter, etc. are the same.
- Also follow the instruction manuals of the products used in conjunction with this product.

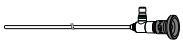
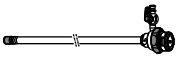
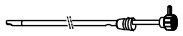
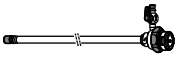
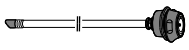
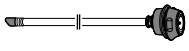
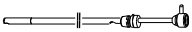
ATTENTION

Only insert the curette (1a) in combination with the working element (2).

6.1 Overview of permissible combinations and requirements

The products are used with:

- Endoscopic cameras and light sources
- Endoscopic devices
- Laser surgical devices
- Endoscopic instruments and accessories
- Surgical instruments and accessories
- Laser fibers
- Suction and irrigation devices

Item	Figure	Product no.	Designation, technical data	
			ENDOSCOPES **See GA-S001**	
3		**8654.431**	**TELESCOPE 12° Ø 4 MM WL 297 MM** Total length = 361.7 mm; working length = 302.6 mm, direction of view 12°; object field angle 60°; outer Ø = 4.0 mm	
		**8654.422**	**TELESCOPE 30° Ø 4 MM WL 300 MM** Total length = 362.1 mm; working length = 305 mm, direction of view 30°; object field angle 60°; outer Ø = 4.0 mm	
			"E-Line" CONTINUOUS IRRIGTION DOUBLE SHEATH SYSTEM **See GA-D345**	**Color coding**
4		8655.334	OUTER SHEATH FOR RESECTOSCOPE 24.5 FR.	Green
5		8655.344	INNER SHEATH FOR RESECTOSCOPE 22 FR.	
6		8654.16	OBTURATOR FOR RESECTOSCOPE 22 FR.	
-		8415.11	VIEWING OBTURATOR FOR RESECTOSCOPE 22 FR.	
-		8655.374	OUTER SHEATH FOR RESECTOSCOPE 26 FR.	Yellow
-		8655.384	INNER SHEATH FOR RESECTOSCOPE 24 FR.	
-		8654.17	OBTURATOR FOR RESECTOSCOPE 24 FR.	
-		8415.12	VIEWING OBTURATOR FOR RESECTOSCOPE 24 FR.	
-		8654.175	DILATATIONS OBTURATOR FOR RESECTOSCOPE 24 FR.	
Item	**Figure**	**Product no.**	**Designation, technical data**	
			"Shark" RESECTOSCOPE CONTINUOUS IRRIGATION DOUBLE SHEATH SYSTEM **See GA-D366**	**Color coding**
-		8675424	OUTER SHEATH FOR RESECTOSCOPE 24 FR.	Green
-		8675322	INNER SHEATH FOR RESECTOSCOPE 22 FR.	
-		8673022	OBTURATOR FOR RESECTOSCOPE 22 FR.	
-		8673122	VIEWING OBTURATOR FOR RESECTOSCOPE 22 FR.	
-		8675426	OUTER SHEATH FOR RESECTOSCOPE 26 FR.	Yellow
-		8675324	INNER SHEATH FOR RESECTOSCOPE 24 FR.	
-		8673024	OBTURATOR FOR RESECTOSCOPE 24 FR.	
-		8673124	VIEWING OBTURATOR FOR RESECTOSCOPE 24 FR.	
-		8673224	DILATATIONS OBTURATOR FOR RESECTOSCOPE 24 FR.	

7 Illustration

7.1 Laser resectoscope – continuous irrigation double sheath system (22 / 24.5 Fr.), not rotatable

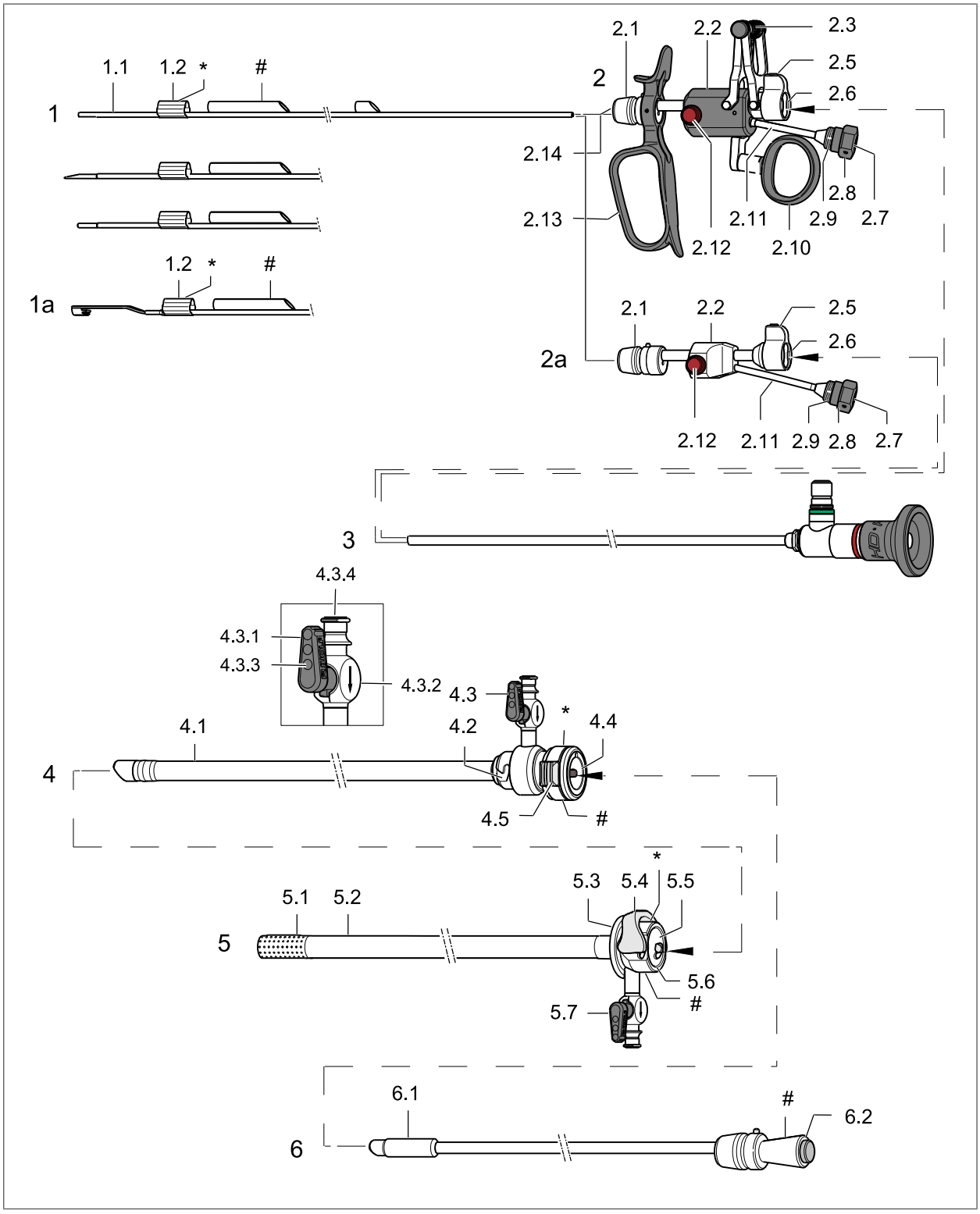


Fig. 2

Item	Designation	Item	Designation
1	Laser fiber guide tubes	4.1	Sheath tube
1a	Curette	4.2	Recess
1.1	Guide tube	4.3	Removable irrigation valve
1.2	Profile tube	4.3.1	Stopcock insert
*	Capacity in µ	4.3.2	Stopcock housing
2	Working element	4.3.3	Capacity indicator on stopcock insert / stopcock housing
2a	Working insert	4.3.4	Luer fitting
2.1	Locking cone	4.4	Locking mechanism
2.2	Lock body / adapter	4.5	Tab with color coding
2.3	Spring	*	French / Fr. specification
2.4	Not assigned	5	Continuous irrigation outer sheath 24.5 Fr.
2.5	Clamping handle	5.1	Drain openings (suction openings)
2.6	Locking mechanism	5.2	Sheath tube
2.7	Clamping sleeve	5.3	Guide washer
2.8	Internal seal	5.4	Bracket with color coding
2.9	Instrument ports	5.5	Pin
2.10	Thumb ring	5.6	Locking mechanism
2.11	Probe guide channel	5.7	Outlet tap (see item 4.3.1 – 4.3.4)
2.12	Pushbutton	*	French / CH specification
2.13	Handle closed	6	Obturator
2.14	Recording	6.1	Obturator piston
3	Telescope 12° / 30°	6.2	Handle with color coding
4	Continuous irrigation inner sheath 22 Fr.	#	Product no.

ATTENTION

Only insert the curette (1a) in combination with the working element (2).

7.2 Laser resectoscope – continuous irrigation double sheath system (24 / 26 Fr.), rotatable

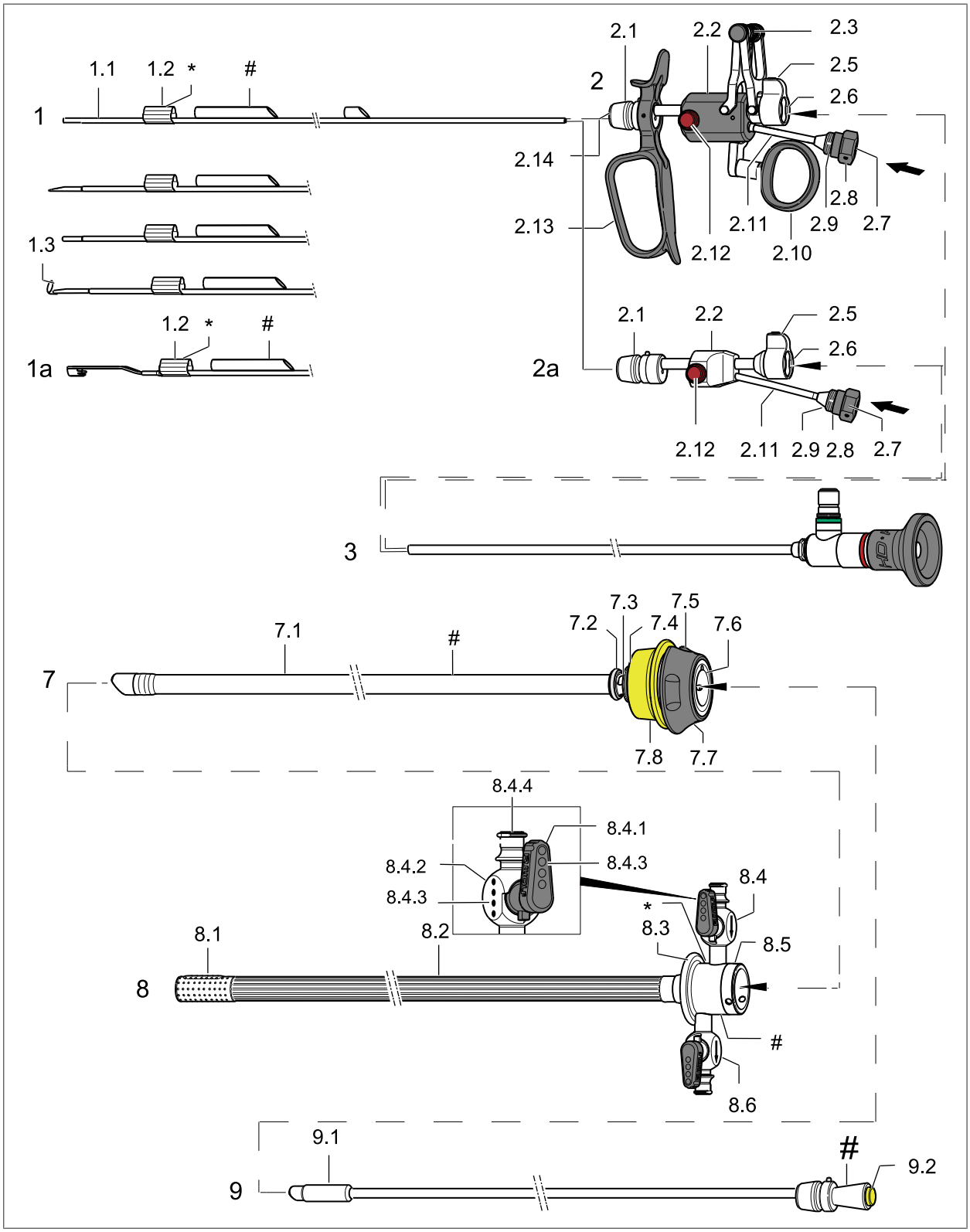


Fig. 3

Item	Designation	Item	Designation
1	Laser fiber guide tubes	7	Inner sheath 24 Fr.
1a	Curette	7.1	Sheath tube
1.1	Guide tube	7.2	O-ring
1.2	Profile tube	7.3	Irrigation holes
1.3	Bracket	7.4	O-ring
*	Capacity in µ	7.5	Recess (for orientation)
2	Working element	7.6	Lock rotating part
2a	Working insert	7.7	Actuating ring
2.1	Locking cone	7.8	Outer ring with color coding
2.2	Lock body / adapter	8	Outer sheath 26 Fr.
2.3	Spring	8.1	Drain openings (suction openings)
2.4	Not assigned	8.2	Sheath tube
2.5	Clamping handle	8.3	Guide washer
2.6	Locking mechanism	8.4	Removable irrigation valve
2.7	Clamping sleeve	8.4.1	Stopcock insert
2.8	Internal seal	8.4.2	Stopcock housing
2.9	Instrument ports	8.4.3	Capacity indicator on stopcock insert / stopcock housing
2.10	Thumb ring	8.4.4	Luer fitting
2.11	Probe guide channel	8.5	Ball catch
2.12	Pushbutton	8.6	Outlet tap
2.13	Handle closed	*	French / Fr. specification
2.14	Recording	9	Obturator
3	Telescope 12° / 30°	9.1	Obturator piston
		9.2	Handle with color coding
		#	Product no.

ATTENTION

Only insert the curette (1a) in combination with the working element (2).

8 Checks

⚠ WARNING

Injuries by damaged or incomplete products!

Injuries of the patient, user and others are possible.

- Do not use the products if they are damaged, incomplete or have loose parts.
- Run through the checks before and after each use.

ATTENTION

Send in damaged or incomplete products together with any loose parts for repair. Repair only by authorized experts.

8.1 Visual checks

1. Check instruments and accessories for:
   - ⇨ Damage
   - ⇨ Sharp edges
   - ⇨ Loose or missing parts
   - ⇨ Raw surfaces.
2. Any inscription, lettering, or labeling necessary for the safe and intended use must be legible.

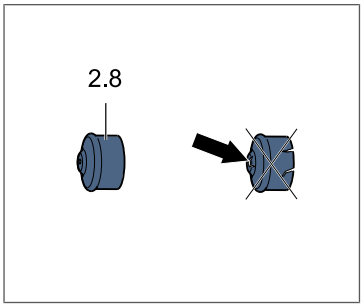


Fig. 4

Fig. 4

– Check the seal (2.8) for damage.
   - ⇨ Replace brittle and cracked seals (2.8).

8.1.1 Inner sheath with distal ceramic tip

⚠ WARNING

Danger of injury!

Improper handling, e.g., dropping, impact, shock, or similar mechanical stress can lead to hairline cracks and / or ceramic chipping in the distal region of the inner sheath.

Injuries to the patient, user, and others are possible.

Look out for surface changes and ensure safe handling.

Do not use a damaged inner sheath, and return it for repair.

NOTICE

Only for the "E-Line" and "Shark" inner sheaths with distal ceramic tip used in combination.

Fig. 5

1. Check the ceramic insulation at the distal end of the inner sheath for damage before each use.

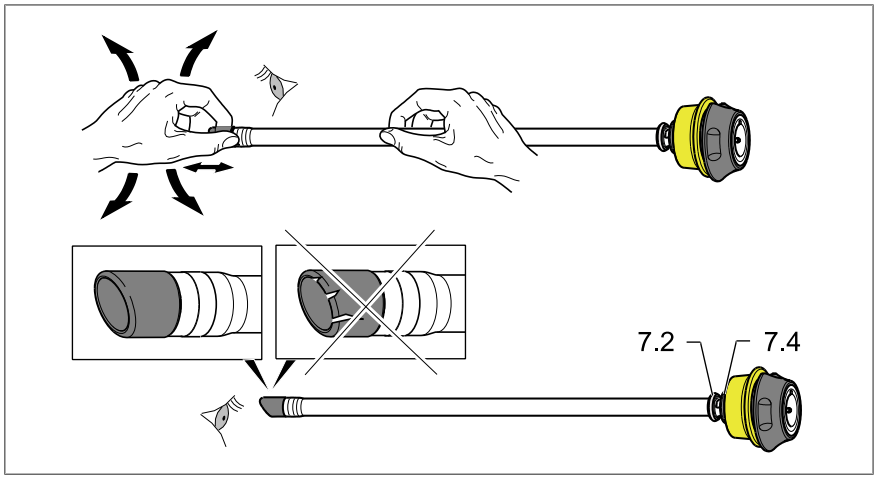


Fig. 5

2. Replace damaged or cracked O-rings (7.2) (7.4).

8.2 Function check

1. Check the compatibility of the individual components.
2. Check that the individual connections are fitted securely.
3. Check the easy assembly and locking mechanisms of the individual instruments. Replace instruments if the connection
   ⇨ does not hold despite locking,
   ⇨ cannot be locked, or can only be locked with difficulty.
4. Check for easy insertion of the laser fiber through the probe guide channel (2.11) and guide tube (1.1).
5. Check the clamping of the laser fiber with the clamping sleeve (2.7).
6. Check the working element (2) with laser fiber guide tube (1) moves freely in the inner sheath (4) (7).
   ⇨ The laser fiber guide tube (1) / curette (1a) must be able to move in the inner sheath (4) (7) via the working element (2) without exerting a great deal of force.
7. Check the continuity of the guide tube (1.1).
8. Check the image quality.
9. Check the irrigation and suction function.
10. Check the entire system for leaks and continuity.

Additionally with "Shark" resectoscope:

– Check the rotatability of the resectoscope.

8.2.1 Stopcock insert

Fig. 6

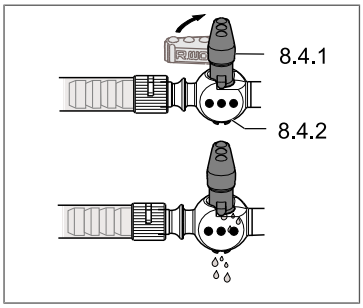


Fig. 6

1. Check that the stopcock insert (8.4.1) can be felt to engage in the stopcock housing (8.4.2).
2. Check the stopcocks (8.4) for leaks.
   ⇨ Turn the stopcock insert (8.4.1) to the locked position.
   ⇨ If the stopcock is not leak tight: Replace the stopcock insert (8.4.2).
3. Check the stopcock insert (8.4.1) for easy operation in the stopcock housing (8.4.2).

8.3 Service life

ATTENTION

For the service life of the products, careful and gentle handling during use and during the entire reprocessing process is essential.

When used as intended and following the instructions in the manufacturer's instructions for use, it is not necessary to limit the service life of the medical products.

If one or several criteria of the described checks are not passed, the medical product must be replaced or returned for repair (by the OEM or a repair facility authorized by the OEM) if necessary.

9 Use

⚠ WARNING

Danger of injury during HF application with continuous irrigation inner sheath 8655324 and inner sheath 8675524!

The continuous irrigation inner sheath 8655324 and the inner sheath 8675524 do not have ceramic insulation in the distal region.

Injuries to the patient, user, and others are possible. Hf arcing and high heat generation can cause damage to the tissue, as well as to the resectoscope sheath and endoscope.

HF application is not permissible.

⚠ WARNING

The products have only limited strength!

Exerting excessive force will cause damage, impair the function, and therefore endanger the patient. Do not use the products if they are damaged or incomplete or have loose parts. Make sure that no missing parts remain in the patient. Immediately before and after each use, check the products for damage, loose parts, and completeness.

⚠ WARNING

Only use the product under visual control and, if necessary, under X-ray control, or bring it to the surgical site.

NOTICE

The procedure with working element (2) and laser fiber guide tube (1) is described below. The procedure with working element (2a) and laser fiber guide tube (1) is identical.

9.1 Preparation / Commissioning

1. Check assembly: Section Reprocessing sequence – Sheath
2. Perform checks: Section 8 Checks

9.1.1 Working element (2)

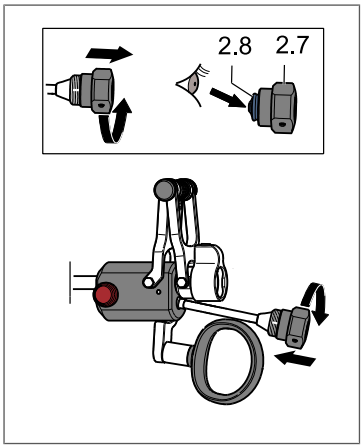


Fig. 7

Fig. 7

1. Unscrew the clamping sleeve (2.7) and check whether the seal (2.8) is there.
2. Check the correct position of the seal (2.8).
3. Screw on the clamping sleeve (2.7) with 1–2 turns.

9.1.2 Inserting the telescope (3) into the working element (2)

Fig. 8

Locking:

The clamping handle (2.5) remains in position "I".

1. Insert the telescope (3) into the working element (2).
   ⇨ The pin (a) engages in the groove (b).
2. Turn the clamping handle (2.5) to position "II".
   ⇨ Both components are locked together.

Releasing:

The clamping handle (2.5) remains in position "II".

1. Turn the clamping handle (2.5) to position "I".
   ⇨ The locking mechanism is unlocked.
2. Remove the telescope (3).

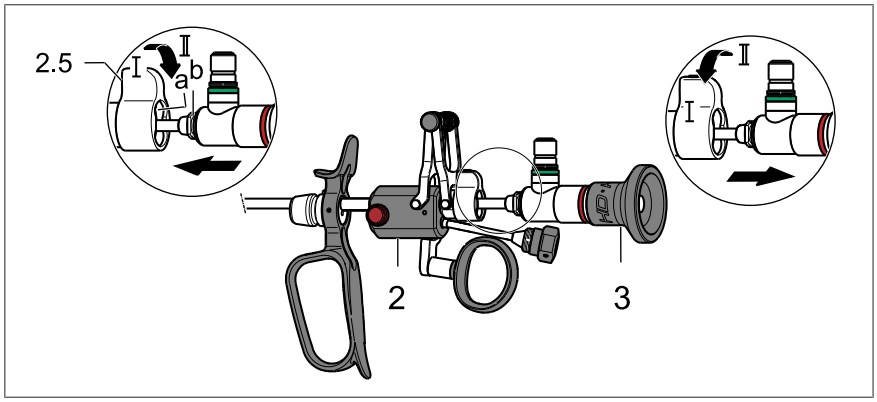


Fig. 8

9.1.3 Inserting the laser fiber guide tube (1) / curette (1a) into the working element (2)

Fig. 9

Locking:

1. Slide the profile tube (1.2) over the telescope (3).
2. Thread the guide tube (1.1) / curette (1a) into the receptacle (2.14) and insert it into the lock body (2.2) as far as it will go.
   ⇨ The guide tube (1.1) / curette (1a) audibly engages and locks automatically.
3. Pull distally on the laser fiber guide tube (1) / curette (1a) and check for tight fit.

Releasing:

– Press the pushbutton (2.12), hold, and remove the laser fiber guide tube (1) / curette (1a).

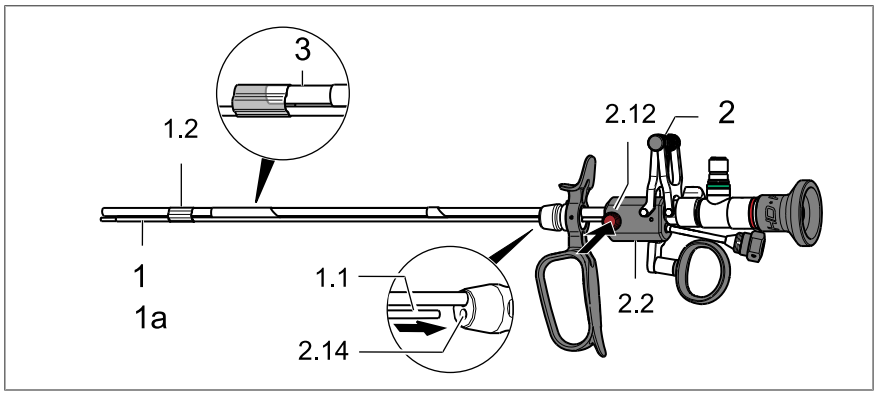


Fig. 9

9.2 Use with "E-Line" continuous irrigation double sheath system

9.2.1 Inserting the continuous irrigation inner sheath (4) into the continuous irrigation outer sheath (5)

Fig. 10

Locking:

– Insert the continuous irrigation inner sheath (4) into the continuous irrigation outer sheath (5) so that the recess (4.2) and the pins (5.5) are on one plane.

Push together until the locking mechanism (5.6) automatically engages.

Releasing:

– Press the bracket (5.4) of the continuous irrigation outer sheath (5) in the direction of the arrow and remove the continuous irrigation inner sheath (4).

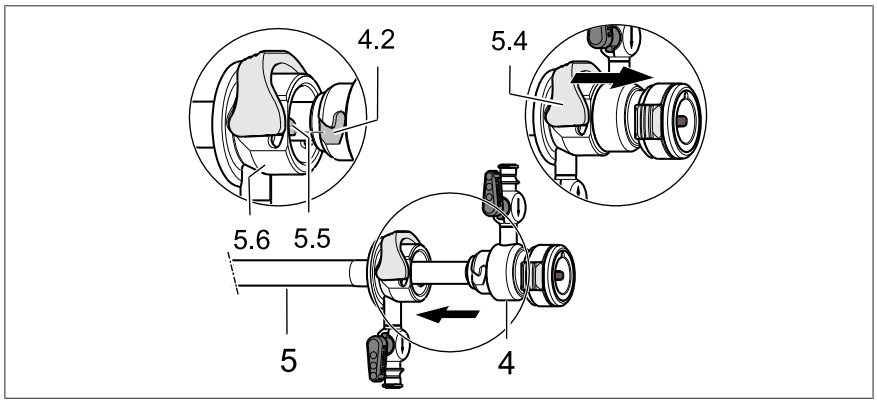


Fig. 10

9.2.2 Inserting the obturator (6) into the resectoscope sheath

Fig. 11

Locking:

– Insert the obturator (6) into the resectoscope sheath so that the groove (a) and pin (b) lie on one plane.

Push together until the locking mechanism (4.4) automatically engages.

NOTICE

If the locking mechanism (4.4) does not engage, press the tab (4.5) as far as it will go; repeat the process.

Releasing:

– Press the tab (4.5) and remove the obturator (6).

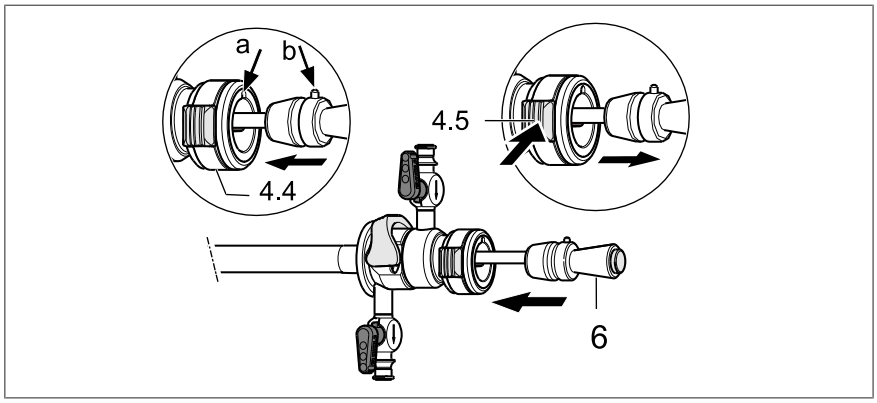


Fig. 11

9.2.3 Inserting the working element (2) with laser fiber guide tube (1) and telescope (3) into the resectoscope sheath

⚠ CAUTION

Incorrect combination of products!

On its distal steel tip, the continuous irrigation inner sheath 8655324 has a reinforced inner contour. Due to this distally reinforced inner contour, insertion of the guide tube with distal bracket 8654996 into the continuous irrigation inner sheath 8655324 is not possible, or only possible with great force.

Combining the guide tube 8654996 and continuous irrigation inner sheath 8655324 is not permissible.

Fig. 12

– The same procedure is described in section 9.2.2 Inserting the obturator (6) into the resectoscope sheath.

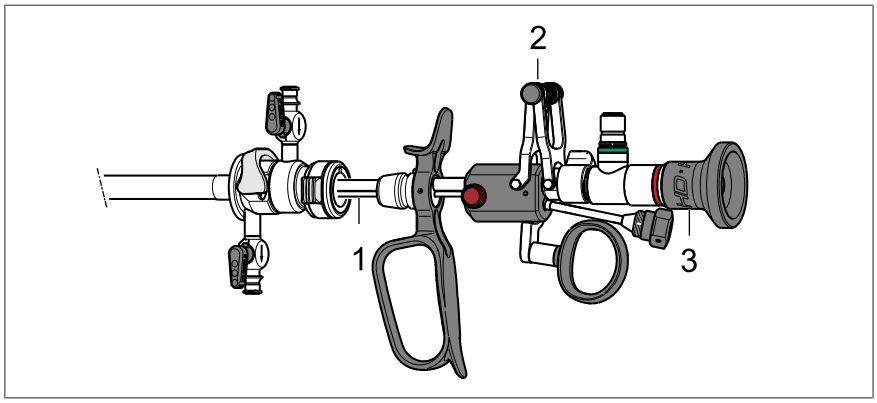


Fig. 12

9.3 Use with "Shark" continuous irrigation double sheath system

9.3.1 Inserting the inner sheath (7) into the outer sheath (8)

Fig. 13

Locking:

1. Check that O-rings (7.2) (7.4) are mounted on the inner sheath (7).
2. Insert the inner sheath (7) into the outer sheath (8) as far as it will go.
   ⇨ The outer sheath (8) automatically (audibly) engages in the inner sheath (7) by means of a ball catch (8.5)
3. Check that the rotatable connection is fitted securely.

Releasing:

– Push the outer ring (7.8) on the inner sheath (7) in the direction of the arrow as far as it will go, hold it, and remove the outer sheath (8).

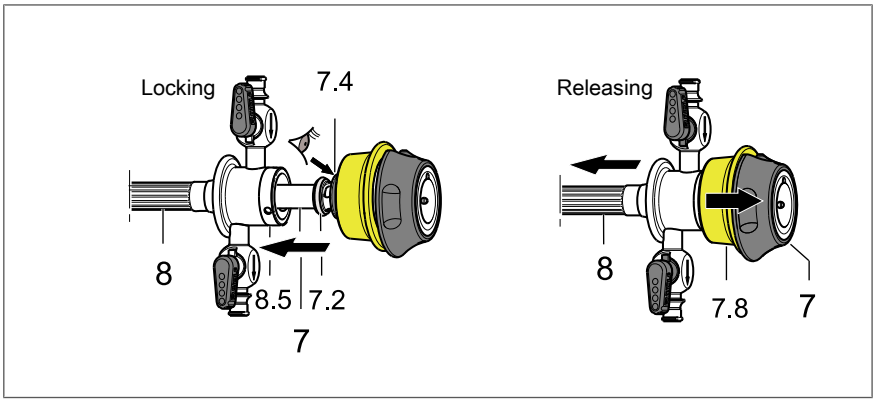


Fig. 13

9.3.2 Orientation guide for inserting the instruments

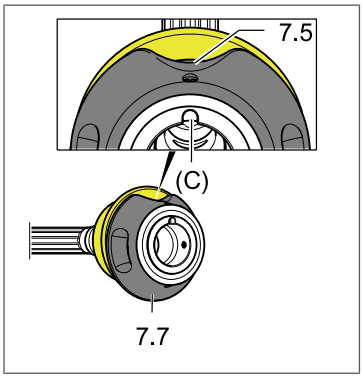


Fig. 14

Fig. 14

NOTICE

The actuating ring (7.7) has a recess (7.5) that has the same position as the groove (c).
When inserting the obturator (9), the working element (2), and the working insert (2a), the groove (c) of the actuating ring (7.7), and the pin (d) of the instruments must be in one plane.
The recess (7.5) serves as an orientation guide.

9.3.3 Inserting the obturator (9) into the resectoscope sheath

Fig. 15

Locking:

– Insert the obturator (9) into the resectoscope sheath so that the groove (c) and pin (d) lie on one plane.

Push together until the obturator (9) automatically engages in the lock rotating part (7.6).

– Check that the connection is fitted securely.

NOTICE

If the obturator (9) does not engage in the lock rotating part (7.6), press the actuating ring (7.7) in the direction of the arrow as far as it will go and repeat the procedure.

Releasing:

– Press the actuating ring (7.7) in the direction of the arrow as far as it will go and remove the obturator (9).

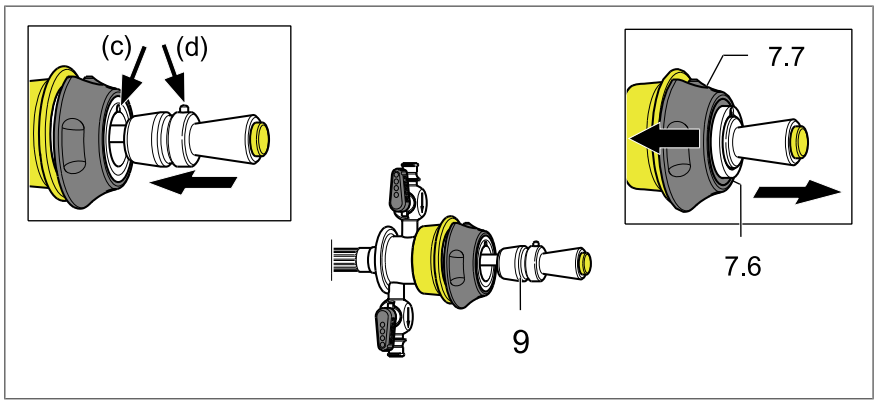


Fig. 15

9.3.4 Inserting the working element (2) with laser fiber guide tube (1) and telescope (3) into the resectoscope sheath

Fig. 16

– The same procedure is described in section 9.3.3 Inserting the obturator (9) into the resectoscope sheath.

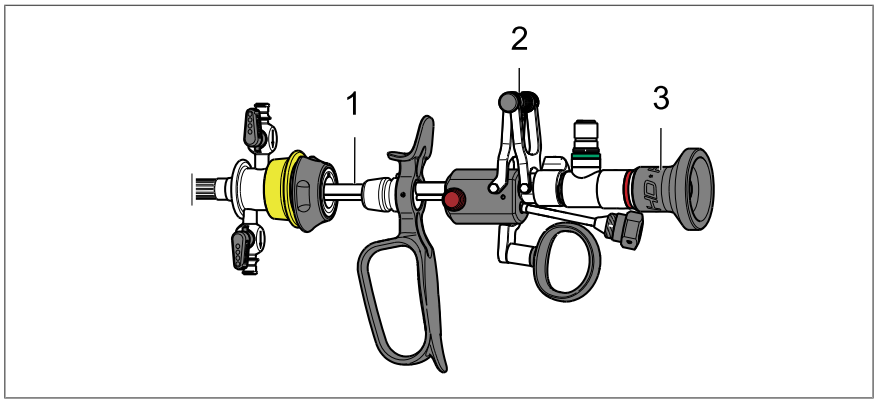


Fig. 16

9.4 Inserting the laser fiber

Fig. 17

1. To insert the laser fiber, loosen the clamping sleeve (2.7) until the laser fiber can be inserted without increased resistance.
2. Insert the laser fiber from the proximal end through the clamping sleeve (2.7) into the working element (2).
   ⇨ The laser fiber must protrude at least 5 mm from the resectoscope sheath when the working element (2) is in the rest position.
3. Tighten the clamping sleeve (2.7) until the laser fiber is axially fixed.

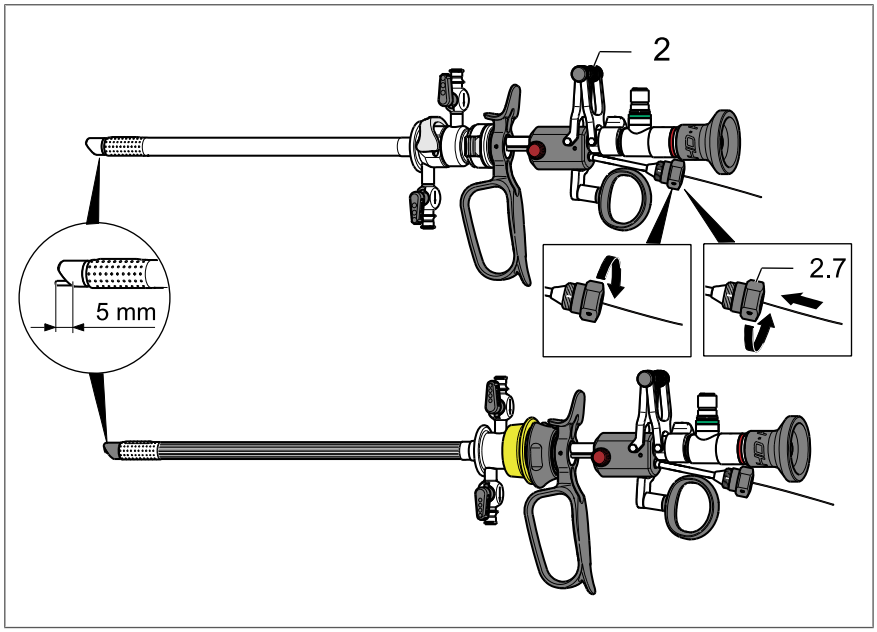


Fig. 17

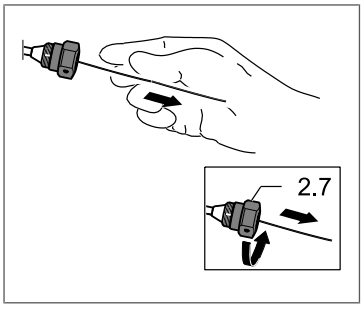


Fig. 18

Fig. 18

– Check that the laser fiber is fitted securely. Retighten the clamping sleeve (2.7) if necessary.

Releasing:

1. Loosen the clamping sleeve (2.7) in the direction of the arrow and remove the laser fiber.
2. Perform function checks: Section [[xref]]

9.5 General notes and instructions for use

NOTICE

When used with the working insert (2a), the laser fiber is fed into the urethra by:
- manual feeding of the laser fiber
- moving the resectoscope sheath in situ.

9.5.1 Connecting the resectoscope sheath to the irrigation and suction system

– Before each use, check the irrigation or suction function of the preassembled instrument set, as well as the entire system for leaks and continuity.

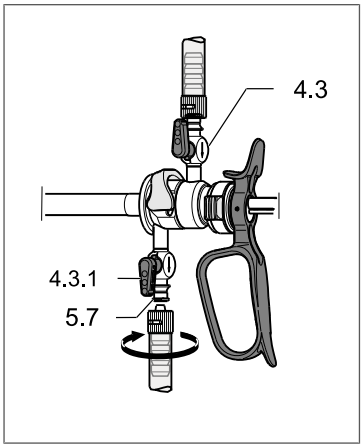


Fig. 19

"E-Line" resectoscope sheaths

Fig. 19

1. Connect the irrigation and drain tube to the irrigation valve (4.3) and outlet tap (5.7).
2. Open the stopcock insert (4.3.1).
3. Switch on the irrigation or suction system and check the irrigation or suction function.

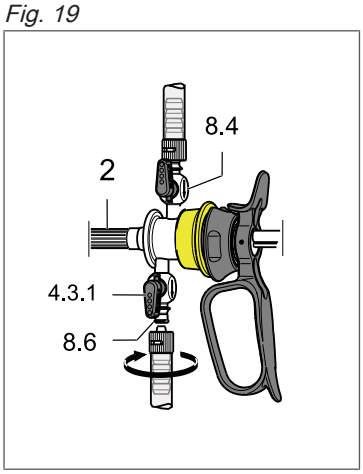


Fig. 20

"Shark" resectoscope sheaths

Fig. 20

1. Connect the irrigation and drain tube to the irrigation valve (8.4) and outlet tap (8.6).
2. Open the stopcock insert (4.3.1).
3. Switch on the irrigation or suction system and check the irrigation or suction function.

9.5.2 Irrigation / suction

⚠ WARNING

Temperature increase when working without irrigation fluid!
Mucosal injuries due to excessive temperatures put the patient at risk.
Activate the laser fiber only in the irrigation fluid and with continuous irrigation.

⚠ CAUTION

Due to the different anatomical conditions, it is not possible to quantify the irrigation and suction powers. These must be adapted by the user to the respective conditions.

9.5.3 Atraumatically inserting the resectoscope sheath

⚠ CAUTION

Do not insert the sheath without the obturator!
This may result in unintentional tissue damage.
Only insert the sheath atraumatically with the obturator in place.

1. Insert the obturator (6) (9) into the resectoscope sheath and insert into the urethra.
   ⇨ Obturator (6) (9): Section 9.2.2 Inserting the obturator (6) into the resectoscope sheath and 9.3.3 Inserting the obturator (9) into the resectoscope sheath
2. Remove the obturator (6) (9).

9.5.4 Connecting the laser resectoscope to system components

1. Connect the fiber light cable to the telescope (3) and suitable light projector, and switch on the light projector.
2. Switch on the supply for irrigation medium.
3. Perform function checks: Section 8.2 Function check
4. Insert products into the resectoscope sheath in situ: Section 9.2.3 Inserting the working element (2) with laser fiber guide tube (1) and telescope (3) into the resectoscope sheath and 9.3.4 Inserting the working element (2) with laser fiber guide tube (1) and telescope (3) into the resectoscope sheath.
   ⇨ Working element (2) with laser fiber guide tube (1) or with curette (1a) and telescope (3)
   ⇨ Working insert (2a) with laser fiber guide tube (1) and telescope (3)

9.6 Laser application

⚠ WARNING

Do not work outside of the field of view!

Unintentional tissue damage and damage to the distal end of the telescope (3), and to the instrument parts is possible!

The laser is activated when

▷ the tip of the laser fiber appears fully in the field of view of the telescope (3) and

▷ the intended application area is contacted using the pilot beam.

The laser fiber must protrude at least 5 mm from the resectoscope sheath when the working element (2) / working insert (2a) is in the rest position (Fig. 21).

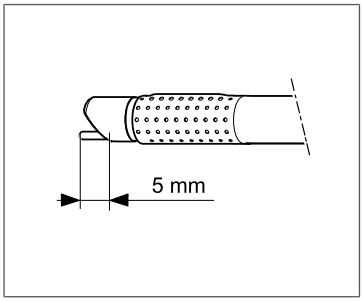


Fig. 21

⚠ WARNING

Sharply focused light beams!

This may result in injuries from potential laser energy in the face around the user's eyes.

When used together with laser equipment, wear the prescribed personal protective equipment.

When using lasers and working with endoscopes in direct view, also use a suitable filter attachment.

⚠ WARNING

Danger of eye damage if used without a filter attachment!

Use a suitable filter attachment on the eyepiece of the telescope (3).

ATTENTION

Heat generation due to focused laser beam!

The heat generated by the laser beam affects the stability of the instrument parts.

Do not direct the laser beam at instrument parts, especially plastic parts.

Maintain a sufficient safety distance.

When using the laser, the instructions of the laser device manufacturer and the general regulations for laser application must be observed.

The prescribed personal protective equipment must be worn.

10 Reprocessing and Maintenance

⚠ WARNING

Risk of infection!

Products and accessories are delivered in an unsterile state.

The use of unsterile products poses an infection risk for patients, users, and others.

Products must be reprocessed at least once before the first use and before every subsequent use.

The user is obligated to ensure that the reprocessing procedure, including resources, material, and personnel, is suitable for achieving the required results.

ATTENTION

Product damage if non-released reprocessing processes are used.

ATTENTION

- Use only cleaning agents and disinfectants whose efficacy and material compatibility with endoscopes and endoscopic accessories has been tested and approved by the chemicals manufacturer.
  - ⇨ Examples of suitable active agents for chemical disinfection:
    - Ortho-phthalaldehyde
    - Ethandial, didecyldimethylammonium chloride
    - Formacedal, glutardialdehyde
    - Sodium carbonate peroxyhydrate
- Disinfectants meeting the test criteria of the VAH (Association for Applied Hygiene R.S.), FDA or other national certification bodies may also be used
- Do not use disinfectants containing peracetic acid without corrosion protection, phenols or chlorine components for the reprocessing of RICHARD WOLF products.

ATTENTION

Do not sterilize the products in hot-air sterilizers.

NOTICE

The AAMI/ANSI ST91 and AAMI/ANSI TIR34 standards must be observed when reprocessing the medical device.

NOTICE

Brand new products.

Before reprocessing, remove all protection foils and transport locks from the products and accessories.

10.1 Reprocessing and Disposal Cycles of Applied Parts and Accessories

Description	For single use	Reusable	Reprocessing			Reprocessing / disposal cycle
			(A)	(B)	(C)	
Working element/insert	No	Yes	■	×	■	After each patient
Guide tube	No	Yes	■	×	■	After each patient
Curette	No	Yes	■	×	■	After each patient
Obturator	No	Yes	■	×	■	After each patient
Sheath	No	Yes	■	×	■	After each patient

Legend:

(A) Manual cleaning

(B) High Level disinfection

(C) Sterilization

■ Applicable

× Not applicable

10.2 Recommended Materials for Reprocessing

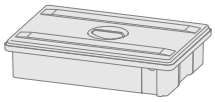
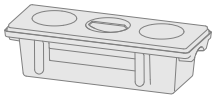
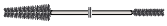
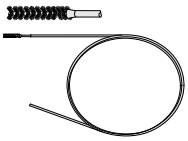
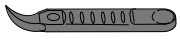
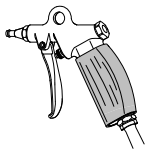
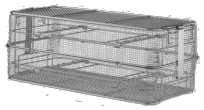
Image	Product no.	Designation, Technical data
	68603	BASIN (WXHXD) 548X100X348 MM Holds: instruments, for cleaning, disinfection, and neutralization, internal dimensions (WxHxD): 548 x 100 x 348 mm, external dimensions (WxHxD): 600 x 139 x 400 mm
	68601	BASIN (WXHXD) 432X100X150 MM Holds: instruments, for cleaning, disinfection, and neutralization, internal dimensions (WxHxD): 432 x 100 x 150 mm, external dimensions (WxHxD): 550 x 157 x 200 mm
	7970403	CLEANING BRUSH Ø 3MM TL 400MM for Ø 1.6-2.5 mm channels, brush length 30 mm, PACK = 10 PCS, color: red, for single use
	7970405	CLEANING BRUSH Ø 5 MM TL 400 MM for channel Ø 3.6–4.5 mm, brush length 48 mm, PU = 10 PCS, color green, for single use
	7970407	CLEANING BRUSH Ø 7MM TL 400MM for Ø 4.6-6.5 mm channels, brush length 48 mm, PACK = 10 PCS, color: purple, for single use
	7970409	CLEANING BRUSH Ø 9MM TL 400MM for Ø 6.6-8.5 mm channels, brush length 48 mm, PACK = 10 PCS, color: orange, for single use

Image	Product no.	Designation, Technical data
	7970703	CLEANING BRUSH Ø 3MM TL 700MM for Ø 1.6-2.5 mm channels, brush length 30 mm, PACK = 10 PCS, color: red, for single use
	7980002	DOUBLE CONICAL STRAIGHT CLEANING BRUSH for stopcock inserts / housings with 3 pegs, brush head 1: conical Ø 5-9 mm, brush head 2: Ø 4 mm PACK = 50 PCS, color: red, for single use
	7980003	DOUBLE CONICAL STRAIGHT CLEANING BRUSH for stopcock inserts / housings with 4 pegs, brush head 1: conical Ø 6-11 mm, brush head 2: Ø 5 mm PACK = 50 PCS, color: yellow, for single use
	7990003	CLEANING BRUSH Ø 0.85 MM TL 1,200 MM For flexible endoscopes with channel Ø 0.8 mm, brush length 10 mm, PU = 10 PCS, color blue, for single use
	86.90	CLEANING BRUSH for surface cleaning, angled, reusable
	8691	CLEANING BRUSH for surface cleaning, straight, PACK = 10 PCS, for single use
	15106.230	O-RING TOOL
	6199.00	WATER JET CLEANING PISTOL (cleaning gun)
-	-	LINT-FREE DISPOSABLE CLOTH
-	-	SYRINGE (20 ML)
-	-	INSTRUMENT OIL

Manual cleaning		
-	89.00 163503	ADAPTER consisting of sealing cap 89.00, irrigation connector 163503, and silicone tube (a) ID x OD x L = 8 x 12 x 50 mm
-	-	COLD TAP WATER (drinking water quality) 10–25 °C

Sterilization		
	-	FDA approved tray or instrument rack
	8428.901	STERILIZATION PROTECTION SLEEVE

10.3 Reprocessing the Working Element/Insert

10.3.1 Initial Treatment at the Point of Use

Reprocessing at the point of use is carried out to remove coarse soiling on the product.

Requirement

- Auxiliary instrument has been removed.
- Product is separated from the system components.

Recommended materials

- SYRINGE (20 ml)
- COLD TAP WATER
- FDA approved tray or instrument rack

See section 10.2 “Recommended Materials for Reprocessing”

NOTICE

Residue adhering to surfaces

Do not use cleaning agents (e.g., aldehydes) or hot water (> 40 °C) for pre-cleaning.

NOTICE

Promotion of corrosion

Do not use physiological saline solution for rinsing out hollow spaces.

NOTICE

Product damage

Must be stored securely in a closed container.

NOTICE

Risk of infection. Contamination of surrounding area

Must be stored securely in a closed container.

1. Remove coarse soiling from products.
2. If more than 6 hours have passed between use and reprocessing, rinse out hollow spaces with cold tap water and narrow hollow spaces (e.g., stopcocks) with a 20 ml syringe filled with water.
3. To ensure secure transport, place the product in a perforated basket.

Initial treatment at the point of use is complete.

10.3.2 Disassembly

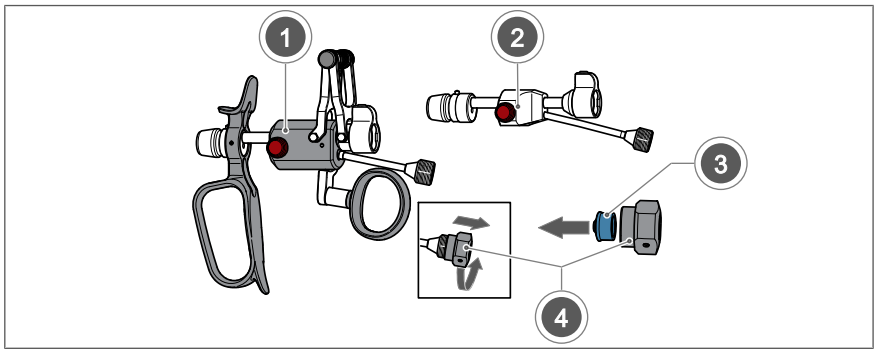
The product must be disassembled before cleaning.

Requirement

- All coarse soiling is removed from the product.

Recommended materials

- -



No.	Model no.	Description
1	8654382	LASER WORKING ELEMENT, PASSIVE 12/30°
2	8654383	LASER WORKING INSERT 12/30°
3	15176.173	SEAL
4	150441178	CLAMPING SLEEVE, BNDL

1. Unscrew the clamping sleeve (4) from the laser working element (1) or laser working insert (2).
2. Remove the seal (3) from the clamping sleeve (4).

The product is dismantled.

10.3.3 Manual Reprocessing

Manual reprocessing consists of pre-cleaning, manual cleaning, and drying.

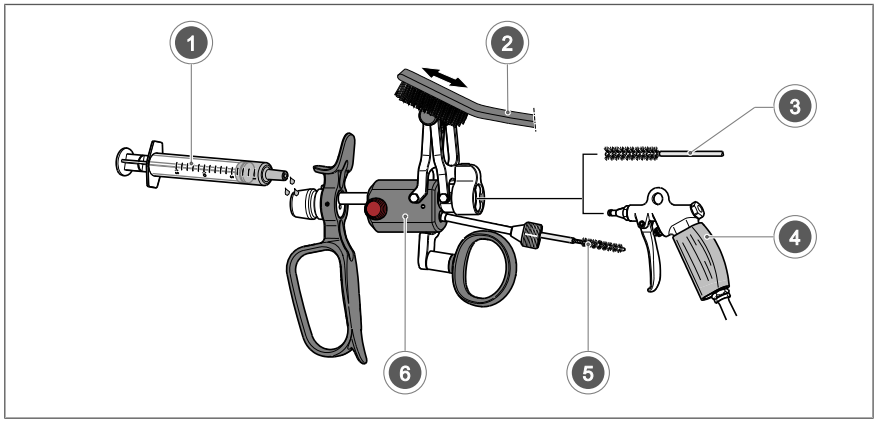
Requirement

- The product is dismantled.
- Basin is filled with cleaning agent as per manufacturer specifications.

Recommended materials

- LINT-FREE DISPOSABLE CLOTH
- COLD TAP WATER
- SYRINGE (20 ml)
- 6199.00 | CLEANING GUN
- 86.90 | CLEANING BRUSH
- 68603 | BASIN (WXHXD) 548 X 100 X 348 MM
- 7970403 | CLEANING BRUSH Ø 3 MM TL 400 MM
- 7970405 | CLEANING BRUSH Ø 5 MM TL 400 MM

See section “Recommended Materials for Reprocessing”



No.	Model no.	Description
1	-	SYRINGE (20 ML)
2	86.90	CLEANING BRUSH
3	7970405	CLEANING BRUSH Ø 5 MM TL 400 MM
4	6199.00	CLEANING GUN
5	7970403	CLEANING BRUSH Ø 3 MM TL 400 MM

Pre-cleaning for the manual cleaning process

1. Rinse the products under cold, running tap water for at least 20 seconds.
2. Thoroughly rinse the channels for at least 20 seconds or in pulsed mode with 5 pressure surges (2.5 – 4.0 bar) with cold tap water using a cleaning gun | e.g., model 6199.00|.

Manual cleaning

1. Immerse all disassembled parts separately in a basin |e.g., model 68603| filled with a certified cleaning solution and leave for 6 minutes at room temperature.
2. Fill the channels completely with the cleaning solution using a syringe, avoiding any trapped bubbles.
   ⇨ **Note!** Complete wetting of the surface
   Completely wet the surfaces of the products with cleaning solution.
   ⇨ **Note!** Observe the manufacturer specifications for the cleaning agent.
   Observe the manufacturer's application concentration and exposure time.
3. Brush the surfaces 3x with the brush |e.g., model 86.90| or until no more residue is visible.
4. Brush the channel for the laser fiber with the brushless end of the cleaning brush |e.g., model 7970403| in front, 5x under the liquid surface level in the direction of the arrow.
5. Brush the channel for the endoscope with the cleaning brush |e.g., model 7970405| under the liquid surface level in the direction of the arrow.
6. Thoroughly rinse the channels for 20 seconds or in pulsed mode with 5 pressure pulses (3.8–4.0 bar) with cold tap water using a cleaning gun |e.g, model 6199.00|.
   ⇨ **Note!**Rinsing the electrode guide tube
   Only rinse the electrode guide tube from the proximal end so that the seal remains in the locking cone.
7. Rinse the products under cold, running tap water for at least 20 seconds.

Drying after manual cleaning

1. Dry the outside of the products using a lint-free, disposable cloth or a drying cabinet.
2. Dry hollow spaces with filtered compressed air.
3. Observe section 10.3.4 "Visual and Function Checks".

Manual reprocessing is complete.

10.3.4 Visual and Function Checks

The cleaning process and the product functions are assessed by means of the visual check and the function inspection.

Requirement

- The product is reprocessed manually.

Recommended materials

- -

Visual check

1. Perform a visual inspection on the product to ensure it is clean.
2. If necessary, repeat the reprocessing procedure until the product is visually clean.
3. Observe the 8.1 "Visual Check" section and perform the check.

Checking functionality

– Observe the 8.2 "Function Check" section and perform the check.

10.3.5 Packaging

Requirement

- The product has been reprocessed manually **and** is dry.

Recommended materials

- FDA approved tray or instrument rack

See section 10.2 “Recommended Materials for Reprocessing”

⚠ CAUTION

Risk of infection

Unsuitable sterile barrier system being used.

A sterile barrier system that is suitable for the sterilization process and complies with both ISO 11607-1 and the relevant national requirements must be used.

NOTICE

Only use an FDA-approved sterile barrier system.

Packaging the product

1. Place all parts in the universal mesh basket.
2. Package the perforated basket with the parts inside it in a suitable sterile barrier system.

10.3.6 Sterilization

Requirement

The following phases of the reprocessing procedure have been completed:

- Section “Manual Reprocessing” **and**
- Section “Packaging”

Recommended materials

- -

Steam sterilization

1. Place the packaged product in the steam sterilizer.
   ⇨ **Note!** Sterilize the products using the fractionated vacuum method (ISO 17665 and ANSI/AAMI ST79), taking into account the corresponding national requirements.
2. Select the following settings for the standard program:
   ⇨ Temperature exposure time: 4 minutes at 270 °F (132 °C)
   ⇨ Drying time: 20–30 minutes (the drying time depends on the sterilization process used)
   ⇨ Maximum temperature: 280 °F (138 °C)
3. Start program.

10.3.7 Storage

Requirement

- The product is sterile.

Recommended materials

- -

NOTICE

The sterile barrier system must comply with both the requirements of ISO 11607-1 and the relevant national requirements.

NOTICE

In order to maintain sterility, sterilized medical devices must be stored in the sterile barrier system.

NOTICE

Store sterilized products in a way that is compliant with ANSI/AAMI ST79.

1. Check the sterile barrier system for damage.
2. Store the sterilized medical device in the sterile barrier system.

10.3.8 Assembly

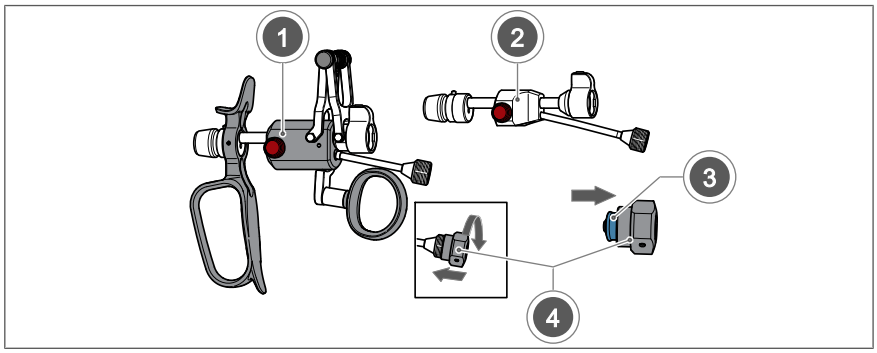
Assemble the parts at the point of use.

Requirement

- The product is sterile.

Recommended materials

- -



No.	Model no.	Description
1	8654382	LASER WORKING ELEMENT, PASSIVE 12/30°
2	8654383	LASER WORKING INSERT 12/30°
3	15176.173	SEAL
4	150441178	CLAMPING SLEEVE, BNDL

1. Insert the seal (3) into the clamping sleeve (4).
2. Screw the clamping sleeve (4) onto the laser working element (1) or the laser working insert (2).

Assembly is complete.

10.3.9 Parameters of the Validation Process

To validate reprocessing, the following materials and machines were used:

Manual

- Cold tap water (drinking water quality): 10 °C–25 °C
- Cleaning agent: 0.8 % Cidezyme (ASP)

Sterilization

- Sterilizer: Selectomat HP 666-1 HRED (MMM)
  - Product is double-packed.

10.4 Reprocessing the Guide Tube

10.4.1 Initial Treatment at the Point of Use

Reprocessing at the point of use is carried out to remove coarse soiling on the product.

Requirement

- Laser fiber has been removed.

Recommended materials

- SYRINGE (20 ml)
- COLD TAP WATER
- FDA approved tray or instrument rack

See section 10.2 “Recommended Materials for Reprocessing”

NOTICE

Residue adhering to surfaces

Do not use cleaning agents (e.g., aldehydes) or hot water (> 40 °C) for pre-cleaning.

NOTICE

Promotion of corrosion

Do not use physiological saline solution for rinsing out hollow spaces.

NOTICE

Product damage

Must be stored securely in a closed container.

NOTICE

Risk of infection. Contamination of surrounding area

Must be stored securely in a closed container.

1. Remove coarse soiling from products.
2. If more than 6 hours have passed between use and reprocessing, rinse out hollow spaces with cold tap water and narrow hollow spaces (e.g., stopcocks) with a 20 ml syringe filled with water.
3. To ensure secure transport, place the product in a perforated basket.

Initial treatment at the point of use is complete.

10.4.2 Manual Reprocessing

Manual reprocessing consists of pre-cleaning, manual cleaning, and drying.

Requirement

- The product is dismantled.
- Basin is filled with cleaning agent as per manufacturer specifications.

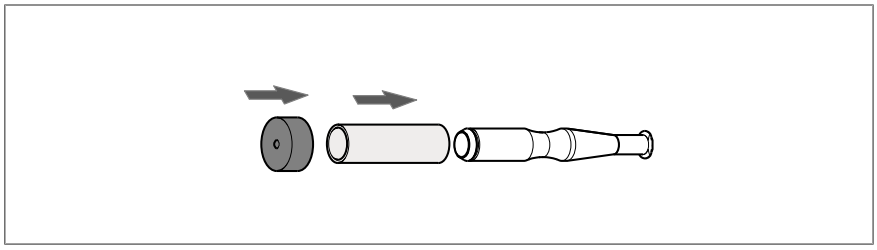
Recommended materials

- LINT-FREE DISPOSABLE CLOTH
- COLD TAP WATER
- 6199.00 | CLEANING GUN
- ADAPTER | consisting of sealing cap 89.00, irrigation connector 163503, and silicone tube ID x OD x L = 8 x 12 x 50 mm
- 68603 | BASIN (WXHXD) 548 X 100 X 348 MM
- 7970403 | CLEANING BRUSH Ø 3 MM TL 400 MM
- 7970405 | CLEANING BRUSH Ø 5 MM TL 400 MM
- 7990003 | CLEANING BRUSH Ø 0.85 MM TL 1200 MM
- 86.90 | CLEANING BRUSH

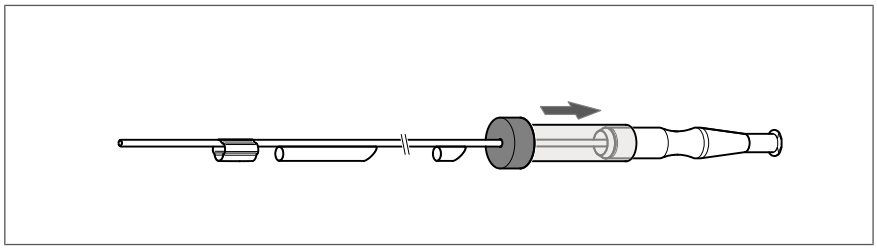
See section “Recommended Materials for Reprocessing”.

Pre-cleaning for the manual cleaning process

1. Assemble the adapter consisting of sealing cap, silicone tube, and irrigation connector.



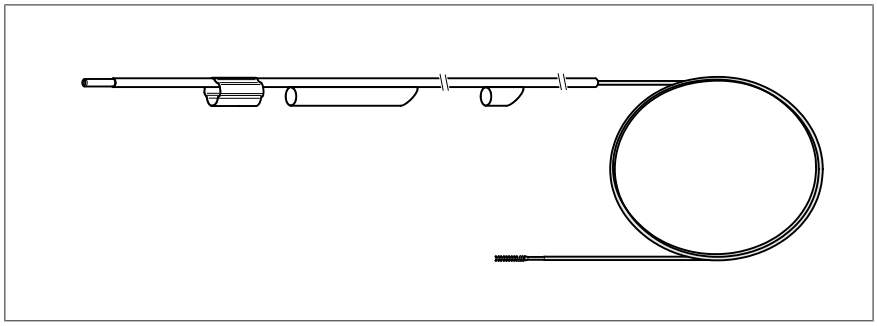
2. Rinse the products under cold, running tap water for at least 20 seconds.
3. Slide the guide tube into the adapter.



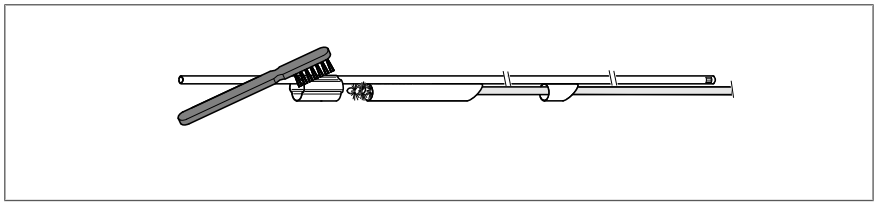
4. Thoroughly rinse the channels for at least 20 seconds or in pulsed mode with 5 pressure surges (2.5 – 4.0 bar) with cold tap water using a cleaning gun | e.g., model 6199.00|.

Manual cleaning

1. Immerse the guide tube with adapter in a basin |e.g., model 68603| filled with a certified cleaning solution for 6 minutes at room temperature.
2. Fill the channels completely with the cleaning solution using a syringe, avoiding any trapped bubbles.
   ⇨ **Note!** Complete wetting of the surface
   Completely wet the surfaces of the products with cleaning solution.
   ⇨ **Note!** Observe the manufacturer specifications for the cleaning agent.
   Observe the manufacturer's application concentration and exposure time.
3. Disconnect and remove the adapter from the guide tube.
4. Brush the guide tube lumen 5x.
   ⇨ **Note!** Using the right brush
   Laser guide models 8654990 and 8654991 with brush 7970403
   Laser guide models 8654992, 8654993, 8654994, 8654995, 8654996, and 8654997 with brush 7990003
   Telescope channel with brush 7970405



5. Brush the surfaces 3x with the brush |e.g., model 86.90| or until no more residue is visible.



6. Rinse the products under cold, running tap water for at least 20 seconds.

Drying after manual cleaning

1. Dry the outside of the products using a lint-free, disposable cloth or a drying cabinet.
2. Dry hollow spaces with filtered compressed air.
3. Observe section 10.4.3 "Visual and Function Checks".

Manual reprocessing is complete.

10.4.3 Visual and Function Checks

The cleaning process and the product functions are assessed by means of the visual check and the function inspection.

Requirement

- Machine **or** manual reprocessing is carried out on the product.

Recommended materials

- -

Visual check

1. Perform a visual inspection on the product to ensure it is clean.
2. If necessary, repeat the reprocessing procedure until the product is visually clean.
3. Observe the 8.1 “Visual Check” section and perform the check.

Checking functionality

– Observe the 8.2 “Function Check” section and perform the check.

10.4.4 Packaging

Requirement

- The product has been reprocessed manually **and** is dry.

Recommended materials

- FDA approved tray or instrument rack

See section 10.2 “Recommended Materials for Reprocessing”

⚠ CAUTION

Risk of infection

Unsuitable sterile barrier system being used.

A sterile barrier system that is suitable for the sterilization process and complies with both ISO 11607-1 and the relevant national requirements must be used.

NOTICE

Only use an FDA-approved sterile barrier system.

Packaging the product

1. Place all parts in the universal mesh basket.
2. Package the perforated basket with the parts inside it in a suitable sterile barrier system.

10.4.5 Sterilization

Requirement

The following phases of the reprocessing procedure have been completed:

- Section “Manual Reprocessing” **and**
- Section “Packaging”

Recommended materials

- -

Steam sterilization

1. Place the packaged product in the steam sterilizer.
   ⇨ **Note!** Sterilize the products using the fractionated vacuum method (ISO 17665 and ANSI/AAMI ST79), taking into account the corresponding national requirements.
2. Select the following settings for the standard program:
   ⇨ Temperature exposure time: 4 minutes at 270 °F (132 °C)
   ⇨ Drying time: 20–30 minutes (the drying time depends on the sterilization process used)
   ⇨ Maximum temperature: 280 °F (138 °C)
3. Start program.

10.4.6 Storage

Requirement

- The product is sterile.

Recommended materials

- -

NOTICE

The sterile barrier system must comply with both the requirements of ISO 11607-1 and the relevant national requirements.

NOTICE

In order to maintain sterility, sterilized medical devices must be stored in the sterile barrier system.

NOTICE

Store sterilized products in a way that is compliant with ANSI/AAMI ST79.

1. Check the sterile barrier system for damage.
2. Store the sterilized medical device in the sterile barrier system.

10.4.7 Parameters of the Validation Process

To validate reprocessing, the following materials and machines were used:

Manual

- Cold tap water (drinking water quality): 10 °C–25 °C
- Cleaning agent: 0.8 % Cidezyme (ASP)

Sterilization

- Sterilizer: Selectomat HP 666-1 HRED (MMM)
  - Product is double-packed.

10.5 Reprocessing the Curette

10.5.1 Initial Treatment at the Point of Use

Reprocessing at the point of use is carried out to remove coarse soiling on the product.

Requirement

- Laser fiber has been removed.

Recommended materials

- SYRINGE (20 ml)
- COLD TAP WATER
- FDA approved tray or instrument rack

See section 10.2 “Recommended Materials for Reprocessing”

NOTICE

Residue adhering to surfaces

Do not use cleaning agents (e.g., aldehydes) or hot water (> 40 °C) for pre-cleaning.

NOTICE

Promotion of corrosion

Do not use physiological saline solution for rinsing out hollow spaces.

NOTICE

Product damage

Must be stored securely in a closed container.

NOTICE

Risk of infection. Contamination of surrounding area

Must be stored securely in a closed container.

1. Remove coarse soiling from products.
2. If more than 6 hours have passed between use and reprocessing, rinse out hollow spaces with cold tap water and narrow hollow spaces (e.g., stopcocks) with a 20 ml syringe filled with water.
3. To ensure secure transport, place the product in a perforated basket.

Initial treatment at the point of use is complete.

10.5.2 Manual Reprocessing

Manual reprocessing consists of pre-cleaning, manual cleaning, and drying.

Requirement

- The product is dismantled.
- Basin is filled with cleaning agent as per manufacturer specifications.

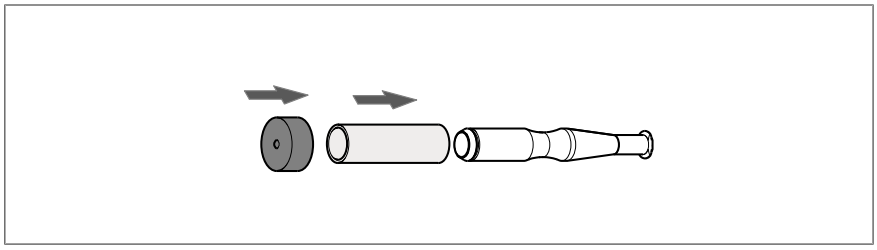
Recommended materials

- LINT-FREE DISPOSABLE CLOTH
- COLD TAP WATER
- 6199.00 | CLEANING GUN
- ADAPTER | consisting of sealing cap 89.00, irrigation connector 163503, and silicone tube ID x OD x L = 8 x 12 x 50 mm
- 68603 | BASIN (WXHXD) 548 X 100 X 348 MM
- 7970403 | CLEANING BRUSH Ø 3 MM TL 400 MM
- 7970405 | CLEANING BRUSH Ø 5 MM TL 400 MM
- 7990003 | CLEANING BRUSH Ø 0.85 MM TL 1200 MM
- 86.90 | CLEANING BRUSH

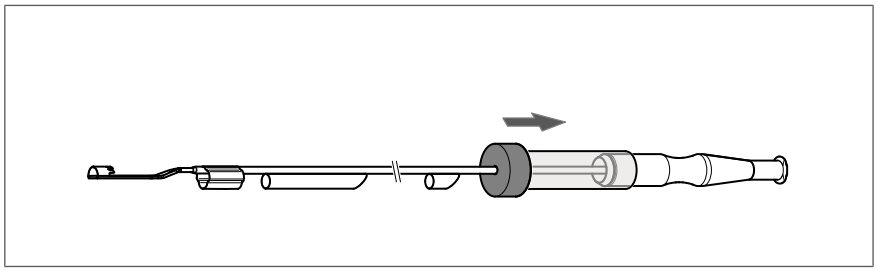
See section “Recommended Materials for Reprocessing”

Pre-cleaning for the manual cleaning process

1. Assemble the adapter consisting of sealing cap, silicone tube, and irrigation connector.



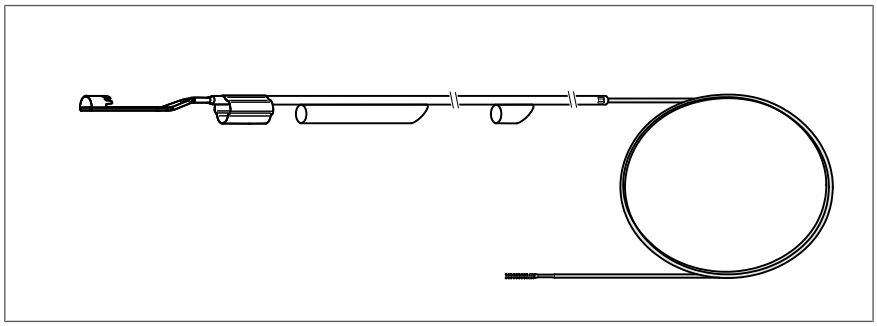
2. Rinse the products under cold, running tap water for at least 20 seconds.
3. Slide the curette into the adapter.



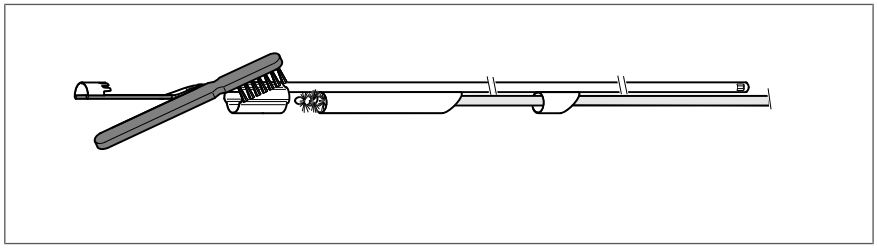
4. Thoroughly rinse the channels for at least 20 seconds or in pulsed mode with 5 pressure surges (2.5 – 4.0 bar) with cold tap water using a cleaning gun |e.g., model 6199.00|.

Manual cleaning

1. Immerse the curette with adapter in a basin |e.g., model 68603| filled with a certified cleaning solution for 6 minutes at room temperature.
2. Fill the channels completely with the cleaning solution using a syringe, avoiding any trapped bubbles.
   ⇨ **Note!** Complete wetting of the surface
   Completely wet the surfaces of the products with cleaning solution.
   ⇨ **Note!** Observe the manufacturer specifications for the cleaning agent.
   Observe the manufacturer's application concentration and exposure time.
3. Disconnect and remove the adapter from the guide tube.
4. Brush the guide tube lumen 5x.
   ⇨ **Note!** Using the right brush
   Laser guide models 8654990 and 8654991 with brush 7970403
   Laser guide models 8654992, 8654993, 8654994, 8654995, 8654996, and 8654997 with brush 7990003
   Telescope channel with brush 7970405



5. Brush the surfaces 3x with the brush |e.g., model 86.90| or until no more residue is visible.



6. Rinse the products under cold, running tap water for at least 20 seconds.

Drying after manual cleaning

1. Dry the outside of the products using a lint-free, disposable cloth or a drying cabinet.
2. Dry hollow spaces with filtered compressed air.
3. Observe section 10.5.3 "Visual and Function Checks".

Manual reprocessing is complete.

10.5.3 Visual and Function Checks

The cleaning process and the product functions are assessed by means of the visual check and the function inspection.

Requirement

- Machine **or** manual reprocessing is carried out on the product.

Recommended materials

- -

Visual check

1. Perform a visual inspection on the product to ensure it is clean.
2. If necessary, repeat the reprocessing procedure until the product is visually clean.
3. Observe the 8.1 “Visual Check” section and perform the check.

Checking functionality

– Observe the 8.2 “Function Check” section and perform the check.

10.5.4 Packaging

Requirement

- The product has been reprocessed manually **and** is dry.

Recommended materials

- FDA approved tray or instrument rack

See section 10.2 “Recommended Materials for Reprocessing”

⚠ CAUTION

Risk of infection

Unsuitable sterile barrier system being used.

A sterile barrier system that is suitable for the sterilization process and complies with both ISO 11607-1 and the relevant national requirements must be used.

NOTICE

Only use an FDA-approved sterile barrier system.

Packaging the product

1. Place all parts in the universal mesh basket.
2. Package the perforated basket with the parts inside it in a suitable sterile barrier system.

10.5.5 Sterilization

Requirement

The following phases of the reprocessing procedure have been completed:

- Section “Manual Reprocessing” **and**
- Section “Packaging”

Recommended materials

- -

Steam sterilization

1. Place the packaged product in the steam sterilizer.
   ⇨ **Note!** Sterilize the products using the fractionated vacuum method (ISO 17665 and ANSI/AAMI ST79), taking into account the corresponding national requirements.
2. Select the following settings for the standard program:
   ⇨ Temperature exposure time: 4 minutes at 270 °F (132 °C)
   ⇨ Drying time: 20–30 minutes (the drying time depends on the sterilization process used)
   ⇨ Maximum temperature: 280 °F (138 °C)
3. Start program.

10.5.6 Storage

Requirement

- The product is sterile.

Recommended materials

- -

NOTICE

The sterile barrier system must comply with both the requirements of ISO 11607-1 and the relevant national requirements.

NOTICE

In order to maintain sterility, sterilized medical devices must be stored in the sterile barrier system.

NOTICE

Store sterilized products in a way that is compliant with ANSI/AAMI ST79.

1. Check the sterile barrier system for damage.
2. Store the sterilized medical device in the sterile barrier system.

10.5.7 Parameters of the Validation Process

To validate reprocessing, the following materials and machines were used:

Manual

- Cold tap water (drinking water quality): 10 °C–25 °C
- Cleaning agent: 0.8 % Cidezyme (ASP)

Sterilization

- Sterilizer: Selectomat HP 666-1 HRED (MMM)
  - Product is double-packed.

10.6 Reprocessing the Obturator

10.6.1 Initial Treatment at the Point of Use

Reprocessing at the point of use is carried out to remove coarse soiling on the product.

Requirement

- Product is separated from the system components.

Recommended materials

- SYRINGE (20 ml)
- COLD TAP WATER
- FDA approved tray or instrument rack

See section 10.2 “Recommended Materials for Reprocessing”

NOTICE

Residue adhering to surfaces

Do not use cleaning agents (e.g., aldehydes) or hot water (> 40 °C) for pre-cleaning.

NOTICE

Promotion of corrosion

Do not use physiological saline solution for rinsing out hollow spaces.

NOTICE

Product damage

Must be stored securely in a closed container.

NOTICE

Risk of infection. Contamination of surrounding area

Must be stored securely in a closed container.

1. Remove coarse soiling from products.
2. To ensure secure transport, place the product in a perforated basket.

Initial treatment at the point of use is complete.

10.6.2 Manual Reprocessing

Manual reprocessing consists of pre-cleaning, manual cleaning, and drying.

Requirement

- The product is dismantled.
- Basin is filled with cleaning agent as per manufacturer specifications.

Recommended materials

- LINT-FREE DISPOSABLE CLOTH
- COLD TAP WATER
- 8691 | CLEANING BRUSH
- 68603 | BASIN (WXHXD) 548 X 100 X 348 MM
- 86.90 | CLEANING BRUSH

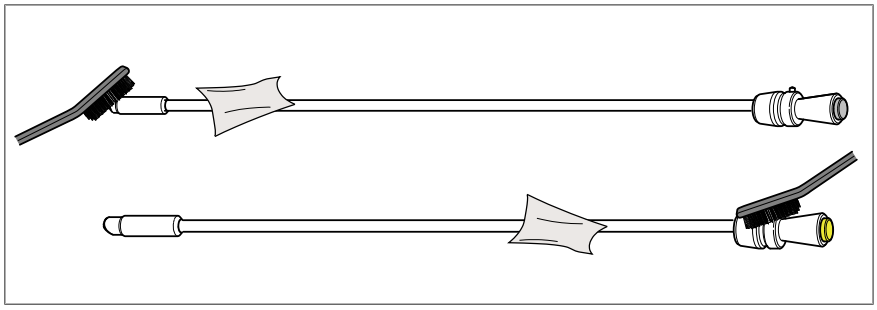
See section “Recommended Materials for Reprocessing”.

Pre-cleaning for the manual cleaning process

– Rinse the products under cold, running tap water for at least 20 seconds.

Manual cleaning

1. Immerse the obturator in a basin |e.g., model 68603| filled with a certified cleaning solution for 6 minutes at room temperature.
   ⇨ **Note!** Complete wetting of the surface
   Completely wet the surfaces of the products with cleaning solution.
   ⇨ **Note!** Observe the manufacturer specifications for the cleaning agent.
   Observe the manufacturer’s application concentration and exposure time.
2. Brush the surfaces 3x with the brush |e.g., model 86.90| or until no more residue is visible.



3. Rinse the products under cold, running tap water for at least 20 seconds.

Drying after manual cleaning

1. Dry the outside of the products using a lint-free, disposable cloth or a drying cabinet.
2. Observe section 10.6.3 “Visual and Function Checks”.

Manual reprocessing is complete.

10.6.3 Visual and Function Checks

The cleaning process and the product functions are assessed by means of the visual check and the function inspection.

Requirement

- Machine **or** manual reprocessing is carried out on the product.

Recommended materials

- -

Visual check

1. Perform a visual inspection on the product to ensure it is clean.
2. If necessary, repeat the reprocessing procedure until the product is visually clean.
3. Observe the 8.1 “Visual Check” section and perform the check.

Checking functionality

– Observe the 8.2 “Function Check” section and perform the check.

10.6.4 Packaging

Requirement

- The product has been reprocessed manually **and** is dry.

Recommended materials

- FDA approved tray or instrument rack

See section 10.2 “Recommended Materials for Reprocessing”

⚠ CAUTION

Risk of infection

Unsuitable sterile barrier system being used.

A sterile barrier system that is suitable for the sterilization process and complies with both ISO 11607-1 and the relevant national requirements must be used.

NOTICE

Only use an FDA-approved sterile barrier system.

Packaging the product

1. Place all parts in the universal mesh basket.
2. Package the perforated basket with the parts inside it in a suitable sterile barrier system.

10.6.5 Sterilization

Requirement

The following phases of the reprocessing procedure have been completed:

- Section “Manual Reprocessing” **and**
- Section “Packaging”

Recommended materials

- -

Steam sterilization

1. Place the packaged product in the steam sterilizer.
   ⇨ **Note!** Sterilize the products using the fractionated vacuum method (ISO 17665 and ANSI/AAMI ST79), taking into account the corresponding national requirements.
2. Select the following settings for the standard program:
   ⇨ Temperature exposure time: 4 minutes at 270 °F (132 °C)
   ⇨ Drying time: 20–30 minutes (the drying time depends on the sterilization process used)
   ⇨ Maximum temperature: 280 °F (138 °C)
3. Start program.

10.6.6 Storage

Requirement

- The product is sterile.

Recommended materials

- -

NOTICE

The sterile barrier system must comply with both the requirements of ISO 11607-1 and the relevant national requirements.

NOTICE

In order to maintain sterility, sterilized medical devices must be stored in the sterile barrier system.

NOTICE

Store sterilized products in a way that is compliant with ANSI/AAMI ST79.

1. Check the sterile barrier system for damage.
2. Store the sterilized medical device in the sterile barrier system.

10.6.7 Parameters of the Validation Process

To validate reprocessing, the following materials and machines were used:

Manual

- Cold tap water (drinking water quality): 10 °C–25 °C
- Cleaning agent: 0.8 % Cidezyme (ASP)

Sterilization

- Sterilizer: Selectomat HP 666-1 HRED (MMM)
  - Product is double-packed.

10.7 Reprocessing the Sheath

10.7.1 Initial Treatment at the Point of Use

Reprocessing at the point of use is carried out to remove coarse soiling on the product.

Requirement

- Auxiliary instrument has been removed.
- Product is separated from the system components.

Recommended materials

- SYRINGE (20 ml)
- COLD TAP WATER
- FDA approved tray or instrument rack

See section 10.2 “Recommended Materials for Reprocessing”

NOTICE

Residue adhering to surfaces

Do not use cleaning agents (e.g., aldehydes) or hot water (> 40 °C) for pre-cleaning.

NOTICE

Promotion of corrosion

Do not use physiological saline solution for rinsing out hollow spaces.

NOTICE

Product damage

Must be stored securely in a closed container.

NOTICE

Risk of infection. Contamination of surrounding area

Must be stored securely in a closed container.

1. Remove coarse soiling from products.
2. If more than 6 hours have passed between use and reprocessing, rinse out hollow spaces with cold tap water and narrow hollow spaces (e.g., stopcocks) with a 20 ml syringe filled with water.
3. To ensure secure transport, place the product in a perforated basket.

Initial treatment at the point of use is complete.

10.7.2 Disassembly

The product must be disassembled before cleaning.

Requirement

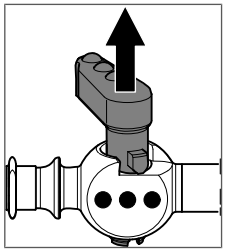
- All coarse soiling is removed from the product.

Recommended materials

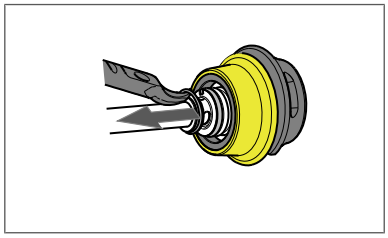
- 15106.230 | O-RING TOOL

See section “Recommended Materials for Reprocessing”

1. Pull out the stopcock insert.



2. If necessary, remove defective O-rings from the inner sheath with the O-ring tool.



The product is dismantled.

10.7.3 Manual Reprocessing

Manual reprocessing consists of pre-cleaning, manual cleaning, and drying.

Requirement

- The product is dismantled.
- Basin is filled with cleaning agent as per manufacturer specifications.

Recommended materials

- LINT-FREE DISPOSABLE CLOTH
- COLD TAP WATER
- 6199.00 | CLEANING GUN
- 68603 | BASIN (WXHXD) 548 X 100 X 348 MM
- 7970409 | CLEANING BRUSH Ø 9 MM TL 400 MM
- 7970407 | CLEANING BRUSH Ø 7 MM TL 400 MM
- 7980002 | DOUBLE CONICAL STRAIGHT CLEANING BRUSH
- 7980003 | DOUBLE CONICAL STRAIGHT CLEANING BRUSH
- 86.90 | CLEANING BRUSH

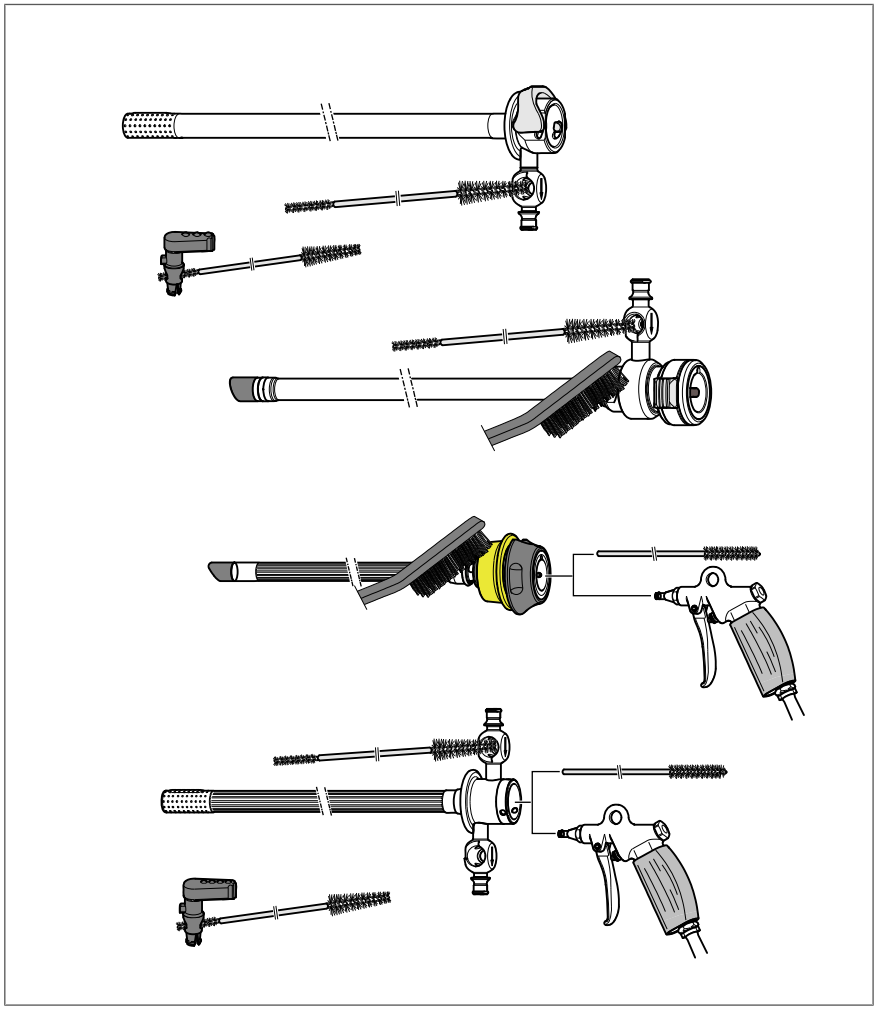
See section “Recommended Materials for Reprocessing”.

Pre-cleaning for the manual cleaning process

1. Rinse the products under cold, running tap water for at least 20 seconds.
2. Thoroughly rinse the channels for at least 20 seconds or in pulsed mode with 5 pressure surges (2.5 – 4.0 bar) with cold tap water using a cleaning gun |e.g., model 6199.00|.

Manual cleaning

1. Immerse all disassembled parts separately in a basin |e.g., model 68603| filled with a certified cleaning solution and leave for 6 minutes at room temperature.
2. Actuate the black and yellow locking rings of the inner sheath and the connection part 10x each.
3. Fill the channels completely with the cleaning solution using a syringe, avoiding any trapped bubbles.
   ⇨ **Note!** Complete wetting of the surface
   Completely wet the surfaces of the products with cleaning solution.
   ⇨ **Note!** Observe the manufacturer specifications for the cleaning agent.
   Observe the manufacturer’s application concentration and exposure time.



4. Brush the Luer connectors, stopcock insert, and stopcock housing with a cleaning brush 5x under the liquid surface level.
   ⇨ **Note!** Using the right brush
   Models 8655314, 8655324 with brush 7980002
   Model 8675426 with brush 7980003
5. Brush the channel with the cleaning brush 6x under the liquid surface (pull through with brushless side first).
   ⇨ **Note!** Using the right brush
   Models 8655314, 8655324 with brush 7970407
   Model 8675426 with brush 7970409
6. Operate the locking sleeves to brush the exposed surfaces with a cleaning brush |e.g., model 86.90| until all visible traces of soiling have been removed.
7. Brush the surfaces 3x with the brush |e.g., model 86.90| or until no more residue is visible.
8. Thoroughly rinse the channels for 20 seconds or in pulsed mode with 5 pressure pulses (3.8–4 bar) with cold tap water using a cleaning gun |e.g., model 6199.00|.
9. Pull back the black and yellow locking sleeves and rinse for 20 seconds or in pulsed mode with 5 pressure surges (3.8–4.0 bar) with cold tap water using a cleaning gun |e.g., model 6199.00|.
10. Rinse the products under cold, running tap water for at least 20 seconds.

Drying after manual cleaning

1. Dry the outside of the products using a lint-free, disposable cloth or a drying cabinet.
2. Dry hollow spaces with filtered compressed air.
3. Observe section 10.7.4 “Visual and Function Checks”.

Manual reprocessing is complete.

10.7.4 Visual and Function Checks

The cleaning process and the product functions are assessed by means of the visual check and the function inspection.

Requirement

- Machine **or** manual reprocessing is carried out on the product.

Recommended materials

- -

Visual check

1. Perform a visual inspection on the product to ensure it is clean.
2. If necessary, repeat the reprocessing procedure until the product is visually clean.
3. Observe the 8.1 “Visual Check” section and perform the check.

Checking functionality

– Observe the 8.2 “Function Check” section and perform the check.

10.7.5 Assembly

Assemble the parts before sterilization.

Requirement

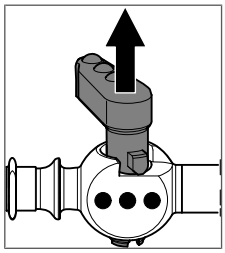
- The product is reprocessed manually.

Recommended materials

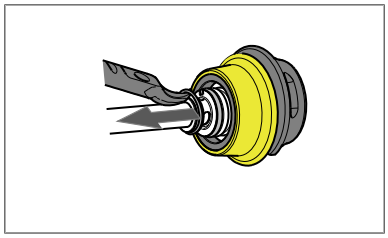
- -

Insert the drawing

1. Install the stopcock insert.
   ⇨ **Note!** Observe the number of points.
   The stopcock insert and stopcock housing must have the same number of points.



2. Replace the missing O-rings on the inner sheath.



Assembly is complete.

10.7.6 Packaging

Requirement

- The product has been reprocessed manually **and** is dry.

Recommended materials

- FDA approved tray or instrument rack

See section 10.2 “Recommended Materials for Reprocessing”

⚠ CAUTION

Risk of infection

Unsuitable sterile barrier system being used.

A sterile barrier system that is suitable for the sterilization process and complies with both ISO 11607-1 and the relevant national requirements must be used.

NOTICE

Only use an FDA-approved sterile barrier system.

Packaging the product

1. Place all parts in the universal mesh basket.
2. Package the perforated basket with the parts inside it in a suitable sterile barrier system.

10.7.7 Sterilization

Requirement

The following phases of the reprocessing procedure have been completed:

- Section “Manual Reprocessing” **and**
- Section “Packaging”

Recommended materials

- -

Steam sterilization

1. Place the packaged product in the steam sterilizer.
   ⇨ **Note!** Sterilize the products using the fractionated vacuum method (ISO 17665 and ANSI/AAMI ST79), taking into account the corresponding national requirements.
2. Select the following settings for the standard program:
   ⇨ Temperature exposure time: 4 minutes at 270 °F (132 °C)
   ⇨ Drying time: 20–30 minutes (the drying time depends on the sterilization process used)
   ⇨ Maximum temperature: 280 °F (138 °C)
3. Start program.

10.7.8 Storage

Requirement

- The product is sterile.

Recommended materials

- -

NOTICE

The sterile barrier system must comply with both the requirements of ISO 11607-1 and the relevant national requirements.

NOTICE

In order to maintain sterility, sterilized medical devices must be stored in the sterile barrier system.

NOTICE

Store sterilized products in a way that is compliant with ANSI/AAMI ST79.

1. Check the sterile barrier system for damage.
2. Store the sterilized medical device in the sterile barrier system.

10.7.9 Parameters of the Validation Process

To validate reprocessing, the following materials and machines were used:

Manual

- Cold tap water (drinking water quality): 10 °C–25 °C
- Cleaning agent: 0.8 % Cidezyme (ASP)

Sterilization

- Sterilizer: Selectomat HP 666-1 HRED (MMM)
  - Product is double-packed.

11 Technical description

11.1 Use, storage, transport, and shipping conditions

Usage conditions	Temperature: +10°C to +40°C, rel. humidity: 20% to 75%, atmospheric pressure: 700 hPa to 1,060 hPa
Storage conditions	Temperature: -20°C to +60°C, rel. humidity: 10% to 90%, atmospheric pressure: 700 hPa to 1,060 hPa
Transport and shipping conditions	Temperature: -20°C to +60°C, rel. humidity: 10% to 90% atmospheric pressure: 700 hPa to 1,060 hPa

ATTENTION

To prevent damage during transport or shipment of the products, we recommend using the original packaging material.

12 Spare Parts and Accessories

NOTICE

For the recommended materials for reprocessing, see section Reprocessing and Maintenance.

The products can be combined individually in line with the their relevant technical data and intended use. A complete overview can be found in the latest catalogs or brochures; alternatively, contact Richard Wolf or one of its representatives.

Figure	Model no.	Designation, technical data
	8874	RUBBER CAP, RED for sealing off the electrode clamping mechanism on the working element, PACK = 5 PCS, reusable
	150441178	CLAMPING SLEEVE, BNDL
	896.0002	STOPCOCK INSERT BNDL CAP 3.0 MM reusable
	896.0003	STOPCOCK PLUG BNDL CAP. 4.2 MM reusable
	15176.173	SEAL
	15364395	O-RING 7.65X1.78 VMQ-70 COATED
	15364396	O-RING 9.25X1.78 VMQ-70 COATED

13 Disposal of product, packaging material and accessories

⚠ WARNING

Danger of infection when disposing of contaminated products!

Incorrect handling during product disposal can lead to injuries and infections of the user or others.

Take safety precautions for the safe disposal of the products.

ATTENTION

To avoid contamining the environment, mind the safety precautions during product disposal and adhere to the country-specific laws and regulations.

14 Warranty and Customer Service

Richard Wolf guarantees our instruments to be free from any defects in materials and workmanship under normal use and service for one year. Richard Wolf general terms and conditions may be found on the back of our invoice.

Parts delivered separately by Richard Wolf are subject to all of the same general terms and conditions for our products, including the limitations of warranty and liability.

All products should be returned to Richard Wolf for any necessary or desired repair or part replacement. No product repair or part replacement should be done other than by Richard Wolf unless the care and instruction manual or other written information indicates that repair or part replacement is authorized. If authorized, parts must be replaced only by parts supplied or specified by Richard Wolf, and product repair and part replacement must be done in strict conformance with Richard Wolf specifications and instructions for repair and part replacement, including post replacement testing and recalibration. Failure to follow this requirement in any way can be dangerous to you, your personnel and your patients and voids the warranty for the product repaired or the product in which the part was replaced and if the part was supplied by Richard Wolf, for that part.

Delivery by Richard Wolf of technical documents such as circuit or other design diagrams does not constitute authorization for product repair or part replacement. Richard Wolf instruments and other products should never be modified or altered under any circumstances.

Contact Richard Wolf if you have any question (1) whether replacement of a part or a repair is authorized by Richard Wolf, or (2) whether you have complete instructions and specifications for part replacement or repair.

These instructions do not attempt to cover all details or variations in equipment, nor to provide for every possible contingency to be met in connection with installation, operation, or maintenance. Should further information be required or should problems arise which are not covered sufficiently for the purchaser's purpose, the matter should be referred to Richard Wolf Medical Instruments Corporation.

Our national sales and service offices, as well as our manufacturing facility, are located in Illinois. Trained manufacturer's representatives are located throughout the U.S. to serve you. For any questions regarding these instruments, or to place an order, contact Richard Wolf customer service department at 847-913-1113 or 800-323-WOLF (9653).

NOTICE

INSTRUMENT ORDERING POLICY

Richard Wolf reserves the right to make substitutions, if necessary, without prior notice.

NOTICE

REPAIR POLICY

Defective merchandise will be repaired or replaced at no charge to the customer, provided the customer delivers such defective merchandise prepaid. Any repairs, maintenance or servicing of Richard Wolf merchandise by anyone other than a factory authorized representative will render our warranty null and void.

NOTICE

REPAIR SHIPMENTS

When returning your instrument for repair, we suggest that you prevent shipping damage to the instrument by reusing the box that it was originally shipped in. Richard Wolf also recommends that the instrument be insured for an amount to cover the cost of replacement.

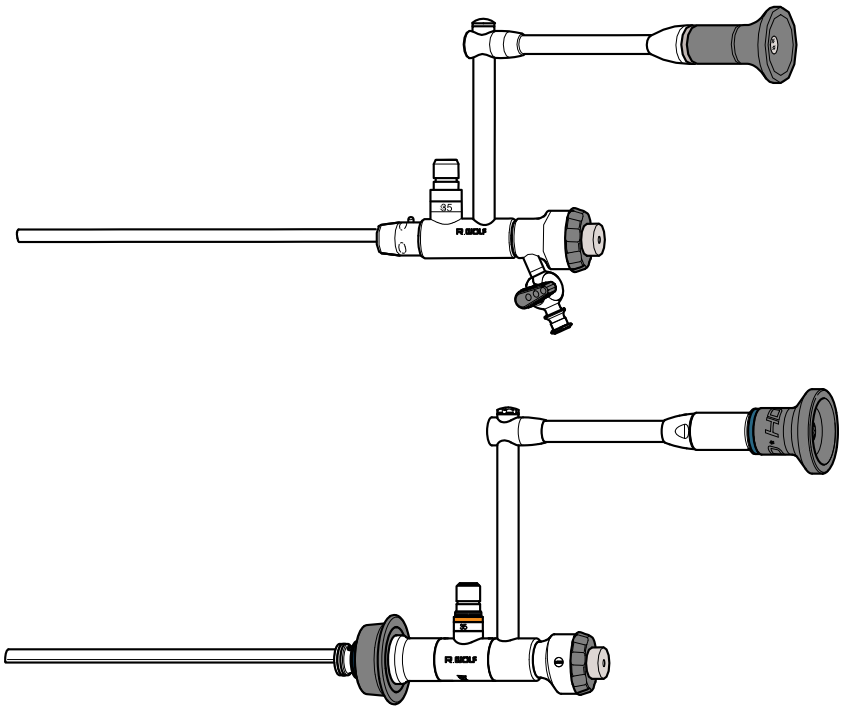
ATTENTION

For general safety and health reasons, Richard Wolf requires that you clean and reprocess all instruments before returning them for repair. If instruments are received in an unsanitary condition, Richard Wolf will clean and reprocess each instrument. A cleaning fee will be applied for each instrument requiring cleaning.

RICHARD WOLF

spirit of excellence

Instructions for use



Morcescopes

PANOVIEW

GA-D336 / en / US / V3.0 / 2023-07 / PK23-0132 /
(RW: en / 2018-12 V9.0 / PK19-9377)

Subject to technical changes!

Due to ongoing development, the product descriptions, figures, and technical data may deviate slightly from the current state.
For further information about our products, please contact Richard Wolf GmbH or a local representative.

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www.richardwolfusa.com

Contents

1 General safety notes and instructions for use

The product must only be used as intended following the instruction manual by adequately trained and qualified medical personnel. Maintenance and repair must be carried out by authorized experts.

Use the product only in the combinations and with the accessories and spare parts specified in this instruction manual. Use other combinations, accessories and replacement parts only if they are expressly intended for the planned application and if the performance characteristics and safety requirements are met. The product must not be altered in any way.

Reprocess the products in accordance with the manual before every use and before return shipment to protect the patient, user and third parties.

This manual is an integral part of the product and must be stored in such a way that it is accessible at any time during its entire life cycle. This manual must be passed on to any subsequent owner or user.

Immediately on receipt, check the product and its accessories for completeness and possible damage. Should the shipment give rise to complaints, please inform the manufacturer or supplier immediately.

Any severe incident occurring in conjunction with this product must be reported to the manufacturer.

⚠ CAUTION

Federal law restricts this device to sale by or on the order of a physician.

2 Safety instructions and levels of danger

⚠ WARNING

This signal word is used to indicate a potentially dangerous situation. Not avoiding this situation can result in death or extremely serious injuries.

⚠ CAUTION

This signal word is used to indicate a potentially dangerous situation. Not avoiding this situation can result in minor or moderate injury.

ATTENTION

This signal word without warning sign is used to indicate a potential danger of material damage.

NOTICE

This signal word indicates additional useful information for the reader, such as hints for easier operation as well as cross references.

3 Technical description

Morcescopes are used with various sheath systems listed below:

- **Morcescope 8970405 / 8970.401**
  - "E-Line" resectoscope continuous irrigation double sheath system (rotatable)
  - With morcescope adapter
  - "Shark" resectoscope continuous irrigation double sheath system (rotatable)
  - With "Shark" adapter
- **Morcescope 8970407**
  - "Shark" resectoscope continuous irrigation double sheath system (rotatable)

The color coding on the products indicates which sheaths and obturator may be combined:

Color coding	Sheath size
"E-Line" resectoscope continuous irrigation double sheath system (rotatable)	
Green	22.5 / 24.5 Fr
Yellow	24 / 26 Fr
"Shark" resectoscope continuous irrigation double sheath system (rotatable)	
Green	22 / 24 Fr
Yellow	24 / 26 Fr

- **Morcescope 8970405 / 8970.401**, consisting of:
  - Sheath tube, integrated light cable, optical system, and working channel
  - Cold light connection
  - Endoscope-side adapter (can be unscrewed)
  - Parallel view and eyecup
  - Automatic sealing element
  - Drain stopcock
- **Morcescope adapter**

For use with "E-Line" resectoscope continuous irrigation double sheath system

- **"Shark" adapter**

For use with "Shark" resectoscope continuous irrigation double sheath system

- **Morcescope 8970407**
  For use with "Shark" resectoscope continuous irrigation double sheath system, consisting of:
  - Sheath tube, integrated light cable, optical system, irrigation channel, and working channel
  - Cold light connection
  - Endoscope-side adapter (can be unscrewed)
  - Parallel view and eyecup
  - Automatic sealing element
  - Outer ring
- **Reprocessing basket**, consisting of:
  - Special brackets and fixing hooks
  - Locking mechanism
  - Utensil basket

4 Indications for use

4.1 Statement

The Morcescope Set, in conjunction with a morcellation probe, and with its sheaths and obturators, is used in the cutting (morcellation) and continuous removal of large detached tissue masses.

In combination with intracorporeal lithotriptors, e.g. operated pneumatically, by ultrasound, electro-hydraulically or by laser under endoscopic control.

Morcescope 8970407

▷ Continuous supply and drain of irrigation fluid via "Shark" continous irrigation outer sheath

When used as a morcescope:

For therapy via the transurethral passage after a TURP (TransUrethral Resection of the Prostate) procedure.

Adapter

The adapters serve to connect endoscope and sheath.

4.2 User and patient population

User

These products are exclusively intended for use by specialized medical personnel and must only be used by medically qualified and adequately instructed persons.

Patient population

The product is intended for adult patients.
The patient population intended for the application of the medical product herein described is not limited with regard to ethnicity, gender, body height and weight. Before use, the attending physician must make sure that the product in view of its dimensions or settings can be used safely in the patient.

5 Contraindications and side effects

5.1 Contraindications

There are currently no known contraindications directly related to the product. The responsible physician must decide on the basis of the patient's general condition whether an intended use is possible or not.

For further information, please refer to the most recent medical literature.

The country-specific laws and regulations must be complied with.

5.2 Side effects

No side effects directly related to the product are known if the system is used as intended.

6 Combinations

Morcescopes are used in conjunction with:

Morcescope

- Light projectors and fiber light cables
- Cameras and lenses
- Pumps for irrigation and suction
- Morcellation systems
- Accessories for endoscopic use

⚠ CAUTION

Be careful not to combine products incorrectly!

Injuries of the patient, user or others as well as damage to the product are possible.

- The products must only be used jointly if the intended use and the relevant technical data such as working length, diameter, etc. are the same.
- Also follow the instruction manuals of the products used in conjunction with this product.

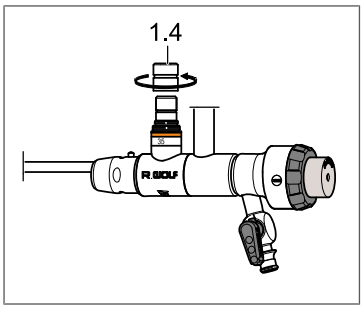


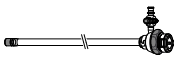
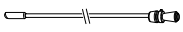
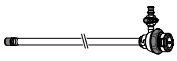
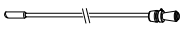
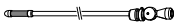
Fig. 1

The endoscope-side adapter (1.4) can be unscrewed and removed to allow the connection of fiber light cables from different manufacturers, using appropriate adapters.

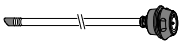
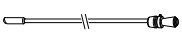
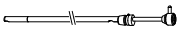
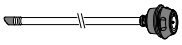
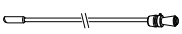
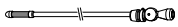
Ordering information can be found on the current catalog pages.

6.1 Overview of permissible combinations

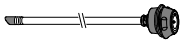
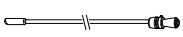
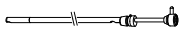
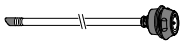
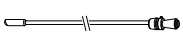
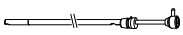
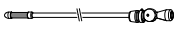
6.1.1 “E-Line” resectoscope continuous irrigation double sheath system with morcescope 8970.401 and 8970405

Item	Figure	Model no.	Designation, technical data	
4		8970.026	E-LINE ADAPTER FOR MORCESCOPE 26 FR	-
“E-Line” resectoscope continuous irrigation double sheath system; for this, see GA-D345 and BB-D345				Color coding
3a		8655.334	OUTER SHEATH FOR RESECTOSCOPE 24.5 FR	Green
3b		8655.344	INNER SHEATH FOR RESECTOSCOPE 22 FR	
2.1		8654.16	OBTURATOR FOR RESECTOSCOPE 22 FR	
2.2		8415.11	VIEWING OBTURATOR FOR RESECTOSCOPE 22 FR	
3a		8655.374	OUTER SHEATH FOR RESECTOSCOPE 26 FR	Yellow
3b		8655.384	INNER SHEATH FOR RESECTOSCOPE 24 FR	
2.1		8654.17	OBTURATOR FOR RESECTOSCOPE 24 FR	
2.2		8415.12	VIEWING OBTURATOR FOR RESECTOSCOPE 24 FR	
2.3		8654.175	DILATION OBTURATOR FOR RESECTOSCOPE 24 FR	

6.1.2 “Shark” resectoscope continuous irrigation double sheath system with morcescope 8970.401 and 8970405

Item	Figure	Model no.	Designation, technical data	
5		8675026	SHARK ADAPTER FOR MORCESCOPE 24/26 FR	-
“Shark” resectoscope continuous irrigation double sheath system; for this, see GA-D366 and BB-D366				Color coding
3c		8675424	OUTER SHEATH FOR RESECTOSCOPE 24 FR	Green
3d		8675322	INNER SHEATH FOR RESECTOSCOPE 22 FR	
2.1		8673022	OBTURATOR FOR RESECTOSCOPE 22 FR	
2.2		8673122	VIEWING OBTURATOR FOR RESECTOSCOPE 22 FR	
3c		8675426	OUTER SHEATH FOR RESECTOSCOPE 26 FR	Yellow
3d		8675324	INNER SHEATH FOR RESECTOSCOPE 24 FR	
2.1		8673024	OBTURATOR FOR RESECTOSCOPE 24 FR	
2.2		8673124	VIEWING OBTURATOR FOR RESECTOSCOPE 24 FR	
2.3		8673224	DILATION OBTURATOR FOR RESECTOSCOPE 24 FR	

6.1.3 “Shark” resectoscope continuous irrigation double sheath system with morcescope 8970407

Item	Figure	Model no.	Designation, technical data	
“Shark” resectoscope continuous irrigation double sheath system; for this, see GA-D366 and BB-D366				Color coding
3c		8675424	OUTER SHEATH FOR RESECTOSCOPE 24 FR	Green
3d		8675322	INNER SHEATH FOR RESECTOSCOPE 22 FR	
2.1		8673022	OBTURATOR FOR RESECTOSCOPE 22 FR	
2.2		8673122	VIEWING OBTURATOR FOR RESECTOSCOPE 22 FR	
3c		8675426	OUTER SHEATH FOR RESECTOSCOPE 26 FR	Yellow
3d		8675324	INNER SHEATH FOR RESECTOSCOPE 24 FR	
2.1		8673024	OBTURATOR FOR RESECTOSCOPE 24 FR	
2.2		8673124	VIEWING OBTURATOR FOR RESECTOSCOPE 24 FR	
2.3		8673224	DILATION OBTURATOR FOR RESECTOSCOPE 24 FR	

7 Illustrations

7.1 “E-Line” resectoscope continuous irrigation double sheath system (rotatable) with morcescope 8970.401 and 8970405

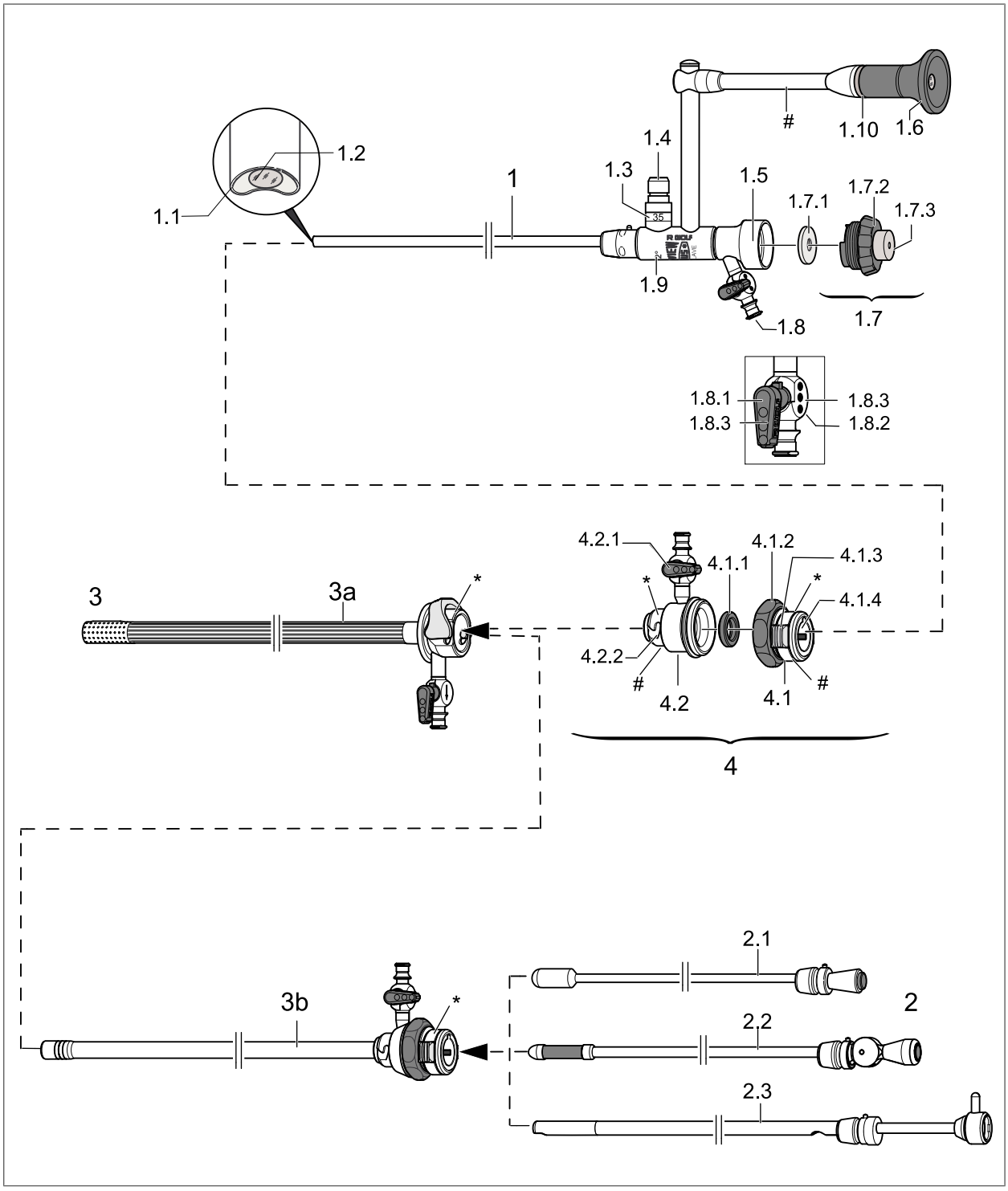


Fig. 2

7.1.1 Key and identification

Item	Designation	Item	Designation
1	Morcescope 0° / 12°		
1.1	Light outlet	1.8	Irrigation connector
1.2	Lens	1.8.1	Stopcock insert
1.3	Code, numerical marker for fiber bundle diameter	1.8.2	Stopcock housing
1.4	Endoscope-side adapter	1.8.3	Capacity indicator on stopcock insert/stopcock housing
1.5	Maximum capacity	1.9	Viewing direction indication
1.6	Eyecup	1.10	Color ring Indication of the direction of view Blue = 0° / orange = 12°
1.7	Automatic sealing element consisting of:		
1.7.1	Sealing membrane	#	Model no.
1.7.2	Sealing element		
1.7.3	Sealing cap		
	“E-Line” resectoscope continuous irrigation double sheath system (rotatable)		
2	Obturators	4	Morcescope adapter consisting of:
2.1	Obturator	4.1	Rotatable connection part
2.2	Viewing obturator	4.1.1	QUAD lip seal
2.3	Dilation obturator	4.1.2	Locking collar
3	Continuous irrigation double sheath system consisting of:	4.1.3	Tab
3a	Continuous irrigation outer sheath	4.1.4	Locking mechanism
3b	Continuous irrigation inner sheath	4.2	Adapter
		4.2.1	Irrigation valve
		4.2.2	Opening
		*	French specification
		#	Model no.

7.2 “Shark” resectoscope continuous irrigation double sheath system (rotatable) with morcescope 8970.401 and 8970405

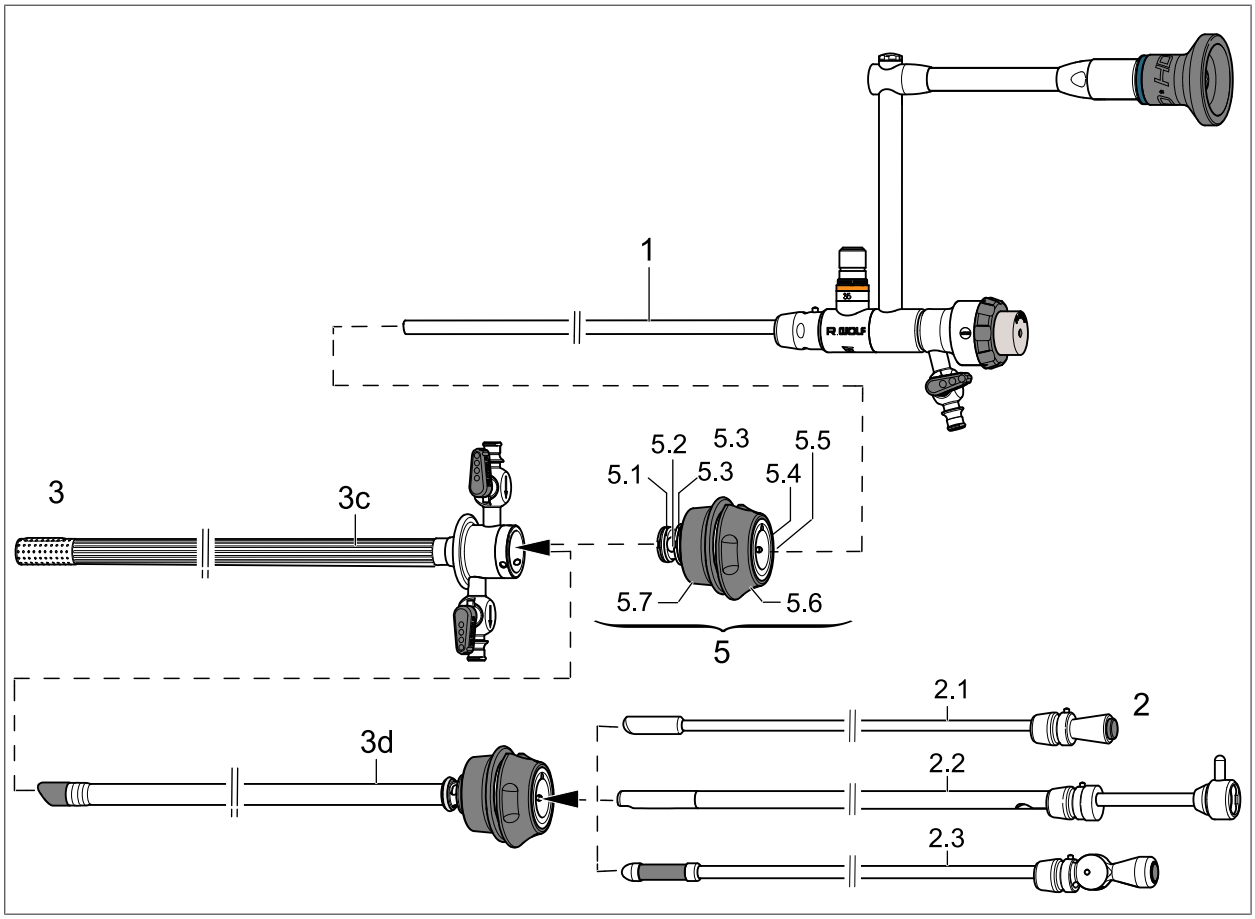


Fig. 3

7.2.1 Key and identification

Item	Designation	Item	Designation
1	Morcescope 0° / 12° Key and identification: see page 8		
	“Shark” resectoscope continuous irrigation double sheath system (rotatable)		
2	Obturators	5	“Shark” adapter
2.1	Obturator	5.1	O-ring
2.2	Viewing obturator	5.2	Irrigation holes
2.3	Dilation obturator	5.3	O-ring
3	Continuous irrigation double sheath system consisting of:	5.4	Lock body
3c	Outer sheath	5.5	Recess (for orientation)
3d	Inner sheath	5.6	Actuating ring
4	Not assigned	5.7	Outer ring

7.3 “Shark” resectoscope continuous irrigation double sheath system (rotatable) with morcescope 8970407

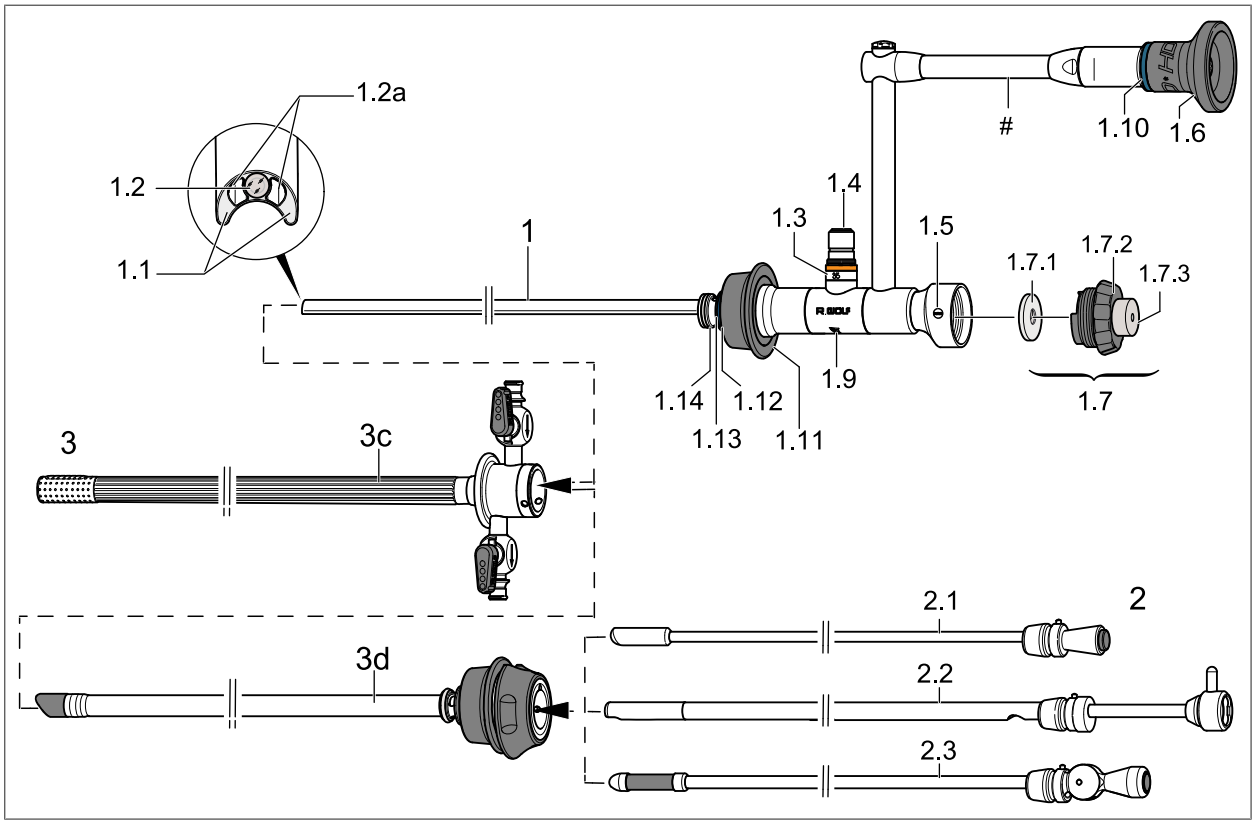


Fig. 4

7.3.1 Key and identification

Item	Designation	Item	Designation
1	Morcescope 0°		
1.1	Light outlet	1.8	Not assigned
1.2	Lens	1.9	Viewing direction indication
1.2a	Irrigation channel	1.10	Color ring Indication of the direction of view Blue = 0° / orange = 12°
1.3	Color ring and numerical code marker for fiber bundle diameter	1.11	Outer ring
1.4	Endoscope-side adapter	1.12	O-ring
1.5	Maximum capacity	1.13	Irrigation holes
1.6	Eyecup	1.14	O-ring
1.7	Automatic sealing element consisting of:		
1.7.1	Sealing membrane	#	Model no.
1.7.2	Sealing element		

Item	Designation	Item	Designation
1.7.3	Sealing cap		
	“Shark” resectoscope continuous irrigation double sheath system (rotatable)		
2	Obturators	3	Continuous irrigation double sheath system consisting of:
2.1	Obturator	3c	Outer sheath
2.2	Viewing obturator	3d	Inner sheath
2.3	Dilation obturator	3d	Inner sheath

7.4 Symbols

Symbols	Designation
	Caution
	Follow the manual
	Product number
	Lot code
	Serial Number
	Manufacturer
	Manufacturing date
	Number, amount
	Data Matrix Code
	Federal law restricts this device to sale by or on the order of a physician.
	CE marking with identification no. of the notified body in accordance with Medical Devices Directive 93/42/EEC. **Applies only** if the **device and/or packaging bears this marking**. Devices of Class I, excluding sterile products and products with a measuring function, are not marked with the four-digit identification number of the notified body. The CE marking on the cover of these instructions for use refers exclusively to the main Richard Wolf product or, if several equivalent products are described, to the highest classified Richard Wolf product. The CE marking of the other products from Richard Wolf – and, if applicable, from other manufacturers – described in these instructions for use results exclusively from the marking on the product and/or the packaging.

8 Application

⚠ CAUTION

Limited product stability!

Excessive force will cause damage to the products, impair their function, and therefore endanger the patient.

Immediately before and after each use, check the products for damage, loose parts, and completeness.

Make sure that no missing parts remain in the patient.

Do not use the products if they are damaged or incomplete or have loose parts.

8.1 Preparation

1. Check assembly:
   - ⇨ Section 10.3 Morcescope (1) 8970.401 and 8970405, morcescope adapter (4)
   - ⇨ Section 10.4 Morcescope (1) 8970407, “Shark” adapter (5)
2. Perform a visual check: Section 9 Checks and 9.1 Visual checks
3. Tighten the endoscope-side adapter (1.4).

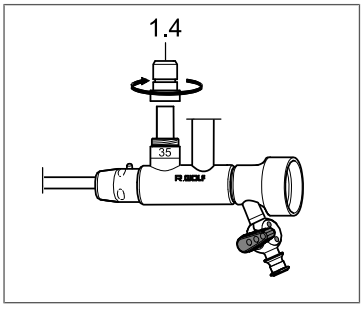


Fig. 5

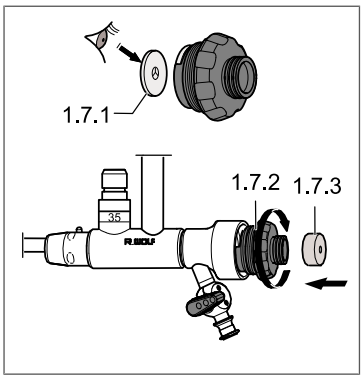


Fig. 6

Installing the automatic sealing element (1.7)

1. Unscrew the sealing element (1.7.2) and check whether a sealing membrane (1.7.1) is included.
2. Firmly retighten the sealing element (1.7.2).
3. Push on the sealing cap (1.7.3).

8.1.1 Connecting the morcescope (1) to the system components

◇ Connect the fiber light cable to the cold light connection and connect to a suitable light source.

ATTENTION

To allow optimum light transmission, the fiber bundle diameter at the endoscope and at the fiber light cable must be the same.
Possible consequences if labels do not match:
Fiber light cable with fiber bundle diameter that is too large (cross-section:)
▹ Excessive heating at the coupling point of the endoscope
Fiber light cable with fiber bundle diameter that is too small (cross-section:)
▹ Reduced light power
The appropriate fiber bundle diameter can be identified by the color ring and by the code on the endoscope. These must match the color ring and the code on the endoscope-side fiber light cable.

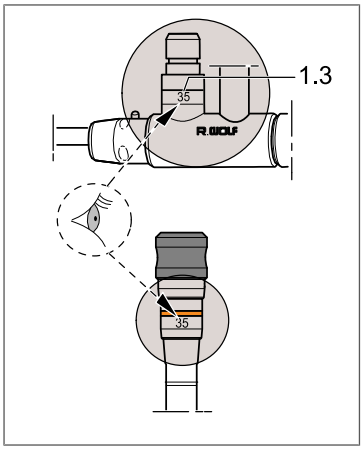


Fig. 7

Morcescope 8970.401

Only the code is present on the endoscope

The code (1.3) on the endoscope and on the endoscope-side fiber light cable must match.

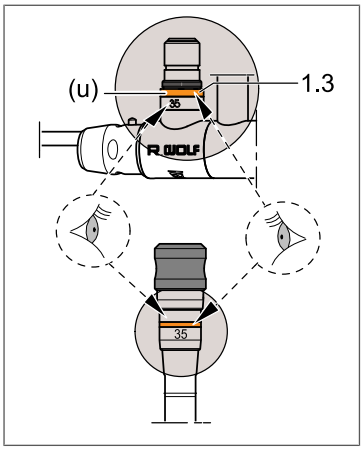


Fig. 8

Morcescope 8970405 / 8970407

Code and color ring are present on the endoscope

The code (1.3) and color ring (u) on the endoscope and on the endoscope-side fiber light cable must match.

⚠ CAUTION

Heat generation due to high light energy!

In unfavorable combinations, the temperature at the coupling point or at the light outlet of the endoscope may increase.

Burns to the patient, user, or others as well as damage to the endoscope are possible.

Reduce the light power or adjust the fiber light cable cross-section.

◇ Perform a function check: Section 9.2 Function check

8.2 “E-Line” resectoscope continuous irrigation double sheath system (rotatable) with morcescope 8970.401 and 8970405

8.2.1 Morcescope adapter (4)

ATTENTION

The morcescope adapter (4) can only be used in combination with the “E-Line” resectoscope continuous irrigation double sheath system 8655.374 / 8655.384.

The preparatory measures for this sheath system can be found in the instructions for use GA-D345.

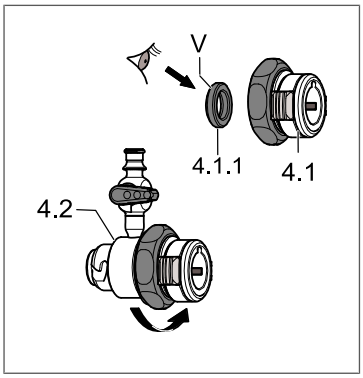


Fig. 9

1. Unscrew the rotatable connection part (4.1) and check whether a QUAD lip seal (4.1.1) is included.
2. Check that the QUAD lip seal (4.1.1) is in the correct position.
   ⇨ The sealing lip (v) points in the direction of the adapter (4.2).
3. Firmly tighten the rotatable connection part (4.1).

8.2.2 Inserting the morcescope (1) into the morcescope adapter (4)

Locking

◇ Insert the morcescope (1) into the morcescope adapter (4) until the groove (a) and pin (b) lie on one plane.

Push together until the locking mechanism (4.1.4) automatically engages.

NOTICE

If the locking mechanism (4.1.4) does not engage, press the tab (4.1.3) as far as it will go and repeat the process.

Releasing

◇ Press the tab (4.1.3) and remove the morcescope (1).

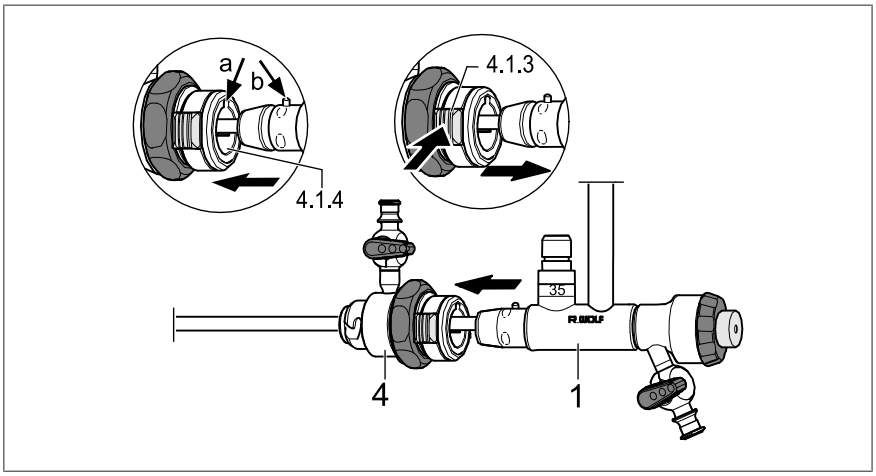


Fig. 10

8.2.3 Inserting the morcescope (1) with the morcescope adapter (4) into the continuous irrigation outer sheath (3a)

Locking

1. Insert the morcescope adapter (4) into the continuous irrigation outer sheath (3a) until the recess (w) and pins (x) lie on one plane.
2. Push together until the locking mechanism automatically engages.

Releasing

◇ Press the bracket (y) of the continuous irrigation outer sheath (3a) in the direction of the arrow and remove the morcescope adapter (4).

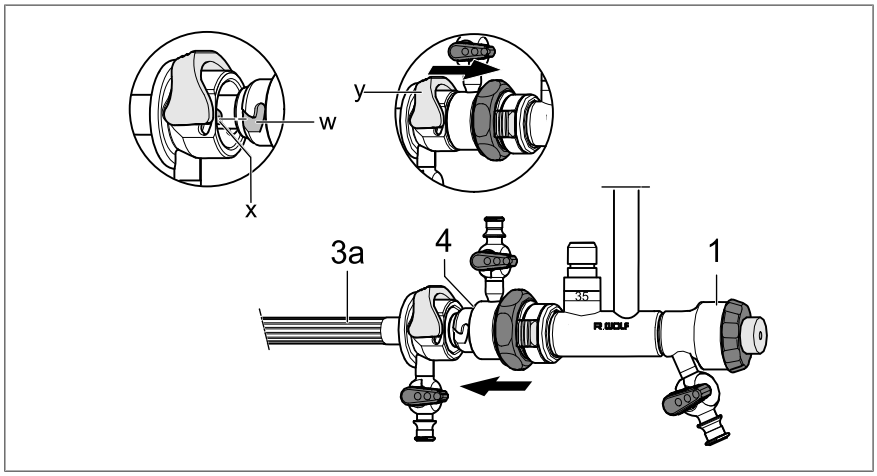


Fig. 11

8.3 “Shark” resectoscope continuous irrigation double sheath system (rotatable) with morcescope 8970.401 and 8970405

8.3.1 Inserting the “Shark” adapter (5) into the outer sheath (3c)

Locking

1. Check that O-rings (5.1) (5.3) are installed on the “Shark” adapter (5).
2. Insert the “Shark” adapter (5) into the outer sheath (3c) as far as it will go.
   ⇨ The outer sheath (3c) automatically (audibly) engages in the “Shark” adapter (5) by means of a ball catch (c).
3. Check the fit of the rotatable connection.

Releasing

◇ Push the outer ring (5.7) on the “Shark” adapter (5) in the direction of the arrow as far as it will go, hold it, and remove the outer sheath (3c).

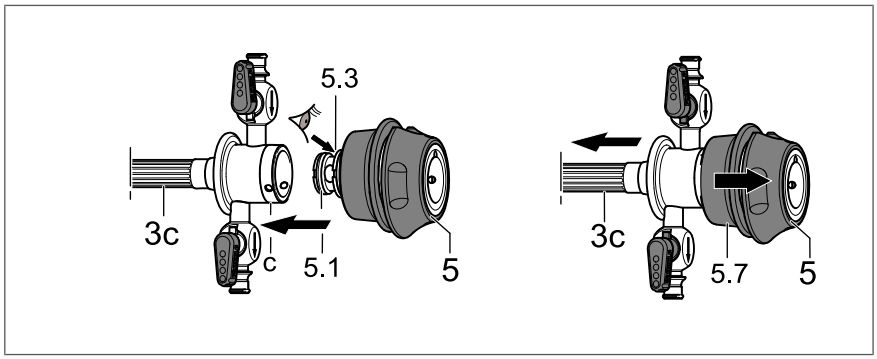


Fig. 12

8.3.2 Orientation guide for inserting the instruments

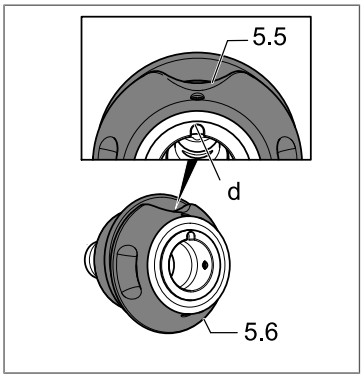


Fig. 13

NOTICE

The actuating ring (5.6) has an opening (5.5) that is in the same position as the groove (d).
When using obturators (2) and the morcescope (1), the groove (d) of the actuating ring (5.6) and the pin (e) of the instruments must lie on one plane.
The opening (5.5) serves as an orientation guide.

8.3.3 Inserting the morcescope (1) into the attached “Shark” adapter (5)

Locking

1. Insert the morcescope (1) into the installed “Shark” adapter (5) so that the groove (e) and pin (f) lie on one plane.
2. Push together until the morcescope (1) automatically engages in the lock body (5.4).
3. Check that the connection is fitted securely.

NOTICE

If the morcescope (1) does not engage in the lock body (5.4), press the actuating ring (5.6) as far as it will go in the direction of the arrow and repeat the process.

Releasing

◇ Press the actuating ring (5.6) as far as it will go in the direction of the arrow and remove the morcescope (1).

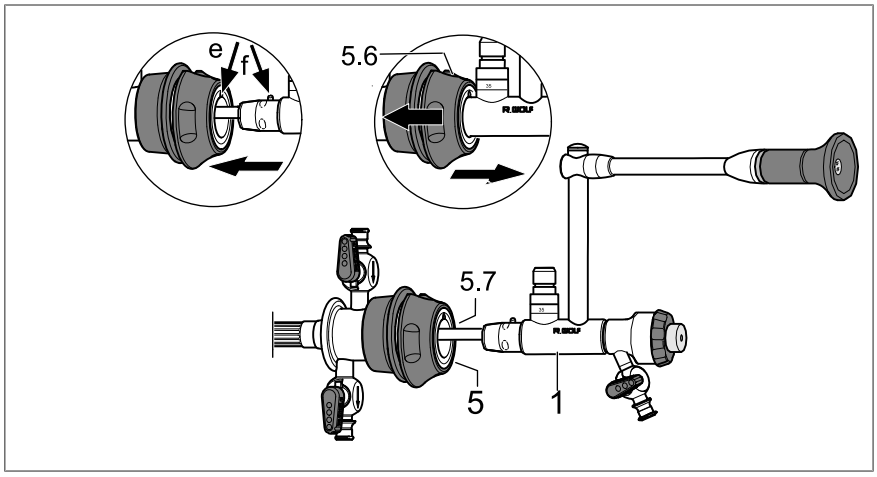


Fig. 14

8.4 “Shark” resectoscope continuous irrigation double sheath system (rotatable) with morcescope 8970407

8.4.1 Inserting the morcescope (1) into the outer sheath (3c)

Locking

1. Check that the O-rings (1.12) (1.14) are installed on the morcescope (1).
2. Insert the morcescope (1) into the outer sheath (3c) as far as it will go.
   ⇨ The outer sheath (3c) automatically (audibly) engages in the morcescope (1) by means of a ball catch (c).
3. Check the fit of the rotatable connection.

Releasing

◇ Push the outer ring (1.11) onto the morcescope (1) in the direction of the arrow as far as it will go, hold it, and remove the outer sheath (3c).

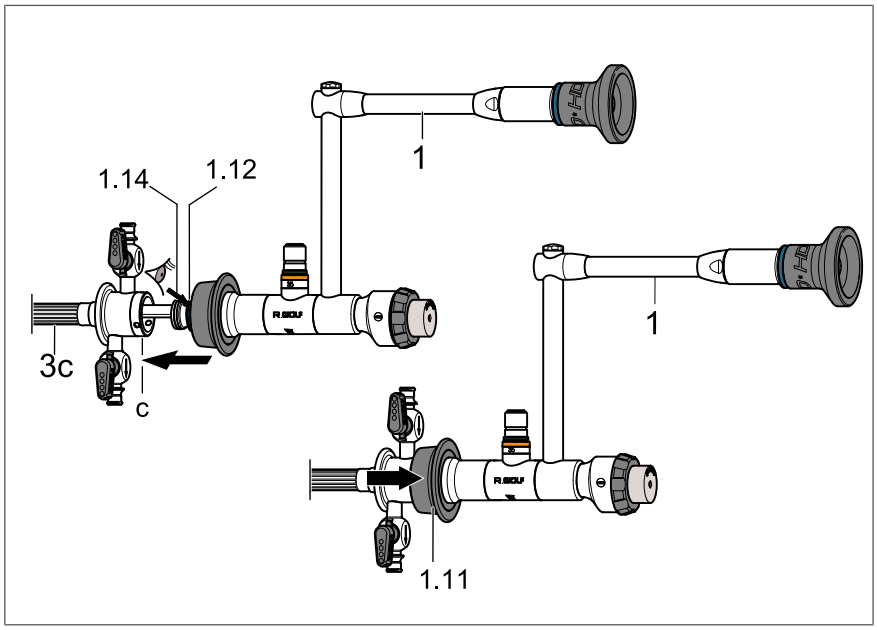


Fig. 15

8.5 General notes and instructions for use

ATTENTION

Only use products with type BF or CF applied parts together with the morcescope (1).

8.5.1 “E-Line” resectoscope continuous irrigation double sheath system with morcescope 8970.401 and 8970405

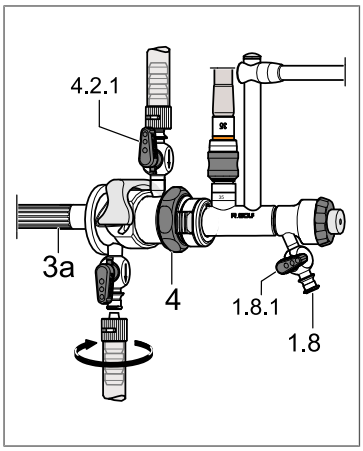


Fig. 16

Continuous irrigation outer sheath (3a) with morcescope adapter (4)

1. Connect the irrigation tube and drain tube to the irrigation valve (4.2.1) and drain stopcock on the outer sheath (3a), as well as to the irrigation system.
2. Open the stopcock insert on the irrigation valve and drain stopcock.
3. Keep the stopcock insert (1.8.1) on the irrigation connector (1.8) closed throughout the entire process.
4. Switch on the irrigation system and check the irrigation function.

8.5.2 “Shark” resectoscope continuous irrigation double sheath system with morcescope 8970.401 and 8970405

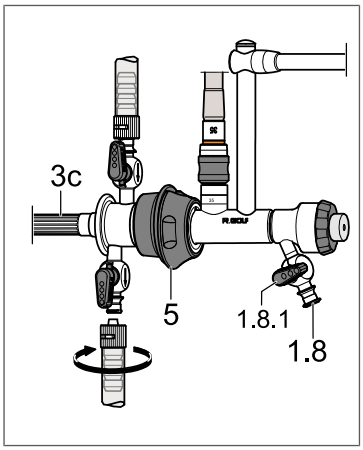


Fig. 17

Continuous irrigation outer sheath (3c) with “Shark” adapter (5)

1. Connect the irrigation tube and drain tube to the irrigation valve and drain stopcock on the outer sheath (3c), as well as to the irrigation system.
2. Open the stopcock insert on the irrigation valve and drain stopcock.
3. Keep the stopcock insert (1.8.1) on the irrigation connector (1.8) closed throughout the entire process.
4. Switch on the irrigation system and check the irrigation function.

8.5.3 “Shark” resectoscope continuous irrigation double sheath system with morcescope 8970407

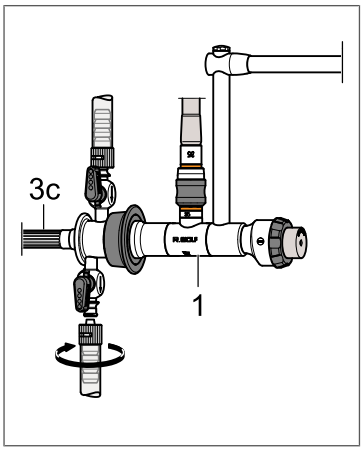


Fig. 18

Morcescope (1) with continuous irrigation outer sheath (3c)

1. Connect the irrigation tube and drain tube to the irrigation valve and drain stopcock on the outer sheath (3c), as well as to the irrigation system.
2. Open the stopcock insert on the irrigation valve and drain stopcock.
3. Switch on the irrigation system and check the irrigation function.

8.5.4 Irrigation fluid

⚠ CAUTION

Excess pressure may cause infiltration!

This may result in serious injury to the patient.

To ensure a low-pressure continuous irrigation effect, suction must be applied via the Morcellator.

⚠ CAUTION

Temperature increase when working without irrigation fluid!

Mucous membrane injuries due to excessive temperatures put the patient at risk.

Activate the laser fiber / Morcellator probe only in the irrigation fluid and with continuous irrigation.

8.5.5 Light

⚠ WARNING

Heat generation due to high light energy!

Risk of unintentional tissue damage

▷ Due to insufficient distance between the light emission area and tissue

▷ Due to soiling in the light emission area

▷ When using high-performance light sources

Do not touch the light emission area and avoid direct contact with tissue. Remove the soiling.

⚠ WARNING

Fire hazard!

The high heat generation in the area where light is emitted can lead to excessive heating or ignition when the endoscope is put down on heat-sensitive, flammable surfaces (dark cloths, etc.).

Place the endoscope in a safe place.

If the endoscope is not going to be used for an extended period, switch off the light source.

⚠ CAUTION

Risk of burns!

Due to the high energy of the light source, the adapter and the glass surface of the fiber light cable are extremely hot when the light cable is unplugged from the light source.

Burns may result from unintentional contact with the patient, user, or others.

Do not touch the adapter or glass surface of the fiber light cable. Allow the light cable to cool down.

⚠ CAUTION

Risk of glare!

Restricted vision may occur.

Do not look into the light outlet of a morcescope connected to a light source.

8.5.6 Power

⚠ WARNING

Danger of electric shock!

Patient leakage currents can add up if the endoscopes are combined with other energetically operated endoscopic accessories.

- Make sure that the combinations do not exceed the permissible patient leakage currents.

8.5.7 Image quality

⚠ CAUTION

Increased risk potential if the image is blurred!

Injuries to the patient are possible.

Cancel procedure for safety reasons.

Check the image quality of the endoscope before use (section 9.2.1 Morcescope (1)).

8.6 Laser application

When using lasers, you must observe the information from the laser device manufacturer and the general regulations for the use of lasers.

You must wear the prescribed personal protective equipment.

⚠ CAUTION

Do not work outside of the field of view!

Unintentional tissue damage as well as damage to the distal end of the morcescope and to the instrument parts are possible!

Do not activate the laser until

▷ The tip of the laser fiber appears fully in the field of view of the morcescope and

▷ The intended application area can be contacted using the pilot beam

ATTENTION

Heat generation due to focused laser beam!

The heat generated by the laser beam affects the stability of the instrument parts.

- Do not direct the laser beam at instrument parts, especially plastic parts.
- Maintain a sufficient safety distance.

⚠ CAUTION

Highly focused light beams!

The potential laser energy can result in injuries to the user's face around their eyes.

When used together with laser equipment, wear the prescribed personal protective equipment.

When using lasers and working with endoscopes in direct view, also use a suitable filter attachment.

⚠ CAUTION

Risk of eye damage if used without a filter attachment!

Use a suitable filter attachment on the eyepiece of the morcescope.

8.7 Tissue morcellation

ATTENTION

Observe the instructions for use of the Morcellator!

ATTENTION

To prevent the bladder from collapsing, we recommend using the irrigation connector on the continuous irrigation outer sheath (3c) as an additional inlet during morcellation to enable connection of a second irrigator container.
Suction is via the Morcellator.
The proximal irrigation connector (1.8) remains closed.

8.7.1 Changing the instrument (“E-Line” resectoscope continuous irrigation double sheath system with morcescope 8970.401 and 8970405)

NOTICE

We recommend the following procedure when changing instruments from laser enucleation to tissue morcellation:

Laser resectoscope sheath with working element and PANOVIEW telescope is in situ.

Disassembling the laser resectoscope

1. Remove the laser fiber.
2. Close the irrigation valve and the drain stopcock on the continuous irrigation inner sheath (3b).
3. Switch off the intake for irrigation medium.
4. Remove one by one:
   - ⇨ Irrigation tube
   - ⇨ Fiber light cable
   - ⇨ Camera head and lens

ATTENTION

Do not remove the continuous irrigation inner sheath (3b) with working element and PANOVIEW telescope from the in-situ continuous irrigation outer sheath (3a).

Preparing the morcescope (1)

1. Adapt to the morcescope (1) one by one:
   - ⇨ Morcescope adapter (4)
   - ⇨ Irrigation tube
   - ⇨ Fiber light cable: Section 8.1.1 Connecting the morcescope (1) to the system components
   - ⇨ Camera head and lens
2. Perform a white balance.

Changing the instrument

1. Remove the continuous irrigation inner sheath (3b) together with the working element and PANOVIEW telescope.
2. Remove the working element and the PANOVIEW telescope.
3. Insert the pre-assembled morcescope (1) into the continuous irrigation outer sheath (3a) with visual guidance in place: Section 8.2.3 Inserting the morcescope (1) with the morcescope adapter (4) into the continuous irrigation outer sheath (3a)
   ⇨ The locking mechanism engages automatically.
4. Switch on the intake for irrigation medium.
5. Open the irrigation valve.
6. Insert the morcellation probe proximally through the automatic sealing element (1.7).

NOTICE

Advantage of the rapid instrument change described above:
▷ The bladder cannot collapse
▷ The prostate does not start to bleed again
This ensures good visibility and orientation.

8.7.2 Changing the instrument (“Shark” resectoscope continuous irrigation double sheath system with morcescope 8970.401 and 8970405)

NOTICE

We recommend the following procedure when changing instruments from laser enucleation to tissue morcellation:

Laser resectoscope sheath with working element and PANOVIEW telescope is in situ.

Disassembling the laser resectoscope

1. Remove the laser fiber.
2. Close the drain stopcock on the continuous irrigation outer sheath (3c).
3. Switch off the intake for irrigation medium.
4. Remove one by one:
   ⇨ Fiber light cable
   ⇨ Camera head and lens

ATTENTION

Do not remove the continuous irrigation inner sheath (3d) with working element and PANOVIEW telescope from the in-situ continuous irrigation outer sheath (3c).

Preparing the morcescope (1)

1. Adapt to the morcescope (1) one by one:
   ⇨ “Shark” adapter (5)
   ⇨ Fiber light cable: Section 8.1.1 Connecting the morcescope (1) to the system components
   ⇨ Camera head and lens
2. Perform a white balance.

Changing the instrument

1. Remove the continuous irrigation inner sheath (3d) together with the working element and PANOVIEW telescope.
2. Insert the pre-assembled morcescope (1) into the continuous irrigation outer sheath (3c) with visual guidance in place: Section 8.3.3 Inserting the morcescope (1) into the attached “Shark” adapter (5)
   ⇨ The outer ring (5.7) engages automatically.
3. Switch on the intake for irrigation medium.
4. Open the irrigation valve.
5. Insert the morcellation probe proximally through the automatic sealing element (1.7).

NOTICE

Advantage of the rapid instrument change described above:
▷ The bladder cannot collapse
▷ The prostate does not start to bleed again
This ensures good visibility and orientation.

8.7.3 Changing the instrument (“Shark” resectoscope continuous irrigation double sheath system with morcescope 8970407)

NOTICE

We recommend the following procedure when changing instruments from laser enucleation to tissue morcellation:

Laser resectoscope sheath with working element and PANOVIEW telescope is in situ.

Disassembling the laser resectoscope

1. Remove the laser fiber.
2. Close the drain stopcock on the continuous irrigation outer sheath (3c).
3. Switch off the intake for irrigation medium.
4. Remove one by one:
   ⇨ Fiber light cable
   ⇨ Camera head and lens

ATTENTION

Do not remove the continuous irrigation inner sheath (3d) with working element and PANOVIEW telescope from the in-situ continuous irrigation outer sheath (3c).

Preparing the morcescope (1)

1. Adapt to the morcescope (1) one by one:
   ⇨ Fiber light cable: Section 8.1.1 Connecting the morcescope (1) to the system components
   ⇨ Camera head and lens
2. Perform a white balance.

Changing the instrument

1. Remove the continuous irrigation inner sheath (3d) together with the working element and PANOVIEW telescope.
2. Insert the pre-assembled morcescope (1) into the continuous irrigation outer sheath (3c) with visual guidance in place: Section 8.4.1 Inserting the morcescope (1) into the outer sheath (3c)
   ⇨ The outer ring (1.11) engages automatically.
3. Switch on the intake for irrigation medium.
4. Open the irrigation valve.
5. Insert the morcellation probe proximally through the automatic sealing element (1.7).

NOTICE

Advantage of the rapid instrument change described above:
▷ The bladder cannot collapse
▷ The prostate does not start to bleed again
This ensures good visibility and orientation.

9 Checks

⚠ CAUTION

Caution: Damaged and incomplete products!
Injuries to the patient, user, and others are possible.
Run through the checks before and after each use.
Do not use the products if they are damaged and incomplete or have loose parts.
Return damaged products together with any loose parts for repair.
Do not attempt to do any repairs yourself.

9.1 Visual checks

1. Check products and accessories for:
   - ⇨ Damage
   - ⇨ Sharp edges
   - ⇨ Loose or missing parts
   - ⇨ Rough surfaces
2. Any inscription, lettering, or labeling necessary for safe use as intended must be legible.
   - ⇨ Any missing or illegible inscription, lettering, or labeling leading to handling or reprocessing errors must be reinstated.
3. Check the following parts for damage:
   - ⇨ Sealing membrane (1.7.1) and sealing cap (1.7.3)
   - ⇨ O-rings (5.1) (5.3) (1.12) (1.14)
   - ⇨ QUAD lip seal (4.1.1)
4. Replace brittle and cracked parts.

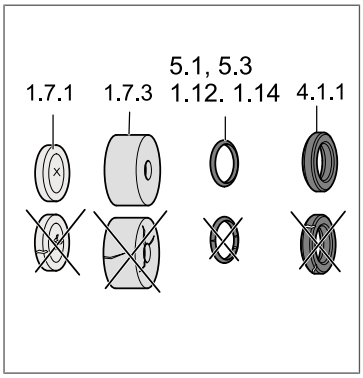


Fig. 19

9.2 Function check

1. Check the compatibility of the individual components.
2. Check that the individual connections are fitted securely.
3. Check the easy assembly and locking mechanisms of the individual products. Replace products if the connection
   - ⇨ does not hold despite locking
   - ⇨ cannot be locked, or can only be locked with difficulty.
4. Check for easy insertion of auxiliary instruments.
5. Check the rotatability of the morcescope (1) in combination with the continuous irrigation outer sheath (3a) (3c).
6. Check the irrigation and suction function.
7. Check the entire system for leaks and continuity.

9.2.1 Morcescope (1)

1. Check the image quality and light output with the system components.
2. Check the glass surfaces for coatings.
   ⇨ Coatings on the glass surfaces can cause a blotchy or cloudy field of view and reduce the light transmission considerably.
   ⇨ Wipe glass surfaces with a pad soaked in alcohol (wood, no metal or plastic) and rub off stubborn coatings with a suitable instrument cleaner.

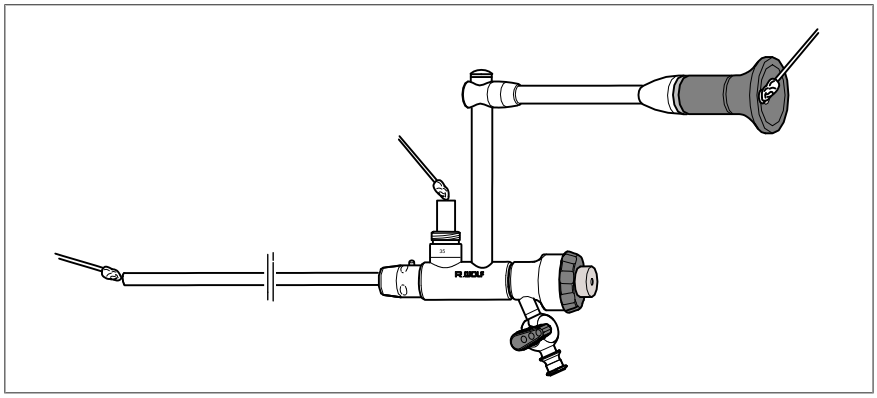


Fig. 20

3. Check the light output without the system components.
4. Hold the distal end of the endoscope toward a light source.
   ⇨ Broken fibers appear as black dots at the cold light connection. Once approx. 30% of the fibers are broken, the light output will no longer be sufficient.

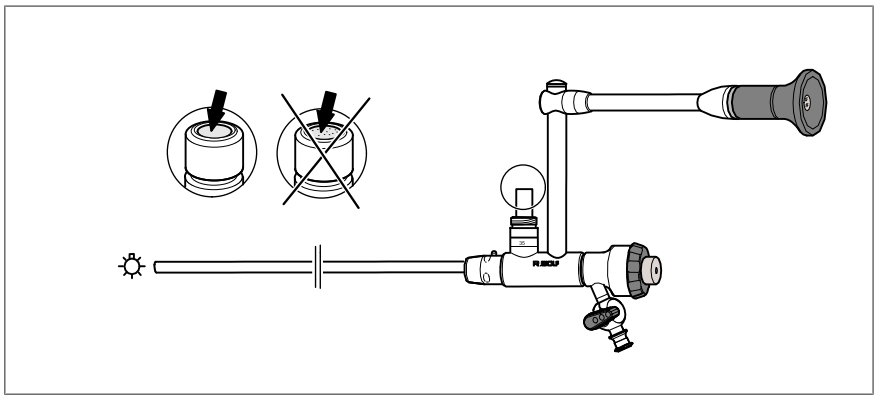


Fig. 21

9.2.2 Irrigation valve and drain stopcock

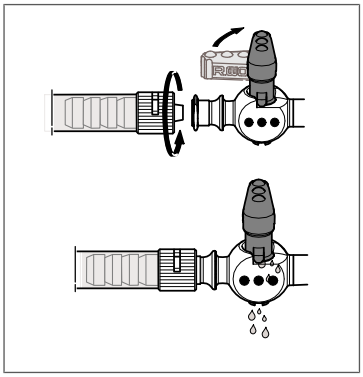


Fig. 22

Stopcock insert

1. Check that the stopcock insert can be felt to engage in the stopcock housing.
2. Check the leak tightness of the stopcocks.
   ⇨ Connect the supply tube, turn the stopcock insert to the locked position.
   ⇨ If the stopcock is leaking: Replace the stopcock insert.
3. Check that the stopcock insert moves easily in the stopcock housing.

10 Reprocessing and maintenance

⚠ WARNING

Creutzfeldt-Jakob Disease!

- If the patient is suspected of having Creutzfeldt-Jakob Disease (CJD) or a variant of the Creutzfeldt-Jakob Disease (vCJD) or the latter have been diagnosed, adequate measures must be taken to prevent possible transmission to other patients, users and third parties.
- The country-specific processing guidelines and regulations must be adhered to.

⚠ CAUTION

Maximum number of reprocessing cycles

Due to the product design and the materials used it is not possible to specify a defined limit of the maximum permissible reprocessing cycles. The service life of medical products is determined by their function and gentle handling.

Before returning defective products for repair, they must have gone through the entire reprocessing cycle.

The user is obliged to make sure that the reprocessing process including the resources, material and personnel are suitable for achieving the required results.

The state of the art and national laws require that validated processes be followed.

⚠ CAUTION

Injury due to damaged or incomplete products!

Injuries of the patient, user and others are possible.

- Run through the checks before and after each use.
- Do not use the products if they are damaged or incomplete or have loose parts.
- Return damaged products together with any loose parts for repair.
- Do not attempt do to any repairs yourself.

ATTENTION

- Use only cleaning agents and disinfectants whose efficacy and material compatibility with endoscopes and endoscopic accessories has been tested and approved by the chemicals manufacturer.
  ⇨ Examples of suitable active agents for chemical disinfection:
  - Ortho-phthalaldehyde
  - Ethandial, didecyldimethylammonium chloride
  - Formacedal, glutardialdehyde
  - Sodium carbonate peroxyhydrate
- Disinfectants meeting the test criteria of the FDA or national certification bodies may also be used.
- Do not use disinfectants containing peracetic acid without corrosion protection, phenols or chlorine components for the reprocessing of RICHARD WOLF products.

ATTENTION

Product damage if non-released reprocessing processes are used.

ATTENTION

Do not sterilize the products in hot-air sterilizers.

ATTENTION

Do not use metal tools or sharp-edged means (such as metal brushes) for cleaning the products.

NOTICE

Brand new products.
Before reprocessing, remove all protection foils and transport locks from the products and accessories.

NOTICE

Do not use cleaning agents, scouring agent or solvents for device care.

NOTICE

For immersion time and concentration follow the instructions of the chemicals manufacturer.

NOTICE

Before sterilization, screw on the screw connections, but only loosely:
▷ To allow a sufficient inflow of sterilization medium
▷ To prevent stress cracks
Tighten all screw connections before use.

NOTICE

Observe the following when cleaning the products:

- Products with long channels: Pull through the cleaning brush.
  - ⇨ Insert the cleaning brush into the channel with the brushless side first and pull out the brush on the other side of the channel.
- Other products/parts: Use a brush pass
  - ⇨ Move the cleaning brush forwards and backwards once.

Example:

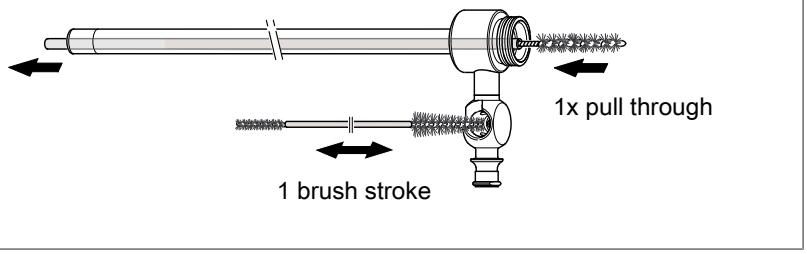


Fig. 23

Required equipment

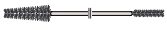
Image	Product no.	Designation, Technical data
-	38042.211	REPROCESSING BASKET
	7970407	CLEANING BRUSH Ø 7MM TL 400MM for Ø 4.6-6.5 mm channels, brush length 48 mm, PACK = 10 PCS, color: purple, for single use
	7970409	CLEANING BRUSH Ø 9MM TL 400MM for Ø 6.6-8.5 mm channels, brush length 48 mm, PACK = 10 PCS, color: orange, for single use
	7970411	CLEANING BRUSH Ø 11MM TL 400MM for Ø 8.6-10.5 mm channels, brush length 48 mm, PACK = 10 PCS, color: white, for single use
	7980002	DOUBLE CONICAL STRAIGHT CLEANING BRUSH for stopcock inserts / housings with 3 pegs, brush head 1: conical Ø 5-9 mm, brush head 2: Ø 4 mm PACK = 50 PCS, color: red, for single use
	8691	CLEANING BRUSH for surface cleaning, straight, PACK = 10 PCS, for single use

Image	Product no.	Designation, Technical data
	15106.230	O-RING TOOL
	64164.031	ADAPTER

10.1 Disassembly before cleaning

1. Remove the morcellation probe.
2. Remove all connections between the morcescope and system components.
   - ⇨ Morcescope (1)
   - ⇨ “Shark” resectoscope continuous irrigation double sheath system
   - ⇨ “E-Line” resectoscope continuous irrigation double sheath system
3. Remove all used parts:
   - ⇨ Morcescope (1): Section Inserting the morcescope (1) into the outer sheath (3c), Inserting the morcescope (1) into the attached “Shark” adapter (5), Inserting the morcescope (1) with the morcescope adapter (4) into the continuous irrigation outer sheath (3a)
   - ⇨ “Shark” adapter (5): Section Inserting the “Shark” adapter (5) into the outer sheath (3c)
   - ⇨ Morcescope adapter (4): Section Inserting the morcescope (1) into the morcescope adapter (4)

10.2 Reprocessing process

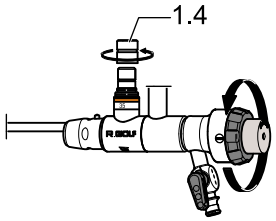
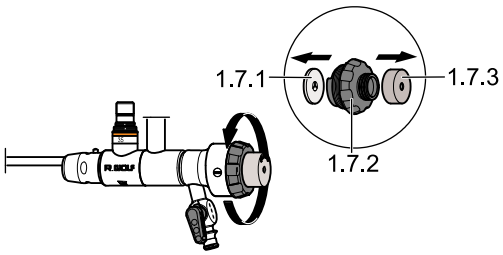
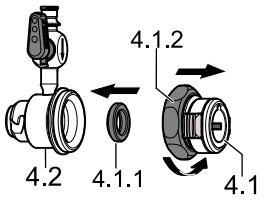
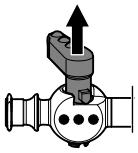
The tables below describe the reprocessing procedures with which Richard Wolf GmbH has performed validations.

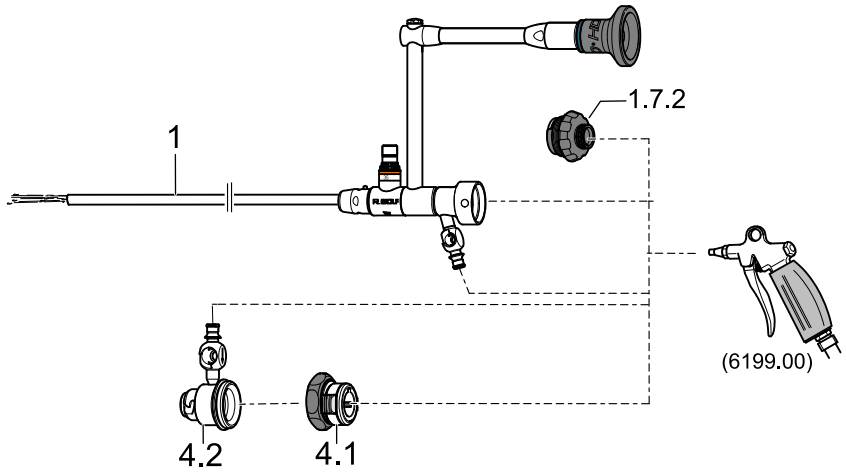
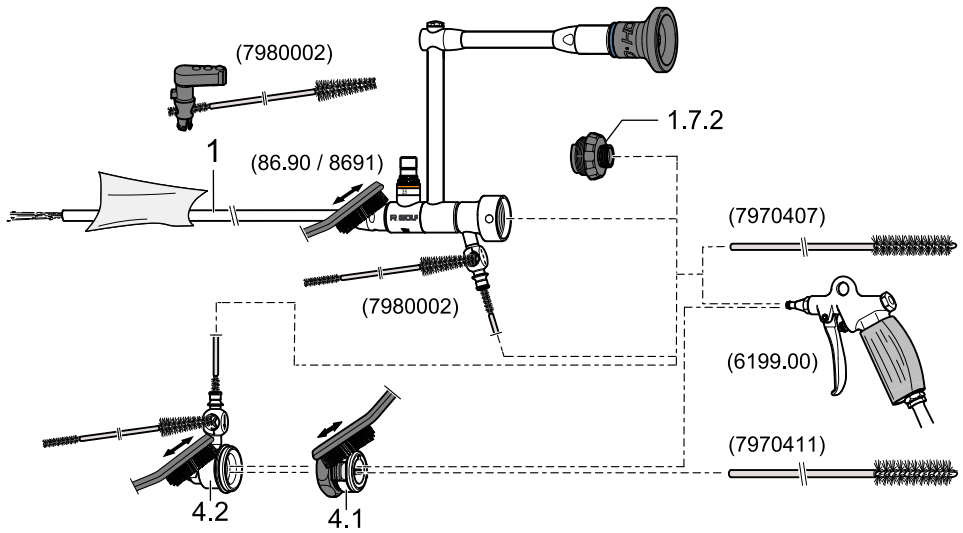
NOTICE

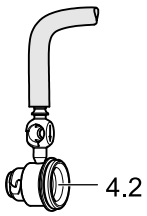
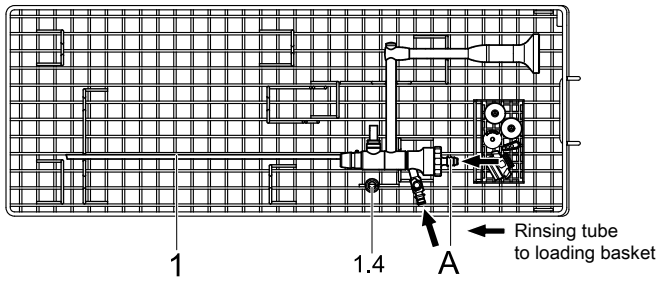
The reprocessing of the “E-Line” or “Shark” resectoscope continuous irrigation double sheath system is described in the relevant instructions for use and must be observed.

▷ See section Overview of permissible combinations

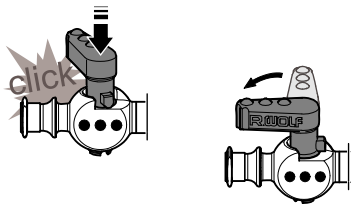
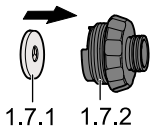
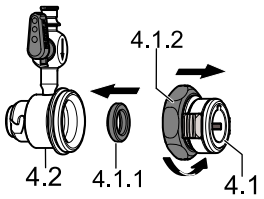
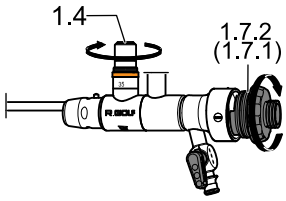
10.3 Morcescope (1) 8970.401 and 8970405, morcescope adapter (4)

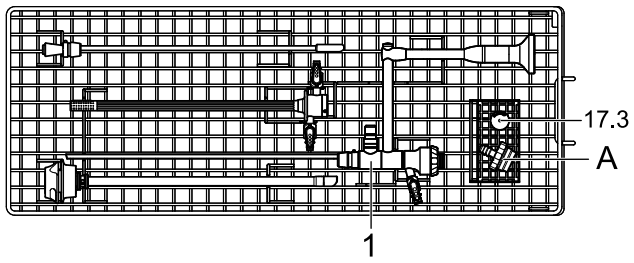
Product:	Morcescope (1) 8970.401 and 8970405, morcescope adapter (4)	
Reprocessing sequence:		
Preparation at place of use:	Immediately after use, remove coarse soiling from the products. If more than 6 h have passed between use and reprocessing, hollow spaces must be rinsed using a 20 ml syringe filled with water. Do not use any agents (e.g., aldehydes) or hot water (>40°C) for precleaning, as these can bake residues to the surface.	
Transport:	To avoid damage to the products and contamination towards the environment, safe storage in a closed container is required.	
Disassembly before cleaning:		◇ Unscrew the endoscope-side adapter (1.4).
		**Automatic sealing element (1.7)** 1. Remove the sealing cap (1.7.3). 2. Unscrew the sealing element (1.7.2) and remove the sealing membrane (1.7.1). ATTENTION! *Replace the sealing membrane (1.7.1) after each use.*
		**Morcescope adapter (4)** 1. Unscrew the locking collar (4.1.2) from the adapter (4.2) and remove the rotatable connection part (4.1). 2. Remove the QUAD lip seal (4.1.1).
		**Stopcock insert** on the irrigation connector (1.8), on the irrigation valve (4.2.1) **Without disassembly tool** ◇ Remove the stopcock insert in the direction of the arrow. ⇨ The stopcock insert clicks out of the stopcock housing. **With disassembly tool** 1. Push the disassembly tool forward as far as it will go and press it together, as shown in the figure. ⇨ The stopcock insert clicks out of the stopcock housing. 2. Remove the stopcock insert.

Product:	Morcescope (1) 8970.401 and 8970405, morcescope adapter (4)
Reprocessing sequence:	
Pre-cleaning:	1. Rinse the products under running tap water. 2. Use a cleaning gun (6199.00) to rinse products with hollow spaces for 20 seconds or with 5 pressure surges (2.5–4 bar) in pulsed mode.
	
	Manual
cleaning:	1. Place products in an approved cleaning solution for at least 5 minutes. ⇨ Exposure time and application concentration as specified by the manufacturer. 2. Rinse the products with a 20 ml syringe filled with an approved cleaning solution. 3. Brush the inside of the products with a suitable cleaning brush (7970407) (7970411) under the liquid surface level (pull through 5 times). 4. Brush the Luer connector, stopcock housing, and stopcock insert with a cleaning brush (model 7980002) under the liquid surface level (at least 5 brush strokes) 5. Brush the outside of the products with a suitable cleaning brush (8691) until no more residue is visible (at least 5 brush strokes). 6. Finally, use a cleaning gun (6199.00) to thoroughly rinse the products for at least 20 seconds or with 5 pressure surges (2.5–4 bar) in pulsed mode.
	

<table>
<tr><td>Product:</td><td>Morcescope (1) 8970.401 and 8970405, morcescope adapter (4)</td></tr>
<tr><td>Disinfection:</td><td>1. Completely fill the channels of the product with an approved disinfectant solution and immerse the product in this solution.
⇨ Exposure time and application concentration as specified by the manufacturer.
2. Finally, use water to thoroughly rinse the products for at least 20 seconds or with 5 pressure surges (2.5–4 bar) in pulsed mode.</td></tr>
<tr><td>Drying:</td><td>Dry the outside of the products using a lint-free disposable cloth or sponge, or, alternatively, in a drying cabinet, and dry hollow spaces with filtered compressed air.</td></tr>
<tr><td colspan="2">Reprocessing sequence:</td></tr>
<tr><td></td><td>Machine</td></tr>
<tr><td>cleaning:</td><td>Before machine cleaning, pre-clean the products manually.
Loading in the reprocessing basket
<table>
<tr><td> 
</td><td>Morcescope adapter (4)
◇ Connect the adapter (4.2) to the loading carrier of the washer-disinfector via the Luer fitting.</td></tr>
</table>
1. Clean the contact surfaces on the morcescope (1) manually and screw on the supplied adapter (A).
2. Place used parts in a utensil basket (small parts sieve):
⇨ Stopcock insert (1.8.1)
⇨ New sealing membrane (1.7.1)
⇨ Sealing element (1.7.2)
⇨ Sealing cap (1.7.3)
⇨ Sealing cap adapter (3)
⇨ Rotatable connection part (4.1)
⇨ QUAD lip seal (4.1.1)
3. Attach the endoscope-side adapter (1.4) to the appropriate bracket.
4. Guide the irrigation tubes through the mesh and connect all connectors.
ATTENTION!
Do not place the inner sheath (3b) (3d) and outer sheath (3a) (3c) in the reprocessing basket for machine cleaning.
Place the inner sheath (3b) (3d) and outer sheath (3a) (3c) onto the insert (irrigation nozzle) of the MIS (minimally invasive surgery) trolley and connect to the washer-disinfector using a suitable tube system.

</td></tr>
</table>

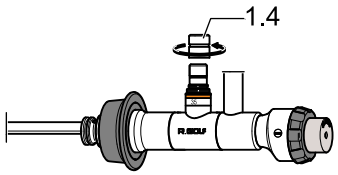
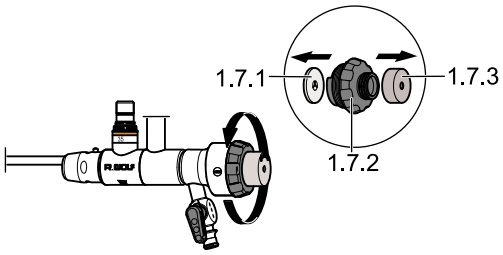
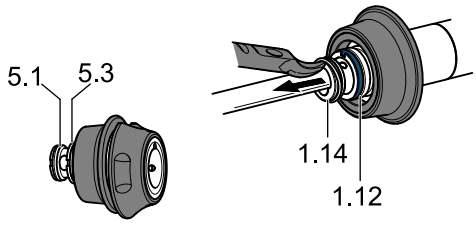
Product:	Morcescope (1) 8970.401 and 8970405, morcescope adapter (4)	
	Programs with no disinfection stage **Alkaline** ■ >4 min precleaning with cold water ■ Empty ■ >6 min cleaning with a cleaner at approx. 55°C ■ Empty ■ >3 min neutralizing*) (<40°C) ■ Empty ■ >2 min intermediate rinsing (<40°C) ■ Empty	
Disinfection:	Carry out thermal machine disinfection following the national requirements with regard to the A0 value (see DIN EN ISO 15883).	
Drying:	Dry the products with the drying cycle of the washer-disinfector. If necessary, additional drying can be achieved manually using a lint-free disposable cloth or sponge, or, alternatively, a drying cabinet. Dry hollow spaces with filtered compressed air.	

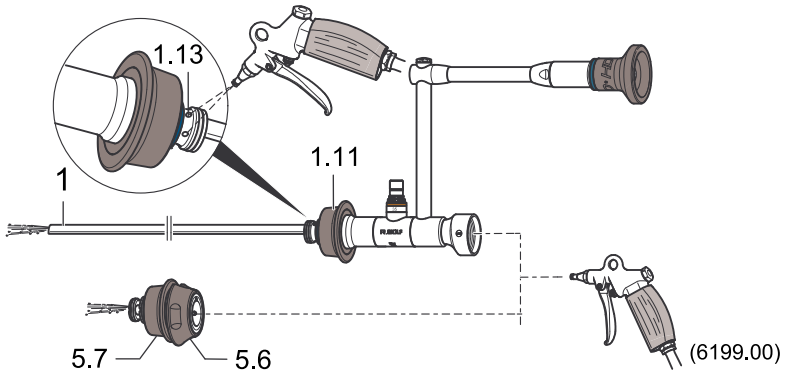
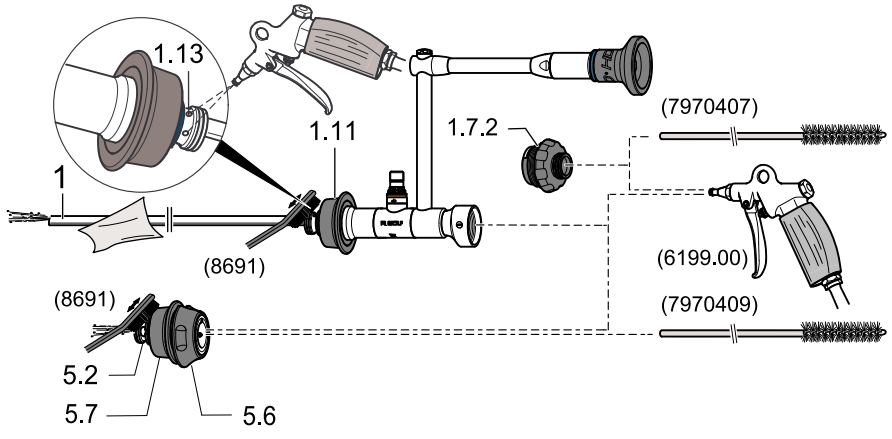
<table>
<tr><td>Product:</td><td colspan="2">Morcescope (1) 8970.401 and 8970405, morcescope adapter (4)</td></tr>
<tr><td colspan="3">Reprocessing sequence:</td></tr>
<tr><td>Function test, visual checks, maintenance:</td><td colspan="2">Visually check for cleanliness. If necessary, repeat the reprocessing procedure until the product is visually clean.
◇ Perform visual checks: see section Visual checks</td></tr>
<tr><td rowspan="4">Assembly before sterilization:</td><td> 
</td><td>Stopcock insert
on the irrigation connector (1.8), on the irrigation valve (4.2.1)
1. Insert the stopcock insert into the stopcock housing.
⇨ The stopcock insert can be felt to engage.
2. Open the stopcock insert.</td></tr>
<tr><td> 
</td><td>Automatic sealing element (1.7)
◇ Insert the new sealing membrane (1.7.1) into the sealing element (1.7.2).</td></tr>
<tr><td> 
</td><td>Morcescope adapter (4)
1. Attach the QUAD lip seal (4.1.1).
2. Check that the QUAD lip seal (4.1.1) is in the correct position.
⇨ The sealing lip (v) points in the direction of the adapter (4.2).
3. Attach the rotatable connection part (4.1) to the adapter (4.2).
4. Screw on the locking collar (4.1.2) before sterilization, but only loosely.</td></tr>
<tr><td> 
</td><td>Morcescope (1)
◇ Loosely screw on the following parts with just 1–2 revolutions:
⇨ Endoscope-side adapter (1.4)
⇨ Sealing element (1.7.2) with inserted sealing membrane (1.7.1)</td></tr>
</table>

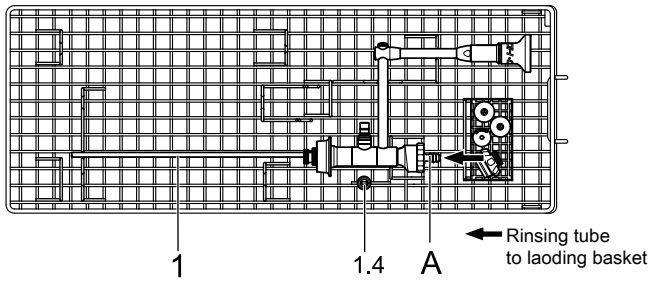
Product:	Morcescope (1) 8970.401 and 8970405, morcescope adapter (4)
Packaging:	Place products in the reprocessing basket 38042.211 and pack for sterilization, taking into account applicable standards. ◇ Place the following parts in a utensil basket (small parts sieve): ⇨ Irrigation adapter (A) ⇨ Sealing cap (1.7.3) ⇨ Morcescope adapter (4) (not shown)
	
	FDA-cleared sterilization wrap validated for the specific moist heat sterilization cycle be used to wrap the reprocessing basket according to ANSI/AAMI/ISO 11607-1.
Sterilization:	Use only moist heat/steam sterilization on a dynamic air-removal-cycle with 3 vacuum pulses. ■ Temperature exposure time: 3 min at 270 °F (132 °C) ■ Drying time: 10 - 20 min (The drying time depends on the sterilization process used) ■ Maximum temperature: 280 °F (138 °C)
Storage:	Store the sterilized products in accordance with ANSI/AAMI ST79.

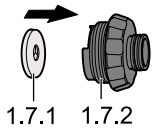
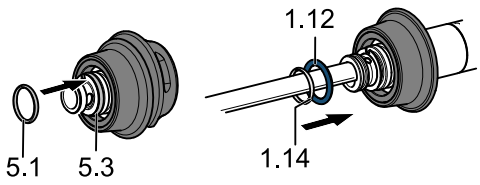
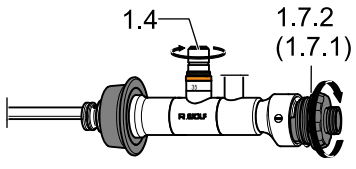
*) Depending on the use of the cleaning agent and the rinsing water, add a citric-based acid.

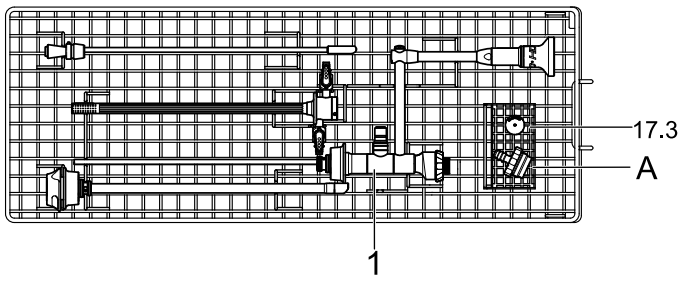
10.4 Morcescope (1) 8970407, “Shark” adapter (5)

<table>
<tr><td>Product:</td><td colspan="2">Morcescope (1) 8970407, “Shark” adapter (5)</td></tr>
<tr><td colspan="3">Reprocessing sequence:</td></tr>
<tr><td>Preparation at place of use:</td><td colspan="2">Immediately after use, remove coarse soiling from the products. If more than 6 h have passed between use and reprocessing, hollow spaces must be rinsed using a 20 ml syringe filled with water. Do not use any agents (e.g., aldehydes) or hot water (>40°C) for precleaning, as these can bake residues to the surface.</td></tr>
<tr><td>Transport:</td><td colspan="2">To avoid damage to the products and contamination towards the environment, safe storage in a closed container is required.</td></tr>
<tr><td rowspan="3">Disassembly before cleaning:</td><td> 
</td><td>◇ Unscrew the endoscope-side adapter (1.4).</td></tr>
<tr><td> 
</td><td>Automatic sealing element (1.7)
1. Remove the sealing cap (1.7.3).
2. Unscrew the sealing element (1.7.2) and remove the sealing membrane (1.7.1).
ATTENTION!
Replace the sealing membrane (1.7.1) after each use.</td></tr>
<tr><td> 
</td><td>Morcescope (1) “Shark” adapter (5)
◇ Only remove defective O-rings (1.12) (1.14) from the morcescope (1) or “Shark” adapter (5.1) (5.3) with O-ring holder.</td></tr>
</table>

Product:	Morcescope (1) 8970407, “Shark” adapter (5)
Precleaning:	1. Rinse the products under running tap water. 2. Use a cleaning gun (6199.00) to rinse all channels of the products for 20 seconds or with 5 pressure surges (2.5–4 bar) in pulsed mode. ⇨ While doing so, pull back the actuating ring (5.6) and outer ring (5.7) (1.11), and rinse the exposed area. ⇨ Rinse all irrigation holes (1.13)
	
Reprocessing sequence:	
	Manual
Cleaning:	1. Immerse the “Shark” adapter (5) and the proximal part of the morcescope (1) in an undiluted cleaning agent up to the irrigation holes (1.13). Actuate the actuating ring (5.6) and outer ring (5.7) (1.11) 10 times each. 2. Place products in an approved cleaning solution for at least 10 minutes. ⇨ Exposure time and application concentration as specified by the manufacturer. 3. Brush the inside of the products with a suitable cleaning brush (7970407) (7970409) under the liquid surface level (pull through 5 times). ⇨ Pull back the actuating ring (5.6) and outer ring (5.7) (1.11), and brush the exposed area of the “Shark” adapter (5) or morcescope (1). 4. Brush the outside of the products with a suitable cleaning brush (8691) until no more residue is visible (at least 5 brush strokes). 5. Finally, use a cleaning gun (6199.00) to thoroughly rinse all channels of the products for at least 20 seconds or with 5 pressure surges (at least 3.8 bar) in pulsed mode. ⇨ Pull back the actuating ring (5.6) and outer ring (5.7) (1.11), and rinse the exposed area. ⇨ Rinse all irrigation holes (1.13)
	

Product:	Morcescope (1) 8970407, “Shark” adapter (5)
Disinfection:	1. Completely fill the channels of the product with an approved disinfectant solution and immerse the product in this solution. ⇨ Exposure time and application concentration as specified by the manufacturer. 2. Finally, use water to thoroughly rinse the products for at least 20 seconds or with 5 pressure surges (at least 3.8 bar) in pulsed mode.
Drying:	Dry the outside of the products using a lint-free disposable cloth or sponge, or, alternatively, in a drying cabinet, and dry hollow spaces with filtered compressed air.
Reprocessing sequence:	
	Machine
Manual pre-cleaning	1. Place the products in cold tap water for at least 5 minutes. 2. Brush the inside of the products with a suitable cleaning brush (7970407) (7970409) under the liquid surface level (pull through 5 times) 3. Brush the outside of the products with a suitable cleaning brush (8691) until no more residue is visible (at least 5 brush strokes). 4. Finally, use a cleaning gun (6199.00) to rinse all channels of the products for at least 20 seconds or with 5 pressure surges per channel (at least 3.8 bar) in pulsed mode. ⇨ Pull back the actuating ring (5.6) and outer ring (5.7) (1.11), and rinse the exposed area.
Cleaning:	Place the “Shark” adapter (5) onto an insert (irrigation nozzle) of the MIS trolley. **Loading in the reprocessing basket**
	1. Clean the contact surfaces on the morcescope (1) manually and screw on the supplied adapter (A). 2. Place used parts in a utensil basket (small parts sieve): ⇨ New O-ring (7.2) (7.4) ⇨ New sealing membrane (1.7.1) ⇨ Sealing element (1.7.2) ⇨ Sealing cap (1.7.3) ⇨ Sealing cap adapter (3) 3. Attach the endoscope-side adapter (1.4) to the appropriate bracket. 4. Guide the irrigation tubes through the mesh and connect all connectors. *ATTENTION!* *Do not place the inner sheath (3d) and outer sheath (3c) in the reprocessing basket for machine cleaning.* *Place the inner sheath (3d) and outer sheath (3c) onto the insert (irrigation nozzle) of the MIS (minimally invasive surgery) trolley and connect to the washer-disinfector using a suitable hose system.*
	

<table>
<tr><th>Product:</th><th colspan="2">Morcescope (1) 8970407, “Shark” adapter (5)</th></tr>
<tr><td></td><td colspan="2">Programs with no disinfection stage
Alkaline
■ >4 min precleaning with cold water
■ Empty
■ >6 min cleaning with a cleaner at approx. 55°C
■ Empty
■ >3 min neutralizing*) (<40°C)
■ Empty
■ >2 min intermediate rinsing (<40°C)
■ Empty</td></tr>
<tr><td>Disinfection:</td><td colspan="2">Carry out thermal machine disinfection following the national requirements with regard to the A0 value (see DIN EN ISO 15883).</td></tr>
<tr><td>Drying:</td><td colspan="2">Dry the products with the drying cycle of the washer-disinfector.
If necessary, additional drying can be achieved manually using a lint-free disposable cloth or sponge, or, alternatively, a drying cabinet. Dry hollow spaces with filtered compressed air.</td></tr>
<tr><td>Function test, visual checks, maintenance:</td><td colspan="2">Visually check for cleanliness. If necessary, repeat the reprocessing procedure until the product is visually clean.
◇ Perform visual checks: see section Visual checks</td></tr>
<tr><td rowspan="3">Assembly before sterilization:</td><td> 
</td><td>Automatic sealing element (1.7)
◇ Insert the new sealing membrane (1.7.1) into the sealing element (1.7.2).</td></tr>
<tr><td> 
</td><td>Morcescope (1), “Shark” adapter (5)
◇ If the O-rings (1.12) (1.14) or (5.1) (5.3) have been removed, position new O-rings in the O-ring grooves in the morcescope (1) or “Shark” adapter (5).</td></tr>
<tr><td> 
</td><td>Morcescope (1)
◇ Loosely screw on the following parts with just 1–2 revolutions:
⇨ Endoscope-side adapter (1.4)
⇨ Sealing element (1.7.2) with inserted sealing membrane (1.7.1)</td></tr>
</table>

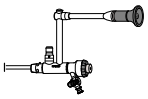
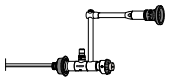
Product:	Morcescope (1) 8970407, “Shark” adapter (5)
Packaging:	Place products in the reprocessing basket 38042.211 and pack for sterilization, taking into account applicable standards. ◇ Place the following parts in a utensil basket (small parts sieve): ⇨ Adapter (A) ⇨ Sealing cap (1.7.3) ⇨ “Shark” adapter (5) (not shown)
	
	FDA-cleared sterilization wrap validated for the specific moist heat sterilization cycle be used to wrap the reprocessing basket according to ANSI/AAMI/ISO 11607-1.
Sterilization:	Use only moist heat/steam sterilization on a dynamic air-removal-cycle with 3 vacuum pulses. ■ Temperature exposure time: 3 min at 270 °F (132 °C) ■ Drying time: 10 - 20 min (The drying time depends on the sterilization process used) ■ Maximum temperature: 280 °F (138 °C)
Storage:	Store the sterilized products in accordance with ANSI/AAMI ST79.

*) Depending on the use of the cleaning agent and the rinsing water, add a citric-based acid.

11 Technical data and ordering information

NOTICE

The combinations of the morcescope and continuous irrigation double sheath systems are listed in the section 6.1 Overview of permissible combinations.

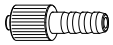
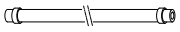
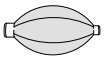
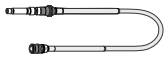
Item	Figure	Model no.	Designation, technical data
			TISSUE MORCELLATION
1		8970.401	MORCESCOPE 12° 24 FR WL 224 MM PANOVIEW Total length = 386.3 mm; total height = 137.8 mm; object field angle 80°; inner Ø = 5 mm; outer Ø = width 6.0 mm / height 3.6 mm
		8970405	MORCESCOPE 0° 24 FR WL 224 MM PANOVIEW Total length = 386.3 mm; total height = 137.8 mm; object field angle 80°; inner Ø = 5 mm; outer Ø = width 6.0 mm / height 3.6 mm
		8970407	MORCESCOPE 0° 24 FR WL 199 MM PANOVIEW Total length = 393 mm; total height = 119 mm; object field angle 80°; inner Ø = 5.1 mm; outer Ø = width 7.6 mm / height 8.2 mm
1.7		8920.311	AUTOM. SEALING ELEMENT ID 5.7 MM consisting of:
1.7.1			15115.101 Membrane valve
1.7.2			15176.106 Sealing element
1.7.3			15176.058 Sealing cap, sky blue
4		8970.026	E-LINE ADAPTER FOR MORCESCOPE 26 FR
5		8675026	SHARK ADAPTER FOR MORCESCOPE 24/26 FR

12 Spare parts and accessories

12.1 Spare parts

Item	Figure	Model no.	Designation, technical data
1.4		8095.00	ENDOSCOPE-SIDE ADAPTER for morcescope 8970.401 for endoscopes with code only
		15005.199	ENDOSCOPE-SIDE ADAPTER for morcescopes 8970405 and 8970407 for endoscopes with code and color ring
4.1.1		15176.127	QUAD lip seal
4.1		8654.3842	CONNECTION PART FOR RESECTOSCOPE 26 FR
4.2		8970.0261	ADAPTER FOR MORCESCOPE
1.8.1		896.0003	STOPCOCK INSERT BUNDLE CAP. 4.2 MM Indicator: 4 nubs Packaging unit PU = 5 pcs
1.7.1		89.103	SEALING MEMBRANE Ø 17 MM, yellow Packaging unit PU = 10 pcs
1.7.2		15176.106	Sealing element
1.7.3		89.00	SEALING CAP CAPACITY <2.4 MM Packaging unit PU = 10 pcs
		89.01	SEALING CAP CAPACITY 2.4–3.4 MM Packaging unit PU = 10 pcs
		89.02	SEALING CAP CAPACITY 3.4–5.1 MM Packaging unit PU = 10 pcs
1.14		15364.267	O-ring 10.00 X 1.00-SI 429-70
5.1		15364.395	O-ring 7.65 X 1.78 VMQ-70 coated
1.12 5.3		15364.396	O-ring 9.25 X 1.78 VMQ-70 coated

12.2 Accessories

Image	Product no.	Designation, Technical data
	886.00	TUBE WITH LUER-LOCK CONNECTOR
	889.01	TUBE CONNECTOR
	889.02	RESECTOSCOPE TUBE L 300 MM
	103.00	PRESSURE BALL For blowing air through channels
	806635231	FIBER LIGHT CABLE BUNDLE

The products can be combined as required provided the relevant technical data and intended uses are observed. For the general overview please refer to the latest catalog sheets and brochures, or contact Richard Wolf GmbH or your Richard Wolf representative.

13 Operating, storage, transport, and shipping conditions

Operating conditions	+10ºC to +40ºC, 30% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa
Storage, transport, and shipping conditions	-20ºC to +60ºC, 10% to 90% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa

NOTICE

To prevent damage during transport or shipment of the products, we recommend using the original packaging material.

13.1 Reprocessing basket

Operating conditions	Sterilization as appropriate for the endoscopes placed inside the reprocessing baskets and the accessories for endoscopic use
Storage conditions	As appropriate for the endoscopes placed inside the reprocessing baskets and the accessories for endoscopic use
Shipping conditions when empty	-20ºC to +60ºC, 10% to 90% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa

ATTENTION

Do not use the reprocessing basket for shipping the morcescope (1) and the accessories for endoscopic use.

13.2 Disposal of the product, packaging material, and accessories

The relevant regulations and laws valid in the country of use must be observed when disposing of equipment.

▷ For further information, please contact the manufacturer.

14 Warranty and Customer Service

Richard Wolf guarantees our instruments to be free from any defects in materials and workmanship under normal use and service for one year. Richard Wolf general terms and conditions may be found on the back of our invoice.

Parts delivered separately by Richard Wolf are subject to all of the same general terms and conditions for our products, including the limitations of warranty and liability.

All products should be returned to Richard Wolf for any necessary or desired repair or part replacement. No product repair or part replacement should be done other than by Richard Wolf unless the care and instruction manual or other written information indicates that repair or part replacement is authorized. If authorized, parts must be replaced only by parts supplied or specified by Richard Wolf, and product repair and part replacement must be done in strict conformance with Richard Wolf specifications and instructions for repair and part replacement, including post replacement testing and recalibration. Failure to follow this requirement in any way can be dangerous to you, your personnel and your patients and voids the warranty for the product repaired or the product in which the part was replaced and if the part was supplied by Richard Wolf, for that part.

Delivery by Richard Wolf of technical documents such as circuit or other design diagrams does not constitute authorization for product repair or part replacement. Richard Wolf instruments and other products should never be modified or altered under any circumstances.

Contact Richard Wolf if you have any question (1) whether replacement of a part or a repair is authorized by Richard Wolf, or (2) whether you have complete instructions and specifications for part replacement or repair.

These instructions do not attempt to cover all details or variations in equipment, nor to provide for every possible contingency to be met in connection with installation, operation, or maintenance. Should further information be required or should problems arise which are not covered sufficiently for the purchaser's purpose, the matter should be referred to Richard Wolf Medical Instruments Corporation.

Our national sales and service offices, as well as our manufacturing facility, are located in Illinois. Trained manufacturer's representatives are located throughout the U.S. to serve you. For any questions regarding these instruments, or to place an order, contact Richard Wolf customer service department at 847-913-1113 or 800-323-WOLF (9653).

NOTICE

INSTRUMENT ORDERING POLICY

Richard Wolf reserves the right to make substitutions, if necessary, without prior notice.

NOTICE

REPAIR POLICY

Defective merchandise will be repaired or replaced at no charge to the customer, provided the customer delivers such defective merchandise prepaid. Any repairs, maintenance or servicing of Richard Wolf merchandise by anyone other than a factory authorized representative will render our warranty null and void.

NOTICE

REPAIR SHIPMENTS

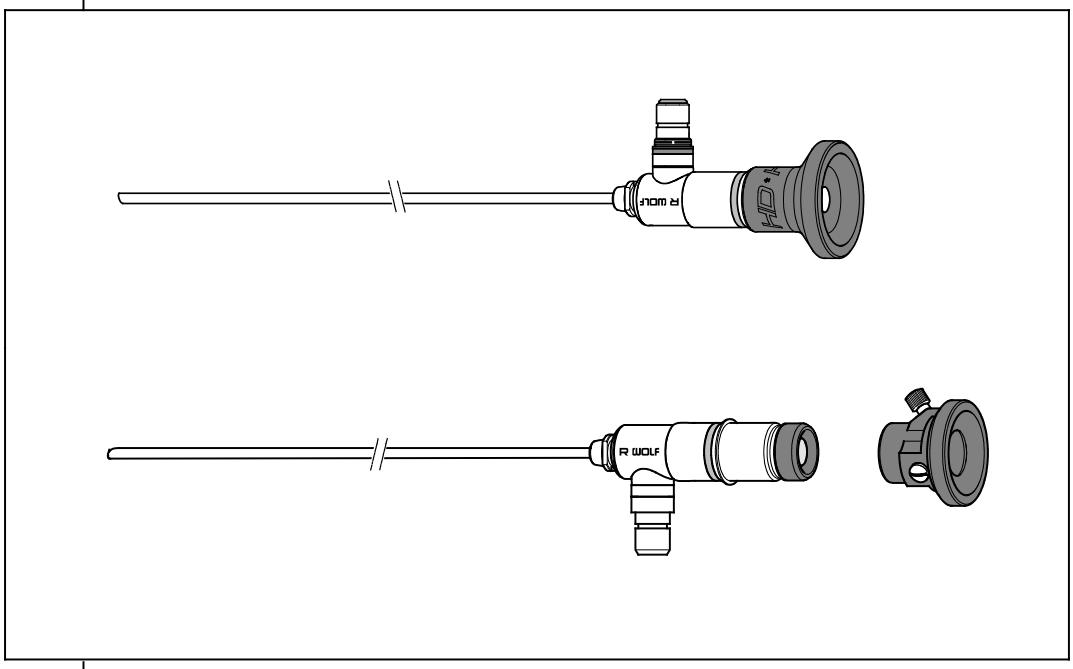
When returning your instrument for repair, we suggest that you prevent shipping damage to the instrument by reusing the box that it was originally shipped in. Richard Wolf also recommends that the instrument be insured for an amount to cover the cost of replacement.

ATTENTION

For general safety and health reasons, Richard Wolf requires that you clean and reprocess all instruments before returning them for repair. If instruments are received in an unsanitary condition, Richard Wolf will clean and reprocess each instrument. A cleaning fee will be applied for each instrument requiring cleaning.

RICHARD WOLF
spirit of excellence

Instruction Manual



Rigid Endoscopes

PANOVIEW
PLUS
#PLUS#
PLUS
lumina SL
3
ULTRA

GA-S001 / en-US / 2017-03 V3.0 / ECO 2016-0136 (RW: 2017-01 V10.0 / PDB 16-8711)

⚠ Important general notes and instructions ⚠

Make sure that this product is used only as intended and described in this instruction manual, by adequately trained and qualified medical personnel, and that maintenance and repair are only carried out by authorized experts.

Use the product only in the combinations and with the accessories and spare parts specified in this instruction manual. Use other combinations, accessories and replacement parts only if they are expressly intended for the planned application and if the performance characteristics and safety requirements are not impaired. Do not alter the product in any way.

Reprocess the products before every application and before returning them for repairs as required by the instruction manual in order to protect the patient, user and others.

This manual is an integral part of the product and must be stored in such a way that it is accessible at any time during its entire life cycle. This manual must be passed on to any subsequent owner.

Immediately upon receipt, check the product and its accessories for completeness and possible damage. Should the shipment give right to complaints, please inform the manufacturer or supplier immediately.

Subject to technical changes!
Due to ongoing developments, the illustrations and technical data may deviate slightly.

CAUTION :
Federal law restricts this device to sale by or on the order of a physician.

Safety instructions and levels of danger

Symbols	Level of danger
⚠	***WARNING!*** ***Failure to observe can result in death or serious injury.***
⚠	***CAUTION!*** ***Failure to observe can result in slight injury or damage to the product.***
☞	***IMPORTANT!*** *Failure to observe can result in damage to the product or surroundings.*
☞	***NOTE!*** *Tips for optimum use and other useful information.*

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Contents

1 Technical description

The rigid endoscopes available in different product variants and consist of the following:

◇ **Endoscope**

with fixed eyecup

- with sheath tube, integrated light guide, optical system
- with locking cone
- cold-light connector
- with adapter (can be unscrewed)
- with color coding ring indicating the direction of view

with plug-on eyecup

- with sheath tube, integrated light guide, optical system
- with locking cone
- cold-light connector
- with adapter (can be unscrewed)
- with color coding ring indicating the direction of view
- with plug-on eyepiece adapter

Possible identification of the fiber bundle diameter on the endoscope:

- The product is marked with the code number and a color coding ring (new design).
- only the code number (numerical) is on the product.
- no code number and no coding ring are on the product

2 Intended use

The rigid endoscopes are used for visualizing the inside of the patient via natural or surgically created passages.

These products are exclusively intended for use by specialized medical personnel and must only be used by medically qualified and adequately instructed persons.

3 Indications and field of use

Rigid endoscopes

are designed for examination, diagnosis and / or therapy in conjunction with endoscopic accessories in the various medical disciplines.

4 Contraindications and side effects

4.1 Contraindications

CJD - **C**reutzfeldt **J**akob **D**isease or a
vCJD - **V**ariant of the **C**reutzfeldt-**J**akob **D**isease
BSE - **B**ovine **S**pongiform **E**ncephalopathy; so-called mad cow disease (e.g. Creutzfeldt-Jakob Disease)
TSE - **T**ransmissible **S**pongiform **E**ncephalopathy

On the basis of the patient's general condition the doctor in charge must decide whether the planned use is possible or not.

The laws and regulations valid in your country must be complied with.

For further notes and instructions please refer to the latest medical literature.

Contraindications directly related to the product are presently unknown

4.2 Side effects

No side effects are to be expected if the system is used as intended.

5 Combinations

The rigid endoscopes are used in conjunction with:

Rigid endoscopes

- ◇ Light sources and fiber light cables / fusion fiber light cable
- ◇ Video cameras and objective lenses
- ◇ Mirror reflex cameras
- ◇ Endoscopic accessories, e.g.
  - ◗ Trocar sleeves, forceps and scissors, electrodes

⚠ *CAUTION!*

Do not combine products incorrectly!

Injuries of the patient, user or others as well as damage to the product are possible.

The different products can only be used together if their intended uses and relevant technical data (such as working length, diameter, peak voltage, etc.) are the same.

Follow the instruction manuals or the corresponding system manuals of the products used in combination with this product.

Follow the "Notes and instructions on HF applications", order no.: GA-S 002 as well as the HF device manufacturer's instructions.

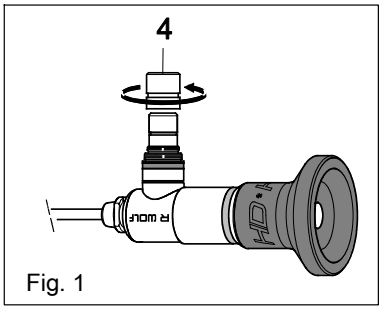


Fig. 1

Fig. 1

- ◇ The adapter (4) on the endoscope can be unscrewed and replaced by the corresponding adapters to connect fiber light cables of other manufacturers.
  - ◗ For order data, please follow the latest catalog pages.
  - ◗ For this, see **GA-A287** and **GA-A009**

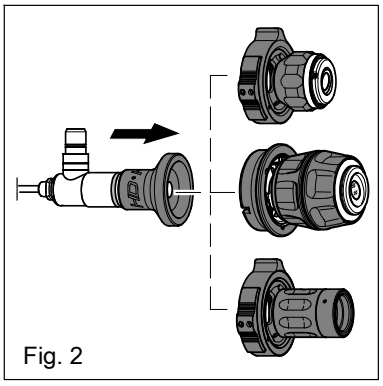


Fig. 2

Fig. 2

- ◇ Objective lenses with C-mount thread for working via the monitor or under direct view.
  - ◗ For order data, please follow the latest catalog sheets.
  - ◗ For this, see GA-S022

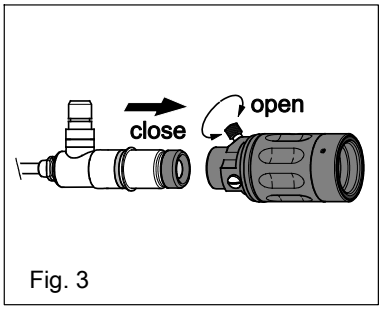


Fig. 3

Fig. 3

- ◇ Objective lenses with RW-mount thread for working via the monitor or under direct view.
  - ◗ For order data, please follow the latest catalog pages.
  - ◗ For this, see GA-S022

Fig. 4

◇ Plug-on eyecup (18) for the connection of objective lenses with C-mount thread to endoscopes with plug-on eyepiece adapter (14).
Plug-on eyecup, rotatable, special design for video TUR.

◗ For order data, please follow the latest catalog pages.

◗ For this, see GA-S022

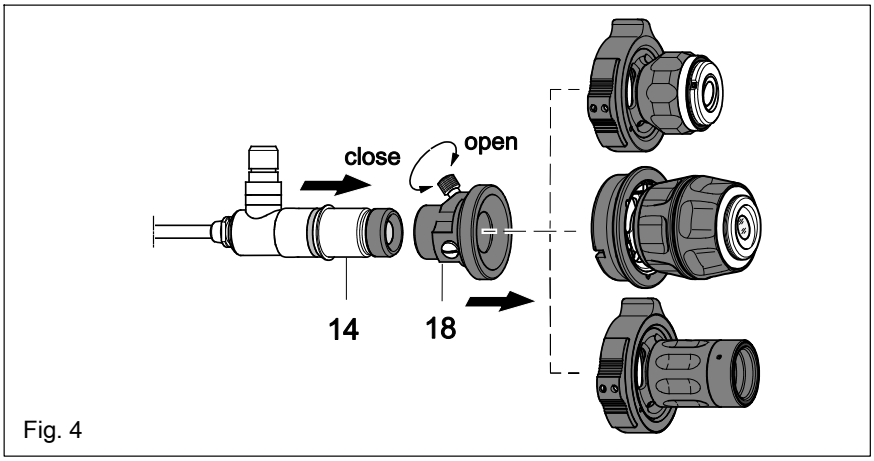


Fig. 4

6 Illustration

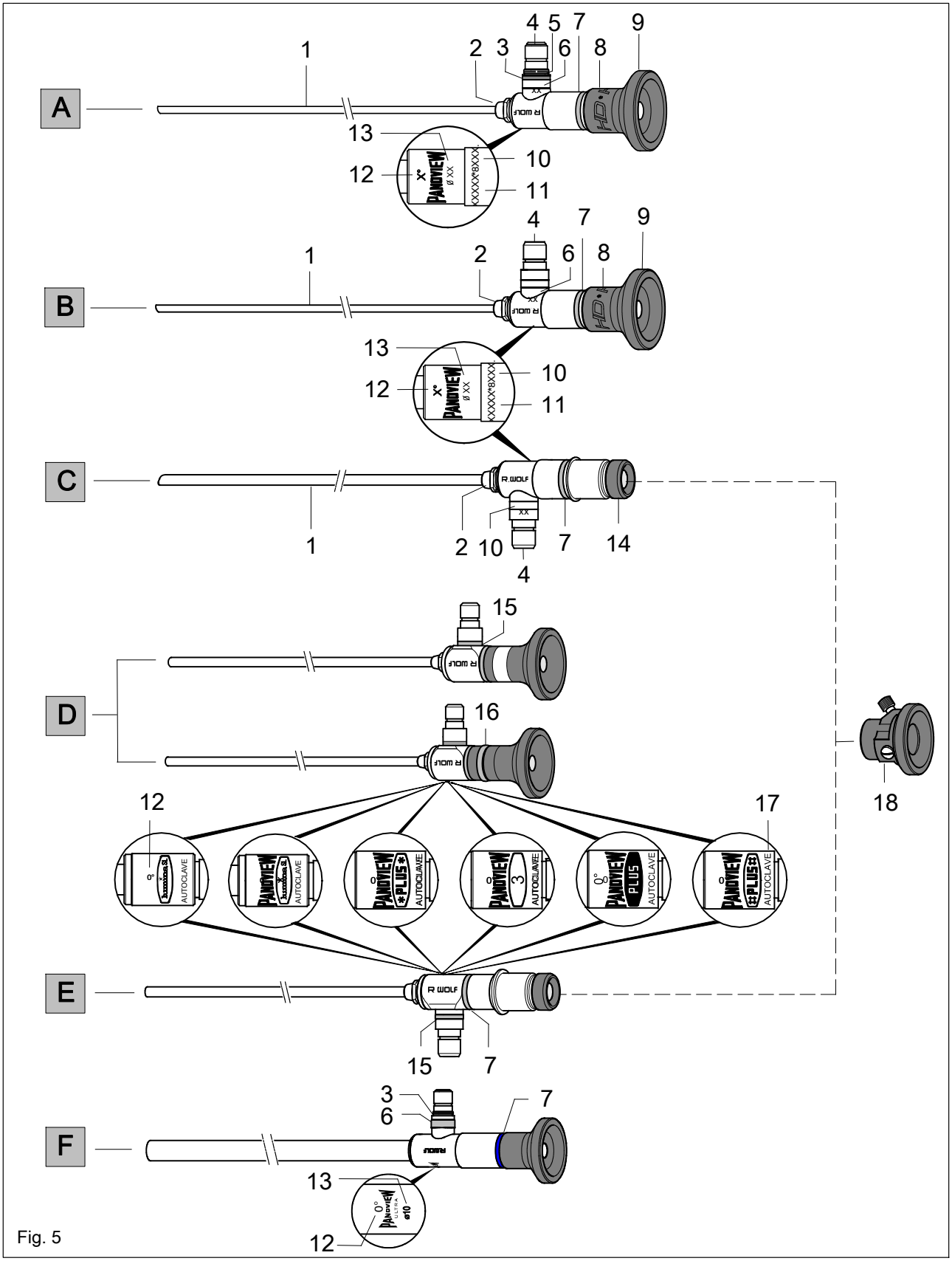


Fig. 5

6.1 Legend and identification

Item	Designation	Item	Designation
A	**Endoscope** (new design) **- with fixed eyepiece and eyecup** **- with color coding ring and code number** (numerical) identification of fiber bundle diameter	B	**Endoscope** (new design) **- with fixed eyepiece and eyecup** **- with code number** (numerical) identification of fiber bundle diameter
C	**Endoscope** (new telescope design) **- with plug-on eyecup** **- with code number** (numerical) identification of fiber bundle diameter	D	**Endoscope** **- with fixed eyepiece and eyecup**
E	**Endoscope** **- with plug-on eyecup**	F	**Endoscope (PANOVIEW ULTRA)** **- with fixed eyepiece and eyecup** **- with color coding ring and code number** (numerical) identification of fiber bundle diameter
1	**Sheath tube**	10	**Product no.**
2	**Locking cone**	11	**Serial no.**
3	**Color coding ring** identification of fiber bundle diameter	12	**Numerical indication of direction of view**
4	**Adapter**	13	**Sheath tube diameter**
5	**External thread** for connecting suitable adapters	14	**Plug-on eyepiece adapter**
6	**Numerical identification number** identification of fiber bundle diameter	15	**Color coding ring, red** Identification of steam-sterilizability using the fractionated pre-vacuum procedure at 134°C (273°F)
7	**Color coding ring** Identification of direction of view	16	**Convex ring** only on PANOVIEW- *PLUS* Identification of increased object field; high detail resolution
8	**HD** Identification of high definition	17	**AUTOCLAVE** Identification of steam-sterilizability
9	**Eyepiece with eyecup**	18	**Plug-on eyecup**

Item	Explanations for items 3, 6 and 7	Color	Code number	Fiber bundle diameter in [mm]	
				Fiber light cable	FUSION Fiber light cable
3	**Color coding ring** Identification of fiber bundle diameter	blue	-	1.6	-
		green	-	2.5	-
		orange	-	3.5	-
		gray	-	5.0	5.0
6	**Numerical identification number** Identification of fiber bundle diameter	-	16	1.6	-
		-	25	2.5	-
		-	35	3.5	-
		-	45	5.0	5.0
		-	50		
		Color		Direction of view [°]	
7	**Color coding ring** Identification of direction of view	blue		0	
		green		5	
		orange		12 / 45 - 50	
		red		30 - 30	
		gray		50	
		purple		60	
		yellow		70	
		brown		90	
		white		110	

Symbols	Designation
	Follow the instruction manual
	Observe the instruction manual
REF	Order number
LOT	Lot identification
SN	Serial no.
	Manufacturer
CE	Identification in conformity with Medical Product Directive 93/42/EEC, **only** valid if the **product and/or the packaging is marked with this identification**. Products of category IIa and above, as well as sterile products or products with measuring function of category I, are additionally marked with the code no. of the notified body (0124).

7 Application

⚠ *CAUTION!*
The products have only limited strength!
Excessive force will cause damage, impair the function and therefore endanger the patient.
Immediately before and after each use, check the products for damage, loose parts and completeness.
Make sure that no missing parts remain in the patient.
Do not use the products if they are damaged or incomplete or have loose parts.

7.1 Preparation

◇ Carry out a check: see section 8

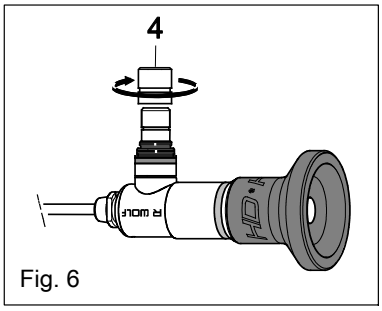


Fig. 6

Fig. 6

◇ Screw the adapter (4) to the endoscope.

7.1.1 Identification of fiber bundle diameter on endoscope

☞ *IMPORTANT!*
To achieve optimum light transmission, the fiber bundle diameters of the endoscope and fiber light cable must match.
Possible consequences if there is a mismatch:

◇ *Fiber light cables with excessively large fiber bundle diameter (cross-section) cause*
➧ *excessive heating at the coupling point with the endoscope*

◇ *Fiber light cables with excessively small fiber bundle diameter (cross-section) cause*
➧ *reduced light output*

⚠ *CAUTION!*
Intense heat due to high light energy!
Unfavorable combinations can cause a temperature increase at the coupling point of the fiber light cable and at the light outlet of the endoscope.
Burns on the patient, user and others as well as damage to endoscope are possible.
Reduce the light output or adapt the light cable cross section.

Due to the different product variants, the identification of the fiber bundle diameter on the endoscope differs.

Possible identification on the endoscope:

◇ The product is marked with the code number and color coding ring (new design).
◇ Only the code number (numerical) is on the product.
◇ No code number and no color coding ring is found on the product.

The fiber bundle diameter of the fiber light cable / fusion fiber light cable is marked with a color coding ring and a code number on the endoscope connector of the light cable.

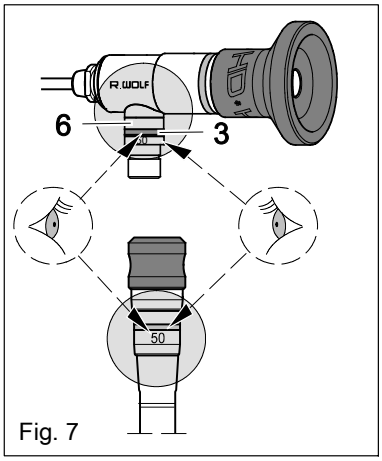


Fig. 7

A code number and color coding ring are found on the endoscope

Fig. 7

The code number (6) and the color coding ring (3) on the endoscope and on the endoscope connector of the fiber light cable must be the same.

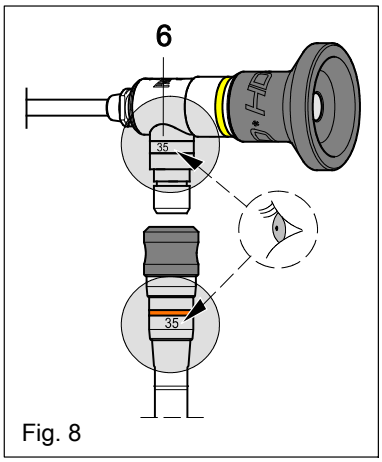


Fig. 8

If there is only the code number on the endoscope

Fig. 8

The code number (6) on the endoscope and on the endoscope connector of the fiber light cable must be the same.

☞ ***NOTE!***

If there is no code number and no color coding ring on the endoscope, contact RICHARD WOLF for appropriate fiber light cable size.

7.1.2 Connecting the fiber light cable to the endoscope and the system components

Connecting the fiber light cable

Fig. 9

◇ Connect the fiber light cable (x) or (y) to the adapter (4) on the endoscope and to a suitable light source.

◗ Fiber light cable (x)
- adapter, endoscope-to-light cable (tab)

◗ Fiber light cable (y) / fusion fiber light cable / special fiber light cable
- adapter, endoscope-to-light cable (quick-release coupling with actuation ring)

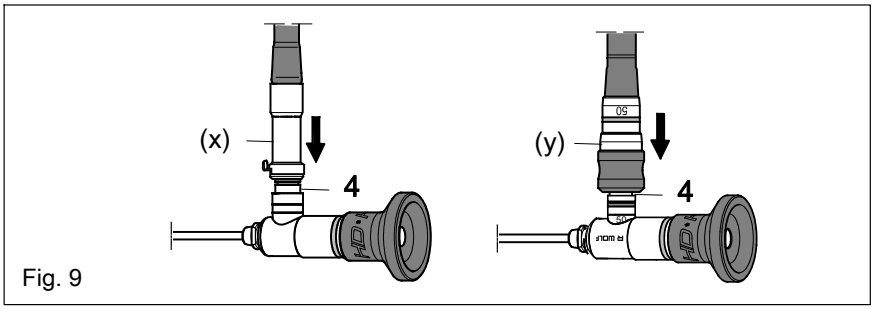


Fig. 9

Removing the fiber light cable

Fig. 10

◇ Fiber light cable (x):
Push the tab in direction of arrow and remove the fiber light cable (x).

◇ Fiber light cable (y) / fusion fiber light cable / special fiber light cable
push the fiber light cable (y) slightly against the endoscope, slide the quick-release coupling (ring actuation) in the direction indicated by the arow and remove the fiber light cable (y).

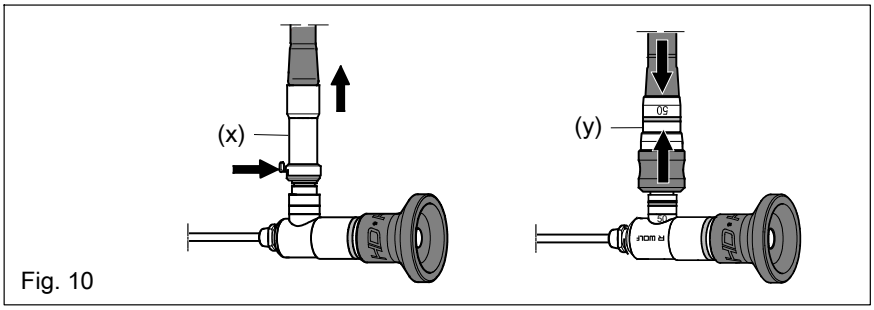


Fig. 10

☞ ***NOTE!***

For further information and notes on the fiber light cables please refer to the descriptions in manuals GA-A287 and GA-A009.

7.2 Indications for Use

☞ *IMPORTANT!*

Use only products with type BF or CF applied parts in conjunction with the endoscope.

7.2.1 Light

⚠ *WARNING!*

Intense heat due to high light energy!

Danger of inadvertent tissue damage

- *due to insufficient distance between the light exit area and the tissue*
- *due to soiling/contamination in the light exit area*
- *if high performance sources are used*

Do not touch the light exit area and avoid direct contact with the tissue. Remove any soiling.

In neurosurgery use only halogen light sources up to a maximum of 250 W or other light sources (e.g. gas discharge lamps, xenon) up to a maximum of 180 W. Do not use fluid light cables.

⚠ *WARNING!*

Fire hazard!

When placing the endoscope onto heat-sensitive flammable surfaces (dark drapes etc.) the high light energy at the light exit area of the endoscope can cause high temperatures or even ignition.

Store the endoscope in a safe place.

Switch off the light source if the endoscope is not used for a period of time.

⚠ *CAUTION!*

Danger of burns!

Due to the high energy output of the light source the adapters and the glass surface of the fiber light cable are extremely hot when disconnected from the light source.

This may cause burns if inadvertently the patient, user or others touch the parts.

Do not touch the adapter and the glass surface of the fiber light cable. Allow the fiber light cable to cool down.

⚠ *CAUTION!*

Danger of dazzling!

Danger of impaired sight.

Do not look into the light exit area / free end of an endoscope / fiber light cable which is connected to a light source.

7.2.2 Electrical current

⚠ *WARNING!*

Danger of electric shock!

Patient leakage currents can add up if the endoscopes are combined with other powered endoscopic accessories.

Make sure that the combinations do not exceed the permissible patient leakage currents.

7.2.3 Image quality

⚠ *CAUTION!*

Increased risk potential if the image is blurred!

Danger of injuring the patient.

Stop the intervention for safety reasons if the image is blurred.

Check the image quality of the endoscope before use (section 8.2).

7.3 HF applications

Follow the **"Notes and instructions on HF applications"**, order no.: GA-S 002 as well as the HF device manufacturer's instructions.

⚠ *CAUTION!*
If high-frequency current is used, leakage currents may cause burns!
This may result in burns around the user's eye.
Use the endoscope only with the eyecup connected.

7.4 Laser application

When applying a laser make sure you follow the laser device manufacturer's instructions as well as the general regulations on the use of lasers.
Wear the required personal protection gear.

⚠ *CAUTION!*
Highly coherent laser beam!
This may result in injuries from laser energy in the user's face around the eye.
Wear the required personal protection gear when using this product in conjunction with laser devices.
An additional suitable filter attachment is required when using lasers and working with endoscopes under direct view.

8 Checks

⚠ *CAUTION!*
Be careful if products are damaged or incomplete!
Injuries of the patient, user and others are possible.
Run through the checks before and after each use.
Do not use the products if they are damaged, incomplete or have loose parts.
Return damaged products together with any loose parts for repair.
Do not attempt to do any repairs yourself.

8.1 Visual check

◇ Check the endoscopes in particular in the distal area and the accessories for:
- damage
- sharp edges
- loose or missing parts
- rough surfaces.

◇ Any inscriptions or identification necessary for the safe intended use must be legible.
- To prevent wrong handling or reprocessing, any illegible lettering, labeling or identification must be reinstated.

8.2 Function check

Fig. 11

◇ Check image quality and light output in conjunction with the system components.

◇ Check the glass surfaces for any deposits.
- Deposits on the glass surfaces can cause a spotted or blurred field of view and hence impair light transmission considerably.
- Clean the glass surfaces with a swab soaked with alcohol (wooden swab carrier, not metal or plastic) and hard-to-remove deposits with a suitable instrument cleaner.

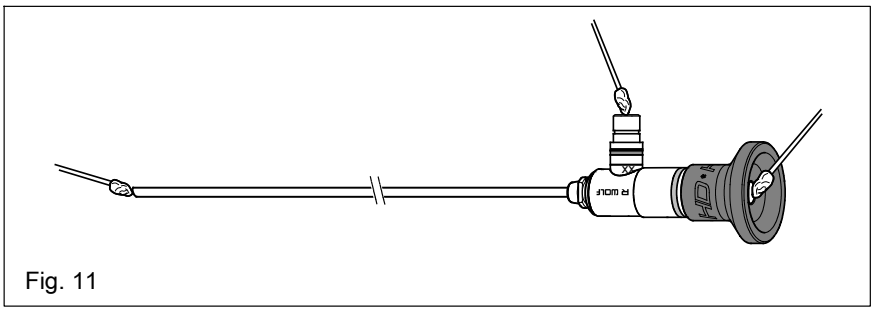


Fig. 11

Fig. 12

◇ Check the light output without the system components.

◇ Hold the distal end of the endoscope towards a light source.
- Broken fibers appear as black dots at the cold-light connector. If approx. 30% of the fibers are broken, the light output is no longer sufficient.

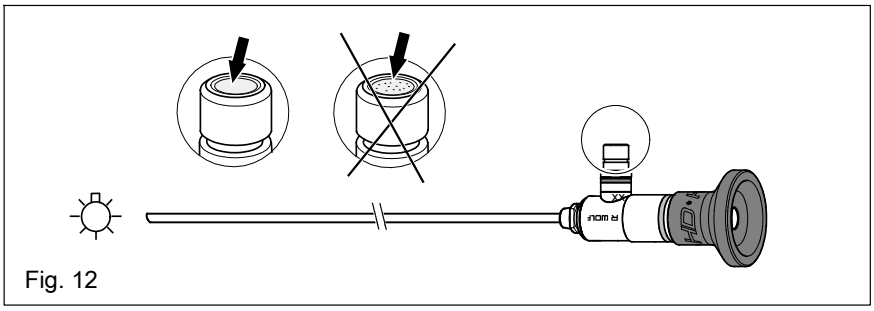


Fig. 12

9 Reprocessing and maintenance

⚠ ***WARNING!***
Creutzfeldt-Jakob Disease!
If the patient is suspected of having Creutzfeldt-Jakob Disease (CJD) or a variant of the Creutzfeldt-Jakob Disease (vCJD) or the latter have been diagnosed, adequate measures must be taken to prevent possible transmission to other patients, users and third parties.
For this purpose, apply the country-specific reprocessing guidelines and regulations.

☞ ***IMPORTANT!***
Do not clean plastic parts using metal or sharp-edged tools (such as metal bristle brushes).

9.1 Reprocessing procedure

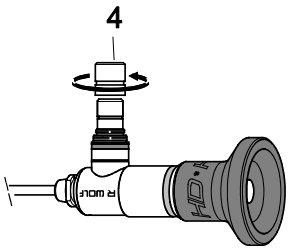
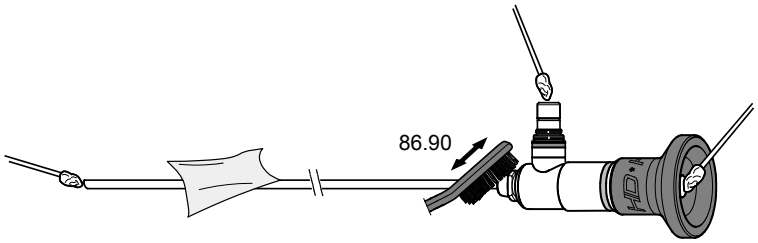
The following describes the reprocessing procedure used by Richard Wolf GmbH for the validation.

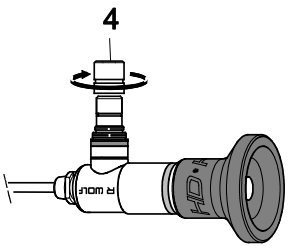
☞ ***IMPORTANT!***

- *If used as intended and following the manufacturer's instruction manual, it is not necessary to limit the number of possible reprocessing cycles.*
- *Careful and gentle handling of medical products during the entire reprocessing process has an essential influence on the service life of the products.*
- *Before returning defective products for repair, they must have been subjected to the entire reprocessing cycle.*
- *It is the user's responsibility to make sure that the reprocessing process including the resources, material and personnel, is suited to yield the required results.*
- *The national and international requirements regarding the validation of the reprocessing process established by the user must be observed.*

☞ ***IMPORTANT!***
Further notes and instructions on reprocessing are described in manual GA-J020 ***"Reprocessing of RICHARD WOLF Heat-stable Instruments"*** *and must be followed.*

☞ ***IMPORTANT!***
Do ***not*** *sterilize the products in hot-air sterilizers.*

Product:	Endoscopes (A) - (F)
Reprocessing sequence:	
Preparation at the point of use:	Immediately after use, remove coarse soiling from the products. Do not use any agents (e.g. aldehyde) or hot water above 40 °C for pre-cleaning, as this may bake residues to the surfaces.
Transport:	To avoid product damage and contamination of the environment, safe storage in a closed container is necessary.
Disassembly before cleaning:	 Remove the adapter (4) from the endoscope.
Pre-cleaning:	No special requirements
	Manual reprocessing
Cleaning:	1. Immerse the products in a certified cleaning solution for at least 5 minutes. ◗ For the immersion time and the concentration to be used, please refer to the manufacturer's specifications. 2. Brush the outer surfaces with a cleaning brush (86.90) until any visible residues have been removed. 3. At the end, thoroughly rinse the products with tap water for at least 20 seconds. 
Disinfection:	1. Immerse the products in a certified disinfectant solution. ◗ For the immersion time and the concentration to be used, please refer to the manufacturer's specifications. 2. At the end, thoroughly rinse the products with tap water for at least 20 seconds.
Drying:	1. Dry the outer surfaces of the products using a lint-free disposable cloth or swab or, alternatively, dry in a drying cabinet. 2. Clean glass surfaces with a swab soaked in alcohol.
	Machine
Cleaning:	Place the endoscope and adapter (4) into the holders provided in the special reprocessing basket and connect to the machine washer-disinfector. Program parameters ◗ >4 min of pre-washing with cold water ◗ Empty ◗ >6 min of washing with a cleaner at <55°C ◗ Empty ◗ >3 min of neutralization*) with tap water (<40°C) ◗ Empty ◗ >2 min of intermediate rinsing*) with tap water (<40°C) ◗ Empty
Disinfection:	Carry out thermal machine disinfection taking into account the national requirements with regard to the A0 value 3000 (see DIN EN ISO 15883).
Drying:	Dry the products with the drying cycle of the machine washer-disinfector. If necessary, additional drying can be achieved manually using a lint-free disposable cloth or swab, or, alternatively, a drying cabinet. Clean glass surfaces with a swab soaked in alcohol.

Product:	Endoscopes (A) - (F)
Reprocessing sequence:	
Function test, visual check, maintenance:	Check visually for cleanliness. If necessary, repeat the reprocessing procedure until the product is visually clean. ◗ **Carry out a visual check: see section 8.1**
Assembly before sterilization:	 ☞ ***NOTE!*** *Before sterilization screw on adapter (4) only loosely to allow a sufficient flow of the sterilization medium.* *Tighten all screw connections before use.* Fasten the adapter (4) to the endoscope only loosely, i.e. 1 - 2 turns.
Packaging:	Place the products into the reprocessing basket and wrap for sterilization, taking into account the applicable standards.
Sterilization:	Sterilize the products using the fractionated pre-vacuum method (ISO17665) taking into account the national requirements. ◗ Temperature exposure time: 4 min at 134°C $^{+4°C}$ (273°F $^{+7°F}$) 132°C $^{+4°C}$ (270°F $^{+7°F}$) (only for USA) ◗ Evacuation: 3 x ◗ Drying time**): 10 - 20 min 20 - 30 min (only for USA) ◗ Maximum sterilization temperature: 138°C For steam-sterilizable products the prion program (134°C, 18 minutes) is permissible. ***NOTE!*** *The STERIS® Vpro Max and STERRAD® sterilization procedures are approved for endoscopes and endoscopic accessories with regard to their material compatibility. Follow the sterilizer manufacturer's specifications.*
Storage:	Store the sterilized products in a restricted area at approximately 24°C / 75°F, with at least 4 air exchanges per hour and a relative humidity that does not exceed 70%, in accordance with ANSI / AAMI ST79.

*) depending on the use of the cleaner and the rinsing water, add an acid based on citric acid.
**) The drying time depends on the sterilization process used.

9.2 Alternate Sterilization Methods

◇ For possible alternate sterilization methods, refer to our website, www.richardwolfusa.com under „Reprocessing Resources“ for lists of Richard Wolf instruments approved for various reprocessing methods.

9.3 High Level Disinfection

Follow the high level disinfectant manufacturer's instructions for use regarding concentration, soak time, rinsing, and disposal of the solution.

⚠ ***CAUTION!***
Cidex OPA solution should not be used to process any urological instruments used to treat patients with a history of bladder cancer.
In rare instances, Cidex OPA solution has been associated with anaphylaxis -like reactions in bladder cancer patients undergoing repeated cystoscopies.
Cidex OPA solution should not be used to process instruments for patients with known sensitivity to Cidex OPA or any of its components.

☞ ***NOTE!***
It is the responsibility of the user to determine whether high level disinfection is the appropriate reprocessing method for the intended use of the instrument, based on the user's own standard of care in compliance with Spaulding classification.

10 Spare parts and accessories

Item	Illustration	Product no.	Designation	
18		8885.901	**Plug-on connector**	
			Adapters for connection to RICHARD WOLF fiber light cables	
4		15005.199	**Adapters endoscope side** for endoscopes - with code number and color coding ring	
		8095.00	**Adapters endoscope side** for endoscopes - only with code number - no code number and no color coding ring - Color coding ring, red (indication of steam-sterilzability)	
			Adapters for connection to fiber light cables made by other manufacturers	
-		808801	**Adapters endoscope side** for endoscopes - with code number and color coding ring	STORZ 3.5 mm / 4.5 mm, OLYMPUS Standard, Stryker
-		8088.81	**Adapters endoscope side** for endoscopes - only with code number - no code number and no color coding ring - Color coding ring, red (indication of steam-sterilzability)	STORZ 3.5 mm / 4.5 mm, OLYMPUS Standard, OLYMPUS WA032...A
-		8087.00		ACMI and CIRCON
-		86.90	**Cleaning brush** Steam-sterilizable universal brush	

The products can be combined as required provided the relevant technical data and intended uses are observed. For a general overview please refer to the latest catalog pages, brochures or contact Richard Wolf or your representative.

11 Operating, storage, transport and shipping conditions

Operating conditions	+10°C to +40°C, 30% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa
Storage, transport and shipping conditions	-20°C to +60°C, 10% to 90% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa

☞ ***NOTE!***

To prevent damage during transport or shipment of the products we recommend using the original packaging material.

11.1 Disposal of product, packaging material and accessories

For the disposal comply with the country-specific laws and regulations.

➧ For further information please contact the manufacturer.

12 Warranty and Customer Service

Richard Wolf guarantees our instruments to be free from any defects in materials and workmanship under normal use and service for one year. Richard Wolf general terms and conditions may be found on the back of our invoice.

Parts delivered separately by Richard Wolf are subject to all of the same general terms and conditions for our products, including the limitations of warranty and liability.

All products should be returned to Richard Wolf for any necessary or desired repair or part replacement. No product repair or part replacement should be done other than by Richard Wolf unless the care and instruction manual or other written information indicates that repair or part replacement is authorized. If authorized, parts must be replaced only by parts supplied or specified by Richard Wolf, and product repair and part replacement must be done in strict conformance with Richard Wolf specifications and instructions for repair and part replacement, including post replacement testing and recalibration. Failure to follow this requirement in any way can be dangerous to you, your personnel and your patients and voids the warranty for the product repaired or the product in which the part was replaced and if the part was supplied by Richard Wolf, for that part.

Delivery by Richard Wolf of technical documents such as circuit or other design diagrams does not constitute authorization for product repair or part replacement. Richard Wolf instruments and other products should never be modified or altered under any circumstances.

Contact Richard Wolf if you have any question (1) whether replacement of a part or a repair is authorized by Richard Wolf, or (2) whether you have complete instructions and specifications for part replacement or repair.

These instructions do not attempt to cover all details or variations in equipment, nor to provide for every possible contingency to be met in connection with installation, operation, or maintenance. Should further information be required or should problems arise which are not covered sufficiently for the purchaser's purpose, the matter should be referred to Richard Wolf Medical Instruments Corporation.

Our national sales and service offices, as well as our manufacturing facility, are located in Illinois. Trained manufacturer's representatives are located throughout the U.S. to serve you. For any questions regarding these instruments, or to place an order, contact Richard Wolf customer service department at 847- 913- 1113 or 800- 323- WOLF (9653).

INSTRUMENT ORDERING POLICY
Richard Wolf reserves the right to make substitutions, if necessary, without prior notice.

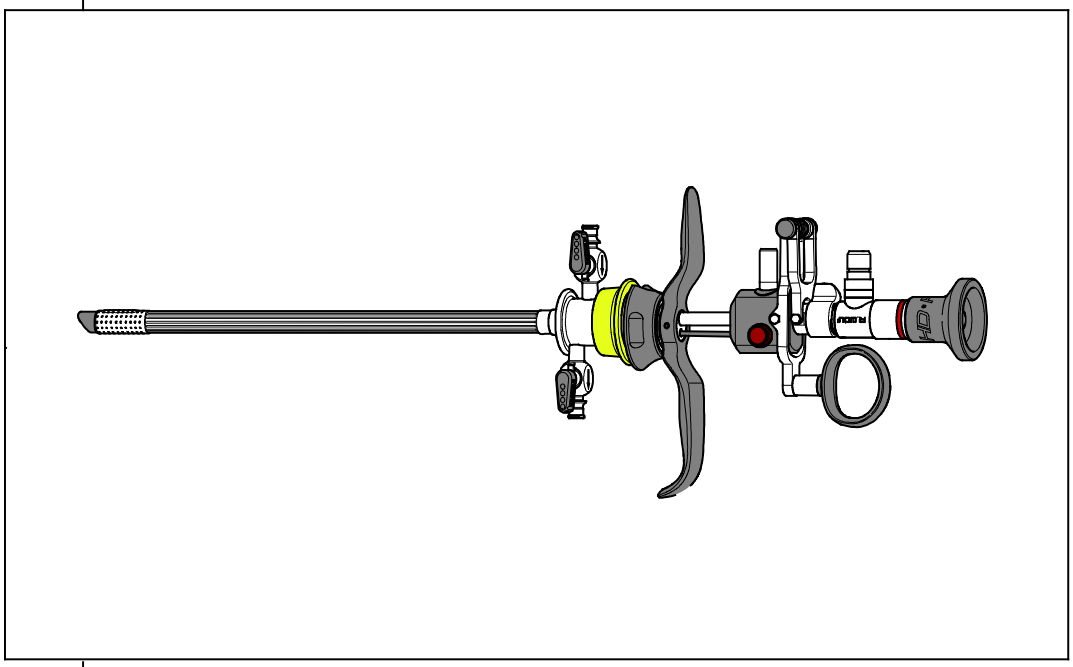
REPAIR POLICY
Defective merchandise will be repaired or replaced at no charge to the customer, provided the customer delivers such defective merchandise prepaid. Any repairs, maintenance or servicing of Richard Wolf merchandise by anyone other than a factory authorized representative will render our warranty null and void.

REPAIR SHIPMENTS
When returning your instrument for repair, we suggest that you prevent shipping damage to the instrument by reusing the box that it was originally shipped in. Richard Wolf also recommends that the instrument be insured for an amount to cover the cost of replacement.

IMPORTANT
For general safety and health reasons, Richard Wolf requires that you clean and sterilize all instruments before returning them for repair. If instruments are received in an unsanitary condition, Richard Wolf will clean and sterilize each instrument and add a $ 100.00 cleaning charge for each instrument requiring cleaning.

RICHARD WOLF
spirit of excellence

Instruction Manual



Shark

Resectoscopes

with Continuous-Irrigation Double-Sheath System

with Intermittent Irrigation

GA-D366-US / en / 2017-02 V4.0 / ECO 2016-0202 (RW: 2015-09 V4.0 / PDI 15-7978)

⚠ Important general notes and instructions ⚠

Make sure that this product is used only as intended and described in this instruction manual and by adequately trained and qualified medical personnel, Maintenance and repair must be carried out by authorized experts.

Use the product only in the combinations and with the accessories and spare parts specified in this instruction manual. Use other combinations, accessories and replacement parts only if they are expressly intended for the planned application and if the performance characteristics and safety requirements are met. The product must not be altered in any way.

Reprocess the product in accordance with the manual before every use and before return shipment to protect the patient, user and third parties.

This manual is an integral part of the product and must be stored in such a way that it is accessible at any time during its entire life cycle. This manual must be passed on to any subsequent owner or user.

Immediately upon receipt, check the product and its accessories for completeness and possible damage. Should the shipment give rise to complaints, please inform the manufacturer or supplier immediately.

Subject to technical changes!
Due to ongoing developments the illustrations and technical data may deviate slightly.

CAUTION!
Federal law restricts this device to sale by or on the order of a physician.

Safety instructions and levels of danger

Symbol	Level of danger
⚠	***WARNING!*** Failure to observe can result in death or extremely serious injuries.
⚠	***CAUTION!*** Failure to observe can result in slight injury or damage to the product.
☞	***IMPORTANT!*** Failure to observe can result in damage to the product or surroundings.
☞	***NOTE!*** User tips for optimum device use and other useful information.

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Contents

1 Technical description

“SHARK“ resectoscopes are used for **t**rans**u**rethral **r**esection of the **p**rostate (**TURP**) and for **t**rans**u**rethral **r**esection of **b**ladder tumors (**TURB**) in the lower urinary tract.

A color coding on the products identifies permissible combinations of sheath, adapter and obturator:

Color coding	Sheath size
“SHARK“ monopolar resectoscope (continuous irrigation double sheath system)	
green	22 / 24 Fr.
yellow	24 / 26 Fr.
“SHARK“ monopolar resectoscope (intermittent irrigation)	
yellow	24 Fr.
black	26 Fr.

The individual products are listed in the following:

◇ **PANOVIEW telescopes (endoscopes)**
- PANOVIEW 0°, 12° and 30° telescopes

◇ **Resectoscope sheaths**
- Resectoscope sheaths, rotatable
- Resectoscope sheaths, non-rotatable

◇ **Obturators**
- Obturator
- Viewing obturator
- Dilation obturator

◇ **Working elements**
- Working element, active: Cutting is effected actively with spring-assisted release
- Working element, passive: Cutting is effected by spring pressure

◇ **Electrodes, monopolar**
- Disposable electrodes, sterile, monopolar

◇ **Monopolar HF connection cable**

2 Intended use

"SHARK" resectoscopes are used for endoscopically controlled tissue ablation.

These products are exclusively intended for use by specialized medical personnel and must only be used by medically qualified and adequately instructed persons.

2.1 PANOVIEW telescopes (endoscopes)

Visualization of the patient's inside via natural passages.

2.2 Obturators

Atramautic insertion of the resectoscope sheath in the urethra.

◇ **Viewing obturator**

- It houses and locks in place the PANOVIEW telescope
- For atramautic insertion of the resectoscope sheath in the urethra under visual control.

◇ **Dilation obturator**

- Atramautic insertion of the resectoscope sheath in the urethra by dilating the distal elastic obturator piston over the inclinable handle.

2.3 Working elements

House and lock in place the PANOVIEW telescope and the electrode as well as controlled insertion of the electrode in the operating field under visual control.

2.4 Electrodes, monopolar

For ablating, severing, cutting and coagulating soft tissue

◇ **Disposable (i.e. single-use) electrodes**

- combined cutting / coagulating

With regard to their reprocessing / reusability, the electrodes are distinguished as follows:

◇ **Disposable electrodes, sterile, monopolar ("SHARK")**

- Identification feature: the product numbers start with **"4"**
  example: **4**6782235

2.5 Monopolar HF connection cable

For connection of the monopolar "SHARK" resectoscope to HF surgical devices with monopolar connector.

2.6 "SHARK" resectoscope (continuous irrigation double sheath system) [A]

2.6.1 "SHARK" resectoscope, rotatable

- ◇ **inner sheath**
  - houses and automatically locks in place the outer sheath and the working element
  - establishes the rotatable connection between the inner sheath and outer sheath with working element, PANOVIEW telescope and electrode
- ◇ **outer sheath**
  - houses and automatically locks in place the inner sheath and supports it allowing for rotation
  - Continuous irrigation fluid supply
  - Draining or evacuating irrigation fluid

2.6.2 "SHARK" resectoscope, non-rotatable

- ◇ **inner sheath**
  - houses and automatically locks in place the outer sheath and the working element
  - establishes the non-rotatable connection between the inner sheath and outer sheath with working element, PANOVIEW telescope and electrode
- ◇ **outer sheath**
  - houses and automatically locks in place the inner sheath
  - Continuous irrigation fluid supply
  - Draining or evacuating irrigation fluid

2.7 "SHARK" resectoscope (intermittent irrigation) [B] [C]

2.7.1 "SHARK" resectoscopes with rotatable irrigation adapters [B]

- ◇ **(B1) - Resectoscope sheath with Luer connector**
- ◇ **(B2) - Resectoscope sheath with irrigation stopcock**
- ◇ **Resectoscope sheath**
  - Houses and automatically locks in place the rotatable irrigation adapter
  - establishes the connection between the resectoscope sheath and the working element with PANOVIEW telescope and electrode
- ◇ **Rotatable irrigation adapter (B1)**
  - Continuous supply of irrigation fluid via Luer connector
- ◇ **Rotatable irrigation adapter (B2)**
  - controllable supply of irrigation fluid via irrigation stopcock

2.7.2 "SHARK" resectoscope with central stopcock, non-rotatable [C]

- ◇ **Sheath with central stopcock**
  - continuous supply of irrigation fluid (position of stopcock plug: "IN")
  - holds the fluid once the bladder capacity is reached (position of stopcock plug: "0")
  - drainage / evacuation of the irrigation fluid (position of stopcock plug: "OUT")
- ◇ **Adapter**
  - holds and automatically locks in place
    - the sheath with central stopcock
    - the working element with PANOVIEW telescope and electrode

3 Indications and field of use

For minimally invasive diagnosis and / or therapy in conjunction with PANOVIEW telescopes and / or endoscopic accessories in the various medical disciplines such as

- ◇ Urology
- ◇ Gynecology

Application:

- ◇ Transurethral resection of the prostate (TURP)
- ◇ Transurethral resection of bladder tumors (TURB)
- ◇ Adenomas and soft-tissue tumors
- ◇ Slitting of the neck of the bladder and incision of the prostate
- ◇ Myoma resection and endometrial ablation

4 Contraindications and side effects

4.1 Contraindications.

Contraindications directly related to the product are presently unknown. On the basis of the latest state of the art in medicine and the patient's condition, the doctor in charge must decide whether the planned application is possible or not.
With regard to sex, provenience, anamnesis and other framework conditions, the patient selection for the application of the described medical product is not restricted.

4.2 Side effects

No side effects are to be expected if the system is used as intended.

5 Combinations

“SHARK“ resectoscopes are always used in conjunction with:

- ◇ Light sources and fiber light cables
- ◇ HF surgical devices
- ◇ Pumps for irrigation or suction
- ◇ Endoscopic accessories

⚠ *CAUTION!*
Do not combine products incorrectly!
Injuries of the patient, user or others as well as damage to the product are possible.
The different products may only be used together if their intended uses and the relevant technical data (working length, diameter, peak voltage, etc.) are the same.
Follow the instruction manuals of the products used in combination with this product.
Follow the "Notes and instructions on HF applications", order no.: GA-S 002 as well as the HF device manufacturer's instructions.

⚠ *CAUTION!*
Do not use electrodes made by other manufacturers.

5.1 System overview “SHARK“ resectoscopes

For this, please refer to supplemental sheet BB-D366, system overview on “SHARK“ resectoscopes.
“SHARK“ resectoscope sheaths can also be used in conjunction with bipolar working elements 8680.xxx.

➧ for this, see supplemental sheet BB-D342, system overview on “S-LINE“ S(a)line resectoscopes

6 Illustration

6.1 Resectoscope sheaths (continuous irrigation double sheath system) [A]

Resectoscope sheaths (intermittent irrigation) [B] [C]

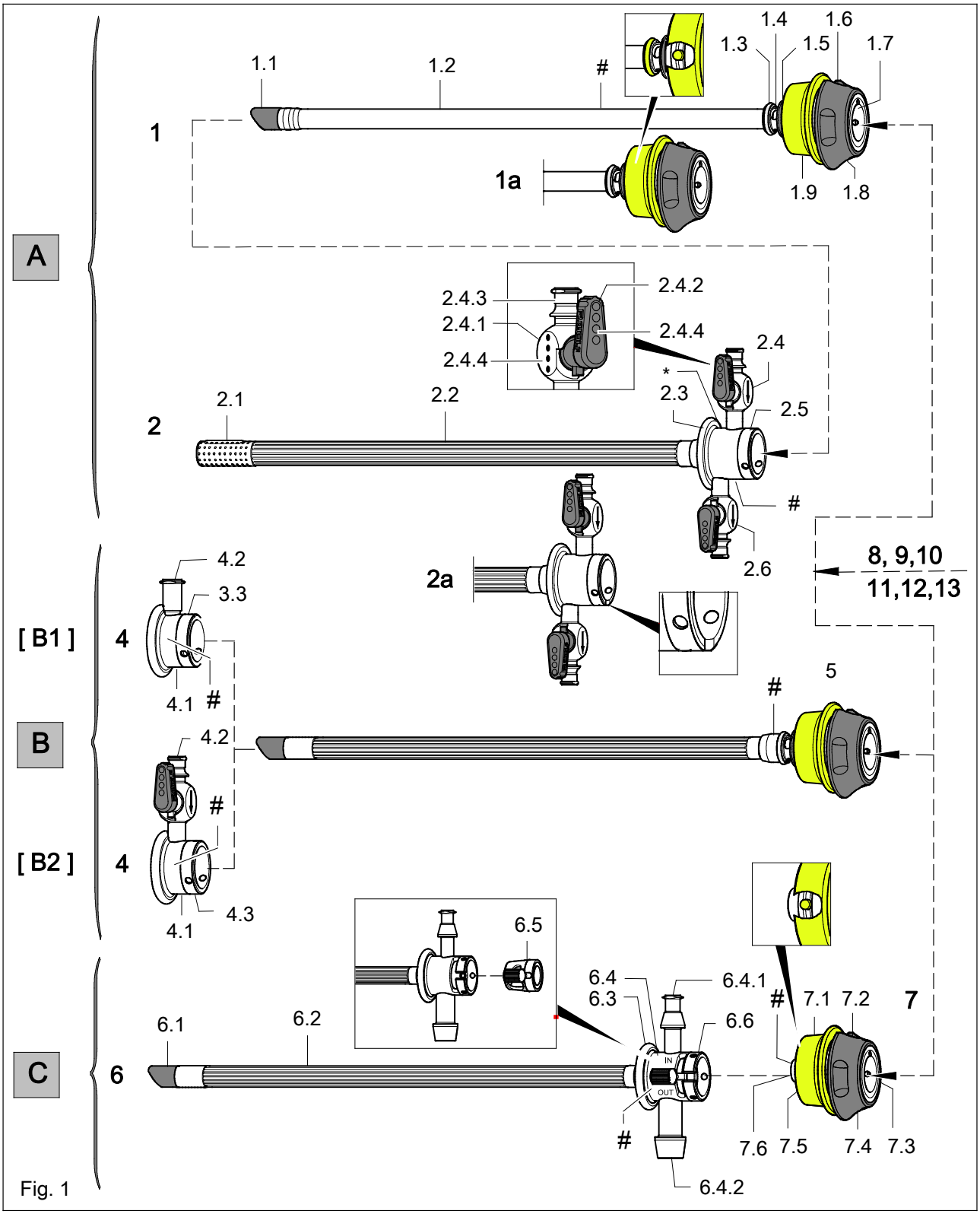


Fig. 1

6.1.1 Legend and identification

Item	Designation	"SHARK" resectoscopes				
		A	B		C	A
			[B1]	[B2]		
		rotatable			non-rotatable	
1	**Inner sheath**	■	■	■	□	□
1a	**Inner sheath (with pin)**	□	□	□	□	■
1.1	Insulating insert (ceramic tip)	■	■	■	□	■
1.2	Sheath tube	■	■	■	□	■
1.3	O-ring	■	■	■	□	■
1.4	Irrigation holes	■	■	■	□	■
1.5	O-ring	■	■	■	□	■
1.6	Recess (for orientation)	■	■	■	□	■
1.7	Lock body	■	■	■	□	■
1.8	Actuation ring	■	■	■	□	■
1.9	Outer ring with color coding	■	■	■	□	■
2	**Outer sheath**	■	□	□	□	□
2a	**Outer sheath (with groove)**	□	□	□	□	■
2.1	Drain holes (suction holes)	■	□	□	□	■
2.2	Sheath tube	■	□	□	□	■
2.3	Flange	■	□	□	□	■
2.4	Irrigation stopcock, complete	■	□	□	□	■
2.4.1	Stopcock housing	■	□	□	□	■
2.4.2	Stopcock plug	■	□	□	□	■
2.4.3	Luer fitting	■	□	□	□	■
2.4.4	Identification for passage on - stopcock housing, stopcock plug	■	□	□	□	■
2.5	Ball catch	■	□	□	□	■
2.6	Drain stopcock, complete (see 2.4)	■	□	□	□	■
3	**Rotatable irrigation adapter**	□	■	□	□	□
4.1	Rotatable irrigation ring	□	■	□	□	□
4.2	Luer fitting	□	■	□	□	□
3.3	Ball catch	□	■	□	□	□
4	**Rotatable irrigation adapter**	□	□	■	□	□
4.1	Rotatable irrigation ring	□	□	■	□	□
4.2	Luer stopcock, complete (see 2.4)	□	□	■	□	□
4.3	Ball catch	□	□	■	□	□
5	**Resectoscope sheath (other items as under 1)**	□	■	■	□	□
6	**Resectoscope sheath with central stopcock**	□	□	□	■	□
6.1	Insulating insert (ceramic tip)	□	□	□	■	□
6.2	Sheath tube	□	□	□	■	□
6.3	Flange	□	□	□	■	□
6.4	Retainer body, complete	□	□	□	■	□
6.4.1	Luer fitting "IN"	□	□	□	■	□
6.4.2	"OUT" connector	□	□	□	■	□
6.5	Stopcock plug	□	□	□	■	□
6.6	Ball catch	□	□	□	■	□

■ = applicable □ = not applicable

Item	Designation	"SHARK" resectoscopes				
		A	B		C	A
			[B1]	[B2]		
		rotatable			non-rotatable	
7	**Adapter (with pin)**	☐	☐	☐	■	☐
7.1	Outer ring with color coding	☐	☐	☐	■	☐
7.2	Recess (for orientation)	☐	☐	☐	■	☐
7.3	Sleeve	☐	☐	☐	■	☐
7.4	Actuation ring	☐	☐	☐	■	☐
7.5	O-ring	☐	☐	☐	■	☐
7.6	Lock body	☐	☐	☐	■	☐
*	Fr. indication	■	■	■	■	■
#	Product no.	■	■	■	■	■

■ = applicable ☐ = not applicable

6.2 Obturators, working elements and electrodes

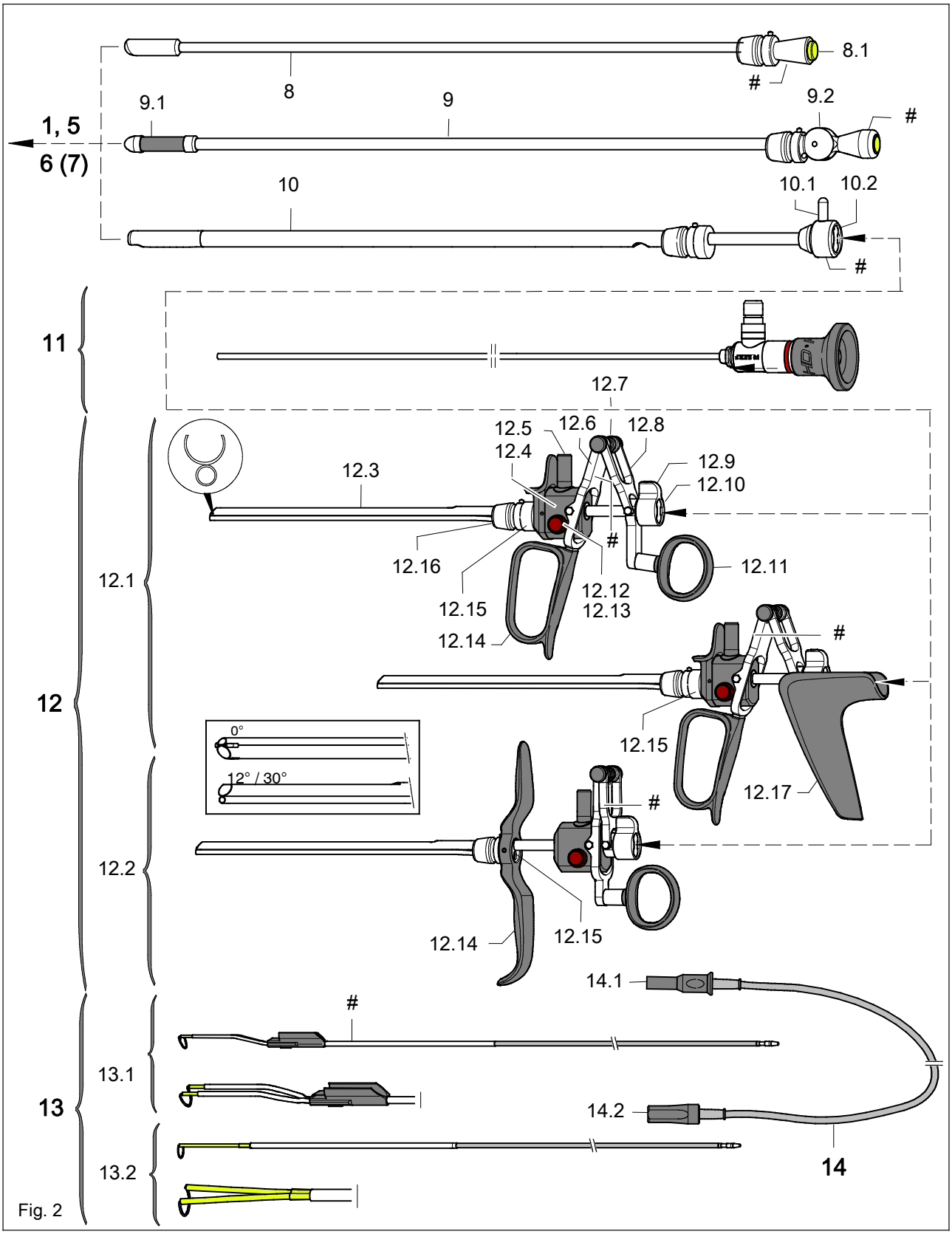


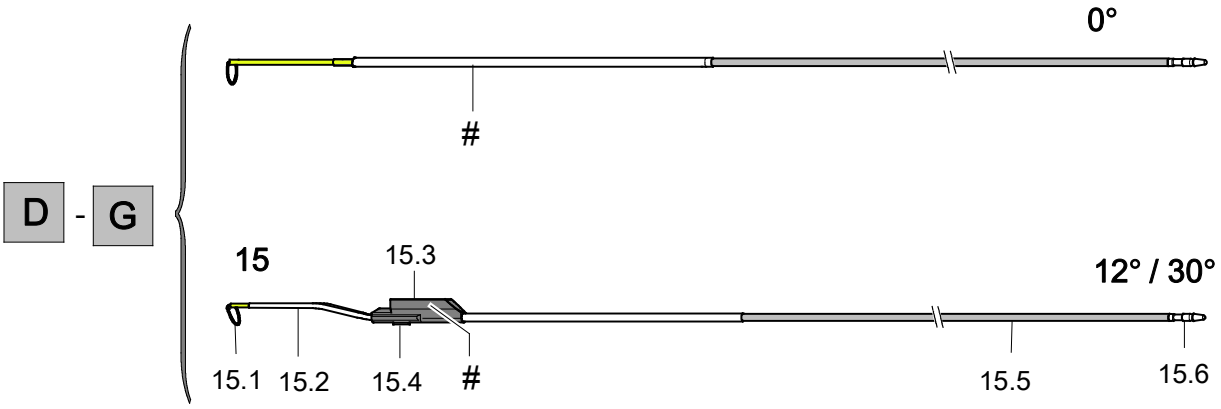
Fig. 2

6.2.1 Legend and identification

Item	Designation	Item	Designation
8	**Obturator**	**12**	**Working element**
8.1	Handle with color coding	12.1	Working element, active cutting action Cutting is effected actively with spring-assisted release
9	**Dilation obturator**	12.2	Working element, passive cutting action Cutting is effected by spring pressure
9.1	Dilatable obturator piston	12.3	Guide rail
9.2	Inclinable handle with color coding	12.4	Lock body
10	**Viewing obturator**	12.5	HF connector
10.1	Locking lever with color coding	12.6	Arm, front
10.2	Locking ring	12.7	Spring
11	**Endoscope**	12.8	Arm, rear
		11.9	Locking lever
		12.10	Locking ring
		12.11	Thumb ring
		12.12	Pushbutton
		12.13	Cap
		12.14	Handle
		12.15	Seal
		12.16	Locking cone
		12.17	Thumb support
		13	**Disposable electrodes, sterile, monopolar** See figure 3
		13.1	Electrodes for 4 mm, 12° / 30° telescope
		13.2	Electrodes for 4 mm, 0° telescope
		14	**Monopolar HF connection cable**
		14.1	Device plug Connection to HF surgical device
		14.2	Instrument plug Connection to HF connector (12.5)
		#	Product no.

6.3 Electrodes, monopolar

6.3.1 Disposable electrodes, sterile, monopolar [D] - [G]



D - G

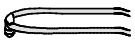
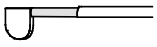
Item	0°	12° / 30°
D		
E1		
E2	-	
E3	-	
F		
G1	-	
G2		-

Fig. 3

6.3.2 Legend and identification

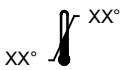
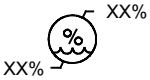
Item	Designation	Item	Designation
15	**Electrode structure**		
15.1	Electrode head	15.5	Proximal insulation (stem) Color coding: ◗ transparent for disposable electrodes, sterile, monopolar
15.2	Distal insulation (fork) Color coding: ◗ **green** for 22 / 24 Fr. resectoscope sheath ◗ **yellow** for 24 / 26 Fr. resectoscope sheath ◗ **black** for 26 Fr. resectoscope sheath	15.6	Contact section
15.3	Telescope guide, black (plastic part)		
15.4	Guide nose ◗ **without** guide nose - color coding **green** for inner sheath 22 Fr. ◗ **with** guide nose - 1st Stage - color code **yellow** for inner sheath 24 Fr. ◗ **with** guide nose - 2nd Stage - color code **black** for inner sheath 26 Fr.	#	**Product no.** ◗ **on sterile packaging** for disposable electrodes, sterile, monopolar
D - G	**Disposable electrodes, sterile, monopolar**		
16	**Electrode shapes**	**16**	**Electrode shapes**
D	**Cutting electrode, loop**	**F**	**Hook electrode**
E1	**Coagulation electrode, roller**	**G1**	**Blade electrode**
E2	**Coagulation electrode, sphere**	**G2**	**Blade electrode**
E3	**Coagulation electrode, button**		

6.4 Symbol

6.4.1 Reprocessable products (unsterile)

Symbol	Designation
	Attention, Caution
	Observe the instruction manual
REF	Order number
LOT	Lot identification
SN	Serial no.
	Unsterile
	Manufacturer
CE	Identification in conformity with Medical Product Directive 93/42/EEC, **only** valid if the **product and/or the packaging is marked with this identification**. Products of category IIa and above, as well as sterile products or products with measuring function of category I, are additionally marked with the code no. of the notified body (0124).

6.4.2 Disposable products (sterile)

Symbol	Designation
	Observe the instruction manual
REF	Order number
LOT	Lot identification
	Manufacturing date
Σ	Number, amount
	Expiry date
	Do not reuse
	Do not resterilize
STERILE EO	Sterilized with ethylene oxide
	Manufacturer
	Do not use if package is damaged
	Keep away from sunlight
	Temperature limitation
	Humidity limitation
CE	Identification in conformity with Medical Product Directive 93/42/EEC, **only** valid if the **product and/or the packaging is marked with this identification**. Products of category IIa and above, as well as sterile products or products with measuring function of category I, are additionally marked with the code no. of the notified body (0124).

7 Operating instruction

⚠ *WARNING!*
Do not reprocess disposable items!
The service life of products marked as disposable, i.e. for one single use only, has been designed for only one use in or on a single patient.
If disposable items are reprocessed to be used again, this may impair/change the product properties and therefore endanger the patient, user and others.
Possible dangers / risk factors:

- *Strength problems*
- *Damage to the product*
- *Severe impairment of the function*
- *Substantially increased risk of infection*
- *Biocompatibility problems*

If a disposable item is reprocessed, the product responsibility lies with the user or reprocessor.
In this case the manufacturer can no longer guarantee the safety and performance of the product.

⚠ *CAUTION!*
The products have only limited strength!
Excessive force will cause damage, impair the function and therefore endanger the patient.
Immediately before and after each use, check the products for damage, loose parts and completeness.
Make sure that no missing parts remain in the patient.
Do not use the products if they are damaged or incomplete or have loose parts.

7.1 Preparation

Carry out the following preparatory measures for the corresponding “SHARK“ resectoscopes:

◇ Check assembly: see section 9.5
◇ Carry out a check: see sections 8 and 8.1

7.1.1 Insert the inner sheath (1) into the outer sheath (2) [A]

“SHARK“ resectoscope, rotatable [A]

Fig. 4

Locking:

◇ Check that the O-rings (1.3) (1.5) on the inner sheath (1) are in place.
◇ Insert the inner sheath (1) into the outer sheath (2) as far as it will go.
  ➧ The outer sheath (2) snaps audibly into the inner sheath (1) and is held automatically by a ball catch (2.5).
◇ Check that the rotatable connection is secure.

Unlocking:

◇ Push the outer ring (1.9) on the inner sheath (1) in direction of arrow as far as it will go, hold and remove the outer sheath (2).

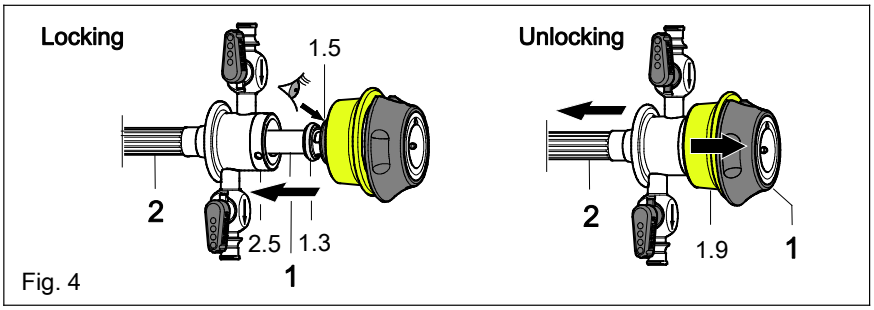


Fig. 4

7.1.2 Attach the rotatable irrigation adapter (3) (B1) or (4) (B2) to the resectoscope sheath (5) [B]

"SHARK" resectoscope with rotatable irrigation adapters [B]

Fig. 5

Locking:

◇ Check that the O-rings (1.3) (1.5) are installed on the resectoscope sheath (5).

◇ Insert the resectoscope sheath (5) into the rotatable irrigation adapter (3) or (4) as far as it will go.

➧ The rotatable irrigation adapter (3) or (4) audibly snaps into the resectoscope sheath (5) where it is automatically held by means of the ball catch (3.3) (4.3).

◇ Check that the rotatable connection is secure.

Unlocking:

◇ Slide outer ring (1.9) on the resectoscope sheath (5) in direction of arrow as far as it will go, hold and remove the rotatable irrigation adapter (3) or (4).

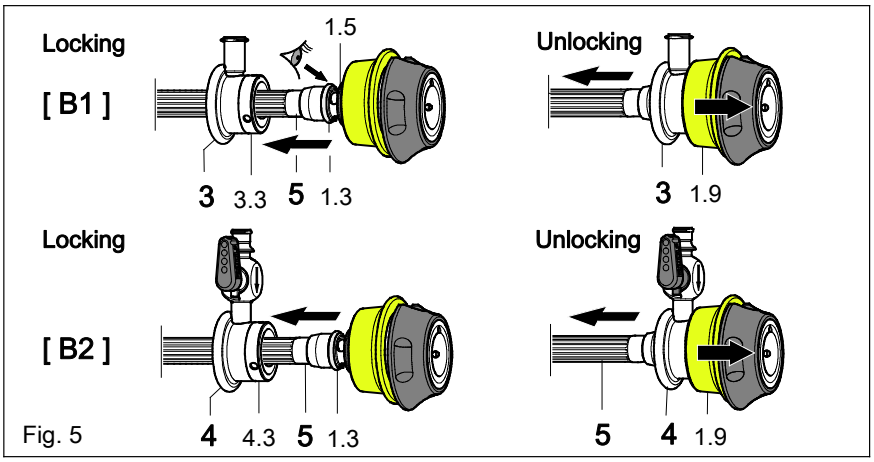


Fig. 5

7.1.3 Insert the inner sheath (1a) into the outer sheath (2a) [A]

"SHARK" resectoscope, non-rotatable [A]

Fig. 6

Locking:

◇ Check that the O-rings (1.3) (1.5) on the inner sheath (1a) are in place.

◇ Insert the inner sheath (1a) into the outer sheath (2a) in the snap-in position.

➧ The groove (a) and the pin (b) are aligned.

◇ Slide the outer sheath (2a) into the inner sheath (1a) as far as it will go.

➧ The outer sheath (2) snaps audibly onto the inner sheath (1a) and is held automatically by a ball catch (2.5).

◇ Check the components for secure connection.

Unlocking:

◇ Push the outer ring (1.9) on the inner sheath (1a) in direction of arrow as far as it will go, hold and remove the outer sheath (2a).

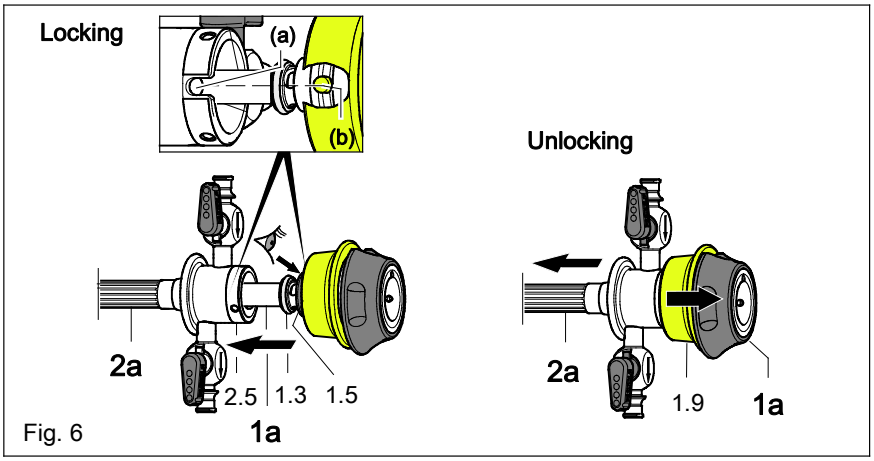


Fig. 6

7.1.4 Attach the stopcock plug (6.5) and adapter (7) to the resectoscope sheath with central stopcock (6) [C]

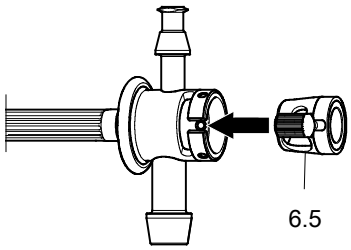


Fig. 7

"SHARK" resectoscope with central stopcock, non-rotatable [C]

Fig. 7

◇ Insert the stopcock plug (6.5) in direction of arrow as far as it will go.

Fig. 8

Locking:

◇ Check that the O-ring (7.5) is installed on the adapter (7).

◇ Position the adapter (7) radially to the resectoscope sheath with central stop-cock (6) in the snap-in position.

➧ The groove (a) and the pin (b) are aligned.

◇ Slide the resectoscope sheath with central stopcock (6) into the adapter (7) as far as it will go.

➧ The resectoscope sheath with central stopcock (6) snaps (audibly) into the adapter (7) and is held automatically by a ball catch (6.6).

◇ Check the components for secure connection.

Unlocking:

◇ Slide the outer ring (7.1) on the adapter (7) in direction of arrow as far as it will go, hold and remove the resectoscope sheath with central stopcock (6).

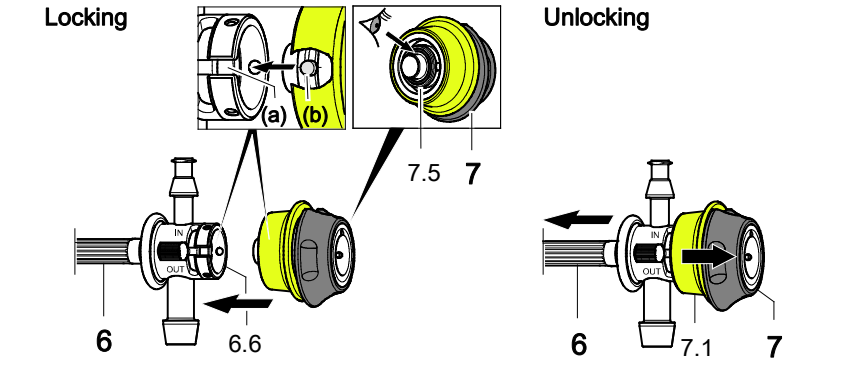


Fig. 8

7.1.5 Orientation aid when installing the instruments

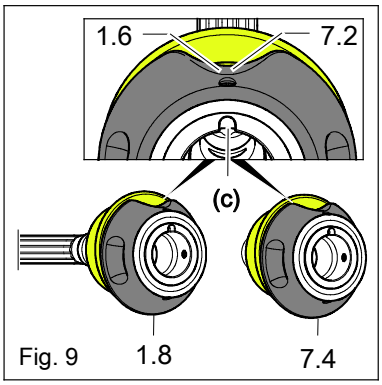


Fig. 9

Fig. 9

☞ ***NOTE!***

The actuation ring (1.8) (7.4) has a recess (1.6) (7.2) which is opposite the position of the groove (c).
When inserting the obturators (8) (9) (10) and the working element (12), the groove (c) of the actuation ring (1.8) (7.4) and the pin (d) of the instruments must be aligned.
The recess (1.6) (7.2) provides orientation.

7.1.6 Inserting obturator (8) into resectoscope sheath

Fig. 10

Locking:

◇ Insert the obturator (8) into the resectoscope sheath in such a way that the groove (c) and the pin (d) are aligned.
Push together until the obturator (8) engages automatically in the lock body (1.7) or (7.6).

◇ Check the components for secure connection.

☞ ***NOTE!***

If the obturator (8) won't engage in the lock body (1.7) or (7.6), press the acutation ring (1.8) or (7.4) in direction of arrow as far as it will go and repeat the procedure.

Unlocking:

◇ Push the actuation ring (1.8) or (7.4) in direction of arrow as far as it will go and remove the obturator (8).

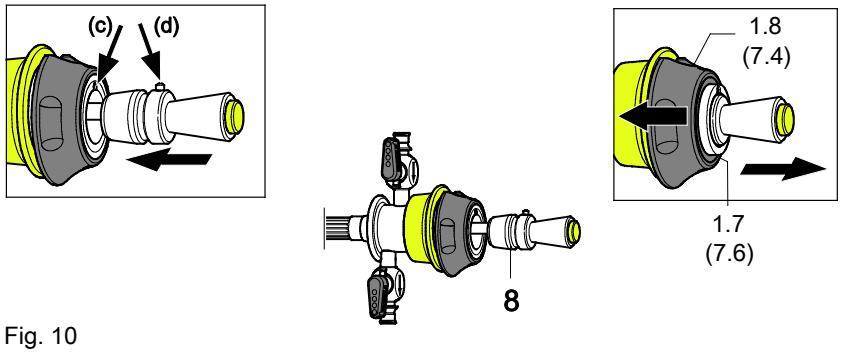


Fig. 10

7.1.7 Inserting dilation obturator (9) in resectoscope sheath

Fig. 11

☞ ***IMPORTANT!***

Insert or withdraw the dilation obturator (9) only when the inclinable handle (9.2) is in horizontal position.

Locking and unlocking:

◇ Same procedure as described under section 7.1.6.

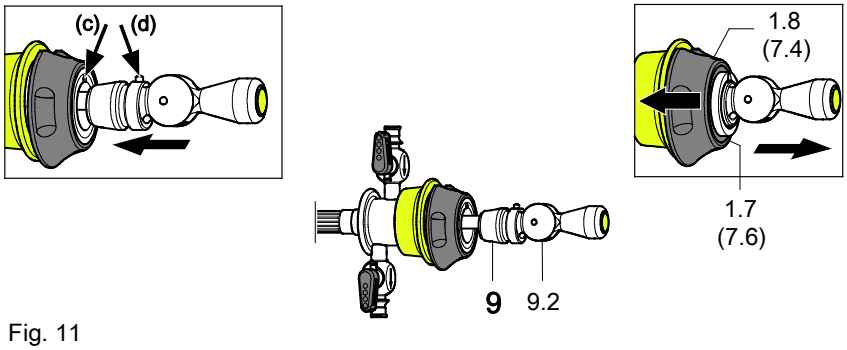


Fig. 11

Fig. 12

Dilating the flexible obturator piston (9.1)

◇ Angle the inclinable handle (9.2) up to the stop position (90° position).
  ◗ The handle (9.2) is locked in the end position.

☞ *IMPORTANT!*

The dilatable obturator piston is only conically dilated creating an atraumatic transition between the obturator tip and the end of the sheath when the handle is in the end position.

◇ Check dilation of obturator piston (9.1).
◇ Do not use the dilation obturator (9)
  ◗ if it is not possible to move the inclinable handle (9.2) to its end position.
  ◗ if damage (e.g. cracks) has occured on the dilatable obturator piston (9.1).

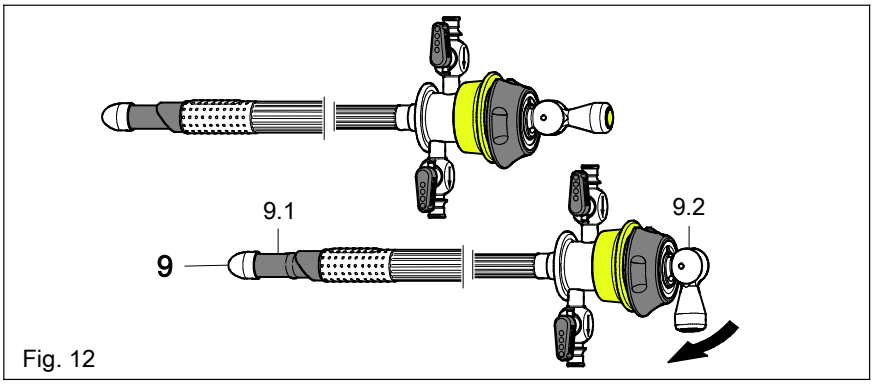


Fig. 12

7.1.8 Inserting PANOVIEW telescope (11) into viewing obturator (10)

Fig. 13

Locking:

The locking lever (10.1) must be in position “I".

◇ Insert the PANOVIEW telescope (11) into the viewing obturator (10).
  ◗ The pin (e) engages in the groove (f).
◇ Turn the locking lever (10.1) to position "II".
  ◗ Both components are locked together.
◇ Check the components for secure connection.

Unlocking:

The clamping lever (10.1) must be in position “II".

◇ Turn the locking lever (10.1) to position "I".
  ◗ The locking mechanism is unlocked.
◇ Remove the PANOVIEW telescope (11).

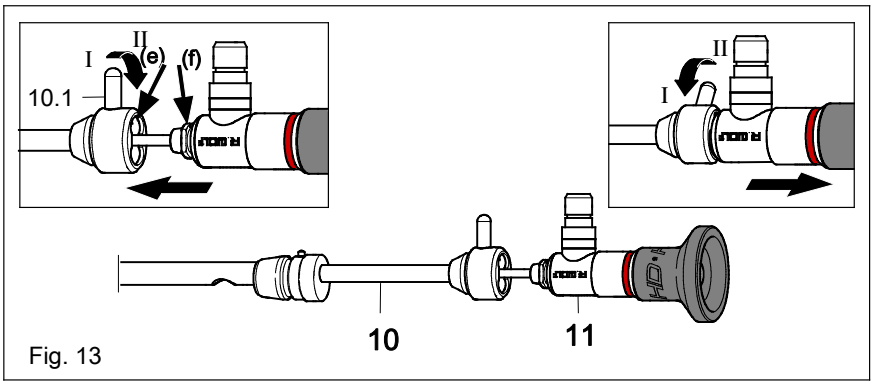


Fig. 13

7.1.9 Inserting viewing obturator (10) with PANOVIEW telescope (11) into the resectoscope sheath

Fig. 14

Locking and unlocking:

◇ Same procedure as described under section 7.1.6.

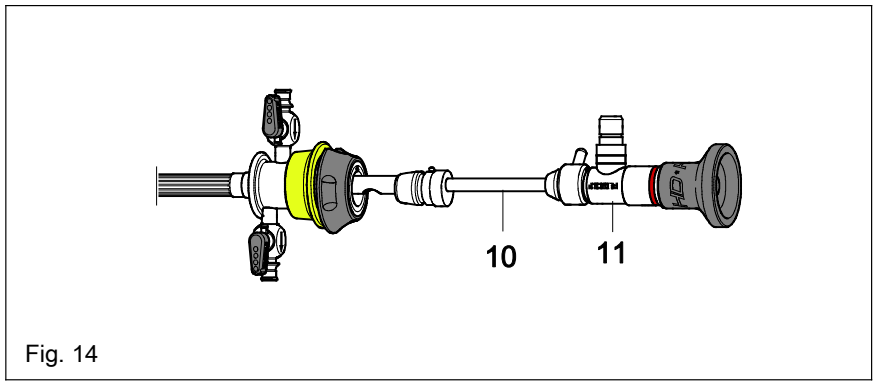


Fig. 14

7.1.10 Inserting the PANOVIEW telescope (11) into the working element (12)

Fig. 15

◇ Same procedure as described under section 7.1.8.

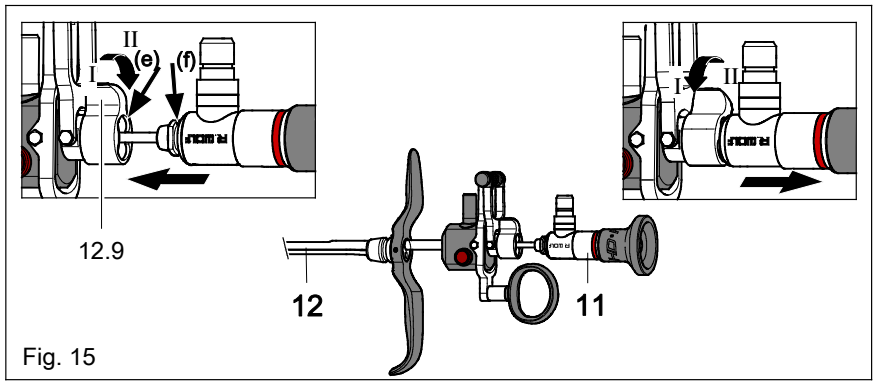


Fig. 15

7.1.11 Inserting electrode (13) into working element (12)

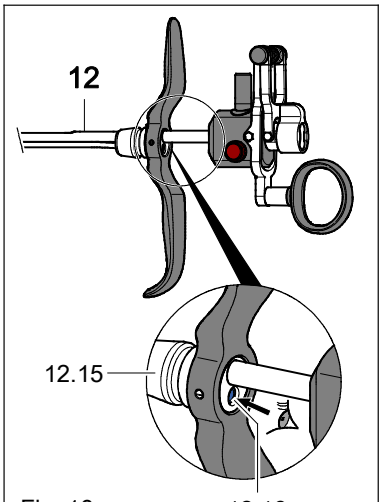


Fig. 16

☞ ***IMPORTANT!***

Before you insert the electrode in the working element (12), make sure that there is a seal (12.15) in the locking cone (12.16) (Fig. 16).

- *See section 9.7 working element (12)*

☞ ***IMPORTANT!***

Observe compatibility of the electrodes (13) and the resectoscope sheath.
In the following additional features for compatibility are listed (for this also see section 10):

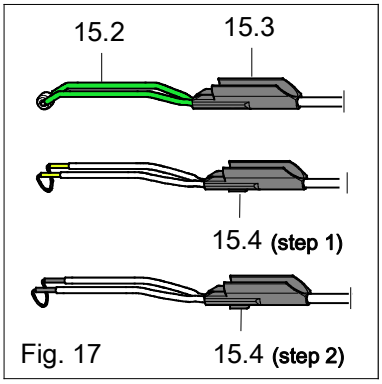


Fig. 17

Fig. 17

Use with cutting electrode

- ***without guide nose (15.3) (15.4) - color coding green (15.2):***
  only compatible in conjunction with 22 / 24 Fr. continuous-irrigation resectoscope sheath or
  22 Fr. intermittent resectoscope sheath
- ***with guide nose (15.4) - 1st step - color coding yellow (15.2):***
  only compatible in conjunction with 24 / 26 Fr. continuous-irrigation resectoscope sheath or
  24 Fr. intermittent resectoscope sheath
- ***with guide nose (15.4) - 2nd step - color coding black (15.2):***
  only compatible in conjunction with 26 Fr. intermittent resectoscope sheath

Use with coagulation electrode / blade electrode / hook electrode

- ***without guide nose (15.3) (15.4) - color coding green (15.2):***
  compatible in conjunction with resectoscope sheath up to 24 Fr.
- ***with guide nose (15.4) - 1st step - color coding yellow (15.2):***
  compatible in conjunction with resectoscope sheath from 24. Fr

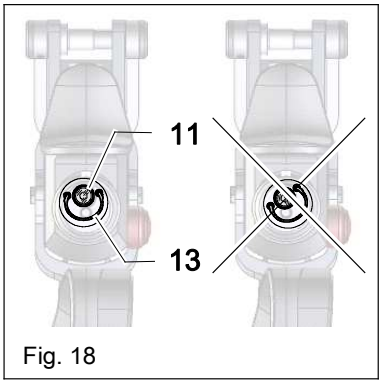


Fig. 18

Fig. 18 / Fig. 19

Locking:

◇ Hold the electrode (13), as shown in Fig. 19 and insert via the guide rail (12.3) into the lock body (12.4) as far as it will go.

➧ The electrode (13) snaps into place.

◇ Center the electrode (13) to the PANOVIEW telescope (11) as shown in Fig. 18.

◇ Check firm connection of electrode (13) by pulling slightly.

Unlocking:

◇ Press the button (12.12) and pull out the electrode (13) by holding it by the telescope guide (15.3).

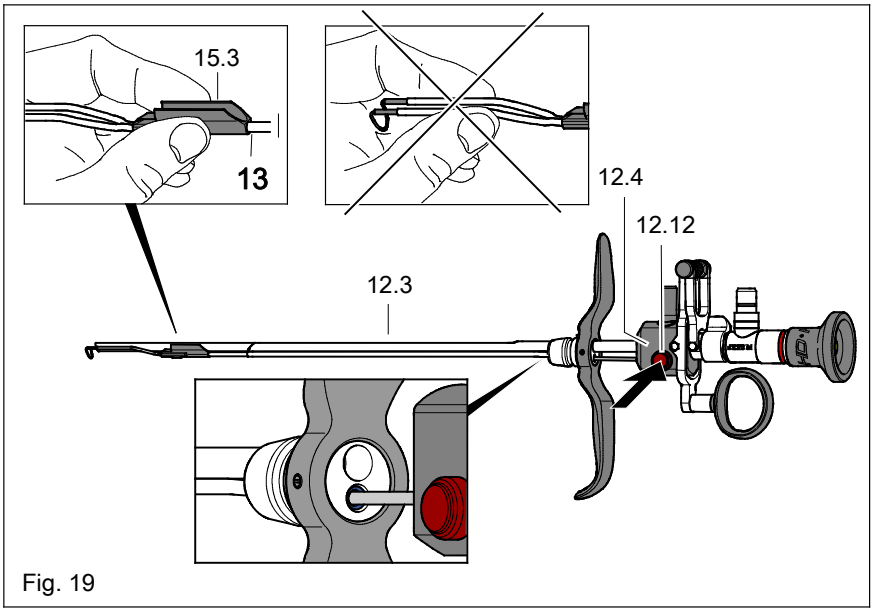


Fig. 19

7.1.12 Inserting working element (12) in resectoscope sheath

Locking and unlocking:

◇ Same procedure as described under section 7.1.6.

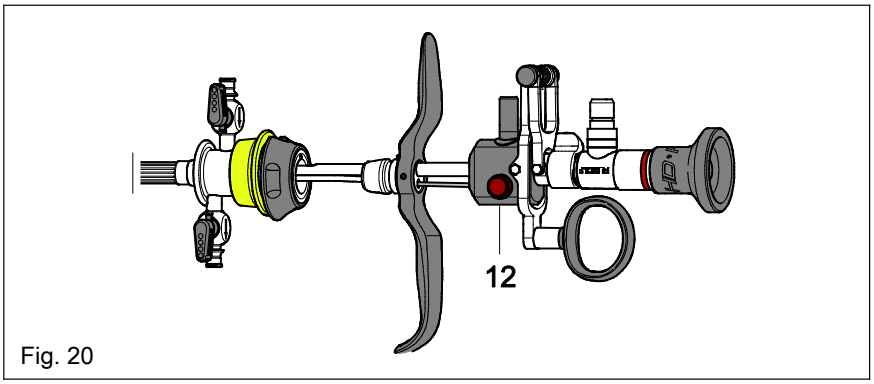


Fig. 20

7.2 Additional Instructions for Use

7.2.1 Connecting the resectoscope sheath to the suction and irrigation system

◇ Check the suction and irrigation function of the preassembled instrument set as well as the entire system for leak-tightness and patency (free passage) before each use.

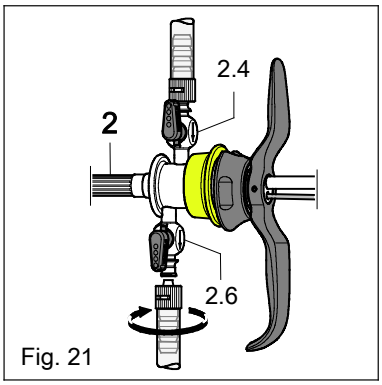


Fig. 21

Resectoscope sheaths (continuous irrigation double sheath system) [A]

Outer sheath (2)

Fig. 21

◇ Connect the irrigation and drain tubes to the irrigation stopcock (2.4) and drain stopcock (2.6).

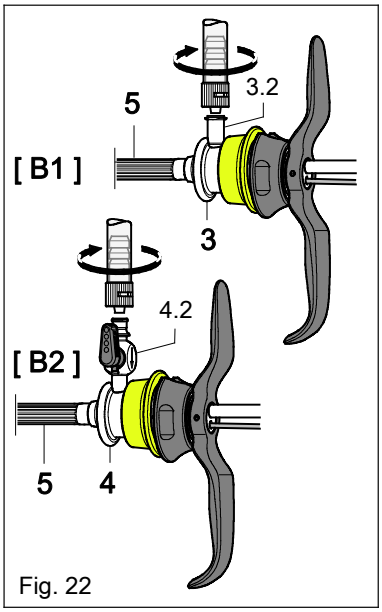


Fig. 22

Resectoscope sheaths (intermittent irrigation) [B] [C]

Resectoscope sheath (5) with rotatable irrigation adapter (3) (B1) / (4) (B2)

Fig. 22

◇ Connecting the irrigation tube
- ◗ Rotatable irrigation adapter (B1) to Luer connector (3.2)
- ◗ Rotatable irrigation adapter (B2) to Luer stopcock (4.2)

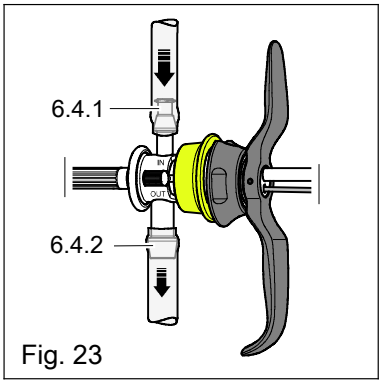


Fig. 23

Resectoscope sheaths with central stopcock [C]

Fig. 23

◇ Connect the irrigation and drain tubes to the luer fitting **"IN"** (6.4.1) and the **"OUT"** connector (6.4.2).

7.2.2 Atraumatic insertion of resectoscope sheath

⚠ *CAUTION!*
Do not insert the resectoscope sheath without obturator!
This may cause inadvertent tissue damage.
Insert the resectoscope sheath only atraumatically with the obturator in place.

◇ Insert the obturator into the resectoscope sheath and introduce into the urethra.
- ◗ Obturator (8): see section 7.1.6
- ◗ Dilation obturator (9) see section 7.1.7
- ◗ Viewing obturator (10): see section 7.1.9

Connect the fiber light cable to the PANOVIEW telescope (11) and to a suitable light source. Switch on the light source.

◇ Remove the obturator (8) (9) (10).

7.2.3 Connecting the “SHARK“ resectoscope with the system components

◇ Connect the fiber light cable to the PANOVIEW telescope (11) and a suitable light source. Switch on the light source.
◇ Connect the monopolar HF connection cable to the instrument and to the HF surgical device.
◇ Insert the working element (12) with the electrode (13) and the PANOVIEW telescope (11) into the resectoscope sheath already in place: See section 7.1.12
◇ Switch on the irrigation fluid supply.
◇ Carry out a function check: see section 8.2

Resectoscope sheaths with central stopcock [C]

When reaching the bladder capacity:
◇ To stop the supply: Turn the stopcock plug (6.5) to the “0" position.
- ◗ The plug (6.5) of the stopcock engages in this position.

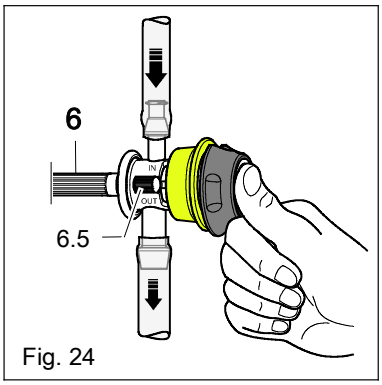


Fig. 24

Fig. 24

◇ Remove the working element (12).
◇ Lift the resectoscope sheath (6) proximally and close the opening with your thumb.
◇ Turn stopcock plug (6.5) to “OUT".
- ◗ The siphon effect empties the bladder and evacuates any tissue strips or concretions.

Resectoscope sheath [B] with rotatable irrigation adaptor (B1)

When using a two-way stopcock, only a drain but no evacuation of tissue strips etc. is possible via this drain.

7.2.4 Irrigation fluid

⚠ *CAUTION!*
Take care not to use the wrong irrigation fluid!
Caution when using high conductivity irrigation fluid in the case of monopolar HF applications!
• Increased danger of patient leakage currents
• No function of the HF instrument
The user must choose the irrigation fluid as required by the application. The irrigation fluid must have a low electrical conductivity for monopolar HF applications.
Do not use saline (NaCl solution) for monopolar HF applications.

⚠ *CAUTION!*
Danger of elevated temperatures when working without irrigation fluid!
Injuries to the mucous membrane due to excessive temperatures endanger the patient.
Activate the electrode only while it is immersed in irrigation fluid and under continuous irrigation.

7.2.5 Electrical current

⚠ *WARNING!*
Danger of electric shock!
Patient leakage currents can add up if the endoscopes are combined with other powered endoscopic accessories.
Make sure that the combinations do not exceed the permissible patient leakage currents.

7.3 HF applications

Follow the **"Notes and instructions on HF applications"**, order no. GA-S 002 as well as the HF device manufacturer's instructions.

⚠ *WARNING!*
Danger of injury if the HF instrument is not visible through the scope !
Inadvertent tissue damage as well as damage to the distal end of the endoscope and instrument parts is possible.
Use the HF instruments within the scope of their specifications (voltage strength, mode of operation).
Activate HF instruments only after the part carrying high-frequency current has become fully visible through the scope and contact is made with the area to be treated.

⚠ *WARNING!*
Explosion hazard if the electrode is activated in an air or gas bubble (e.g. roof of the bladder)!
This may cause injuries of the bladder or uterus wall.
Activate HF current only if:
- *the electrode is visible through the scope and is fully immersed in irrigation fluid.*
- *the required tissue contact is made.*

☞ *NOTE!*
In order to remove the air bubbles generated during vaporization, we recommend using continuous-irrigation resectoscopes sheaths or suprapubic aspiration.

⚠ *CAUTION!*
Careful if HF voltage is too high !
Danger of injury resulting from damage to the electrode insulation!
Exceeding the maximum recurring peak voltage for the electrode in combination with HF surgical devices and / or selecting the wrong mode can destroy the insulation and cause leakage currents.
The patient, user or others may suffer tissue damage!
Use electrodes in conjunction with HF surgical devices only at a recurring peak voltage of max. 2 kV, even in forced or spray coagulation.

We recommend using the following power settings:

Single-use electrodes

- *Cutting mode:* *120 - 180 Watt*
  Coagulation mode: *maximum 100 watts*

⚠ *CAUTION!*
Danger of HF arcing during spray coagulation!
Insufficient distance between the parts conducting high-frequency current and other conductive parts can lead to unintentional tissue damage and damage to the instrument.
When the HF current is activated any parts of HF instruments carrying high frequency current must have a safety distance of at least 8 mm from the distal end of the endoscope / sheath (Fig. 25).
In the case of HF arcing, replace the electrode immediately, check the endoscope for damage and send it in for repair if necessary to avoid consequential damage.

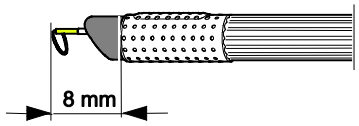


Fig. 25

⚠ *CAUTION!*
Careful with excessively high power settings in the area of the sphincter/cervix!
This may cause thermal damage and a dysfunction of the sphincter or cervix
When the tissue turns brown or black or is carbonized this is an indication of excessive power.
Depending on the electrode power and mode, the depth effect (necrosis) is approx. 0.5 to 2 mm. Make sure that in particular in the proximity of the sphincter and cervix you use the utmost care and the smallest possible HF power.

⚠ *CAUTION!*
Careful if HF output power is incorrectly selected!
Injuries of the patient as well as damage to the product are possible.
The power should be set on the basis of the surgeon's experience and training in view of the corresponding indication.

⚠ *CAUTION!*
Do not activate HF current with installed stricture scalpel!
The stricture scalpel is not insulated and can cause injuries of the mucuous membrane when HF current is activated.
Remove the HF monopolar connection cable from the HF connector of the working element before working with stricture scalpels.

☞ *NOTE!*
Excessive power settings can cause clearly increased electrode wear. We recommend starting at a lower power setting to determine the optimum power setting.

8 Checks

⚠ *CAUTION!*
Be careful if products are damaged or incomplete!
Injuries of the patient, user and others are possible.
Run through the checks before and after each use.
Do not use the products if they are damaged, incomplete or have loose parts.
Return damaged products together with any loose parts for repair.
Do not attempt to do any repairs yourself.

8.1 Visual check

◇ Check products and accessories for damage, sharp edges, loose or missing parts and rough surfaces. Check the insulation with particular care.
◇ Any lettering, labeling or identification necessary for the safe intended use must be legible.
➧ To prevent wrong handling or reprocessing, any illegible lettering, labeling or identification must be reinstated.
➧ Use new sterile electrodes.

8.1.1 Monopolar HF connection cable (14)

◇ Check the insulation and / or cable plugs for cracks and fractures and replace if necessary.

8.1.2 “SHARK“ resectoscopes

⚠ *WARNING!*
Danger of injury!
Incorrect handling, e.g. fall, shock, blows or similar mechanical loads can cause hair cracks and / or spalling of the ceramic coating in the distal area of the resectoscope sheath.
Injuries of the patient, user or third parties are possible.
Mind surface changes and ensure safe handling.
Do not use damaged resectoscope sheaths, return damaged sheaths for repair.

Fig. 26

◇ Check the ceramic insulation at the distal end of the resectoscope sheath for damage before every use.

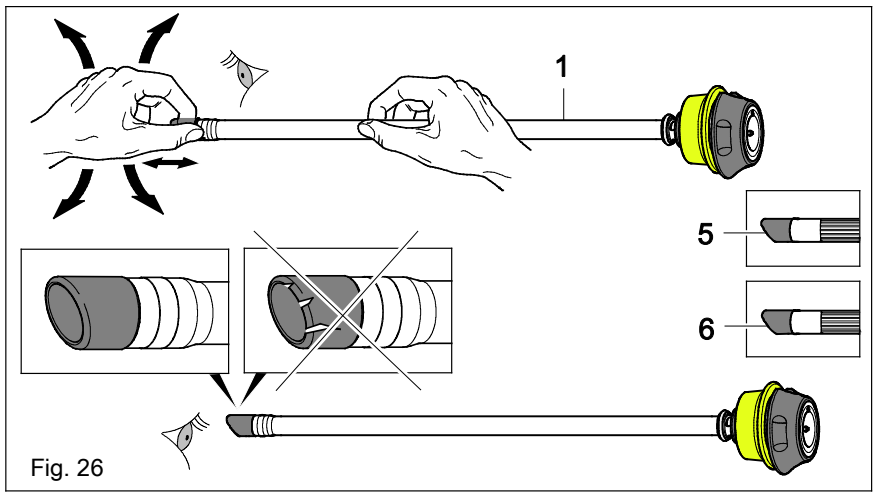


Fig. 26

◇ Replace damaged or brittle O-rings / caps (12.13).
➧ O-rings (1.3) (1.5) - “SHARK“ resectoscope, rotatable [A] [B]
➧ O-ring (7.5) - “SHARK“ resectoscope with central stopcock [C] non-rotatable

8.1.3 Electrodes, monopolar

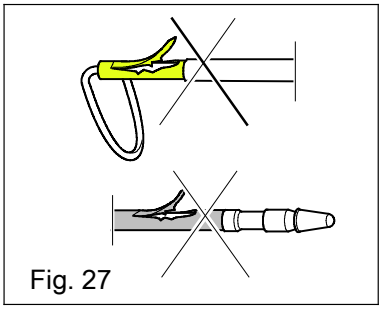


Fig. 27

Fig. 27

◇ Check the insulation. Replace the electrode if
- ◗ the insulation is damaged
- ◗ the distal insulation is worn

☞ ***IMPORTANT!***

For sterile products:

***Sterility** is only guaranteed for undamaged and unopened packaging.*
- ◗ *Do not use the product if the sterile packaging is damaged or the use-by date has expired.*

◇ Single-use electrodes, sterile, monopolar
- ◗ Check sterile packaging.

8.2 Function check

◇ Check the individual components for compatibility.

◇ Check for easy assembly and proper functioning of the locking mechanisms of the individual products. Replace the products if the connection
- ◗ although locked is not secure.
- ◗ cannot be locked or can only be locked with difficulty.

◇ Check rotatability of resectoscope [A] [B].

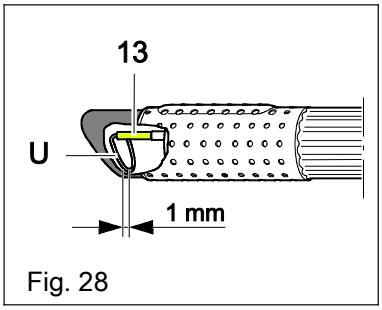


Fig. 28

Fig. 28

◇ Check if electrode (13) is locked in place:
- ◗ Insert the working element (12) into the resectoscope sheath (section 7.1.11) and fully retract the electrode (13) by means of working element (12). In this end position, the loop (U) of the electrode must be positioned approx. 1 mm behind the edge of the sheath.
  This is essential to ensure trouble-free tissue ablation.

◇ Check the function of the HF monopolar connection cable (14) in conjunction with the “SHARK“ resectoscope and the HF surgical device.

◇ Check the irrigation or suction function.

◇ Check the entire system for leak-tightness and free passage (patency).

8.2.1 Irrigation stopcock (2.4), drain stopcock (2.6) and luer stopcock (4.2)

◇ Check that the stopcock plug (2.4.2) is securely locked in the stopcock housing (2.4.1).

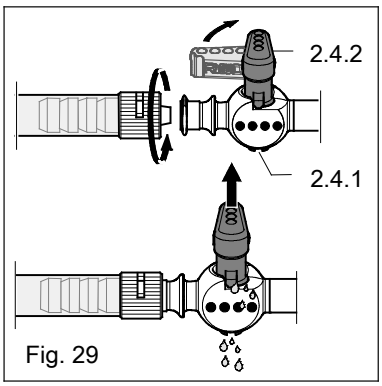


Fig. 29

Fig. 29

◇ Check the stopcocks (2.4) (2.6) (4.2) for leakage.
- ◗ Connect the supply tube, turn the stopcock plug (2.4.2) to its locked position.
- ◗ In case of leaking stopcocks: Replace the stopcock plug (2.4.2).

◇ Check that the stopcock plug (2.4.2) moves easily in the stopcock housing (2.4.1).

9 Reprocessing and maintenance

9.1 Dilation obturator (9)

☞ *IMPORTANT!*

Do not immerse the dilation obturator (9) in alcohol.
The flexible silicone tube of the obturator piston (9.1) can swell and become damaged.

9.2 Electrodes (13)

☞ *IMPORTANT!*

Disposable electrodes may only be used once. Discard disposable electrodes after use.

☞ *IMPORTANT!*

Do not clean plastic parts using metal or sharp-edged tools (such as metal brushes).

9.3 Disassembly before cleaning

◇ Separate the HF monopolar connection cable (14) from the “SHARK“ resectoscope first.
◇ Remove all connections between the “SHARK“ resectoscope and system components.
◇ Remove all parts used:
- Working element (12): see section 7.1.12
- Electrode (13): see section 7.1.11
- PANOVIEW telescope (11): see section 7.1.10
- “SHARK“ resectoscope [C] - adapter (7): Section: 7.1.4
- “SHARK“ resectoscope [B] - rotatable irrigation adapter (3) (B1) and (4) (B2): see section 7.1.2
- “SHARK“ resectoscope [A] - outer sheath (2) (2a) : see section 7.1.1 and 7.1.3

9.4 Reprocessing procedure

The following tables describe the reprocessing methods and processes used by Richard Wolf GmbH for validation.

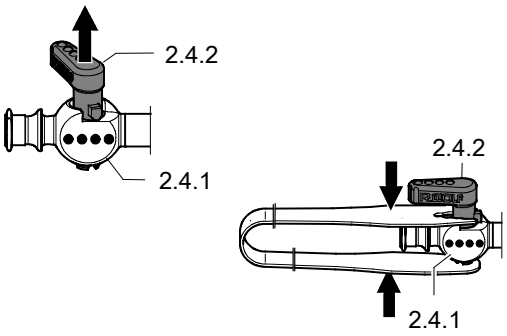
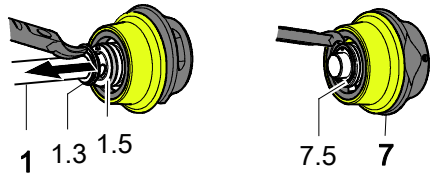
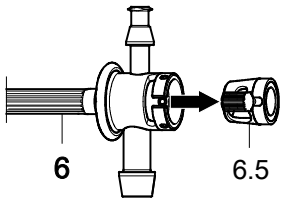
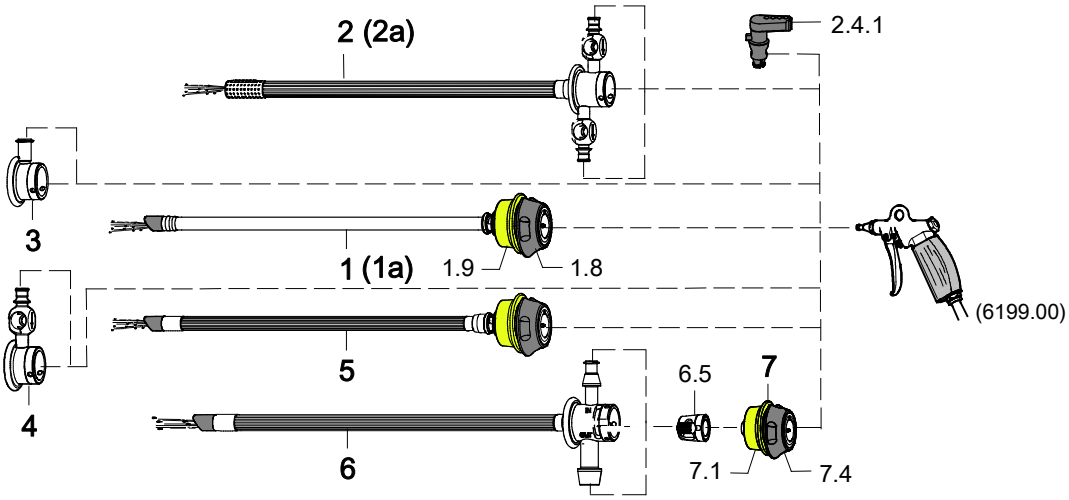
☞ *IMPORTANT!*

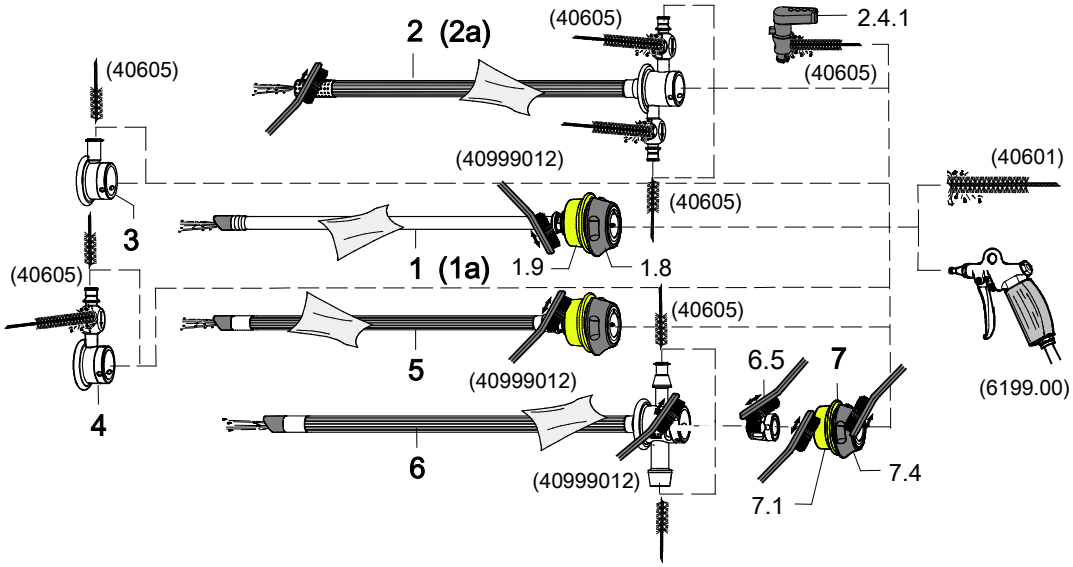
- *If the instrument is used as intended and provided that the manufacturer's manual is followed, it is not necessary to limit the number of possible reprocessing cycles.*
- *Careful and gentle handling of medical products during the entire reprocessing process has an essential influence on the service life of the products.*
- *Before returning defective products for repair, they must have been subjected to the entire reprocessing cycle.*
- *The user must ensure that the reprocessing process including the resources, materials and personnel are suitable to achieve the required results.*
- *Comply with the national and international requirements regarding the validation of the user's reprocessing process.*

☞ *IMPORTANT!*

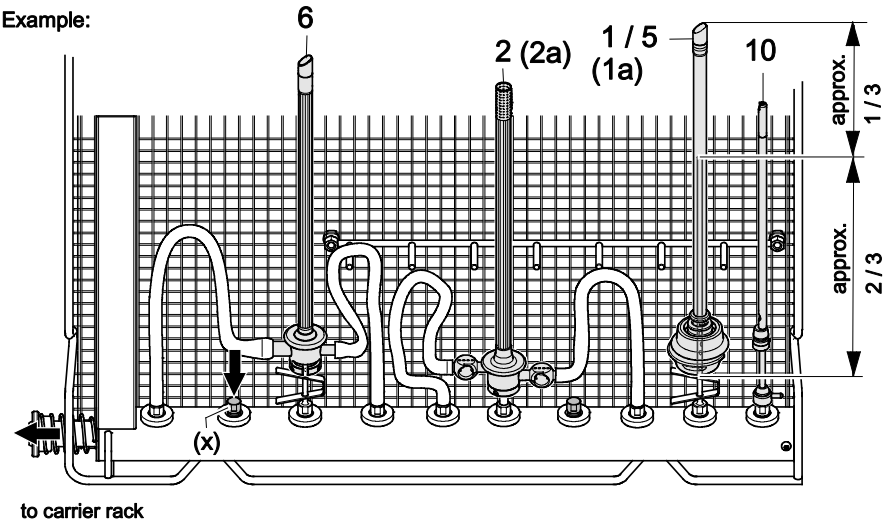
*Do **not** sterilize the products in hot-air sterilizers.*

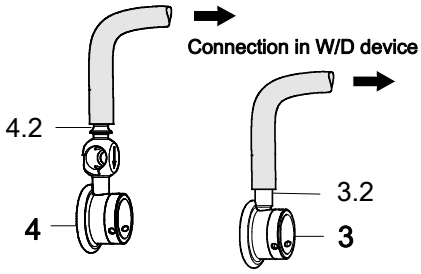
9.5 Resectoscope sheaths [A] [B] [C]

Product:	Resectoscope sheaths [inner sheath (1) (1a) and outer sheath (2) (2a)], resectoscope sheath (5), resectoscope sheath with central stopcock (6), rotatable irrigation adapter (3) (4), adapter (7)
Reprocessing guide:	
Preparation at the point of use:	Immediately after use, remove coarse soiling from the products. If there are more than 6 h between use and reprocessing, rinse out the hollow spaces with a 20 ml syringe filled with water. Do not use any cleaning products (e.g. aldehydes) or hot water (>40°C) for pre-cleaning as this may bake possible residues to the surfaces.
Transport:	To avoid damage to the products and contamination of the environment, the products must be stored safely in a closed container.
Disassembly before cleaning:	 **Outer sheath (2) and rotatable irrigation adapter (4)** **Stopcock plug (2.4.2)** **Without disassembly tool** 1. Remove the stopcock plug (2.4.2) in direction of arrow. ➧ Stopcock plug (2.4.2) disengages from the stopcock housing (2.4.1). **With disassembly tool** 2. Push forward the disassembly tool as far as it will go (see illustration) and compress. ➧ Stopcock plug (2.4.2) disengages from the stopcock housing (2.4.1). 3. Remove the stopcock plug (2.4.2).
	 **Inner sheath (1), adapter (7)** Remove only defective O-rings using the O-ring tool: ➧ Remove O-rings (1.3) (1.5) from the inner sheath (1) ➧ Remove O-ring (7.5) from the adapter (7)
	 **Resectoscope sheath with central stopcock (6)** 1. Turn the stopcock plug to the “0" position. 2. Push the stopcock plug (6.5) out of the housing.
Pre-cleaning:	1. Rinse the products under running tap water. 2. Rinse out the products with hollow spaces for 20 seconds or in pulsed mode by applying 5 pressure surges (2.5 - 4 bar) using a water cleaning gun (6199.00). ➧ For this purpose, pull back the actuation ring (1.8) (7.4) and outer ring (1.9) (7.1) and rinse the exposed area. 

Product:	Resectoscope sheaths [inner sheath (1) (1a) and outer sheath (2) (2a)], resectoscope sheath (5), resectoscope sheath with central stopcock (6), rotatable irrigation adapter (3) (4), adapter (7)
Reprocessing guide:	
	Manual reprocessing
Cleaning:	1. Immerse the proximal part of the inner sheath (1) (1a) up to the irrigation holes (1.4) and the adapter (7) in cleaning solution. Actuate the actuation ring (1.8) (7.4) and the outer ring (1.9) (7.1) 10 x each. 2. Immerse the products in a certified cleaning solution for 10 minutes. ➧ For the exposure time and concentration follow the manufacturer's specifications. 3. Then brush the inner surfaces of the products with suitable cleaning brushes (40605) (40601) until any visible residues have been removed (at least 5 brush strokes). ➧ Pull back the actuation ring (1.8) (7.4) and the outer ring (1.9) (7.1) and brush the exposed area of the inner sheath (1) and the adapter (7). 4. Brush the outer surfaces of the products with a suitable cleaning brush (40999012) until any visible residues have been removed (at least 5 brush strokes). 5. At the end, thoroughly rinse out the products for at least 20 seconds or in pulsed mode by applying 5 pressure surges to each channel (at least 3.8 bar) using a cleaning gun (6199.00). ➧ Pull back the actuation ring (1.8) (7.4) and the outer ring (1.9) (7.1) and rinse the exposed area. 
Disinfection:	1. Fill the channels of the product with a certified disinfectant solution and immerse the product in this solution. ➧ For the exposure time and concentration follow the manufacturer's specifications. 2. At the end, thoroughly rinse out the products with water for at least 20 seconds or in pulsed mode by applying 5 pressure surges (at least 3.8 bar).
Drying:	Dry the outer surfaces of the products with a lint-free disposable cloth or swab, or, alternatively, a drying cabinet. Dry hollow spaces with filtered compressed air.
	Machine reprocessing
Manual Pre-cleaning	1. Immerse the products for at least 5 minutes in cold tap water. 2. Then brush the inner surfaces of the products with suitable cleaning brushes (40605) (40601) and the outer surface (40999012) until any visible residues have been removed (at least 5 brush strokes). 3. At the end, thoroughly rinse out the products for at least 20 seconds or in pulsed mode by applying 5 pressure surges to each channel (at least 3.8 bar) using a cleaning gun (6199.00). ➧ Pull back the actuation ring (1.8) (7.4) and the outer ring (1.9) (7.1) and rinse the exposed area.

Product:	Resectoscope sheaths [inner sheath (1) (1a) and outer sheath (2) (2a)], resectoscope sheath (5), resectoscope sheath with central stopcock (6), rotatable irrigation adapter (3) (4), adapter (7)
Reprocessing guide:	
Cleaning:	1. Place the following products onto the inserts (rinsing nozzles) of the MIS cart: ◗ Inner sheath (1) (1a) and resectoscope sheath (5) ◗ Connect the outer sheath (2) (2a) via the luer connector and the resectoscope sheath with central stopcock (6) via the luer connector and connection element to the washer-disinfector rack. ☞ ***IMPORTANT!*** *Close any rinsing holes that are not used with dummy plugs (x).* *When choosing the rinsing nozzles/rinsing sleeves, follow the washer-disinfector manufacturer's instructions.* 2. Place small parts in a small parts basket (sieve): ◗ Stopcock plug (2.4.2) (6.5) ◗ New O-rings (1.3) (1.5) (7.5)





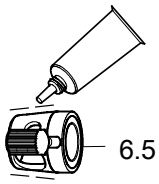
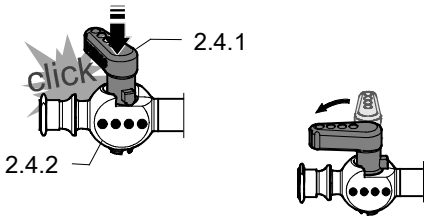
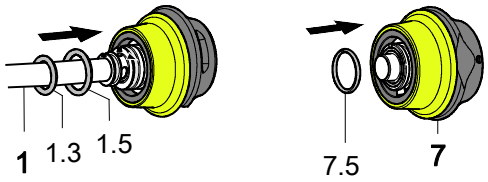
Connect the rotatable irrigation adapter (3) (4) via the luer connector (3.2) and luer stopcock (4.2) to the washer-disinfector rack.

Programs without disinfection step

alkaline

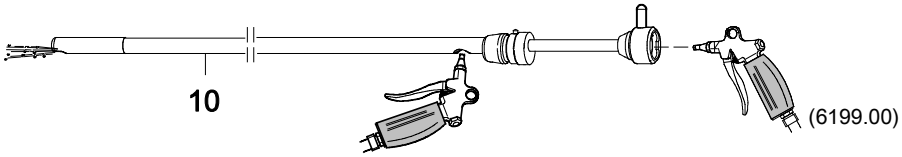
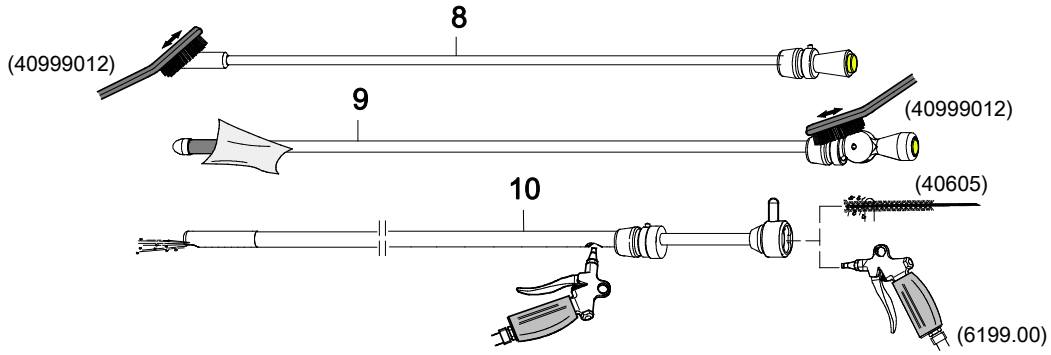
◗ >4 min of precleaning with cold water
◗ empty
◗ >6 min of cleaning with a cleaning agent at approx. 55°C
◗ empty
◗ >3 min of neutralization*)(<40°C)
◗ empty
◗ >2 min of intermediate rinsing (<40°C)
◗ empty

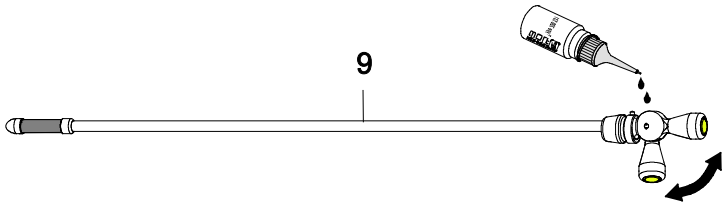
Disinfection:	Carry out thermal machine disinfection following the national requirements with regard to the A0 value (see DIN EN ISO 15883).
Drying:	Dry the products with the drying cycle of the washer-disinfector. If necessary, additional drying can be achieved manually using a lint-free disposable cloth or swab, or, alternatively, a drying cabinet. Dry hollow spaces with filtered compressed air.

Product:	Resectoscope sheaths [inner sheath (1) (1a) and outer sheath (2) (2a)], resectoscope sheath (5), resectoscope sheath with central stopcock (6), rotatable irrigation adapter (3) (4), adapter (7)
Reprocessing guide:	
Care:	 After manual / machine disinfection (drying): Sparingly grease the cone of the stopcock plug (6.5) with instrument grease.
Function test, visual check, maintenance:	Check visually for cleanliness. If necessary, repeat the reprocessing procedure until the product is visually clean. Sterilize the stopcock plug (6.5) separately from the resectoscope sheath with central stopcock (6). ◗ **Carry out a visual check: see sections 8.1 and 8.1.2**
Assembly before sterilization:	 **Outer sheath (2) and rotatable irrigation adapter (4)** **Stopcock plug (2.4.2)** Insert the stopcock plug (2.4.2) in the stopcock housing (2.4.1). ◗ The stopcock plug (2.4.1) engages noticeably.
	 **Inner sheath (1), adapter (7)** Position new O-rings in the O-ring groove if the O-rings had been removed: ◗ O-Rings (1.3) (1.5) on inner sheath (1) ◗ O-ring (7.5) on adapter (7)
Packaging:	Package the products for sterilization as required by the valid standards.
Sterilization:	Sterilize the products using the fractionated pre-vacuum method (ISO17665) taking into account the national requirements. ◗ Temperature exposure time: 4 min at 132°C $^{+4°C}$ (270°F $^{+7°F}$) ◗ Evacuation: 3 x ◗ Drying time:**) 20 - 30 min ◗ Maximum sterilization temperature: 138°C
Storage:	Store the sterilized products in a restricted area at approximately 24°C / 75°F, with at least 4 air exchanges per hour and a relative humidity that does not exceed 70%, in accordance with ANSI / AAMI ST79.
Validation:	**To validate reprocessing, the following materials and machines were used:** **Manual reprocessing** ◗ Cleaning agent: 0.8% cleanser Cidezyme/Enzol (Johnson&Johnson) ◗ In the case of automatic pre-cleaning in the washer-disinfector: Cleaning agent: Cleaner 0.5% neodisher MediClean (Dr. Weigert) **Machine reprocessing** ◗ AWD: Miele G 7735 CD ◗ Program: Vario-TD ◗ Cleaning agent: Cleaner 0.5% neodisher MediClean (Dr. Weigert) **Sterilization** ◗ Sterilizer: Selectomat HP 666-1HR (MMM)
Additional instructions:	It is the responsibility of the user to ensure that the reprocessing equipment has been installed, calibrated and validated according to the manufacturer of the sterilizer specifications.

*) Depending on the use of the cleaner and the rinsing water, add an acid based on citric acid.
**) The drying time depends on the sterilization process used.

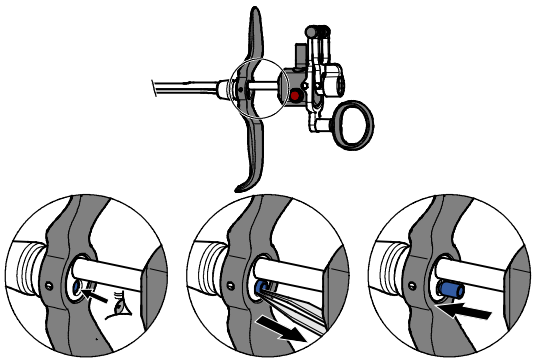
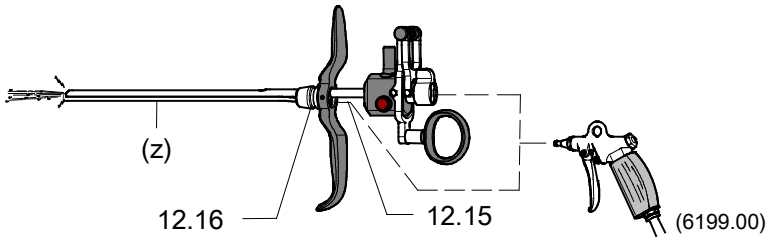
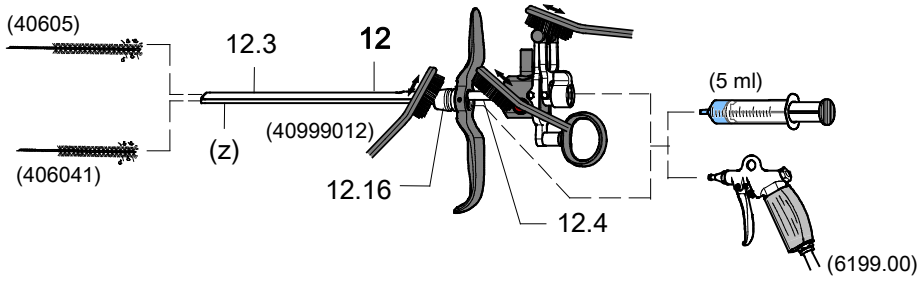
9.6 Obturators

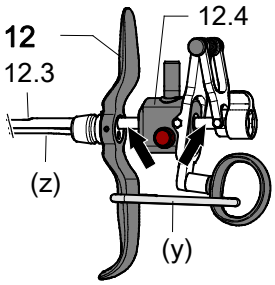
Product:	Obturator (8), dilation obturator (9), viewing obturator (10)
Reprocessing guide:	
Preparation at the point of use:	Immediately after use, remove coarse soiling from the products. Do not use any cleaning products (e.g. aldehydes) or hot water (>40°C) for pre-cleaning as this may bake possible residues to the surfaces. **Viewing obturator (10)** If there are more than 6 hours between use and reprocessing, rinse out the hollow spaces of the instrument with a 5 ml syringe filled with water.
Transport:	To avoid damage to the products and contamination of the environment, the products must be stored safely in a closed container.
Pre-cleaning:	1. Rinse the products with water under the tap. 2. Rinse out the viewing obturator (10) for 20 seconds or in pulsed mode by applying 5 pressure surges (2.5 - 4 bar) using a cleaning gun (6199.00). 
	Manual reprocessing
Cleaning:	1. Immerse the products in a certified cleaning solution for at least 5 minutes. ⧫ For the exposure time and concentration follow the manufacturer's specifications. 2. Clean the outer surfaces of the products with a suitable cleaning brush (40999012) (for at least 5 seconds) until any visible residues have been removed. 3. At the end, thoroughly rinse the products under the tap. 
Disinfection:	1. Immerse the products in a certified disinfectant solution. ⧫ For the exposure time and concentration follow the manufacturer's specifications. 2. At the end thoroughly rinse the products with water for at least 20 seconds.
Drying:	Dry the outer surfaces of the products using a lint-free disposable cloth or swab or, alternatively, dry in a drying cabinet.
	Machine reprocessing
Cleaning:	1. Manually preclean the products before machine cleaning. 2. Place the viewing obturator (10) onto an insert (rinsing nozzle) of the MIS cart. ⧫ for this, see the illustration under "Cleaning" on page 32 3. Place the products (8) (9) on a sliding tray of the washer-disinfector: **Programs without disinfection step** **alkaline** ⧫ >4 min of precleaning with cold water ⧫ empty ⧫ >6 min of cleaning with a cleaning agent at approx. 55°C ⧫ empty ⧫ >3 min of neutralization*)(<40°C) ⧫ empty ⧫ >2 min of intermediate rinsing (<40°C) ⧫ empty

Product:	Obturator (8), dilation obturator (9), viewing obturator (10)
Reprocessing guide:	
Disinfection:	Carry out thermal machine disinfection following the national requirements with regard to the A0 value (see DIN EN ISO 15883).
Drying:	Dry the products with the drying cycle of the washer-disinfector. If necessary, additional drying can be achieved manually using a lint-free disposable cloth or swab, or, alternatively, a drying cabinet.
Care:	After manual / machine disinfection (drying): 1. Sparingly oil the inclinable handle (9.2) of the dilation obturator (9) by applying 1 - 2 drops of instrument oil. ◗ The other surfaces must be oil-free! 2. Remove any excess oil. 
Function check, visual check, maintenance:	Check visually for cleanliness. If necessary, repeat the reprocessing procedure until the product is visually clean. Check dilation on dilatable obturator piston (9.1): **See section 7.1.7** **Carry out a visual check: see section 8.1**
Packaging:	Package the products for sterilization as required by the valid standards.
Sterilization:	Sterilize the products using the fractionated pre-vacuum method (ISO17665) taking into account the national requirements. ◗ Temperature exposure time: 4 min at 132°C $^{+4°C}$ (270°F $^{+7°F}$) ◗ Evacuation: 3 x ◗ Drying time:**) 20 - 30 min ◗ Maximum sterilization temperature: 138°C
Storage:	Store the sterilized products in a restricted area at approximately 24°C / 75°F, with at least 4 air exchanges per hour and a relative humidity that does not exceed 70%, in accordance with ANSI / AAMI ST79.
Validation:	**To validate reprocessing, the following materials and machines were used:** **Manual reprocessing** ◗ Cleaning agent: 0.8% cleanser Cidezyme/Enzol (Johnson&Johnson) ◗ In the case of automatic pre-cleaning in the washer-disinfector: Cleaning agent: Cleaner 0.5% neodisher MediClean (Dr. Weigert) **Machine reprocessing** ◗ AWD: Miele G 7735 CD ◗ Program: Vario-TD ◗ Cleaning agent: Cleaner 0.5% neodisher MediClean (Dr. Weigert) **Sterilization** ◗ Sterilizer: Selectomat HP 666-1HR (MMM)
Additional instructions:	It is the responsibility of the user to ensure that the reprocessing equipment has been installed, calibrated and validated according to the manufacturer of the sterilizer specifications.

*) Depending on the use of the cleaner and the rinsing water, add an acid based on citric acid.
**) The drying time depends on the sterilization process used.

9.7 Working element (12)

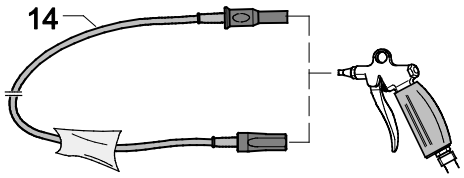
Product:	Working element (12)
Reprocessing sequence:	
Preparation at the point of use:	Remove coarse soiling from the product immediately after use, If there are more than 6 h between use and reprocessing, rinse out the hollow spaces with a 20 ml syringe filled with water. Do not use any cleaning products (e.g. aldehydes) or hot water (>40°C) for pre-cleaning as this may bake possible residues to the surfaces.
Transport:	To avoid damage to the products and contamination of the environment, the products must be stored safely in a closed container.
Pre-cleaning:	 ☞ ***IMPORTANT!*** *Check the seal (12.15) in the locking cone (12.16) for visible damage (e.g. cracks). Replace only defective seals (12.15) before cleaning.* 1. Remove defective seals (12.15) using tweezers. 2. Install new seals (12.15) in the locking taper (12.16).
	1. Rinse the product under running tap water. 2. Rinse out the products with hollow spaces for 20 seconds or in pulsed mode by applying 5 pressure surges (2.5 - 4 bar) using a cleaning gun (6199.00). ☞ ***NOTE!*** *Rinse out the electrode guide tube (z) only from proximal end to keep the seal (12.15) in the locking taper (12.16) from being washed out.* 
	Manual reprocessing
Cleaning:	1. Immerse the product in a certified cleaning solution for at least 5 minutes. ⧫ For the exposure time and concentration follow the manufacturer's specifications. 2. Rinse out the product with a 5 ml syringe filled with a certified cleaning solution. 3. Brush the product in particular in the area of the lock body (12.4) and the locking taper (receptacle) (12.16) with a suitable cleaning brush (40999012) (for at least 5 seconds), until any visible residues have been removed. 4. Brush the inner surfaces of the guide rail (12.3) with a suitable cleaning brush (40605) (at least 5 brush strokes). 5. Brush the inner surfaces of the electrode guide tube (z) only from the distal end using a suitable cleaning brush (406041) (at least 5 brush strokes). 

Product:	Working element (12)
Reprocessing sequence:	
Ultrasonic cleaning	 ☞ ***IMPORTANT!*** *To allow thorough cleaning in the area of the lock body, avoid any contact between the lock body and adjacent surfaces.* *For this purpose RICHARD WOLF offers a cleaning clip.* 1. Place a cleaning clip (y) into the handle grips of the working element (12). ◗ The lock body (12.4) is in cleaning position. 2. Immerse the product in a certified cleaning and disinfectant solution approved for ultrasonic cleaning. The guide rail (12.3) and the electrode guide tube (z) must be filled with this solution before. ◗ Exposure time: 5 min ◗ Frequency: 35 kHz ◗ Temperature max.: <40° C After ultrasound cleaning: 3. Rinse out the lumens for 20 seconds or in pulsed mode by applying 5 pressure surges (2.5 - 4 bar) with water using a cleaning gun (6199.00). 4. Rinse the product under running tap water.
Disinfection:	1. Fill the channels of the product with a certified disinfectant solution and immerse the product in this solution. ◗ For the exposure time and concentration follow the manufacturer's specifications. 2. At the end thoroughly rinse out the products with water for at least 20 seconds or in pulsed mode by applying 5 pressure surges (2.5 - 4 bar).
Drying:	Dry the outer surfaces of the product with a lint-free disposable cloth or swab or, alternatively, in a drying cabinet. Dry hollow spaces with filtered compressed air. ☞ ***NOTE!*** *Dry the electrode guide tube (z) with filtered compressed air only from the proximal end to prevent the seal (12.16) from being blown out of the locking cone (12.16).* ◗ *For this purpose, see the illustration under „Precleaning“ on page 36*
	Machine reprocessing
Cleaning:	1. Manually preclean the products before machine cleaning as instructed above. 2. Place a cleaning clip (y) into the handle grips of the working element (12) (see ultrasonic cleaning). ◗ The lock body (12.4) is in cleaning position. 3. Place the working element (12) in a rinsing sleeve in the MIS rack. ◗ When selecting the rinsing sleeves, please follow the washer-disinfector manufacturer's specifications **Programs without disinfection step** **alkaline** ◗ >4 min of precleaning with cold water ◗ empty ◗ >6 min of cleaning with a cleaning agent at approx. 55°C ◗ empty ◗ >3 min of neutralization*)(<40°C) ◗ empty ◗ >2 min of intermediate rinsing (<40°C) ◗ empty
Disinfection:	Carry out thermal machine disinfection following the national requirements with regard to the A0 value (see DIN EN ISO 15883).
Drying:	Dry the products with the drying cycle of the washer-disinfector. If necessary, additional drying can be achieved manually using a lint-free disposable cloth or swab, or, alternatively, a drying cabinet. Dry hollow spaces with filtered compressed air.

Product:	Working element (12)
Reprocessing sequence:	
Function test, visual check, maintenance:	Check visually for cleanliness. If necessary, repeat the reprocessing procedure until the product is visually clean. **Carry out a visual check: see section 8.1**
Packaging:	Package the products for sterilization as required by the valid standards.
Sterilization:	Sterilize the products using the fractionated pre-vacuum method (ISO17665) taking into account the national requirements. ◗ Temperature exposure time: 4 min at 132°C $^{+4°C}$ (270°F $^{+7°F}$) ◗ Evacuation: 3 x ◗ Drying time:**) 20 - 30 min ◗ Maximum sterilization temperature: 138°C
Storage:	Store the sterilized products in a restricted area at approximately 24°C / 75°F, with at least 4 air exchanges per hour and a relative humidity that does not exceed 70%, in accordance with ANSI / AAMI ST79.
Validation:	**To validate reprocessing, the following materials and machines were used:** **Manual reprocessing** ◗ Cleaning agent: 0.8% cleanser Cidezyme/Enzol (Johnson&Johnson) ◗ In the case of automatic pre-cleaning in the washer-disinfector: Cleaning agent: Cleaner 0.5% neodisher MediClean (Dr. Weigert) **Machine reprocessing** ◗ AWD: Miele G 7735 CD ◗ Program: Vario-TD ◗ Cleaning agent: Cleaner 0.5% neodisher MediClean (Dr. Weigert) **Sterilization** ◗ Sterilizer: Selectomat HP 666-1 HRED (MMM)
Additional instructions:	It is the responsibility of the user to ensure that the reprocessing equipment has been installed, calibrated and validated according to the manufacturer of the sterilizer specifications.

*) Depending on the use of the cleaner and the rinsing water, add an acid based on citric acid.
**) The drying time depends on the sterilization process used.

9.8 Monopolar HF connection cable (14)

Product:	Monopolar HF connection cable (14)
Reprocessing guide:	
Preparation at the point of use:	Remove coarse soiling from the HF monopolar connection cable (14) immediately after use. Do not use any cleaning products (e.g. aldehydes) or hot water (>40°C) for pre-cleaning as this may bake possible residues to the surfaces.
Transport:	To avoid damage to the products and contamination of the environment, the products must be stored safely in a closed container.
Pre-cleaning:	Do not clean the monopolar HF connection cable (14) in an ultrasonic bath! No special requirements.
	Manual reprocessing
	 1. Immerse the HF monopolar connection cable (14) in a certified cleaning solution for at least 5 minutes. ◗ For the exposure time and concentration follow the manufacturer's specifications. 2. Clean with a soft lint-free disposable cloth until any visible residues have been removed. 3. At the end, rinse the HF monopolar connection cable (14) under running tap water for at least 20 seconds.
Disinfection:	1. Immerse the HF monopolar connection cable (14) in a certified disinfectant solution. ◗ For the exposure time and concentration follow the manufacturer's specifications. 2. At the end, thoroughly rinse the HF monopolar connection cable (14) with water for at least 20 seconds.
Drying:	Dry the outer surfaces of the HF monopolar connection cable (14) using a lint-free disposable cloth, or, alternatively, a drying cabinet. Dry the plugs with filtered compressed air.
	Machine reprocessing
Cleaning:	Machine reprocessing up to max. 95°C (203°F). Make sure that no other objects / products are placed on the monopolar HF connection cable (14) or touch it. **Programs without disinfection step** **alkaline** ◗ >4 min of precleaning with cold water ◗ empty ◗ >6 min of cleaning with a cleaning agent at approx. 55°C ◗ empty ◗ >3 min of neutralization*)(<40°C) ◗ empty ◗ >2 min of intermediate rinsing (<40°C) ◗ empty
Disinfection:	Carry out thermal machine disinfection following the national requirements with regard to the A0 value (see DIN EN ISO 15883).
Drying:	Dry the products with the drying cycle of the washer-disinfector. If necessary, additional drying can be achieved manually using a lint-free disposable cloth or swab, or, alternatively, a drying cabinet. Dry hollow spaces with filtered compressed air.
Function test, visual check, maintenance:	Check visually for cleanliness. If necessary, repeat the reprocessing procedure until the product is visually clean. **Carry out a visual check: see sections 8.1 and 8.1.1**
Packaging:	Package the HF monopolar connection cable (14) for sterilization as required by the valid standards.
Sterilization:	Sterilize the products using the fractionated pre-vacuum method (ISO17665) taking into account the national requirements. ◗ Temperature exposure time: 4 min at 132°C $^{+4°C}$ (270°F $^{+7°F}$) ◗ Evacuation: 3 x ◗ Drying time:**) 20 - 30 min ◗ Maximum sterilization temperature: 138°C
Storage:	Store the sterilized products in a restricted area at approximately 24°C / 75°F, with at least 4 air exchanges per hour and a relative humidity that does not exceed 70%, in accordance with ANSI / AAMI ST79.

Product:	Monopolar HF connection cable (14)
Reprocessing guide:	
Validation:	**To validate reprocessing, the following materials and machines were used:** **Manual reprocessing** ◗ Cleaning agent: 0.5% cleanser Cidezyme/Enzol (Johnson&Johnson) ◗ Cleaning agent: Cidex (Advanced Sterilization Products) **Machine reprocessing** ◗ AWD: Miele G 7735 CD ◗ Program: Vario-TD ◗ Cleaning agent: Cleaner 0.5% neodisher MediClean (Dr. Weigert) **Sterilization** ◗ Sterilizer: Selectomat HP 666-1 HRED (MMM)
Additional instructions:	It is the responsibility of the user to ensure that the reprocessing equipment has been installed, calibrated and validated according to the manufacturer of the sterilizer specifications.

*) Depending on the use of the cleaner and the rinsing water, add an acid based on citric acid.
**) The drying time depends on the sterilization process used.

9.9 Alternate Sterilization Methods

◇ For possible alternate sterilization methods, refer to our website, www.richardwolfusa.com under „Reprocessing & Sterilization“ for lists of Richard Wolf instruments that are approved for various reprocessing methods.

10 Technical data and order data

For this, see supplemental sheet BB-D366, system overview on “SHARK“ resectoscopes.

10.1 Electrodes for “SHARK“ resectoscopes 8675xxx / 8676xxx, PANOVIEW telescope 4 mm, 12° / 30°

10.1.1 12°/30° disposable electrodes, sterile, monopolar

Item	Product no.	Color coding Fork / Stem	for sheath sizes [in Fr.]	without	with		Designation	Loop
				Guide nose				
				-	1. step	2. step		
D	**46782235**	green / transparent	22 / 24	■	□	□	Cutting electrode mono (10 / box)	Loop Ø 0.35 mm
	46782435	yellow / transparent	24 24 / 26	□	■	□		
	46782635	black / transparent	26	□	□	■		
	46782225	green / transparent	22 / 24	■	□	□		Loop Ø 0.25 mm
	46782425	yellow / transparent	24 24 / 26	□	■	□		
	46782480	yellow / transparent	24 24 / 26	□	■	□	Cutting electrode mono (5 / box)	Loop Ø 0.8 mm
F	**46782205**	green / transparent	22 / 24 24 24 / 26	■	□	□	Hook electrode mono (5 / box)	Hook
	46782605	black / transparent	26	□	□	■		
E1	**46782201**	green / transparent	22 / 24 24 24 / 26	■	□	□	Coag electrode mono (5 / box)	Roller
E2	**46782202**	green / transparent	22 / 24 24 24 / 26	■	□	□	Coag electrode mono (5 / box)	Sphere
E3	**46782203**	green / transparent	22 / 24 24 24 / 26	■	□	□	Coagulation electrode mono (5 / box)	Button
	46782603	black / transparent	26	□	□	■		
G1	**46782204**	green / transparent	22 / 24 24 24 / 26	■	□	□	Knife electrode mono (5 / box)	Knife
	46782604	black / transparent	26	□	□	■		

On the cutting electrodes the color of the fork primarily indicates to what resectoscope sheath they belong (Fr. size). Packaging unit (pack), individually sterilely packed.

■ = suitable for the specified sheath size □ = not suitable

10.2 Electrodes for “SHARK“ resectoscope 8675xxx / 8676xxx, PANOVIEW telescope 4 mm, 0°

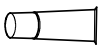
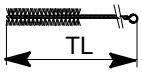
10.2.1 0° disposable electrodes, sterile, monopolar

Item	Product no.	Color coding Fork / Stem	for sheath sizes [in Fr.]	Designation	Loop
D	46792435	yellow / transparent	24	Cutting electrode mono (5 / box)	Loop Ø 0.35 mm
			24 / 26		
	46792635	black / transparent	26		
F	46792205	transparent / transparent	24	Hook electrode mono (5 / box)	Hook
			24 / 26		
E1	46792201	green / transparent	24	Coag electrode mono (5 / box)	Roller
			24 / 26		
G2	46792204	transparent / transparent	24	Knife electrode mono (5 / box)	Knife
			24 / 26		

On the cutting electrodes the color of the fork primarily indicates to what resectoscope sheath they belong (Fr. size). Packaging unit (pack), individually sterilely packed.

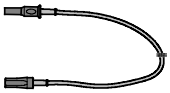
11 Spare parts and accessories

11.1 "SHARK" resectoscopes

Item	Illustration	Product no.	Designation	Resectoscope			
				[A]	[B]	[C]	[A]
				rotatable		non-rotatable	
1.3		15364395	O-ring 7.65 X 1.78-VMQ-70, coated	■	■	□	■
		15364392	O-ring, coated, 7.65 X 1.78-SI	■	■	□	■
1.5 7.5		15364396	O-ring 9.25 X 1.78-VMQ-70, coated	■	■	□	■
		15364393	O-ring, coated, 9.25 X1.78 HNBR	■	■	□	■
2.4.2		896.0003	**Stopcock bndl cap 4.2 mm** Capacity 4.2 mm; Identification: 4 pegs Packaging unit = 5 pcs.	■	■	□	■
-		38310.0001	**Disassembly tool**	■	■	□	■
11.13		88748874	**Rubber cap red** for sealing off the electrode clamping mechanism on the working channel, color: red Packaging unit = 5 pcs.	■	■	■	■
12.15		15176172	**Sealing**	■	■	■	■
-		15106.230	**O-ring tool**	■	■	■	■
-		200.532	**Instrument oil**	■	■	■	■
-		20012	**Instrument grease** 10 ml tube, steam sterilizable	□	□	■	□
(y)		15242024	**Cleaning clamp for working elements**	■	■	■	■
-		40605	**Cleaning brush Ø 5 mm WL 75 mm** Total length TL = 600 mm;	■	■	■	■
-		406041	**Cleaning brush Ø 3 mm WL 50 mm** Total length TL = 400 mm	■	■	■	■
-		40601	**Cleaning brush Ø 11 mm WL 100 mm** Total length TL = 600 mm	■	■	■	■
-		40999012	**Cleaning brush Ø 5 mm WL 42 mm** universal brush for external surface	■	■	■	■

■ = yes □ = no

11.2 Monopolar HF connection cable (14)

Item	Illustration	Product no.	Designation	Cable length	only compatible with HF surgical device
14		815.032	HF connection cable mono L 3 m	3 m	ERBE, ACC, ICC
		815.052	HF connection cable mono L 5 m	5 m	
		815.033	HF connection cable mono L 3 m	3 m	Bovie, Valleylab, ERBE Int.
		815.053	HF connection cable mono L 5 m	5 m	

The products can be combined as required provided the relevant technical data and intended uses are observed. For a general overview please refer to the latest catalog pages, brochures or contact Richard Wolf or your representative.

12 Operating, storage, transport and shipping conditions

Operating conditions	+10°C to +40°C, 30% to 75% rel. humidity, atmospheric pressure700 hPa to 1060 hPa
Storage, transport and shipping conditions	-20°C to +60°C, 10% to 90% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa

Disposable items, sterile products	Follow instructions on package !

☞ ***IMPORTANT!***

Store sterile products in the original packaging until use.
Incorrect storage may lead to loss of sterility.

☞ ***NOTE!***

To prevent damage during transport or shipment of the products we recommend using the original packaging material.

12.1 Disposal of product, packaging material and accessories

For the disposal comply with the country-specific laws and regulations.

➧ For further information please contact the manufacturer.

13 Warranty and Customer Service

Richard Wolf guarantees our instruments to be free from any defects in materials and workmanship under normal use and service for one year. Richard Wolf general terms and conditions may be found on the back of our invoice.

Parts delivered separately by Richard Wolf are subject to all of the same general terms and conditions for our products, including the limitations of warranty and liability.

All products should be returned to Richard Wolf for any necessary or desired repair or part replacement. No product repair or part replacement should be done other than by Richard Wolf unless the care and instruction manual or other written information indicates that repair or part replacement is authorized. If authorized, parts must be replaced only by parts supplied or specified by Richard Wolf, and product repair and part replacement must be done in strict conformance with Richard Wolf specifications and instructions for repair and part replacement, including post replacement testing and recalibration. Failure to follow this requirement in any way can be dangerous to you, your personnel and your patients and voids the warranty for the product repaired or the product in which the part was replaced and if the part was supplied by Richard Wolf, for that part.

Delivery by Richard Wolf of technical documents such as circuit or other design diagrams does not constitute authorization for product repair or part replacement. Richard Wolf instruments and other products should never be modified or altered under any circumstances.

Contact Richard Wolf if you have any question (1) whether replacement of a part or a repair is authorized by Richard Wolf, or (2) whether you have complete instructions and specifications for part replacement or repair.

These instructions do not attempt to cover all details or variations in equipment, nor to provide for every possible contingency to be met in connection with installation, operation, or maintenance. Should further information be required or should problems arise which are not covered sufficiently for the purchaser's purpose, the matter should be referred to Richard Wolf Medical Instruments Corporation.

Our national sales and service offices, as well as our manufacturing facility, are located in Illinois. Trained manufacturer's representatives are located throughout the U.S. to serve you. For any questions regarding these instruments, or to place an order, contact Richard Wolf customer service department at 847-913-1113 or 800-323-WOLF (9653).

INSTRUMENT ORDERING POLICY
Richard Wolf reserves the right to make substitutions, if necessary, without prior notice.

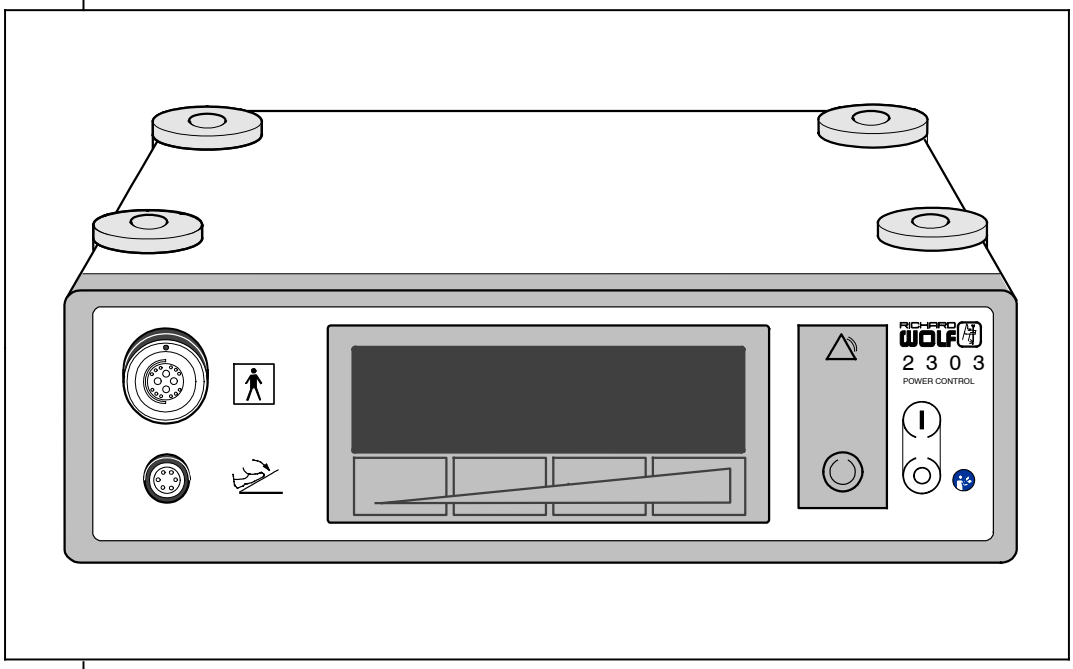
REPAIR POLICY
Defective merchandise will be repaired or replaced at no charge to the customer, provided the customer delivers such defective merchandise prepaid. Any repairs, maintenance or servicing of Richard Wolf merchandise by anyone other than a factory authorized representative will render our warranty null and void.

REPAIR SHIPMENTS
When returning your instrument for repair, we suggest that you prevent shipping damage to the instrument by reusing the box that it was originally shipped in. Richard Wolf also recommends that the instrument be insured for an amount to cover the cost of replacement.

IMPORTANT
For general safety and health reasons, Richard Wolf requires that you clean and sterilize all instruments before returning them for repair. If instruments are received in an unsanitary condition, Richard Wolf will clean and sterilize each instrument and add a $ 100.00 cleaning charge for each instrument requiring cleaning.

RICHARD WOLF
spirit of excellence

Instruction Manual



MOTOR CONTROL UNIT
2303

Motor handpiece 8564.121/8564122

. .

⚠ Important general notes and instructions ⚠

Make sure that this product is used only as intended and described in this instruction manual and by adequately trained and qualified medical personnel, Maintenance and repair must be carried out by authorized experts.

Use the product only in the combinations and with the accessories and spare parts specified in this instruction manual. Use other combinations, accessories and replacement parts only if they are expressly intended for the planned application and if the performance characteristics and safety requirements are met. The product must not be altered in any way.

Reprocess the product in accordance with the manual before every use and before return shipment to protect the patient, user and third parties.

This manual is an integral part of the product and must be stored in such a way that it is accessible at any time during its entire life cycle. This manual must be passed on to any subsequent owner or user.

Immediately upon receipt, check the product and its accessories for completeness and possible damage. Should the shipment give rise to complaints, please inform the manufacturer or supplier immediately.

Subject to technical changes!
Due to ongoing developments the illustrations and technical data may deviate slightly.

CAUTION :
Federal law restricts this device to sale by or on the order of a physician.

Safety instructions and levels of danger

Symbols	Level of danger
⚠	*WARNING!* Failure to observe can result in death or extremely serious injuries.
⚠	*CAUTION !* Failure to observe can result in slight injury or damage to the product.
☞	*IMPORTANT!* Failure to observe can result in damage to the product or surroundings.
☞	*NOTE !* User tips for optimum device use and other useful information.

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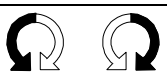
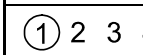
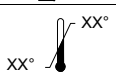
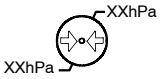
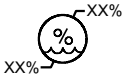
1 General information

1.1 Symbols

Symbol	Designation
	Attention, Caution
	Follow the instruction manual
	Follow the instruction manual
	Off (power: disconnection from power/mains)
	On (power: connection to the power/mains)
	Equipotentality
	Mains / Line fuse
	Alternating current (AC)
	TYPE BF APPLIED PART
	Socket for footswitch
	Alarm
	Ready (Triggering of function check)
	Signal input (CAN BUS)
	Signal output (CAN BUS)
	Identification of sensor field
	Display blinks: “No footswitch"
	Display blinks: “No POWER STICK"
	Indication “CCW rotation"
	Indication “CW rotation"
	Indication “Oscillation"
	Selected speed range display
	Counter-clockwise rotation
	Clockwise rotation
	Oscillation
	Back to previous menu
	Increase value by one
	Decrease value by one

Symbol	Designation
	Selection
	Confirm value
	Single step
	“Adjust speed" selector
	“Select speed range" selector
	“Device settings“ selector
	Oscillation rate adjustment
	Speed range adjustment
	Speed adjustment
	Adjust stop position (works only without footswitch)
	Reset to factory setting
	Language selection
	Control level “B" activated
	Footswitch
	Change between control levels “A" and “B"
	A: Speed range 1 through 4 B: Single step
	A: “CCW“ rotation B: Reduce speed
	A: “CW“ rotation B: Increase speed
	A: “Oscillating“ rotation B: Speed control
REF	Order number
LOT	Lot identification
	To be used before (date):
	Do not reuse
STERILE EO	Sterilized with ethylene oxide
	Do not resterilize
Σ	Number, amount
	Do not use if package is damaged
	Keep away from sunlight!
	Permissible temperature range

Symbol	Designation
	Permissible atmospheric pressure range
	Permissible humidity range
	Manufacturing date
	Manufacturer
	Recycle the product separately. Do not discard together with other waste.
	A Registered Trademark of ETL, a Recognized Testing Laboratory, listing compliance as Medical Electrical Equipment to standard CAN/CSA C 22.2 No. 601.1 (**c**) and UL 60601-1 (**us**)
	A Registered Trademark of a Recognized Testing Laboratory, confirm the compliance to the standard of Medical Electrical Equipment CAN/CSA C22.2 No.60601-1 (**c**) and ANSI/AAMI ES60601-1 (**us**)
	Datamatrix Code
Rx ONLY	Federal law restricts this device to sale by or on the order of a physician.
CE	Identification in conformity with medical devices directive 93/42/EEC **only valid** if the **product and/or packaging is marked with this symbol**. Products of category IIa and above as well as sterile products or products with measuring function of category I, are additionally marked with the code number of the notified body (0124).

1.2 Overview of motor handpieces (POWER STICK M4)

Model no.	Short text
8564.121	Motor handpiece bndl
8564122	Motor handpiece max. 6000 rpm

1.2.1 Performance characteristics

- Drive of Richard Wolf motorized handles
- Directions of rotation: CCLW, CLW and oscillation.
- Adaptation of the opening angle on rotary instruments

1.3 Indications for use

1.3.1 Statement

POWER CONTROL 2303 in conjunction with POWER STICK M4 (8564.121/8564122) is used for energizing R.WOLF rotary blades, burrs and morcellators (tissue punches) for removing tissue in endoscopic operations.
At the same time aspiration allows continuous removal of ablated tissue.

The products are used in conjunction with endoscopic accessories:

- in arthroscopy e.g. for meniscal resection, for the removal of soft tissue as well as for intra-articular transsection or abrasion of osseous tissue (e.g. in ACL or shoulder applications).
- in thoracic surgery e.g. to remove hematomas.
- in sinus surgery e.g. to remove polyps.
- in spinal surgery (arthroscopic microdiscectomy (AMD)) e.g. for removing degenerated tissue.
- in urology for the fragmentation and the removal of detached prostatic adenomas after Laser-TURP.

☞ *IMPORTANT!*
*In conjunction with the sealing insert, open (15178145), the POWER STICK M4 may **only** be used for applications in urology.*

1.3.2 User and patient population

User

This product is designed exclusively for use by specialized medical personnel and may only be applied by medically qualified and adequately trained persons.

Patient population

Before use the doctor in charge must ensure that the product can be safely used in terms of its dimensions or settings

⚠ *CAUTION!*
In case of therapeutic applications an adequate backup device with the same capabilities must be available should the device fail.

1.4 Contraindications and side effects

Contraindications directly related to the product are presently unknown. On the basis of the lastest medical knowledge and the patient's condition, the doctor in charge must decide whether the planned use is possible or not. For further notes and instructions please refer to the latest medical literature.

Target group limitations: Relative or absolute contraindications can result from the general patient findings, or in special cases where the patient risk for motorized tools is significantly increased.

Relevant cases described in the pertinent literature must be observed!

For the medical products to be assessed, the patient selection is not generally limited with regard to sex, age, proveniance, anamnesis and other framework conditions.

Specific risk groups are not known. General contraindications to surgical interventions must be observed taking into account the patient's general condition. Follow the latest medical literature.

1.5 General notes and instructions for use

☞ *CAUTION!*
Do not combine products incorrectly!
Injury may result to the patient, user or others, and damage may result to the product.
The different products may only be combined if the intended use and the relevant technical data (working length, diameter, etc.) are the same.
Make sure you follow to the instruction manuals of the products used in combination with this product!

⚠ *CAUTION!*
All R.Wolf disposable rotary blades and burrs are sterilely packed in double wrapping and are designed for single use only.
Any products which are not used should be kept in the outer packaging (cardboard box). Do not use products with damaged outer sterile wrapping/packaging (plastic bag).

⚠ *CAUTION!*
Reduced cutting performance and wear on the rotary blade/abrader!
If the rotary blade/abrader is pushed against the tissue at high pressure this will not improve the cutting performance but may instead cause damage and increased wear and tear on the inner blade/abrader.

⚠ *CAUTION!*
In the packaging, the inner and outer parts of the rotary blades and burrs are not connected.
Do not mix up the inner and outer parts of the same or different rotary blades and burrs.
If the inner and outer parts of the rotary blades and burrs are interchanged, the product may be damaged, causing patient injuries.

☞ *IMPORTANT!*
Rapid cooling of a hot motorized handle can cause stresses in the material and may lead to failure of the device or a reduced service life.

1.6 Combinations

☞ ***IMPORTANT!***

In addition to this instruction manual, follow the manuals for the products used in combination with this product.
If other products are used in combination with this product, make sure that the intended uses and relevant technical data (working length, diameter etc.) are the same.
Use only approved components and connection cables.
When using rotary blades/burrs for spinal surgery, ensure that the working channel of discoscopes and the internal diameter of working sleeves is sufficiently large. Use instruments with 2.5 mm, 3.5 mm and 4.0 mm diameter through discoscopes and instruments with 4.5 mm diameter through suitable working sleeves.
Use only suction devices and devices for supplying irrigation fluid that do not reduce the protection rating "BF" of the motorized handle in accordance with IEC / EN 60601. The user is responsible for selecting a suitable irrigation fluid.

☞ ***IMPORTANT!***

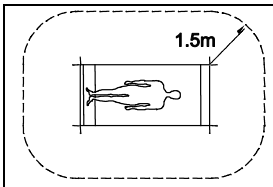
Due to differing anatomy, it is not possible to quantify irrigation and suction rates. It is the user's responsibility to adapt the settings to the requirements.

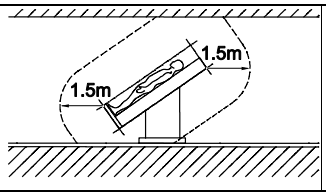
1.6.1 Equipotentality

The potential equalization cable establishes a direct connection between a medical electrical device and an equipotential bonding rail.

It serves to equalize differences in potential between enclosures of electrical equipment and firmly installed conductive parts in the patient environment.

1.6.2 Requirements for the products / components of a combination





The general requirements depend on whether the products / components are inside or outside the patient environment.

Medically used room		Non-medically used room	Requirements / measures
inside the patient environment	outside the patient environment		Leakage currents to IEC/EN 60601-1
MP - - - MP	-	-	Verification of the total patient leakage current
MP - - - MP **	-	-	Verification of leakage currents **a)** additional protective earth connection (consult the corresponding manufacturer), **or** **b)** additional isolating transformer for medical applications **
MP - - - NMP * *			
MP - - - NMP **			
MP NMP			
MP NMP			
MP - - - MP / NMP **			
MP - - - NMP	-	-	Verification of leakage currents **a)** no plugs with metal housing, **or** **b)** additional isolation device (to avoid voltage differentials)
MP - - - MP / NMP		-	Verification of leakage currents **a)** common protective earth connection, **or** **b)** additional protective earth connection at **MP** (clarify with the corresponding manufacturer), **or** **c)** additional isolation device (to avoid voltage differentials), **or** **d)** no plugs with metal housing in the patient environment

‖	additional "isolating transformer" to IEC/ EN60601-1 **	▯	additional isolating device to IEC/ EN 60601-1		Multiple socket strip *
- - -	Functional connection	~	Power supply grid		

MP = **medical electrical device** to IEC/ EN 60601-1, ANSI/AAMI es60601-1, CSA C22.2 No. 60601-1
NMP = **non-medical electrical device** in accordance with product-specific IEC/EN/UL standards

* When connected via the same multiple socket strip under standard conditions, the earth leakage current of the socket strip must not exceed 5 mA.
** e.g. Richard Wolf video cart with "isolating transformer"

Only connect devices with a safety extra-low voltage of no more than 60V DC / 42.4V AC peak to the connectors for electrical connections, i.e. the signal inputs and outputs.

☞ ***IMPORTANT!***

The persons combining products to form a system are responsible for not impairing the system's compliance with performance and safety requirements, and that the technical data and the intended use are adequately fulfilled. Possible electromagnetic or other interference that may occur between the product and other products can cause faults or malfunctions.

When selecting the system components, make sure that they meet the necessary requirements of the medical environment they are used in, in particular IEC/ EN 60601-1 (3. Edition IEC/EN 60601-1, section 16). In case of doubt contact the manufacturer(s) of the system components.

Do not touch connectors for electrical connections between various components (such as signal input connectors and signal output connectors for video signals, data exchange, controls etc.) and the patient at the same time.

1.7 Electromagnetic compatibility (EMC) - IEC 60601-1-2 : 2014

NOTE:
The device/system in the following called **product** always relates to the POWER CONTROL 2303.

Guidelines and manufacturer's declaration - Electromagnetic emissions

The product is intended for use in the environment specified below. The user must assure that the product is used in such an environment.		
Emissions measurement / test	**Compliance**	**Electromagnetic environment - Guidelines**
HF emissions to CISPR 11	Group 1	The product uses HF energy for its internal function. The HF emission level is extremely low and is not likely to cause any interference in nearby electronic equipment.
HF emissions to CISPR 11	Class A	The product is suitable for use in buildings other than residential buildings and buildings that are immediately connected to the public power supply network that also supplies buildings used for residential purposes provided the following warning is observed: **Warning:** The product is only intended for use by specialized medical staff. This product can cause radio interference which may make it necessary to take suitable remedial measures such as new alignment, new positioning or screening of the product or a filter in the connection to the installation site.
Harmonic emissions to IEC 61000-3-2	Class A	
In conformity with IEC 61000-3-3 “Emission of voltage fluctuations / flicker"		

Guidelines and manufacturer's declaration - Electromagnetic immunity

The product is intended for use in the environment specified below. The user must assure that the product is used in such an environment.			
Immunity tests	**IEC 60601 test level**	**Compliance**	**Electromagnetic environment - Guidelines**
Electrostatic discharge (ESD) to IEC 61000-4-2	± 8 KV contact discharge ± 15 KV air discharge	Yes	Floors should be wood, concrete or ceramic tile. With floors made of synthetic material, the relative humidity of the ambient air must be at least 30%.
Electrical fast transients, bursts to IEC 61000-4-4	± 2 KV for power supply lines ± 1 KV for input and output lines	Yes	Mains/line power quality should be that of a typical commercial or hospital environment.
Surge voltage (surges) to IEC 61000-4-5	± 1 KV line to line voltage ± 2 KV line to ground voltage	Yes	Mains/line power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and supply voltage variations to IEC 61000-4-11	0% U_T * ; 1/2 period at 0.45, 90, 135, 180, 225, 270 and 315 degrees 0% U_T * ; 1 Period and 70% U_T * ; 25/30 Periods single-phase: at 0 degrees 0% U_T * ; 250/300 Periods	Yes	Mains/line power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during power mains/line interruptions it is recommended that the product be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field, to IEC 61000-4-8	30A/m	Yes	Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment.
* NOTE! U_T is the line / mains voltage prior to application of the test level.			

Guidelines and manufacturer's declaration - Electromagnetic immunity for products that are not life-supporting

The device is intended for operation in the electromagnetic environment specified below. The device user must make sure that the device is used in such an environment.

Immunity tests	Test level to IEC 60601	Compliance level	Electromagnetic environment - Guidelines
Conducted HF interference to IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms} 150 kHz to 80 MHz	Portable and mobile communication devices should not be used at a lesser distance from the device (including the lines) than the recommended safe distance of 30 cm. The field strength of stationary transmitters determined during an on site investigation should be below the compliance level in all frequencies.[b] In the environment of devices with the following symbol malfunctions are possible: 
	6 V_{rms} [a] in ISM frequency bands 15 kHz to 80 MHz	6 V_{rms} [a] in ISM frequency bands 15 kHz to 80 MHz	
Radiated HF interference to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	

REMARKS:
These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by absorption and reflexion from buildings, objects and people.

a) The ISM frequency frequency bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.

b) The field strength of stationary transmitters, such as base stations of mobile phone communication and land mobile radios, amateur radio stations, AM and FM broadcasting trannsmitters can not be precisely predetermined in theory. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength at a location where the device is used exceeds the aforementioned compliance level, the device must be observed with regard to its due function. In the case of abnormal operation, additional measures may be required, such as a changed alignment or a different location of the device.

Recommended safe distances between portable and mobile HF telecommunication devices and the product

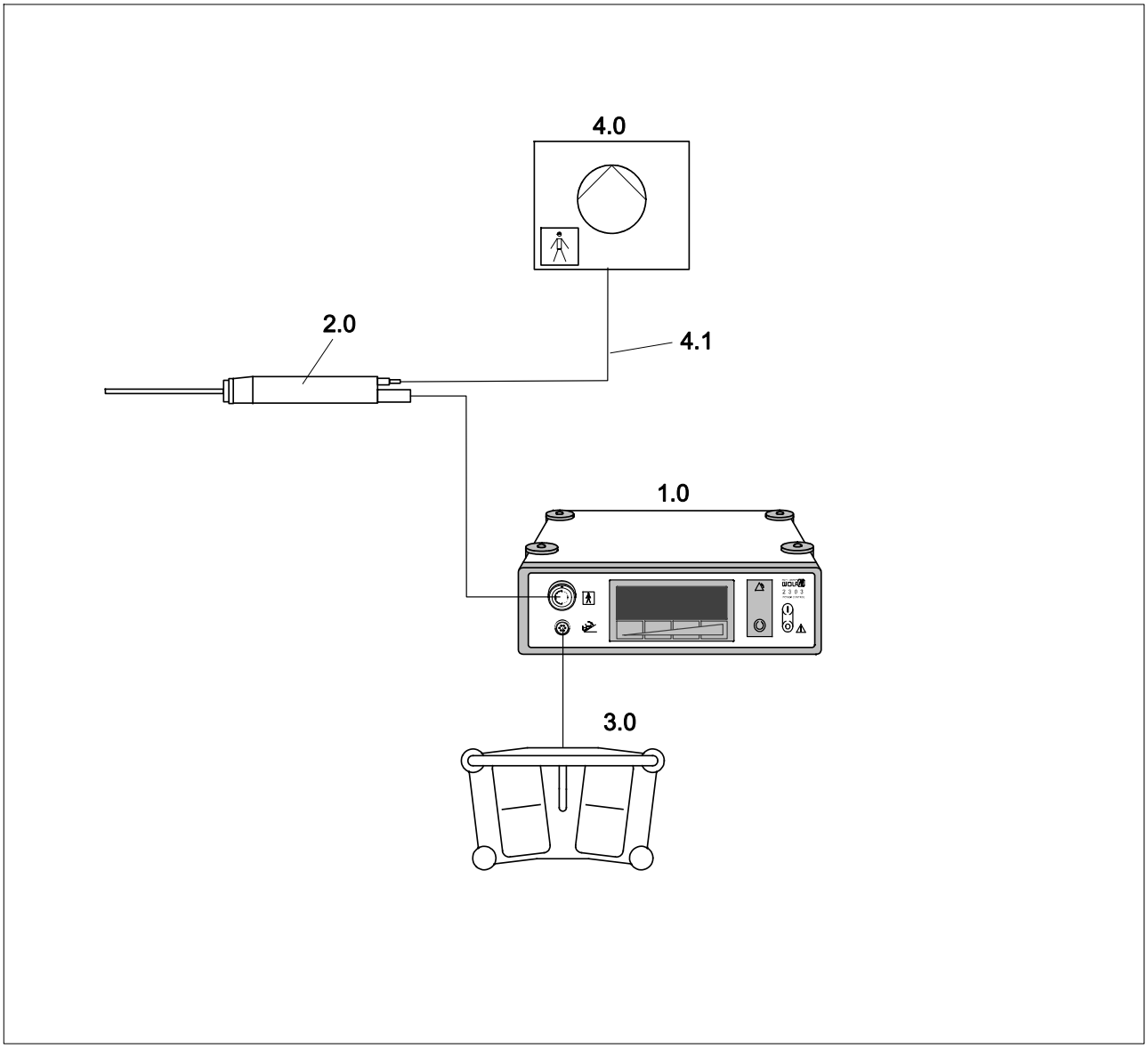
Definition with regard to high frequency wireless communications equipment

Frequency band (MHz)	Test frequency (MHz)	Modulation	Compliance level (V/m)
380–390	385	Pulse[a] – 18 Hz	27
430–470	450	FM ± 5 kHz Hub or pulse[a] – 18 Hz	28
704–787	710, 745, 780	Pulse[a] – 217 Hz	9
800–960	810, 870, 930	Pulse[a] – 18 Hz	28
1700–1990	1720, 1845, 1970	Pulse[a] – 217 Hz	28
2400–2570	2450	Pulse[a] – 217 Hz	28
5100–5800	5240, 5500, 5785	Pulse[a] – 217 Hz	9

REMARKS:
A minimum safety distance of 30 cm between portable HF communications devices operated in the specified frequency band and the product should be maintained. This includes, amongst others, mobile phones, WiFi, RFID and Bluetooth devices. Non-compliance can reduce the performance specifications of the product.

a) Pulse modulation is defined as a square signal with a pulse duty factor of 50%.

1.8 Combination with POWER STICK M4

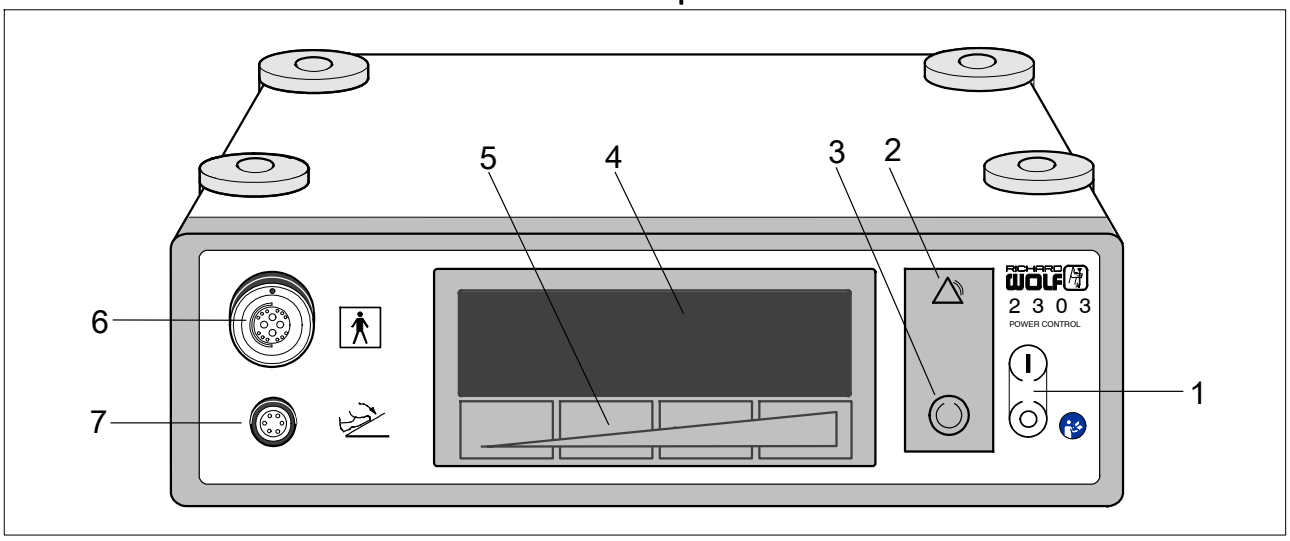


1.8.1 Legend

1.0 POWER CONTROL 2303
2.0 POWER STICK M4
3.0 Footswitch
4.0 Suction pump
4.1 Suction tube

2 Illustration

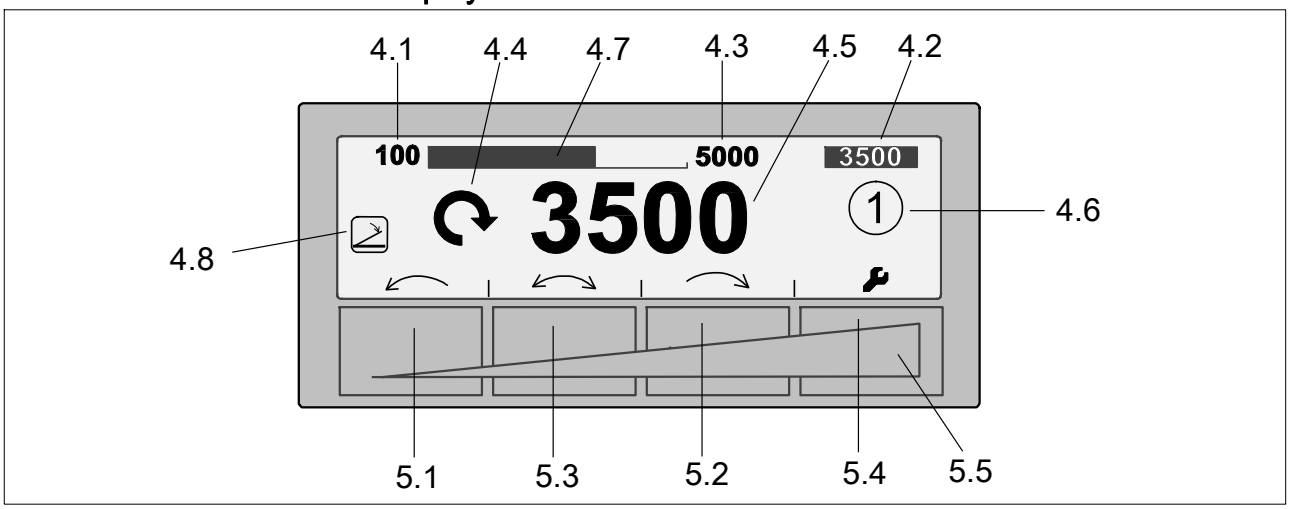
2.1 Illustration of POWER CONTROL front panel



2.1.1 Legend

1	Power/mains switch	**5**	Sensor field (sensor surface)
2	”Alarm” indicator	**6**	Socket for motorized handle (Type BF applied part)
3	“Ready” button	**7**	Socket for footswitch
4	LCD		

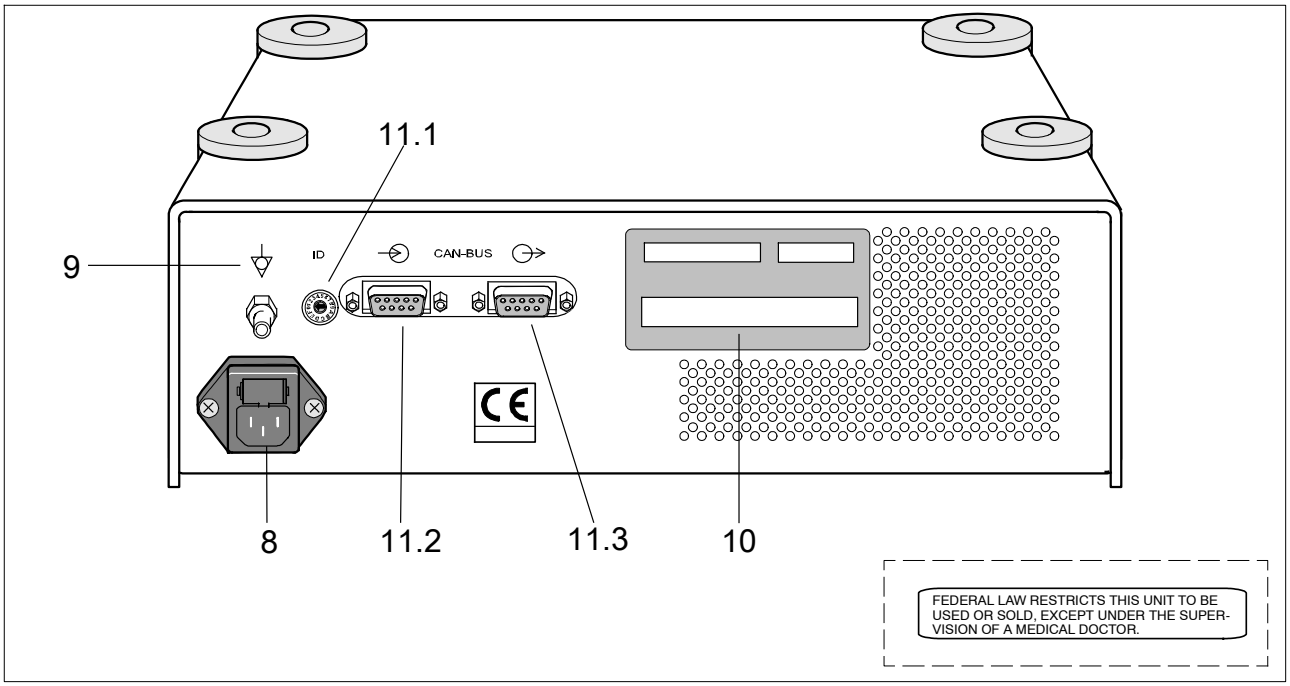
2.2 Illustration of LCD display



2.2.1 Legend

4.1	“Minimum speed”	**4.8**	“No footswitch" indicator
4.2	“Preselected speed”	**5.1**	“Rotate CCW” sensor
4.3	“Maximum speed”	**5.2**	“Rotate CW” sensor
4.4	“Actual direction of rotation”	**5.3**	“Oscillation” sensor
4.5	“Actual speed”	**5.4**	“Device settings” sensor
4.6	"Preselected speed range"	**5.5**	“Speed / stop position adjustment” sensor field
4.7	Speed		

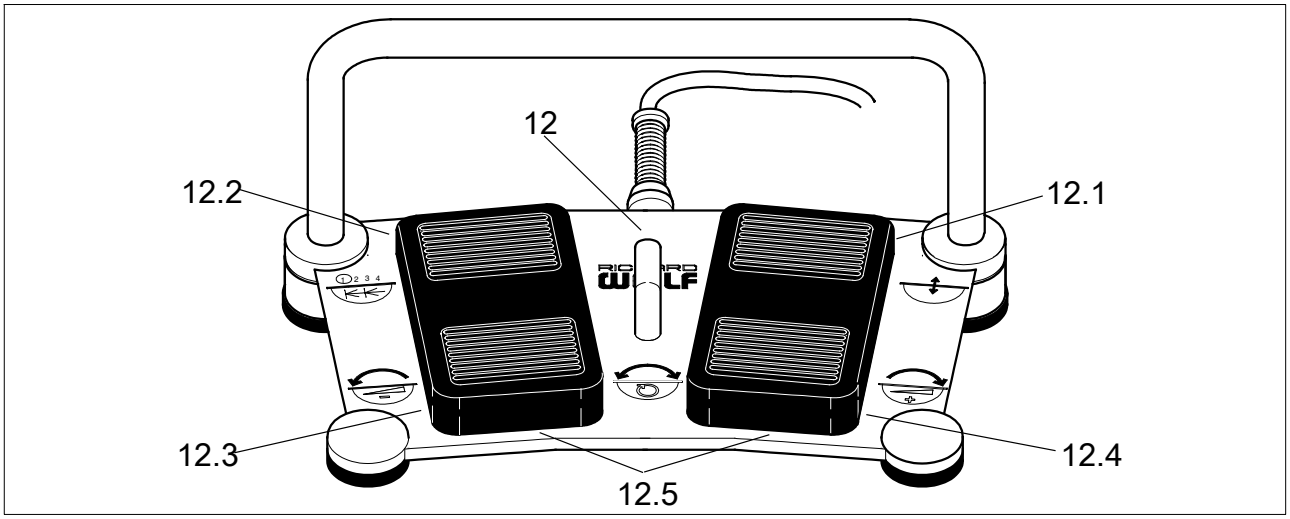
2.3 Illustration of POWER CONTROL rear panel



2.3.1 Legend

8 Power input connector with fuse holder
9 Equipotential connector
10 Identification plate
11.1 CAN-BUS address selector
11.2 CAN BUS input connector
11.3 CAN BUS output connector

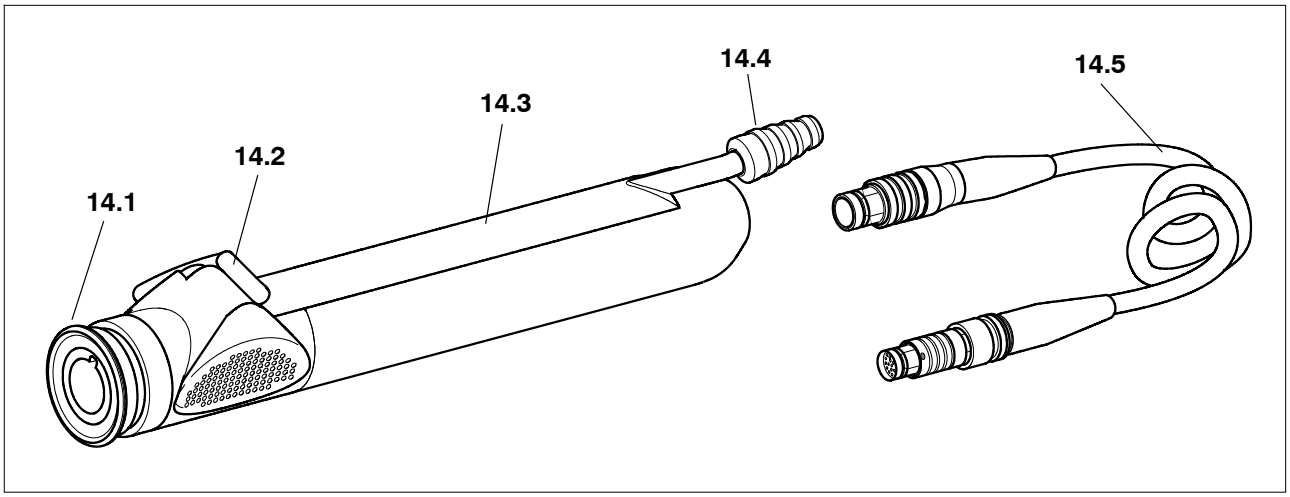
2.4 Illustration of footswitch



2.4.1 Legend

12 Footswitch
12.1 Switchover between functions “**A**" and “**B**"
12.2 **A**: Speed range 1 through 4 **B**: Single step (blade position)
12.3 **A**: “CCW“ rotation **B**: Reduce speed
12.4 **A**: “CW“ rotation **B**: Increase speed
12.5 **A**: “Oscillation“ **B**: Speed control

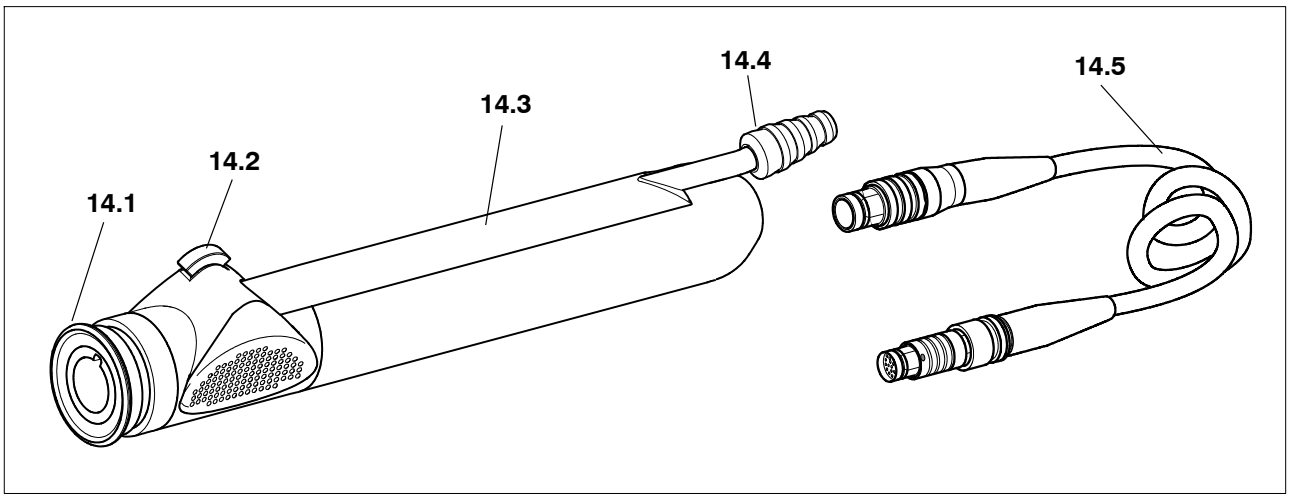
2.5 Illustration of POWER STICK M4 with valve (8564.121)



2.5.1 Legend

14.1 Clamping head
14.2 Valve
14.3 Handle sleeve
14.4 Suction tube
14.5 Connection cable with connectors

2.6 Illustration of POWER STICK M4 with sealing insert, open (8564122) - only for applications in urology



2.6.1 Legend

14.1 Clamping head
14.2 Sealing insert, open
14.3 Handle sleeve
14.4 Suction tube
14.5 Connection cable with connectors

3 Setup

⚠ *WARNING!*
Explosion hazard.
The device is not protected against explosions.
Do not operate this device in areas where there is the danger of explosion.

⚠ *WARNING!*
Danger if a power supply without protective earth is used.
Danger of electric shock!
Connect the device only to a power supply with protective earth connector.

☞ *NOTE!*
Check that the mains/line voltage is the same as the voltage specified on the identification plate. Connect the device only via the supplied power cable or a power cable meeting the same specifications.
Make sure that the ventilation slots are not blocked!

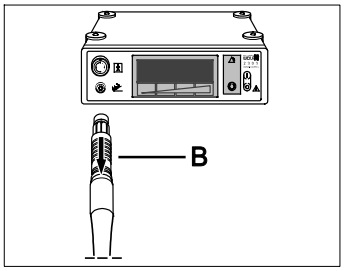
☞ *IMPORTANT!*
Do not the open the device!

⚠ *WARNING!*
Device operation may be jeopardized by other devices located in the immediate vicinity or if devices are stacked.
Other devices located in the immediate vicinity or stacked devices may interfere with each other and cause malfunctions, in particular if devices give off energy (e.g. HF surgical devices).
If devices have to be arranged in this way, make sure that the devices work properly.

⚠ *WARNING!*
Safety distance from portable HF communication devices.
Medical electrical devices can be influenced by mobile HF communication devices.
Do not operate HF communication devices in the immediate vicinity of medical electrical devices. Non-compliance can cause the power characteristics of the device to be impaired.

⚠ *WARNING!*
Influence on interference immunity and interference emission.
Use only accessories or cables specified or supplied by the manufacturer.
Other accessories and cables can cause increased electromagnetic interference or a reduced electromagnetic immunity of the device and lead to malfunctions.

3.1 Preparation of POWER CONTROL



◇ Connect device to mains/power.

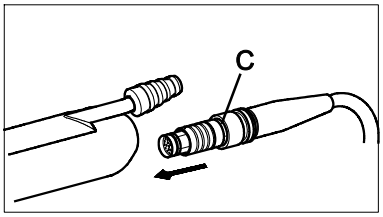
◇ Connect footswitch cable to device.

◇ Switch on the power switch.

☞ ***NOTE!***

To disconnect the cable from the device, pull back the locking sleeve (B) on the connector (front portion with red marking).

3.2 Preparation of POWER STICK M4 (8564.121/8564122)



◇ Connecting the cable to POWER STICK M4.

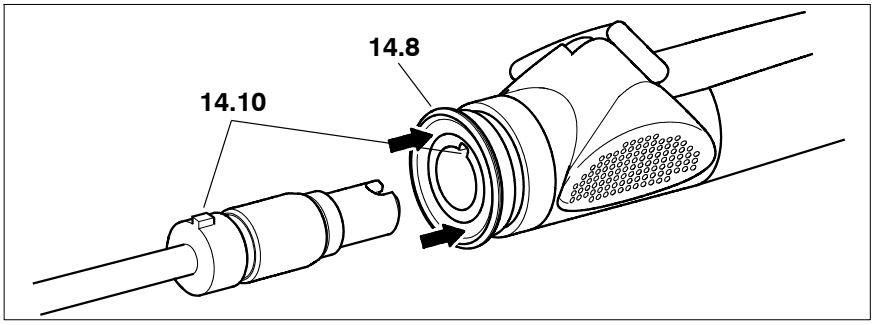
- ◗ Align connector (the red marking (C) must be positioned exactly below the suction connector) and push home.

◇ Connect suction tube between suction pump and suction connector on POWER STICK M4. Set suction valve to “OFF” (only in combination with valve).

◇ Inserting the rotary blades.

- ◗ Retract ring (14.8) on clamping chuck.
- ◗ Insert rotary blade in such a way that the cam is aligned with the groove (14.10) in the clamping chuck.
- ◗ Let go of the ring, the rotary blade is locked in place.

◇ Connect the cable of POWER STICK M4 to the POWER CONTROL unit.



☞ ***IMPORTANT!***

The inner and outer blades are supplied in matched pairs. Do not mix with other blades.

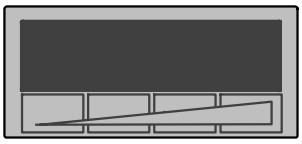
4 Checks

☞ ***IMPORTANT!***
Run through the checks before and after each use.
Do not use the products if they are damaged or incomplete or have loose parts.
Return damaged products together with any loose parts for repair.
Do not attempt to do any repairs yourself.

4.1 Visual check

◇ Carry out the following checks:

- Check devices, instruments and accessories for damage, hygienic condition, completeness and corrosion.
- Check all connection cables and tubes / hoses for damage.
- Check any lettering / labeling for completeness and good legibility.
- Check that the cable connector on the motorized handle is in home position, i.e. fully inserted.
- Check that the valve is plugged in.
- Check that the cutting edges and windows of the blades /abraders are in perfect working order.
- Check footswitch and connection cables for damage and cracks in the insulation of the connection cable.
- Check the sensor surfaces on the POWER CONTROL unit.



4.2 Function check

☞ ***NOTE!***
Make sure that the tools are immersed in liquid and are never operated in dry condition (the heat generated by mechanical friction requires cooling).
The POWER CONTROL M4 self-test can be activated at any time.

◇ Switch on the power switch.

◇ Press the blinking “Ready” button.

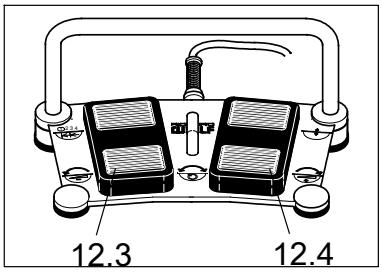
- The device will carry out a self-test. In the case of an error the result is displayed on the LCD.

- If no footswitch is connected, the “No footswitch” indicator will flash.
- If no POWER STICK is connected, the “No POWER STICK” indicator will flash.

4.2.1 Function check of footswitch

◇ Connect the footswitch and the POWER STICK to the device.

➧ Make sure that the markings on the plug and on the socket are aligned.



◇ Direction of rotation of rotary blade

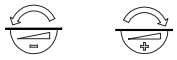
➧ **Direction of rotation "CW":**
Actuate the right pedal (12.4): "CW rotation" is indicated on the LCD.

➧ **Direction of rotation "CCW":**
Actuate the left pedal (12.3): The symbol for ”CCW rotation” is displayed on the LCD.

➧ **Direction of rotation "Oscillation"**:
Actuate both pedals (12.3 and 12.4) simultaneously: "Oscillation" is displayed on the LCD.

4.2.2 Function check - POWER STICK M4 (8564.121/8564122)

◇ The suction control valve must be easy to operate (only 8564.121).



◇ Actuate the pedal at low speed:

➧ The rotary blade (internal part) rotates.

◇ Switch on the suction pump, set the suction control valve to “ON”:

➧ Immerse the attached tool in liquid (the window of the outer blade must be open). If the channel is clogged, clean channel with a cleaning gun.

◇ During operation the motor torque and the cable connection to the POWER STICK are monitored.

◇ In the following cases the motor power supply is automatically switched off and the ”Alarm” display activated while an alarm is sounded:

➧ if the maximum torque is exceeded, e.g. by:
- blocking rotary blades/abraders
- defective drive motor

➧ or if the following fault/error applies:
- the POWER STICK plug is not connected
- the cable connection is interrupted (e.g. parting of cable)

5 Use

5.1 Operation

The POWER STICK M4 can be operated with the POWER CONTROL.The device detects the type of power stick connected and adapts the settings (such as speed ranges) accordingly.

The motor in the handle drives the rotary blades. It is connected to the POWER CONTROL unit via a flexible cable.

By pressing the corresponding pedal the rotary blade turns clockwise, counter-clockwise or in oscillation mode. There is a choice of 4 speed ranges.
The LCD displays the preselected and actual speeds. In each speed range the speed can be changed at any time. Each speed change is stored.

In addition to controlling the POWER CONTROL via the footswitch, direct control on the power control unit is also possible (e.g. if footswitch is defective).

If the unit is operated via the footswitch, additional functions can be activated if required.

To ensure safe operation, the essential functions and components are monitored automatically. In the case of failure or if an error occurs, a message appears on the LCD display, accompanied by an optical and acoustic signal.

5.2 Control elements and modes

5.2.1 General notes and instructions for use

⚠ *WARNING!*
Do not reprocess disposable items!
The service life of products marked as disposable, i.e. for one single use only, has been designed for only one use in or on a single patient.
If disposable items are reprocessed for further use, a deterioration of the product quality cannot be excluded, which will endanger the patient, user and third parties.
Possible dangers / risk factors are:

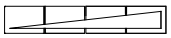
- *considerable functional impairment*
- *greatly increased risk of infection*

If disposable items are reprocessed for further use, the product responsibility lies with the user or reprocessor, respectively.
In this case, the manufacturer can no longer guarantee product safety and performance.

☞ *IMPORTANT!*
Do not touch the surface of the LCD and the sensor surface with sharp or contaminated objects. This will impair image quality and damage the surfaces.

5.2.2 Operation of POWER CONTROL via the sensor surface

At the lower edge of the LCD the current button assignment is displayed. Operation is effected via the sensor surface below the display. The button assignment changes with the context (depending on the mode selected).



◇ The sensor surface can be actuated in three ways:

- Slight touching and maintaining the touch (only without footswitch):
  Explanation of button function (context help)
- Pressure:
  Actuating the button
- Linear movement over the entire width:
  Adjustment of speed or blade position

5.2.3 Language selection

◇ To call the options menu, keep the “Ready" button pressed for 3 seconds.

➧Select language settings.

◇ Select language.

◇ Confirm entry.

5.2.4 Setting the parameters with the footswitch connected

Preselecting the speed range:

◇ **On POWER CONTROL:**

◇ Actuate button 1, 2, 3 or 4.

➧By touching the corresponding button and maintaining the touch, the speed range setting can be checked.

◇ **Using the footswitch:**

◇ By pressing and keeping the pedal depressed, the selected speed is displayed.

◇ Keep pressing the pedal until the required speed range is selected.

➧The selected speed range and the corresponding parameters are displayed on the LCD.

Speed range *	POWER STICK M4
1	100 to 1000 rpm ; Start 600 rpm
2	500 to 1500 rpm ; Start 850 rpm
3	1000 to 2500 rpm ; Start 1500 rpm
4	2000 to 6000 rpm ; Start 3500 rpm
Oscillation	0.5 / 1 / 1.5 or 2 direction changes / sec. Circumferencial speed is variable; Default setting: half of selected speed in range 1 to 4

* If the preset speed range or oscillation is not sufficient, individual adjustment is possible, see section “Changing the factory settings" (5.2.6).

Setting the speed:

◇ **On POWER CONTROL:**
POWER STICK not activated.

➧Press the “Nominal speed" button and adjust the speed within the selected range.

◇ **On POWER CONTROL:**
POWER STICK activated via footswitch.

➧When “Adjust speed" is displayed, move your finger across the width of the sensor surface to adjust the speed as required within the limits of the selected range.

◇ **Using the footswitch:**

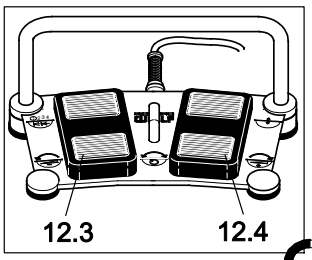
◇ Switch footswitch to control level “B".
➧ Symbol appears on the display.

◇ Keep the corresponding footswitch pedal depressed to increase or decrease the speed.

◇ After speed adjustment, switch footswitch back to control level “A".

Selecting the direction of rotation using the footswitch:

◇ Connect the footswitch and the POWER STICK to the device.
➧ Make sure that the markings on the plug and on the socket are aligned.



◇ Direction of rotation of rotary blade
➧ **Direction of rotation "CW":**
Actuate the right pedal (12.4): "CW rotation" is indicated on the LCD.
➧ **Direction of rotation "CCW":**
Actuate the left pedal (12.3): The symbol for ”CCW rotation” is displayed on the LCD.
➧ **Direction of rotation "oscillation"**:
Actuate both pedals (12.3 and 12.4) simultaneously: "Oscillation" is displayed on the LCD.

Setting the stop position of the rotary blade:

◇ **On POWER CONTROL:**
➧ Not possible if footswitch is connected.

◇ **Using the footswitch:**
Switch footswitch to control level “B".
➧ Symbol appears on the display.

◇ Keep pressing the “single step" pedal and keep it depressed until the blade is in the required position.
➧ As long as the pedal is actuated, the blade moves slowly in single steps, the tool stops when the pedal is released. This position is stored in the POWER CONTROL.
The blade will always stop in this position until it is removed.

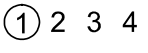
◇ Switch footswitch back to control level “A".

5.2.5 Setting the parameters on the POWER CONTROL, with no footswitch connected

To exit the submenu, press the “Back" button.

Preselecting the speed range:

◇ Activate the setup menu by pressing the “Device settings" button.



◇ Call up the “Speed range selection" submenu and select the required speed range 1, 2, 3 or 4

- Touching the corresponding button and maintaining the touch allows a check of the nominal speed of the speed ranges.
- If you remove your finger from the sensor surface, the control automatically returns to the “Main menu".

Speed adjustment:

◇ Activate the setup menu by pressing “Device settings".

◇ Select the “Adjust speed" function.

◇ The speed is adjusted by means of a linear movement across the entire width of the sensor surface.

- If you remove your finger from the sensor surface, the control automatically returns to the “Main menu".

Stop position adjustment of rotary blade:

◇ Activate the setup menu by pressing “Device settings".

◇ Select the “Single step" function.

◇ The rotary blade is adjusted by means of a linear movement across the entire width of the sensor surface (sensor field).

- If you remove your finger from the sensor surface, the control automatically returns to the “Main menu".

5.2.6 Changing the factory settings

In the options menu, the preset parameters can be changed if required.

◇ To call the options menu, keep the “Ready" button pressed for 3 seconds. In the option menu the following parameters can be changed:

◗ Define speed ranges.

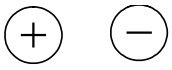
◗ Define oscillation rate.

◗ Select language.

◗ Reset to factory setting.

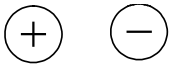
“Speed range adjustment":

◇ Select "Speed range adjustment".



◇ Select the POWER STICK used.

◇ Select the speed range to be adjusted.



◗ Increase or decrease value.

◇ Exit menu.

“Oscillation rate adjustment":

◇ Select "Adjust oscillation rate".

0.5Hz 1.0Hz

◇ Select the desired value.

◗ If you remove your finger from the sensor surface, the control automatically returns to the “Main menu".

◇ Exit menu.

“Language" selection:

◇ See section 5.2.3

Resetting the values to the factory setting:

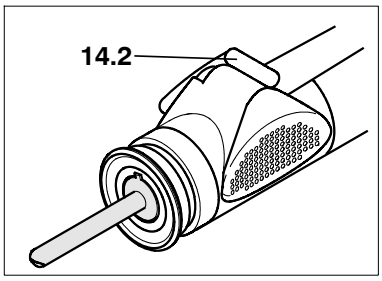
◇ Press the “Reset to factory setting" button.

◗ Any values which you may have adjusted or stored (e.g. speed) are lost. Language selection, however, is not reset.

◇ Use select button to select “Confirmation".

◇ Confirm reset.

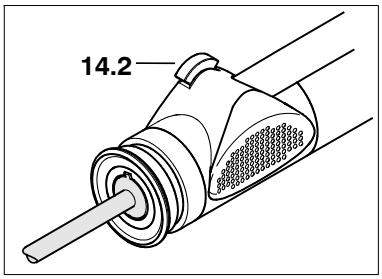
5.2.7 POWER STICK M4 with valve



◇ Positioning the rotary blade:
➧ Cutting window open / closed, see section 5.2.5.

◇ Valve (14.2):
➧ “OFF" position: Valve closed (no suction).
➧ “ON" position: Valve open (suction/aspiration).

5.2.8 POWER STICK M4 with sealing insert, open



◇ Positioning the rotary blade:
➧ Cutting window open / closed, see section 5.2.5.

◇ Sealing insert open (14.2):
➧ The valve is always open (suction) and cannot be adjusted.

5.3 Operation of device

⚠ *CAUTION!*
Caution in the case of poor visibility.
Tissue in the operating area can inadvertently get into the cutting windows and be injured.
Operate the blade only if the cutting window is easily visible.

⚠ *CAUTION!*
Do not resharpen the rotary blades / abraders!
Operate the rotary blades / abraders only in liquid!
Ensure sufficient suction in order to cool the rotary blades / cutters and to remove the ablated tissue from the cutting area.

⚠ *CAUTION!*
Rotating cutting edges of the inner blades / abraders must not touch metal parts (e.g. trocar sleeves) or arthroscopes,
as this may damage both instruments.
In the case of such contact, immediately check the instruments for damage and completeness. Extract any missing parts.
Do not use the instruments if damage such as deformed cutting edges, cracks or fractures are visible.
Make sure that no missing instrument parts remain in the patient.

⚠ *CAUTION!*
Danger of electric shock when touching the connection device and the patient at the same time.

Do not touch the connection device and the patient at the same time.

☞ *IMPORTANT!*
Follow the instructions on interval operation, as otherwise the grip surface of POWER STICK M4 can become very hot.

☞ *IMPORTANT!*
The inner and outer blades are supplied in matched pairs. Do not mix with other blades.

☞ *NOTE!*
An increased suction rate has a positive impact on cutting performance and reduces the danger of clogging.

☞ *IMPORTANT!*
In conjunction with the sealing insert, open (15178145), the POWER STICK M4 may ***only*** *be used for applications in urology.*

5.3.1 Speed settings

Usual speed for **rotary blades**:

100 - 1500 rpm

Recommended speed for **rotary abraders**:

800 - 3000 rpm
(in special cases up to 6000 rpm ; only POWER STICK M4)

Efficient speed for **oscillation mode**:

100 - 1500 rpm

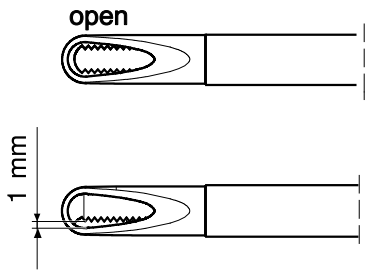
☞ ***NOTE!***

Cutters only cut when turning clockwise.
High speeds increase friction, which may result in abrasion, wear and the formation of cracks in the abraders.

⚠ ***CAUTION!***

Caution at high speeds beyond 3000 rpm ; only POWER STICK M4
Danger of thermal damage to the tissue by excessive temperatures.
Ensure sufficient cooling of tissue and tool by providing adequate irrigation.
Use at high speed should be limited to the shortest possible duration and moderate contact pressure.

5.3.2 Instructions and notes on morcellation in urology



Stop position of internal blade:

Cutting window is only small with a gap width of approx. 1 mm, see adjacent drawing
Carry out the adjustment in accordance with section 5.2.4.

Recommended Settings:

◇ Normal and firm adenoma tissue:

- Speed setting stage 3 : 1500 rpm (n oscillation mode corresponding to 750 rpm cw or ccw operation)
- Direction of rotation : oscillation mode
- Oscillation frequency : 2,0 Hz

◇ Soft adenoma tissue:

- Speed setting stage 3: min. 1400 rpm / max. 1500 rpm
- Direction of rotation : clockwise or counter clockwise (not oscillation mode).

The user must select an adequate setting.

⚠ ***CAUTION!***
If the bladder is not completely filled the bladder wall can be damaged if it is sucked towards the blade of the rotary morcellator.
Use morcellation only if you can see the blade through the scope and do not morcellate near the bladder wall.
To prevent the bladder from collapsing we recommend connecting a second irrigation bottle to the drainage stopcock of the Morce Scope or the Continuous Flow Sheath. This will clearly increase the irrigation flow. The irrigation fluid is drained through the rotary morcellator.

☞ ***IMPORTANT!***
Work only with the recommended speed settings and under continuous irrigation.
If the speed is set too high or if there is no irrigation the inner blade can seize or wear out quickly. If the speed is too low it can clog up.
If the suction channel is clogged by tissue parts, morcellation is adversely affected.
Clean a clogged suction channel with a suitable cleaning brush (see section 8.6.4).
For each use have a spare rotary morcellator at hand.

☞ ***IMPORTANT!***
Activate the rotary morcellator only when the tissue to be cut is pulled towards the blade.

☞ ***NOTE!***
We recommend using the Richard WOLF ***PIRANHA 2208*** *suction pump.*

5.4 Alarms

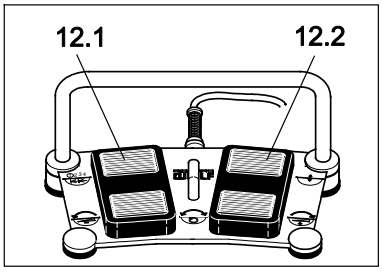
The POWER CONTROL displays all error messages as written text on the display. Severe faults/errors, such as motor overload, device defective, are also issued optically and acoustically (see also section 7.1).

◇ “Alarm" indicator lights up and alarm is sounded if:

- the connection between POWER CONTROL and POWER STICK is incorrect,
- a parting of the cable is detected
- the motor is overloaded
- If device is defective (e.g. processor error)

Upon successful correction the POWER CONTROL can be used as usual.

5.5 Emergency shutdown of POWER STICK



◇ If due to a defect (such as a defective footswitch) the POWER STICK no longer switches off, the emergency shutdown function can be activated by pressing the rear pedals 12.1 or 12.2.

- If the footswitch is defective, emergency operation is possible by controlling the device via the device front panel.
- After an emergency shutdown, do not operate the POWER CONTROL and POWER STICK anymore and contact the service department immediately.

5.5.1 Taking out of service

◇ To take the device out of service, switch off the power switch and disconnect the device from the power supply / mains.

6 Operation in the RIWO NET SYSTEM

6.1 Combination with RIWO NET SYSTEM

Via the integrated CAN BUS interface the POWER CONTROL 2303 can be integrated into the R.Wolf RIWO NET SYSTEM.

Only the components approved for use with the RIWO NET SYSTEM must be connected to the “CAN BUS” interface.
The components must meet the requirements of the latest instruction manual for the RIWO NET SYSTEM, section on “Combinations”.

The control computer complies with IEC / EN 60601-1 and may therefore be used in the patient environment.

☞ ***IMPORTANT!***
In addition to this manual make sure you follow the latest manual for the RIWO NET SYSTEM.

6.2 Operation

The instruction set used in the interface software is suitable for operating this device within the RIWO NET SYSTEM.

The POWER CONTROL unit can be controlled via the RIWONET SYSTEM with remote control, speech control, touchscreen monitor or manually via the buttons on the device front panel.

☞ ***IMPORTANT!***
The POWER CONTROL unit can still be operated via the front panel buttons, should the RIWO NET SYSTEM fail.

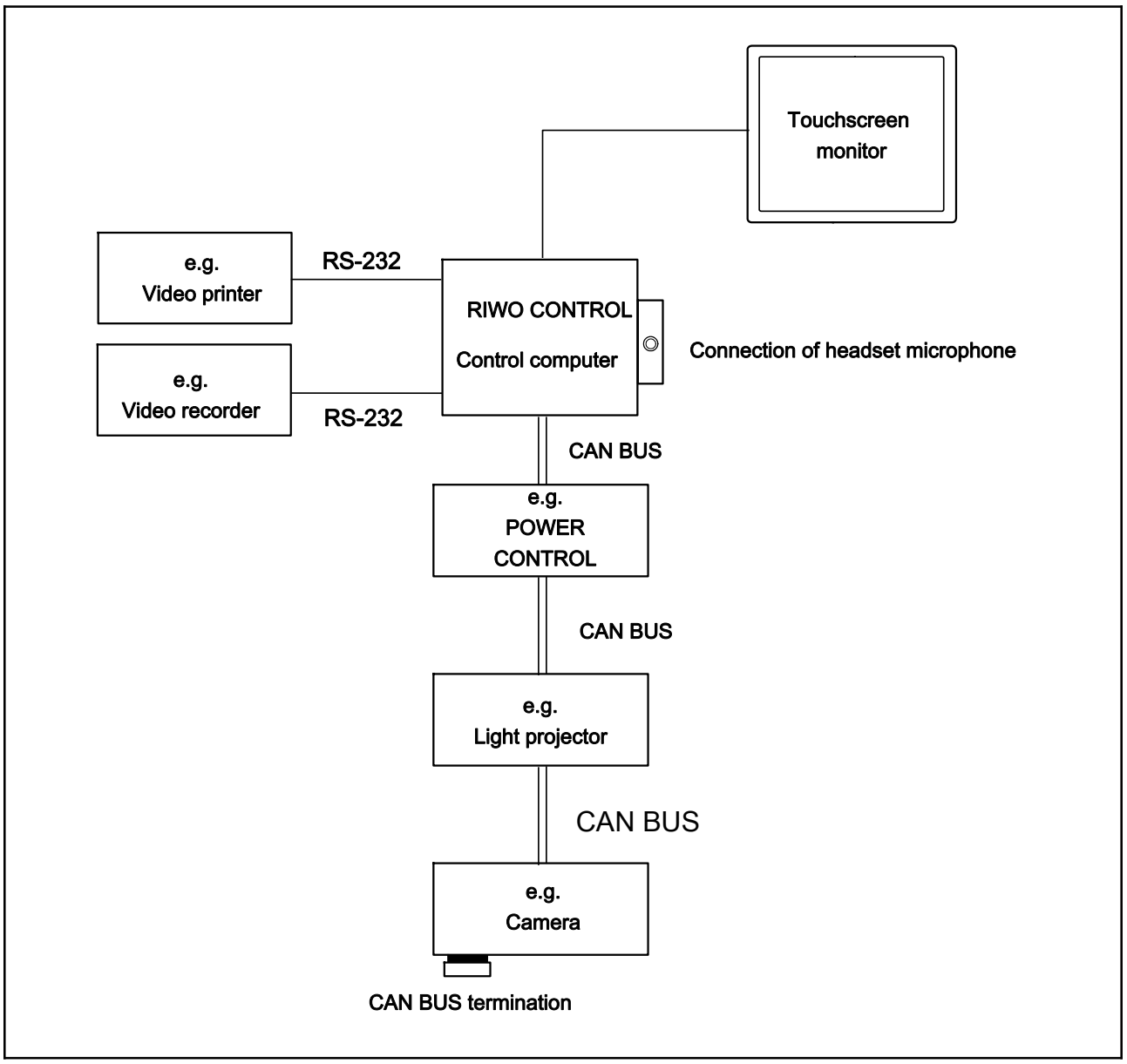
☞ ***IMPORTANT!***
To fully understand the system please read the latest manual for the RIWO NET SYSTEM.

☞ ***IMPORTANT!***
*When controlling the device via the touch-screen monitor, it is sufficient to touch the monitor surface **only lightly**.*

6.3 Adjusting rotary encoding switch "ID"

◇ The “ID” rotary coding switch on the rear panel of the device must be set to “0”.

6.4 Connection to the RIWO NET SYSTEM



☞ ***IMPORTANT!***
The device system must be operated via a "separating transformer with DC coupling"

☞ ***IMPORTANT!***
The last device in the CAN BUS chain requires a termination using the supplied terminating resistor.

6.5 Controlling the devices using the RIWO NET menu

6.5.1 Controlling the devices via the different input media

Via touchscreen monitor

- The function is selected and executed by gently touching the desired menu function (button) directly on the touchscreen monitor.

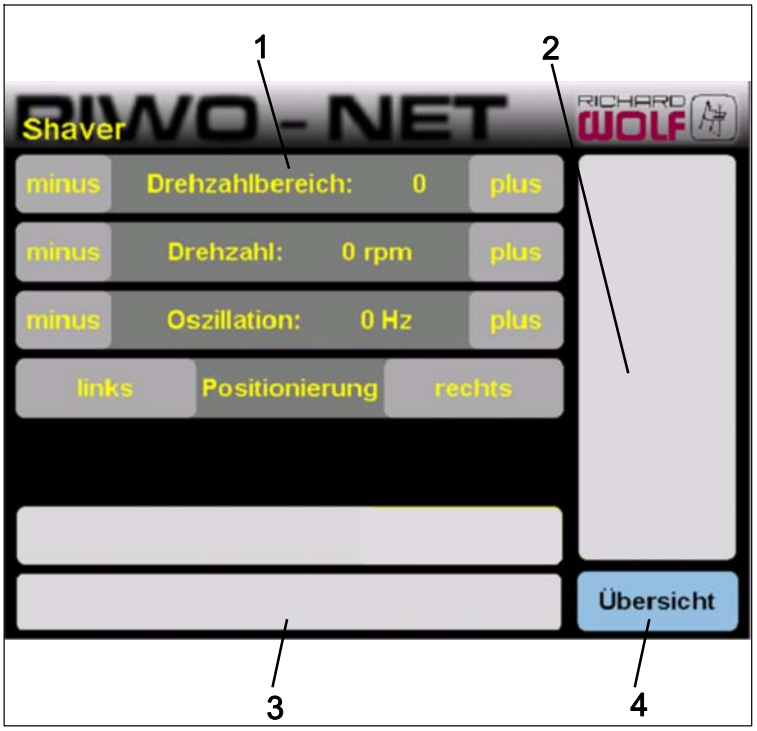
Via voice control:

- The same instructions/commands must be used as displayed on the touchscreen monitor.
- If an instruction/command consists of a “Function” and an “Action”, both terms
  must be pronounced one after the other without pausing.
  Example: “SPEED” - “MINUS” or “SPEED” - “PLUS”.
- Before and after each instruction/command, a short pause of approx. 0.5 seconds is required.

Via remote control unit:

- The arrow buttons serve to select the corresponding device in the main menu and the corresponding function in the submenu.
- The yellow buttons serve to execute the corresponding action.
- The blue buttons serve to return to the main menu.
  From the main menu, the RIWO NET SYSTEM can be exited, in which case the computer is shut down automatically.

6.5.2 Illustration of menu



Legend

1	Control menu	**3**	System messages
2	Status display	**4**	Back to main menu

6.5.3 Main menu

The main menu lists all devices connected to the RIWO NET SYSTEM. Selecting a device calls up and displays the corresponding device menu.

6.5.4 Speed range function

◇ The “speed range” function of the menu serves to select one of the speed ranges 1 through 4.

6.5.5 Speed function

◇ The “speed function” of the menu serves to adjust the speed within the selected speed range.

6.5.6 Oscillation function

◇ The “oscillation” function of the menu serves to select an oscillation rate of 0.5, 1.0, 1.5 or 2.0 Hz.

6.5.7 Positioning function

◇ The “positioning” function of the menu serves to rotate the blade (tool opening) in single step mode clockwise or counter-clockwise.

6.6 System messages

☞ *IMPORTANT!*
If you cannot eliminate the faults or errors with the help of this table, please contact the service department or return the device for repair.
➧*Do not attempt to do any repairs yourself!*

★ Depending on the status or error state the POWER CONTROL displays the following messages on the RIWO NET menu monitor:

6.6.1 Status messages

Type of message	Message text	Possible cause	Corrective action
Status message 1	Motor of “PowerStick” blocked!	Motor overloaded or tool blocked	➧Interrupt application briefly / check tool
Status message 2	No “PowerStick“ connected!	No “PowerStick“ connected	➧Connect PowerStick
Status message 3	No “Footswitch” connected!	No “Footswitch” connected	➧Connect footswitch
Status message 4	Lower limit of range is reached.	Lower limit of range of adjustable parameters is reached	
Status message 5	Upper limit of range is reached.	Upper limit of range of adjustable parameters is reached	
Status message 6	Motor of „PowerStick“ blocked!		
Status message 7	Control level B activated		
Status message 8	Control level A activated		

”**+ Voice ouput**” = The system messages marked with this symbol are accompanied by an acoustic message (only if the ”voice output” option is available).

6.6.2 Warnings

Type of message	Message text	Possible cause	Corrective action
Warning 1	CautionFootswitch actuated or defective	Footswitch is actuated when connecting the cable or defective	➧Let go of footswitch ➧ Contact service department
Warning 2	Caution“Shaver” device error	Device malfunction / defect	➧ Contact service department

6.6.3 Fault / error

Fault / error	Possible cause	Corrective action
Device is not logged into the RIWO NET SYSTEM	Rotary coding switch “ID” not in “0” position	➧Set rotary coding switch “ID” to “0”

7 Reprocessing and maintenance

7.1 Reprocessing

⚠ *WARNING!*
Make sure that no humidity enters the device.
Danger of electric shock!
Before reprocessing switch off and disconnect the device from the power supply / mains.

Clean MOTOR CONTROL UNIT 2303 and the foot switch regularly (i.e. after each use) with a soft cloth moistened with surface disinfectant, alcohol or isopropylalcohol.
Follow the disinfectant manufacturer's instructions!

☞ *NOTE!*
Use an FDA (Food and Drug Administration) cleared or EPA (US Environmental Protection Agency) registered cleaning and disinfection solution/wipes for lowlevel disinfection, alcohol based.

☞ *IMPORTANT!*
Make sure that no humidity enters the device. Do not use any cleaning agents, scouring agents or solvents on this device.

7.2 Maintenance

☞ *IMPORTANT!*
In your inquiries or correspondence please always indicate the model and serial number on the identification plate. Further documentation is available from the manufacturer on request.

RICHARD WOLF Service:

www.richard-wolf.com/en-us/service-and-service-packages

To avoid malfunctions, a regular function test and a check of the controls and the connection for damage must be carried out before every new start-up.

In accordance with the instructions for use (manual), the user is responsible for the functionality of the footswitch.

7.2.1 Maintenance intervals

☞ *IMPORTANT!*
To avoid any incidents or damage caused by aging and wear it is necessary to service the product and the accessories at adequate intervals. Depending on the frequency of use, but at least once a year, have an expert check the functional and operational safety of the equipment.

7.3 Reprocessing procedure

☞ ***IMPORTANT!***

Disinfectants containing peracetic acid without corrosion protection, phenoles or chlorine components must not be used for the reprocessing of Richard Wolf products.
Strictly adhere to the maximum immersion time in the disinfectants used, as described by the manufacturers.

☞ ***IMPORTANT!***

- *When used as intended following the instruction manual, it is not necessary to limit the number of permissible reprocessing cycles.*
- *Careful and gentle handling during the entire reprocessing process has an essential influence on the service life of medical products.*
- *Before returning defective products for repair, they must have been subjected to the entire reprocessing cycle.*
- *The user must ensure that the reprocessing process including the resources, materials and personnel are suitable to achieve the required results.*

☞ ***IMPORTANT!***

*Do **not** sterilize the products in hot-air sterilizers.*

☞ ***IMPORTANT!***

Do not clean plastic parts with metal or sharp-edged tools (such as sharp-edged brushes).

☞ ***NOTE!***

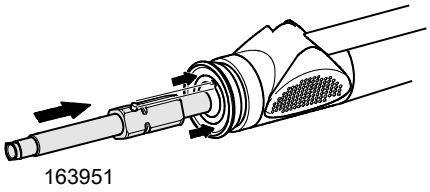
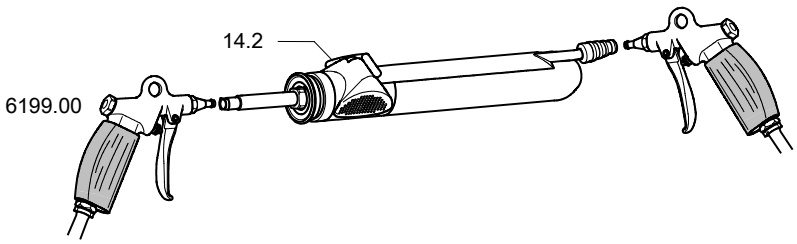
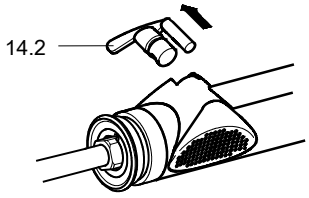
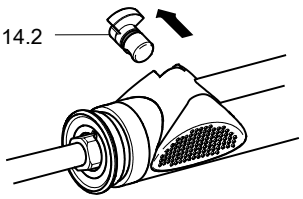
Machine cleaning is to be preferred.
Manual cleaning / disinfection can be carried out if there is no possibility of machine cleaning/disinfection.

☞ ***NOTE!***

Do not use saline solutions for rinsing because that will promote corrosion.

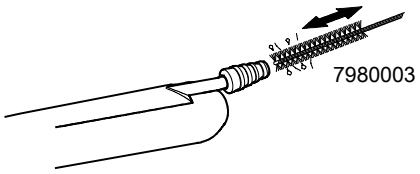
The following tables describe the reprocessing methods and processes used by Richard Wolf GmbH for validation.

7.3.1 POWER STICK M4 (8564.121/8564122)

Product:	POWER STICK M4 (8564.121/8564122)
Reprocessing guide:	
Preparation at the point of use:	Directly after use, remove any coarse soiling from the products. If there are more than 6 h between use and reprocessing, rinse out the hollow spaces with a syringe filled with water. Do not use fixing agents or hot water (> 40 °C), as this will bake any residues to the surfaces and may influence the cleaning success.
Transport:	Safe storage in a closed container and transport of the products to the reprocessing room in order to avoid damage to the products and contamination of the environment.
Pre-cleaning:	Do **not** disassemble the valve or sealing insert - open (14.2) for precleaning. 1. Disconnect the connection cable. 2. Rinse the motor handpiece under running cold water (drinking water quality) for 10 seconds.  163951 3. Attach the rinsing adapter (model 163951). ➧ see section 3.2 4. Immerse the motor handpiece in a certified cleaning solution (e.g. enzymatic solution) for 5 minutes and fill the inside with this solution using a 20 ml syringe. ➧ For exposure time and applied concentration follow the manufacturer's specifications. 5. Actuate valve (14.2) 5 times. 6. Rinse out the channel and the inside of the clamping head with the adapter in place with a cleaning gun (e.g. model 6199.00) in pulsed mode by applying 5 pressure surges (2.5-4 bar) for 5 sec each while actuating the valve (14.2) 5 times.  14.2 6199.00
Disassembly before cleaning	 14.2 **POWER STICK M4 with valve** Push out the valve (14.2) laterally while moving the valve to the “ON" and “OFF" directions.  14.2 **POWER STICK M4 with sealing insert, open** Push out the sealing insert, open (14.2), laterally.

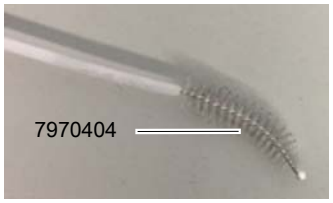
Product:	POWER STICK M4 (8564.121/8564122)
Reprocessing guide:	
Cleaning	**Manual cleaning**

1. Thoroughly rinse all parts (motor handpiece, connection cable, valve or sealing insert, open) with cold water in drinking water quality.
2. Rinse out narrow channels with a 20 ml syringe filled with a certified cleaning solution.
3. Immerse for at least 5 minutes in a certified cleaning solution.
   - ⧫ For exposure time and applied concentration follow the manufacturer's specifications.

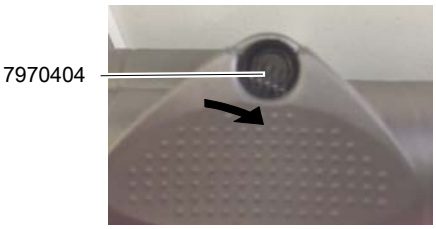


When brushing the suction channel, mind the following:

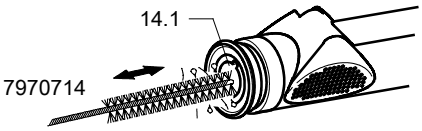
4. Brush the suction channel up to the valve using a cleaning brush (model 7980003) while the instument is fully immersed



5. Slightly bend the front third of the head of the cleaning brush (model 7970404).



6. Brush the suctuion channel with cleaning brush (model 7970404) in such a way that the rear end behind the sealing valve is also brushed.
   For this purpose, slightly move the cleaning brush in order to gain access to the suction channel past the sealing valve.



7. Brush the inside of the clamping head (14.1) with cleaning brush (model 7970714).

8. Brush the outer surfaces with a cleaning brush (model 8691) while the instrument is immersed in water for 5 seconds, or until the surfaces look clean.
9. Rinse out the channels thoroughly for at least 20 seconds, or in pulsed mode by applying 5 pressure surges (2.5 - 4 bar) with a water cleaning gun (e.g. model 6119.00) using cold water (drinking water quality).
10. Rinse the outer surfaces with cold water (drinking water quality).

Disinfection:

1. Immerse the products in a certified disinfectant solution.
   - ⧫ Completely fill the channels of the products with this solution.
   - ⧫ For exposure time and applied concentration follow the manufacturer's specifications.
2. Conclude the process by thoroughly rinsing out the products with cold water (drinking water quality) for at least 20 seconds, or in pulsed mode by applying 5 pressure surges (2.5 - 4 bar).
3. Rinse the outer surfaces with cold water (drinking water quality).

Drying:

Manual drying:
Dry the outer surfaces of the products using a lint-free disposable cloth or swab, or, alternatively, a drying cabinet. Dry hollow spaces with filtered compressed air.

IMPORTANT!

The electrical contacts on the connection cable must be completely dry.

Product:	POWER STICK M4 (8564.121/8564122)
Reprocessing guide:	
Cleaning	**Machine cleaning**
	1. Manually preclean the products before machine cleaning. 2. Connect the motor handpiece via the luer connector of the installed rinsing adapter and via the suction connector to the rack of the washer-disinfector device (WD). 3. Place the small parts into a small parts sieve or sieve tray of the WD. **Program parameters** ◗ 2 min of precleaning with cold tap water. ◗ Emptying. ◗ 5 min of cleaning at 55 °C (applied concentration as specified by the manufacturer). ◗ Emptying. ◗ 3 min of intermediate rinsing with demineralized water (20 °C ± 2 °C). ◗ Emptying. ◗ 2 min of intermediate rinsing with demineralized water (20 °C ± 2 °C).
Disinfection:	Carry out thermal machine disinfection following the national requirements with regard to the A0 value (see DIN EN ISO 15883).
Drying:	Drying the products using the WD drying cycle at max. 100 °C. If necessary, additional drying can be achieved manually with a lint-free disposable cloth or swab, or alternatively in a drying cabinet. Dry hollow spaces with filtered compressed air.
Disassembly before sterilization	1. Remove the rinsing adapter.
Care and assembly before sterilization	***NOTE!*** *Make sure that all parts are dry.* 1. Oil the valve or sealing insert (14.2) with the aid of a medical white oil (e.g. Sterilit instrument oil from Aesculap - no spray). Only medicial oils intended for the care of medical instruments may be used. ◗ Observe the specifications of the instrument oil manufacturer. ◗ The other surfaces must be oil-free! 2. Remove any excess oil. 3. Install the valve or sealing insert, open (14.2).
Function check, visual check, maintenance	Check visually for cleanliness. If necessary, repeat the reprocessing procedure until the product appears visually clean. ◗ Carry out a visual and a functional check: see sections 4.1 and 4.2
Packaging:	Wrap the medical devices for sterilization in sterilization package according to ANSI/AAMI/ ISO 11607-1.
Sterilization:	***IMPORTANT!*** *Do **not** connect the detachable power cords to the motor handpiece for sterilization, sterilize separately instead.* *Set the valve or sealing insert, open (14.2) to "ON" so that the steam can flow freely.* Use only moist heat/steam sterilization on a dynamic air-removal-cycle with 3 vacuum pulses. ◗ Temperature exposure time: 4 min. at 270 °F (132 °C) ◗ Drying time: 20 - 30 min (The drying time depends on the sterilization process used) ◗ Maximum temperature: 280 °F (138 °C)
Storage:	Store the sterilized products in a restricted area at approximately 75 °F (24 °C) with at least 4 air exchanges per hour and a relative humidity that does not exceed 70 %, in accordance with ANSI/AAMI ST79.

7.3.2 Reusable rotary blades, burrs and morcellators

☞ *IMPORTANT!*

Single-use (disposable) rotary morcellators are intended for one single use only and must be discarded after use in accordance with the country-specific regulations.

Product:	**Reusable rotary blades, burrs and morcellators**
Reprocessing guide:	
Preparation at the point of use:	Directly after use, remove any coarse soiling from the products. If there are more than 6 h between use and reprocessing, rinse out the hollow spaces with a syringe filled with water. Do not use fixing agents or hot water (> 40 °C), as this will bake any residues to the surfaces and may influence the cleaning success.
Transport:	Safe storage in a closed container and transport of the products to the reprocessing room in order to avoid damage to the products and contamination of the environment.
Pre-cleaning:	Disassemble rotary blades, burrs and morcellators Rinse out products with hollow spaces for 20 seconds or in pulsed mode by applying 5 pressure surges (3-4 bar) using a cleaning gun (e.g. model 6199.00)
Cleaning	**Manual cleaning**
	1. Rinse the products thoroughly with cold water (drinking water quality). 2. Rinse out narrow channels with a 20 ml syringe filled with a certified cleaning solution. 3. Immerse for at least 5 minutes in a certified cleaning solution. ◗ For exposure time and applied concentration follow the manufacturer's specifications. 4. Brush the channels with suitable cleaning brushes. ◗ see section 8.6.7 5. Brush the outer surfaces with a cleaning brush (model 8691) while the instrument is immersed in water for 5 seconds, or until the surfaces look clean. 6. Rinse out the channels thoroughly for at least 20 seconds, or in pulsed mode by applying 5 pressure surges (3-4 bar) with a water cleaning gun (e.g. model 6119.00) using cold water (drinking water quality). 7. Rinse the outer surfaces under cold water (drinking water quality).
Disinfection:	1. Immerse the products in a certified disinfectant solution. ◗ Completely fill the channels of the products with this solution. ◗ For exposure time and applied concentration follow the manufacturer's specifications. 2. Conclude the process by thoroughly rinsing out the products with cold water (drinking water quality) for at least 20 seconds, or in pulsed mode by applying 5 pressure surges (3 3. Rinse the outer surfaces with cold water (drinking water quality).
Drying:	Manual drying: Dry the outer surfaces of the products using a lint-free disposable cloth or swab, or, alternatively, a drying cabinet. Dry hollow spaces with filtered compressed air.
Cleaning	**Machine cleaning**
	1. Manually preclean the products before machine cleaning. 2. Place the outer and inner parts of the rotary blade, burr and morcellator in a suitable rinsing device of the MIS cart. ◗ > 4 min. of precleaning with cold water. ◗ Emptying. ◗ > 6 min of cleaning at 55 °C (applied concentration as specified by the manufacturer). ◗ Emptying. ◗ > 3 min of neutralization with cold tap water (< 40 °C). (Depending on the use of the cleaner and the rinsing water, add an acid based on citric acid) ◗ Emptying. ◗ > 2 min of intermediate rinsing with cold tap water (< 40 °C). ◗ Emptying.
Disinfection:	Carry out thermal machine disinfection following the national requirements with regard to the A0 value (see DIN EN ISO 15883).
Drying:	Dry the products in the drying cycle of the washer-disinfector. If necessary, additional drying can be achieved manually using a lint-free disposable cloth or swab, or, alternatively, a drying cabinet. Dry hollow spaces with filtered compressed air.

Product:	Reusable rotary blades, burrs and morcellators
Reprocessing guide:	
Function check, visual check, maintenance:	Check visually for cleanliness. If necessary, repeat the reprocessing procedure until the product is visually clean. ◗ Carry out a visual and functional check: see sections 4.1 and 4.2
Packaging:	Wrap the medical devices for sterilization in sterilization package according to ANSI/AAMI/ ISO 11607-1.
Sterilization:	Sterilize reusable rotary blades, burrs and morcellators in assembled condition. Use only moist heat/steam sterilization on a dynamic air-removal-cycle with 3 vacuum pulses. ◗ Temperature exposure time: 4 min. at 270 °F (132 °C) ◗ Drying time: 20 - 30 min (The drying time depends on the sterilization process used) ◗ Maximum temperature: 280 °F (138 °C)
Storage:	Store the sterilized products in a restricted area at approximately 75 °F (24 °C) with at least 4 air exchanges per hour and a relative humidity that does not exceed 70 %, in accordance with ANSI/AAMI ST79.

8 Technical description

8.1 Troubleshooting

☞ *NOTE!*
If you cannot eliminate the faults or errors with the help of this table, please contact the service department or return the device for repair.
◗Do not attempt to do any repairs yourself!

8.1.1 POWER CONTROL

Fault / error	**Possible cause**	**Corrective action**
Device without function	Power switch not switched on Power cable not connected Device fuse defective No mains/line voltage (input voltage)	◗Actuate power switch ◗Connect power cable ◗Replace fuse ◗Check in- house power supply
Power/mains switch is not lit	Fuse defective	◗Replace fuse
No display on the LCD		◗Return the device for repair
“No POWER STICK” display blinks	POWER STICK not connected.	◗Use connection cable to connect POWER STICK to POWER CONTROL
”No footswitch” display blinks	Footswitch not connected	◗Connect footswitch connection cable to POWER CONTROL

8.1.2 POWER STICK

Fault / error	**Possible cause**	**Corrective action**
POWER STICK does not run when footswitch is actuated ”ALARM” indicator is lit and alarm is sounded	Wrong connection between footswitch and POWER CONTROL Rotary blade defective Rotary blade clogged	◗Establish connection ◗Insert new blade ◗Clean rotary blade
POWER STICK does not work(without rotary tool) ”ALARM” indicator is lit and alarm is sounded	Interruption of cable connection Cable defective (parting of cable) Motor defective or blocked	◗Fully connect plug to POWER STICK ◗Fully connect plug to device ◗Use a new cable ◗Return POWER STICK for repair
Install the suction / irrigation valves difficult to move	Excessive friction of seals Seal defective	◗Spearingly grease valve insert and-seals with endoscope grease ◗Replace seal

8.2 Technical data of MOTOR CONTROL UNIT

Model	Voltage V ~	Frequency Hz	Power consumption VA	Current rating A	Fuse A
2303.011 (USA)	100 - 127 220 - 240	50 / 60	110	0,8 - 0,44	T 1.6 AL 250 V

Electromagnetic compatibility (EMC) to	IEC / EN 60601-1-2
Medical Products Directive 93/42/EEC	Class II a
Protection class to IEC / EN 60601-1 (UL 60601-1 / CSA C22.2 No.601.1 - for USA)	I
Protection against electric shock	Type BF applied part
Noise level	max. 56 dB(A)
Degree of protection against the ingress of liquids	IP 20 (not protected)
Duty factor	Continuous operation
Degree of protection in the presence of flammable mix-tures	This device is not protected against explosions (Do not operate this device in an ignitable atmosphere)
Weight (without motorized handle)	7.6 kg (16.7 lbs)
Dimensions WxHxD	330 mm x 100 mm x 360 mm

8.2.1 Interfaces

POWER STICK connector	Socket, 16-pin
Footswitch connector	Socket, 6-pin
For RIWO NET SYSTEM	
CAN BUS input connector	Sub-D socket, 9-pin
CAN BUS output connector	Sub-D socket, 9-pin

8.3 Technical data of POWER STICK

Model	Designation	Length mm	Cross section mm	Weight g	Speed rpm
8564.021	Motor handpiece max. 6000 u/min	175	25 x 28	295	100 - 6000
8564.851	Connection cable	3000	-	275	-

Protection against electric shock	Type BF applied part
Degree of protection against the ingress of liquids	IP X7
Degree of protection in the presence of flammable mixtures	This device is not protected against explosions (Do not operate this device in an ignitable atmosphere)
Mode M4 (8564.021)	Continuous operation duty type with load interval INT. 3 min / 3 min

8.4 Technical data of footswitch

Degree of protection against the ingress of liquids	IP X8
Degree of protection in the presence of flammable mixtures	This device is not protected against explosions (Do not operate this device in an ignitable atmosphere)
Weight	4.0 Kg (8.8 lbs)
Dimensions WxHxD	235 mm x 55 mm x 150 mm

8.5 Operating, storage, transport and shipping conditions

Operating conditions	+10 °C to +40 °C, 20% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa
Storage, transport and shipping conditions	-20 °C to +60 °C, 10% to 90% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa

Disposable items, sterile products	Follow instructions on package !

☞ ***IMPORTANT!***
Store sterile products in the original packaging until use.
Incorrect storage may lead to loss of sterility.

☞ ***NOTE!***
To prevent damage during transport or shipment of the products we recommend using the original packaging material.

8.6 Spare parts and accessories

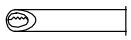
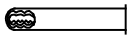
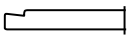
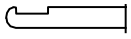
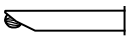
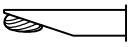
8.6.1 MOTOR CONTROL UNIT

Model	Designation
64 268.019	Device fuse T 1.6 AL 250 V (PACK=10PCS.)
N710006	Power cable (USA), 8.0 ft
2303.901	Footswitch 2 pedals

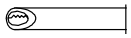
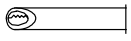
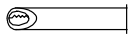
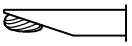
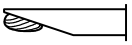
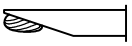
8.6.2 POWER STICK M4

Model	Designation
8564.021	Motor handpiece max. 6000 rpm
8564.851	Connection cable WL 3 m
8564.121	Motor handpiece bndl incl. connection cable (3.0 m), valve and O-ring
15178.124	Valve
8564122	Motor handpiece max. 6000 rpm incl. connection cable (3.0 m), sealing insert, open, and O-ring (only for applications in urology)
15178145	Sealing insert, open (only for urological applications)
15364.274	O-ring

8.6.3 Reusable rotary blades and abraders

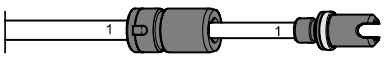
Image	Color	Ø dia. 2.0 mm	Designation	Ø dia. 3.0 mm	Ø dia. 3.5 mm	Ø dia. 4.5 mm	Ø dia. 5.5 mm
	yellow	8564.011 (Power cutter)	Resector		8567.011	8568.011 (toothed) 8568.031 (oval) 8568.032 (oval plus)	8569.011
	blue		Resector aggress		8567.051	8568.051	
	red		End cutter		8567.561	8568.561	
	green		Shaver Cutter	8566.201		8568.201	
	gray		Burr round	8566.301		8568.301	8569.301
	gray		Acromionizer				8569.351
	➧ Further rotary blades on request						

8.6.4 Reusable rotary blades and abraders for spinal surgery (POWER STICK M4)

Image	Color	Designation	Working length mm	Ø dia. 2.5 mm	Ø dia. 3.0 mm	Ø dia. 4.0 mm	Ø dia. 4.5 mm
	yellow	Nucleus Resector smooth	350		89970.1003		
	yellow	Nucleus Resector smooth	350			89970.1004	
	yellow	Resector smooth	220				8792.321
	gray	Burr oval	350	8792.312			
	gray	Burr oval	350		89970.1503		
	gray	Burr oval	350			89970.1504	
	green	Burr oval	350		89970.1513		
	green	Burr oval	350			89970.1514	
		➧ Further rotary blades on request					

8.6.5 Reusable rotary morcellator for urology

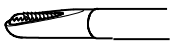
Image	Color	Designation	Outside dia. (mm)	Working length (mm)	Product no.
	yellow	Rotations-Morcellator	4,8	350	**8970.011**
	blue			385	**8970010**



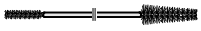
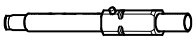
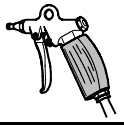
☞ ***NOTE!***

For assembly make sure that the codes of the inner and outer blades correspond.

8.6.6 Single-use Rotary Morcellator for urology

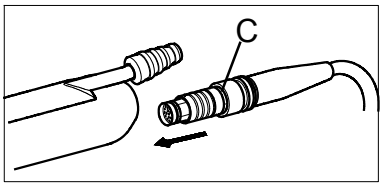
Image	Designation	Outside dia. (mm)	Working length (mm)	Product no.
	Rotations-Morcellator (PACK = 3 PCS)	4,8	335	**49700113**
			385	**49700103**

8.6.7 Accessories for reprocessing

Image	Type	Designation
	7970402	CLEANING BRUSH Ø 2MM TL 400MM for channels Ø 1.0-1.5 mm, brush length 20 mm, PACK = 10 PCS, color: blue, for single use
	7970403	CLEANING BRUSH Ø 3MM TL 400MM for channels Ø 1.6-2.5 mm, brush length 30 mm, PACK = 10 PCS, color: red, for single use
	7970404	CLEANING BRUSH Ø 4MM TL 400MM for channels Ø 2.6-3.5 mm, brush length 30 mm, PACK = 10 PCS, color: yellow, for single use
	7970405	CLEANING BRUSH Ø 5MM TL 400MM for channels Ø 3.6-4.5 mm, brush length 48 mm, PACK = 10 PCS, color: green, for single use
	7970407	CLEANING BRUSH Ø 7MM TL 400MM for channels Ø 4.6-6.5 mm, brush length 48 mm, PACK = 10 PCS, color: purple, for single use
	7970714	CLEANING BRUSH Ø 14MM TL 700MM for channels Ø 10.6-13.5 mm, brush length 48 mm, PACK = 5 PCS, color: pink, for single use
	7980003	DOUBLE CONICAL STRAIGHT CLEANING BRUSH for stopcock inserts / housings with 4 pegs, brush head 1: conical Ø 6-11 mm, brush head 2: Ø 5 mm PACK = 50 PCS, color: yellow, for single use
	8691	CLEANING BRUSH for cleaning surfaces, straight PACK = 10 PCS, for single use
	163951	IRRIGATION ADAPTER (for cleaning)
	6199.00	WATER JET CLEANING PISTOL (cleaning gun)

8.7 Replacing parts on POWER STICK M4

8.7.1 POWER STICK M4 connection cable



◇ Disassembly of connection cable:

➧ Hold the plug at the rubber sleeve and pull it off.

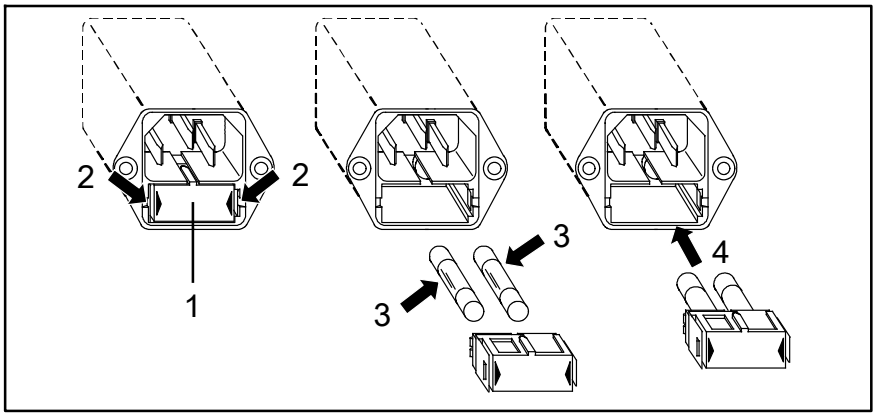
◇ Assembly of connection cable:

➧ Align connector (the red marking (C) must be positioned exactly below the suction connector) and push home.

8.8 Device fuses

⚠ *CAUTION!*
The specifications of the device fuses must correspond with the fuse ratings on the identification plate. Use only the fuses specified in the spare parts list.

★ *Power input connector with fuse holder*



◇ Switch off the device and disconnect the power cable from the wall socket and from the power input connector of the device.

◇ Push together the clamps (2) of the fuse holder (1) and pull out the fuse holder.

◇ Pull out and replace fuses (3).

◇ Reinsert the fuse holder (4) and push it in until it snaps into place.

8.8.1 Disposal of product, packaging material and accessories

For the disposal observe the relevant regulations and laws valid in your country.

➧ For further information please contact the manufacturer.

9 Warranty and Customer Service

Richard Wolf guarantees our instruments to be free from any defects in materials and workmanship under normal use and service for one year. Richard Wolf general terms and conditions may be found on the back of our invoice.

Parts delivered separately by Richard Wolf are subject to all of the same general terms and conditions for our products, including the limitations of warranty and liability.

All products should be returned to Richard Wolf for any necessary or desired repair or part replacement. No product repair or part replacement should be done other than by Richard Wolf unless the care and instruction manual or other written information indicates that repair or part replacement is authorized. If authorized, parts must be replaced only by parts supplied or specified by Richard Wolf, and product repair and part replacement must be done in strict conformance with Richard Wolf specifications and instructions for repair and part replacement, including post replacement testing and recalibration. Failure to follow this requirement in any way can be dangerous to you, your personnel and your patients and voids the warranty for the product repaired or the product in which the part was replaced and if the part was supplied by Richard Wolf, for that part.

Delivery by Richard Wolf of technical documents such as circuit or other design diagrams does not constitute authorization for product repair or part replacement. Richard Wolf instruments and other products should never be modified or altered under any circumstances.

Contact Richard Wolf if you have any question (1) whether replacement of a part or a repair is authorized by Richard Wolf, or (2) whether you have complete instructions and specifications for part replacement or repair.

These instructions do not attempt to cover all details or variations in equipment, nor to provide for every possible contingency to be met in connection with installation, operation, or maintenance. Should further information be required or should problems arise which are not covered sufficiently for the purchaser's purpose, the matter should be referred to Richard Wolf Medical Instruments Corporation.

Our national sales and service offices, as well as our manufacturing facility, are located in Illinois. Trained manufacturer's representatives are located throughout the U.S. to serve you. For any questions regarding these instruments, or to place an order, contact Richard Wolf customer service department at 847- 913- 1113 or 800- 323- WOLF (9653).

INSTRUMENT ORDERING POLICY
Richard Wolf reserves the right to make substitutions, if necessary, without prior notice.

REPAIR POLICY
Defective merchandise will be repaired or replaced at no charge to the customer, provided the customer delivers such defective merchandise prepaid. Any repairs, maintenance or servicing of Richard Wolf merchandise by anyone other than a factory authorized representative will render our warranty null and void.

REPAIR SHIPMENTS
When returning your instrument for repair, we suggest that you prevent shipping damage to the instrument by reusing the box that it was originally shipped in. Richard Wolf also recommends that the instrument be insured for an amount to cover the cost of replacement.

IMPORTANT
For general safety and health reasons, Richard Wolf requires that you clean and sterilize all instruments before returning them for repair. If instruments are received in an unsanitary condition, Richard Wolf will clean and sterilize each instrument and add a $ 100.00 cleaning charge for each instrument requiring cleaning.