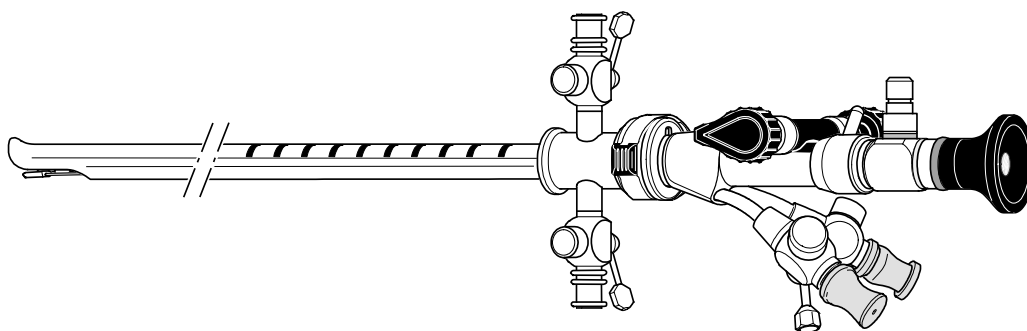


Instructions



“E Line”

Cysto- Urethroscopes

Urethro- Cystoscopes

8650.xxx/8652.xxx/8660.xxx

..

⚠ Important general instructions for use ⚠

Ensure that this product is used only as intended and described in this instruction manual, by adequately trained and qualified personnel, and that maintenance and repair is only carried out by authorized specialized technicians.

Use this product only with the combinations and with the accessories and spare parts listed in this instruction manual. Use other combinations, accessories and replacement parts only if they are expressly intended for this use and if the performance and safety requirements are met.

Reprocess the products before every application and before returning them for repair as required by the instruction manual in order to protect the patient, user or third parties.





Subject to technical changes!

Due to continuous development of our products, illustrations and technical data may deviate slightly from the data in this manual.

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! <i>Failure to observe can result in death or serious injury.</i> |
|  | CAUTION! <i>Failure to observe can result in slight injury or damage to the product.</i> |
|  | IMPORTANT! <i>Failure to observe can result in damage to the product or surrounding.</i> |
|  | NOTE! <i>Tips for optimum use and other useful information.</i> |

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- 1 Intended use**

Cysto- Urethrosopes are used to visualize the bladder, urethra and ureter via the natural passage.
- 1.1 Sheath**

is used to house the endoscope, insert, attachment, working element and auxiliary instrument. At the same time it allows irrigation, water supply and drain.
- 1.2 Obturator/Viewing obturator**

serves to insert the sheath atraumatically. If a viewing obturator is used, the insertion can be observed through the scope.
- 1.3 Inserts**


are used to guide and angle flexible auxiliary instruments, in conjunction with an endoscope.
- 1.4 Attachments**

serve to guide flexible auxiliary instruments in the sheath, in conjunction with an endoscope.
- 2 Indications and field of use**

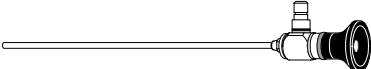
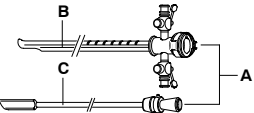

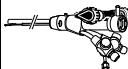
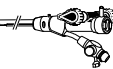
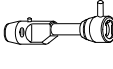
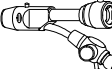
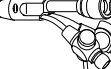
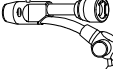
For examination, diagnosis and therapy of the urogenital tract in conjunction with endoscopic accessories. The product must be used only by adequately qualified and trained medical personnel.
- 3 Contraindications**

Contraindications directly related to the product are presently unknown.
On the basis of the patient's general condition the doctor in charge must decide whether the planned use is possible or not. For further instructions please refer to the latest medical literature.
- 4 Combinations**



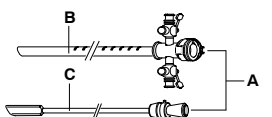
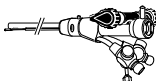
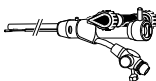
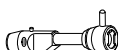
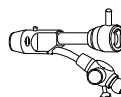
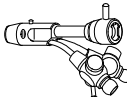
Cysto- Urethrosopes are used in conjunction with light sources and flexible light cables, video cameras or mirror cameras, attachments and inserts, working elements, ureter catheter, bougies, respectively, as well as endoscopic accessories.

 **CAUTION!**
When different products are combined it is necessary that they are compatible in their intended use and relevant technical data (working length, diameter, peak voltage, etc.).
Observe the instruction manuals of the products used in combination with this product.

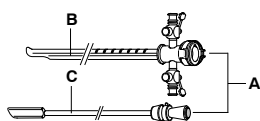
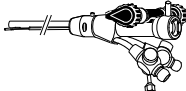
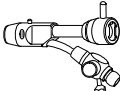

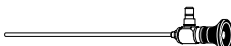
4.1 Overview of E-Line Cysto-Urethroscopes 8650.xxx

| Endoscopes, 4 mm | | | | | | | | |
|---|---|---|---|---|--|---|---|---|
|  | | | 8654.422 (30°) 8650.415 (70°) | | 8650.414 (0°) 8654.431 (12°) 8654.422 (30°) 8650.415 (70°) | | | |
| A | Sheaths (B) incl. Obturator (C) | Viewing obturator | Inserts | | Attachments | | | |
| |  |  |  |  |  |  |  |  |
| | Passage in Fr. | | | | Diagnostics only | | | |
| A | 8650.0141 | - | - | - | X | X | X | - |
| B | 8650.0145 16 Fr. yellow | | | | | | | |
| C | 8650.0147 | | | | | | | |
| A | 8650.0241 | 8650.714 | X | X | X | X | X | - |
| B | 8650.0245/ 8650.0245S01 17.5 Fr. green | | | | | | | |
| C | 8650.0247 | | | | | | | |
| A | 8650.0341 | 8650.724 | X | X | X | X | X | - |
| B | 8650.0345/ 8650.0345S01 19,5 Fr. red | | | | | | | |
| C | 8650.0347 | | | | | | | |
| A | 8650.0441 | 8650.734 | X | X | X | X | X | - |
| B | 8650.0445/ 8650.0445S01 21 Fr. blue | | | | | | | |
| C | 8650.0447 | | | | | | | |
| A | 8650.0541 | 8650.744 | X | X | X | X | X | - |
| B | 8650.0545/ 8650.0545S01 23 Fr. white | | | | | | | |
| C | 8650.0547 | | | | | | | |
| A | 8650.0641 | - | - | - | X | X | X | X |
| B | 8650.0645 25 Fr. black | | | | | | | |
| C | 8650.0647 | | | | | | | |

4.2 Overview of Urethro-Cystoscopes 8652.xxx

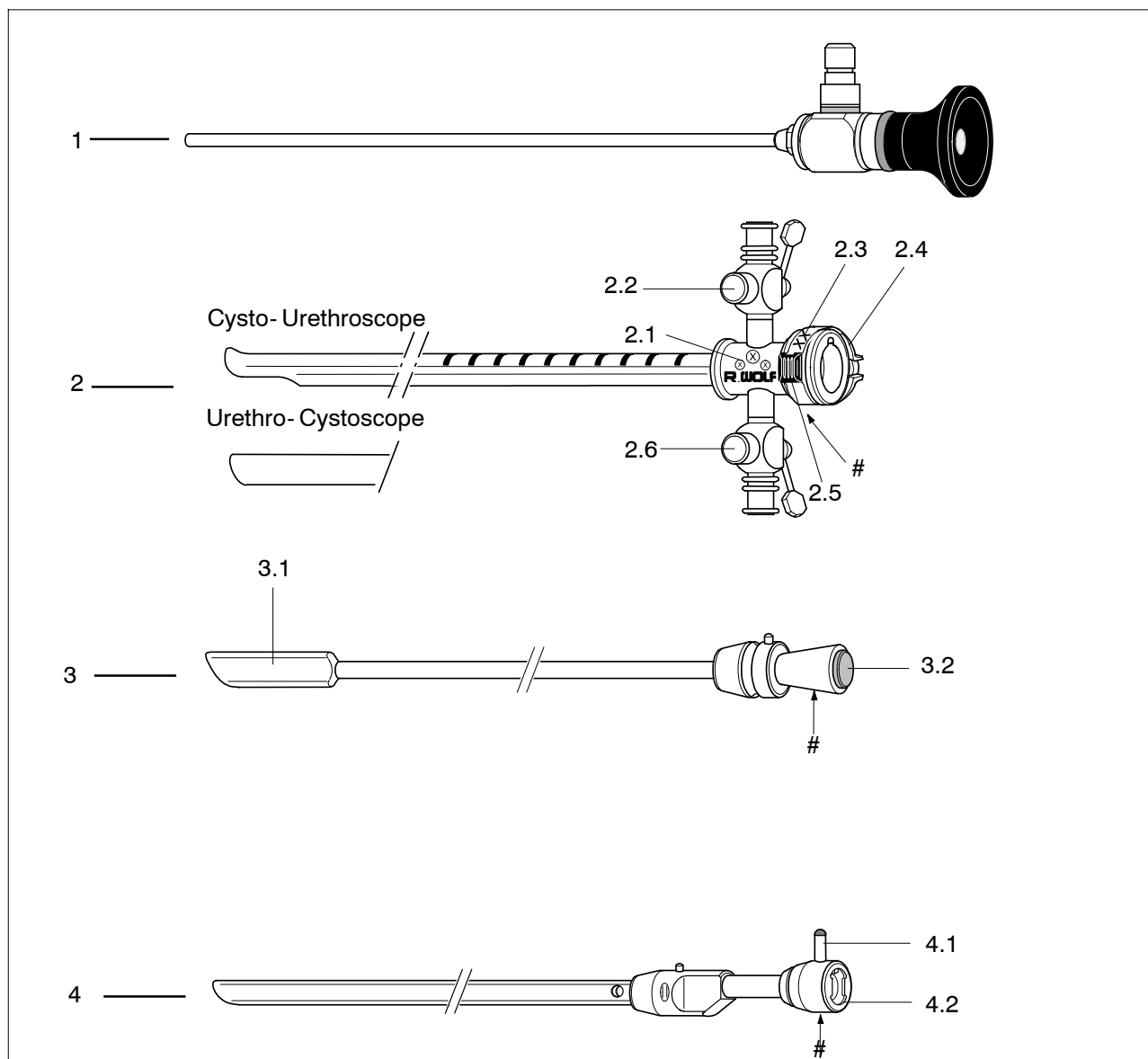
| Endoscopes, 4 mm | | | | | | | | | |
|---|---------------------------------------|---|---|--|---|---|--|--|-----------------------|
|  | | 8654.422 (30°) 8650.415 (70°) | | 8650.414 (0°) 8654.431 (12°) 8654.422 (30°) 8650.415 (70°) | | | | | |
|  | | 8650.412 (12°) 8654.403 (25°) 8654.407 (70°) | | 8650.406 (0°) 8654.412 (12°) 8654.403 (25°) | | | | | |
| | | | | | | | | | |
| A | Sheaths (B) incl. Obturator (C) | Inserts | | Attachments | | | | | |
|  | | 8650.204 | 8650.214 | 8652.254 | 8652.264 | 8652.284 | | | |
| | |  |  |  |  |  | | | |
| | | | | Diagnostics only | | | | | |
| A | 8652.0141 | - | - | X | X | X | | | |
| B | 8652.0145 16 Fr. yellow | | | | | | | | 1 x 5 |
| C | 8652.0147 | | | | | | | | |
| A | 8652.0241 | X | X | X | X | X | | | |
| B | 8652.0245 17,5 Fr. green | | | | | | | | 1 x5 or 2 x 4 |
| C | 8652.0247 | | | | | | | | |
| A | 8652.0341 | X | X | X | X | X | | | |
| B | 8652.0345 19,5 Fr. red | | | | | | | | 1 x 7 or 2 x 5 |
| C | 8652.0347 | | | | | | | | |
| A | 8652.0441 | X | X | X | X | X | | | |
| B | 8652.0445 21 Fr. blue | | | | | | | | 1 x 10 or 2 x 6 |
| C | 8652.0447 | | | | | | | | |

4.3 Small-diameter Cysto-Urethroscope 8660.xxx

| A | Sheaths (B) incl. Obturator (C) | | Inserts | Attachment | | Endoscope |
|---|---------------------------------------|----------------------|---|---|--|---|
|  | | | 8660.224  | 8660.264  | 8660.254  | 3,3 mm  |
| | | Passage in Fr. | | | Diagnostics only | 8660.424 (0°) 8660.425 (70°) |
| A | 8660.0141 | 1 x 5 | - | X | X | |
| B | 8660.0145 14,5 Fr. blue | | | | | |
| C | 8660.0147 | | | | | |
| A | 8660.0241 | 1 x 5 or 2 x 4 | X | X | X | |
| B | 8660.0245 16 Fr. white | | | | | |
| C | 8660.0247 | | | | | |
| A | 8660.0341 | 1 x 7 or 2 x 5 | X | X | X | |
| B | 8660.0345 17,5 Fr. black | | | | | |
| C | 8660.0347 | | | | | |


5 Illustration

5.1 Endoscope, sheaths, obturators

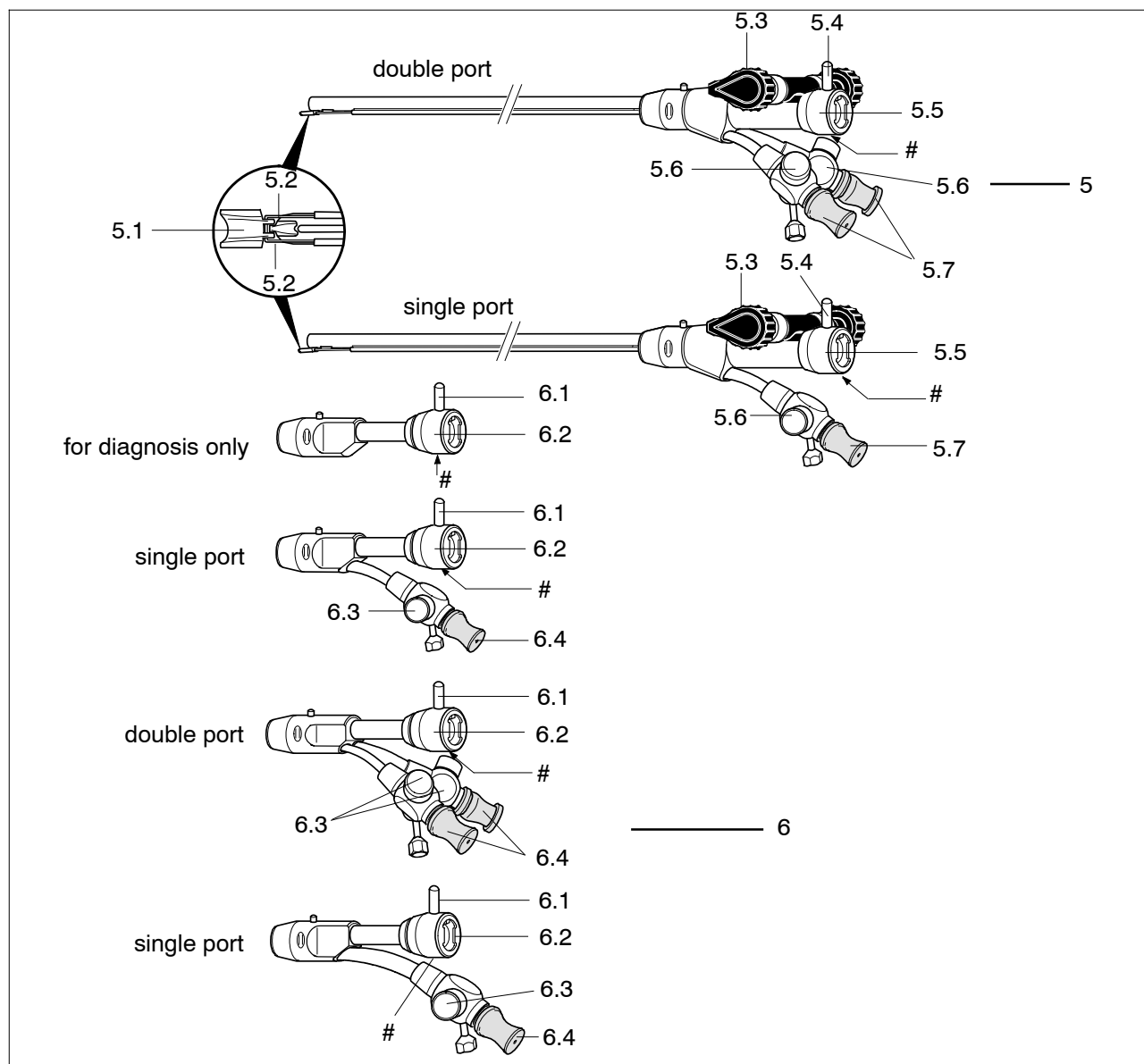


5.1.1 Legend and identification

| Item | Designation | Item | Designation |
|------|--|------|--------------------------------|
| 1 | Endoscope | 3 | Obturator |
| 2 | Cysto- Urethroscope sheath Urethro- Cystoscope sheath | 3.1 | Obturator piston |
| 2.1 | Indication of passage | 3.2 | Colored pin |
| 2.2 | Irrigation stopcock | 4 | Viewing obturator |
| 2.3 | Indication of Fr. | 4.1 | Clamping lever with color code |
| 2.4 | Automatic clamping mechanism | 4.2 | Clamping mechanism |
| 2.5 | Slide with color code | | |
| 2.6 | Drain stopcock | # | Model/type no. |


| | |
|---|--|
|  | 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). |
|---|--|

5.2 Inserts and attachments



5.2.1 Legend and identification

| Item | Designation | Item | Designation |
|------------|---------------------|------------|---------------------------------|
| 5 | Insert, double port | 6 | Attachment for diagnostics only |
| | Insert, single port | | Attachment, single port |
| 5.1 | Albarran lever | | Attachment, double port |
| 5.2 | Control cables | 6.1 | Clamping lever |
| 5.3 | Control wheels | 6.2 | Clamping mechanism |
| 5.4 | Clamping lever | 6.3 | Stopcock |
| 5.5 | Clamping mechanism | 6.4 | Rubber cap |
| 5.6 | Stopcock | | |
| 5.7 | Rubber cap | # | Model/type no. |

| | |
|---|--|
|  | 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). |
|---|--|

6 Use



CAUTION!

The products have only limited strength!

Exerting 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.

Ensure that no missing instrument parts remain in the patient.

Do not use products which are damaged, incomplete or have loose parts.

6.1 Preparation

- ◇ Putting on the rubber caps (5.7) (Fig. 1)

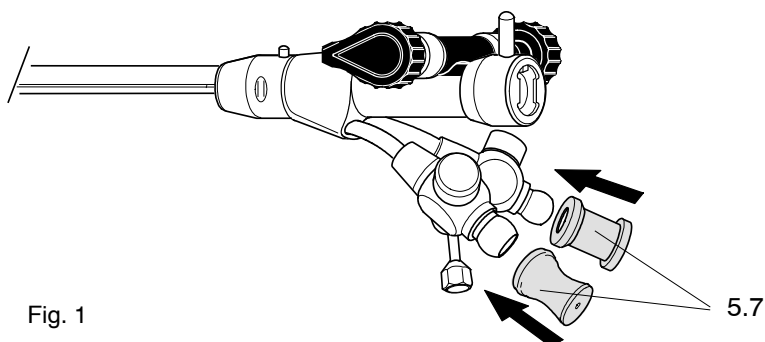


Fig. 1

- ◇ Run through the checks (chapter 7)

6.1.1 Inserting obturator in sheath

- ◇ Insert obturator (3) in sheath (2) in such a way, that groove (a) and pin (b) are aligned, push together until the connection interlocks automatically (Fig. 2).

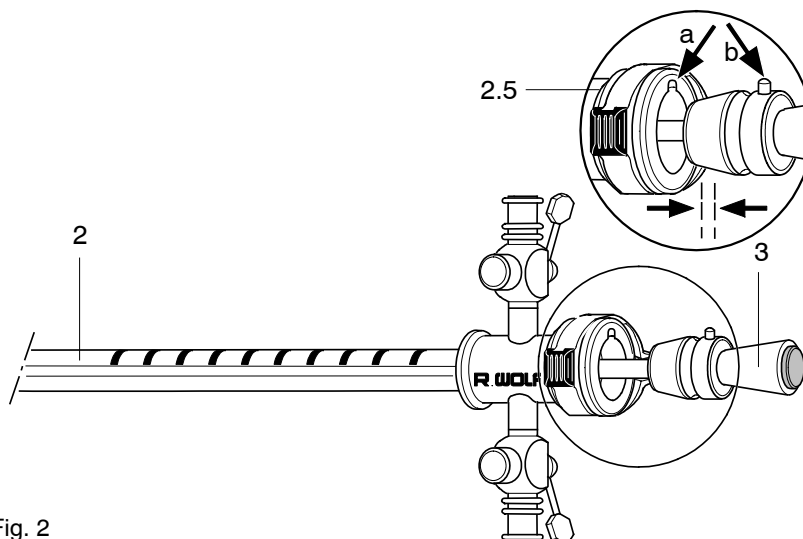


Fig. 2

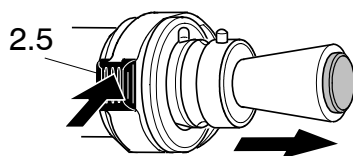


Fig. 3



NOTE!

If the connection won't interlock automatically, push slide (2.5) as far as it will go and repeat the procedure. (Fig.3)

Insert viewing obturator in sheath in the same way.

6.1.2 Inserting endoscope in viewing obturator (Fig. 4)

- ◇ Turn clamping lever (4.1) to position "I" .
- ◇ Insert endoscope (1) in viewing obturator (4).
 - ◆ Nose (c) engages in groove (d).
- ◇ Turn clamping lever (4.2) to position "II".
 - ◆ The two components are interlocked.

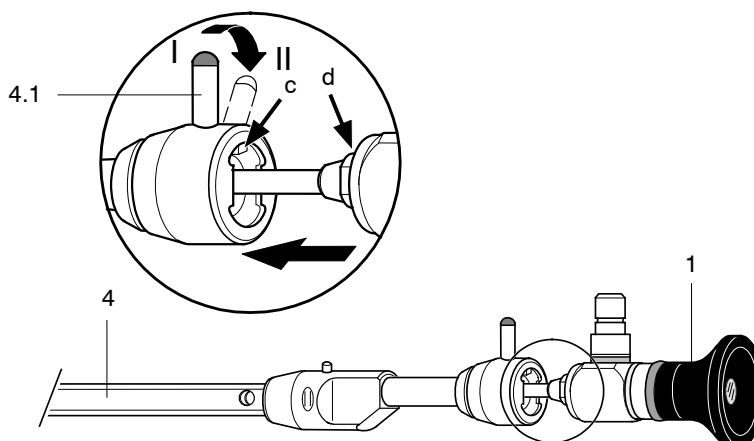


Fig. 4

6.1.3 Inserting endoscope in attachment/insert (Fig. 5)

Inserting the endoscope (1) is explained by example of attachment (6). To insert the endoscope in attachment (5), follow the same procedure.

- ◇ Turn clamping lever (6.1) to position "I" .
- ◇ Insert endoscope (1) in attachment (6).
 - ◆ The nose (e) engages in groove (d).
- ◇ Turn clamping lever (6.1) to position "II".
 - ◆ The two components are interlocked.

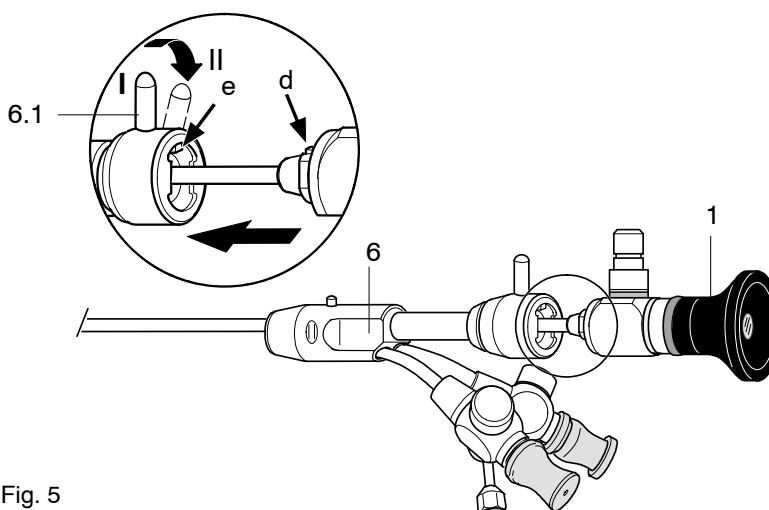


Fig. 5

6.1.4 Inserting attachment or insert in sheath (Fig. 6)

Insertion procedure in the sheath is explained by example of the insert. For the attachment follow the same procedure.



NOTE!

Insert insert (5) with endoscope (1) in place in sheath.

- ◇ The Albarran's lever (5.1) of insert (5) is in home position, i.e. horizontal.
- ◆ The control wheels (5.3) are horizontal, too.

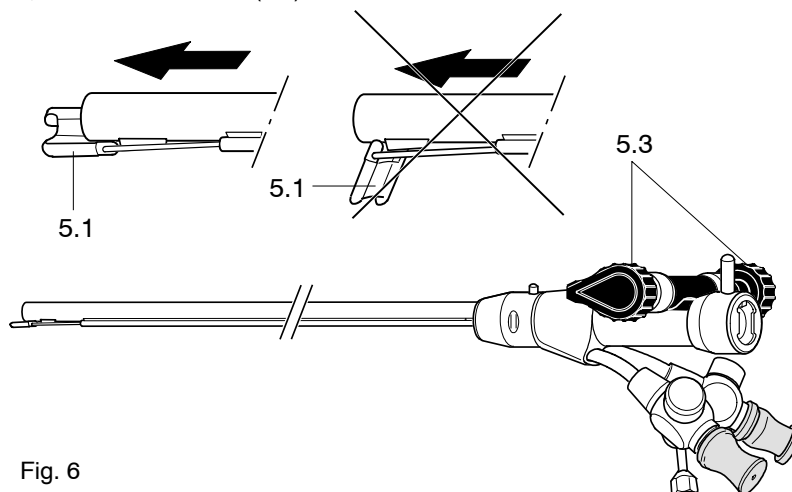


Fig. 6

- ◇ Insert insert (5) with endoscope (1) in place in sheath (2) in such a way that groove (a) and pin (f) are aligned, and push together until the connection is locked automatically. (Fig. 7)

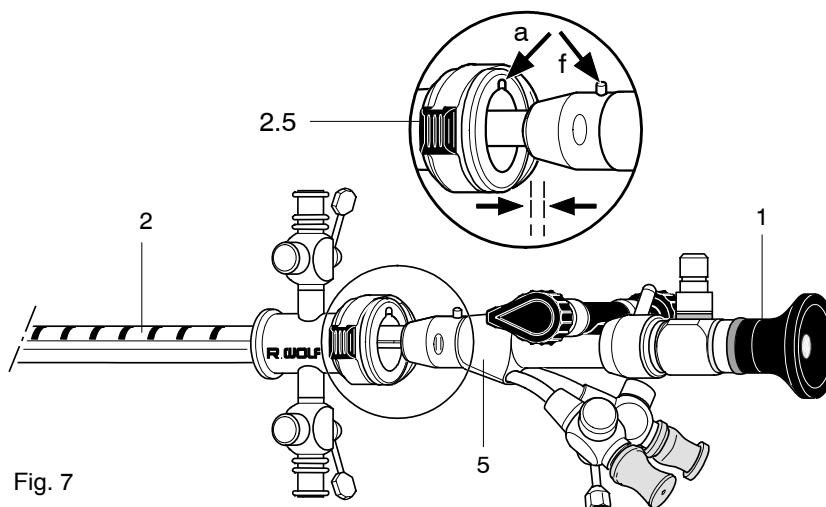


Fig. 7



NOTE!

If the connection is not locked automatically, push slide (2.5) as far as it will go and repeat the procedure. (Fig. 8)

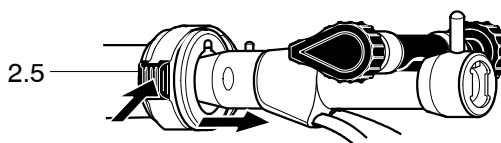


Fig. 8

- ◇ Connect the irrigation and drain tubes to the irrigation stopcock (2.2) and the drain stopcock (2.6). (Fig. 9)
- ◇ Connect a suitable flexible light cable and connect the other end to a suitable light source. (Fig. 9)
- ◇ Perform a functional check (section 7.2)

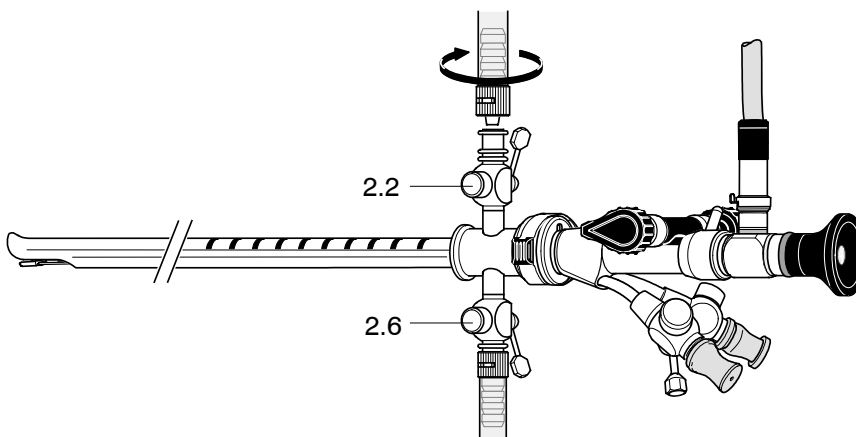


Fig. 9

6.2 Additional instructions for use

6.2.1 Introducing auxiliary instruments

Flexible auxiliary instruments can be used up to the size of the passage (see indication on sheath and in chapter 4) and with a working length of at least 320 mm (Fig. 10)

- ◇ Insertion stopcock (5.6) is open.
- ◇ The Albarran's lever (5.1) is in home position, i.e. horizontal.
 - ◆ The control wheels (5.3) are horizontal, too.
- ◇ Make sure the auxiliary instruments are closed when you insert them through the instrument port (5.6).
- ◇ Turning the control wheels (5.3) moves the Albarran's lever and controls the auxiliary instrument.

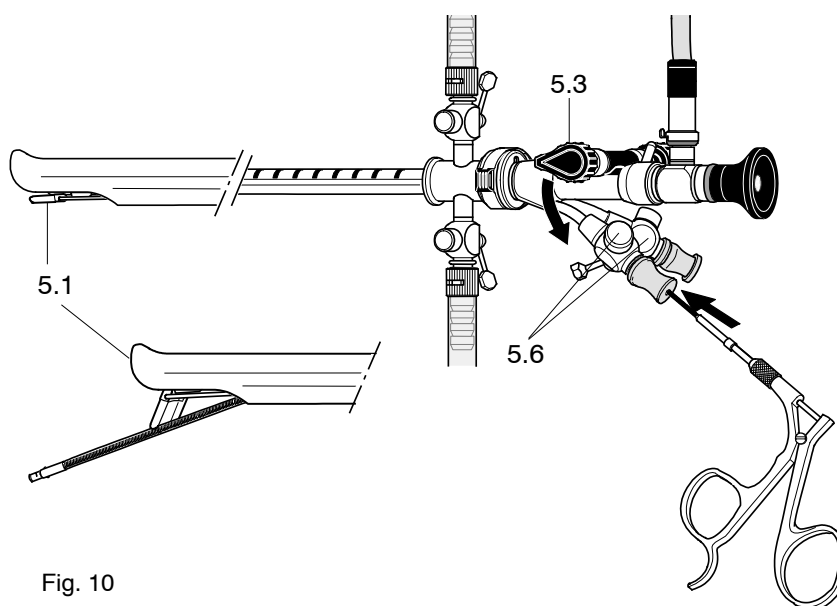


Fig. 10

6.2.2 Current



WARNING!

Danger of electric shock!

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

You should ensure that the combinations do not exceed the authorized patient leakage currents.

6.2.3 HF application



CAUTION!

Follow instructions on HF application (GA-S 002), as well as the HF-device manufacturer's instructions.

For the power specifications of the HF instruments in the cutting/coagulation modes please see the corresponding instruction manuals.



WARNING!

Explosion hazard!

Never activate an HF instrument when the instrument is in an air or gas bubble (e.g. in the bladder).

Activate HF instruments only when they are visible through the scope and are in contact with the tissue.



CAUTION!

HF sparking!

Insufficient distance between live HF parts and other conductive parts can cause tissue damage and may also damage the instrument.

Life parts of HF instruments must be kept at a minimum distance of at least 10 mm from the distal end of the sheath when activated. (Fig. 11)

In case of unintentional HF sparking, replace HF instrument immediately, check Cystoscope for damage and return for repair if necessary.

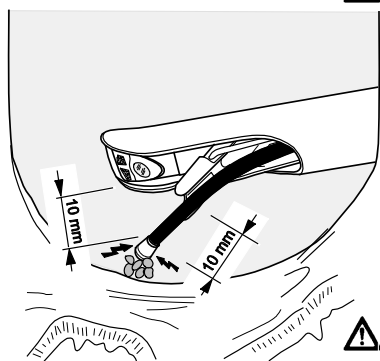


Fig. 11



CAUTION!

The depth effect (necrosis) is approx. 0.5 mm - 2 mm depending on the power setting/mode of the HF instrument used.

It is therefore necessary to be careful in the area of the sphincter and work with the lowest possible HF power. Never start with excessively high power settings. If the remaining tissue becomes brown or black, this is an indicator that the power setting is too high.



CAUTION!

Temperature increase if irrigation fluid is missing!

Danger of damage to the mucous membrane.

Actuate HF instruments only in irrigation fluid and under continuous irrigation.

6.2.4 Laser application



CAUTION!

Use of lasers!

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

The heat generated by the laser beam may reduce the strength of parts of the instrument.

Maintain a sufficient safety distance.

Follow the laser device manufacturers notes and instructions as well as the general regulations on the use of laser devices.



CAUTION!

Danger of eye injuries!

When using lasers, use a suitable filter attachment on the eyepiece of the endoscope and suitable personal protection gear.



CAUTION!

Danger of unintentional tissue damage, damage to the distal end of the endoscope and parts of the instrument using lasers!

Activate laser only when the tip of the laser fiber is visible through the scope and is directed at the tissue to be treated.

Follow the laser device manufacturer's instructions as well as the general regulations on the use of laser devices.

7 Checks



CAUTION!

Be careful If products are damaged or incomplete.

Possible injury of patient, user or third persons.

Run through the checks before and after each use.

Do not use products which are damaged or incomplete or have loose parts.

Return damaged products together with loose parts for repair.

Do not attempt to do any repairs yourself.

7.1 Visual check

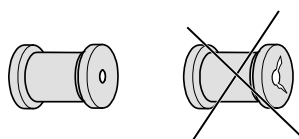


Fig. 12

- ◇ Before and after each use check instruments and accessories for damage, sharp edges, loose or missing parts and rough surfaces.
- ◇ Any lettering, labelling and identification necessary for the safe intended use must be legible.
 - ◆ Missing or illegible lettering, labelling and identifications which may lead to wrong handling or reprocessing must be restored or the parts discarded.
- ◇ Check all connection cables, tubes and connectors for damage.
- ◇ Replace damaged and brittle rubber caps (Fig. 12).

7.2 Function check

- ◇ Check the individual instruments for easy assembly and easy operation of the locking mechanisms.
 - ◆ Replace instruments if the connection loosens even though it was locked.
 - ◆ Replace instruments if the connection cannot be locked or is very difficult to lock.
- ◇ Check image quality.
- ◇ Check deflection of Albarran's lever (5.1) (Fig. 13).
 - ◆ The Albarran lever (5.1) is deflected by turning the control wheels (5.3).

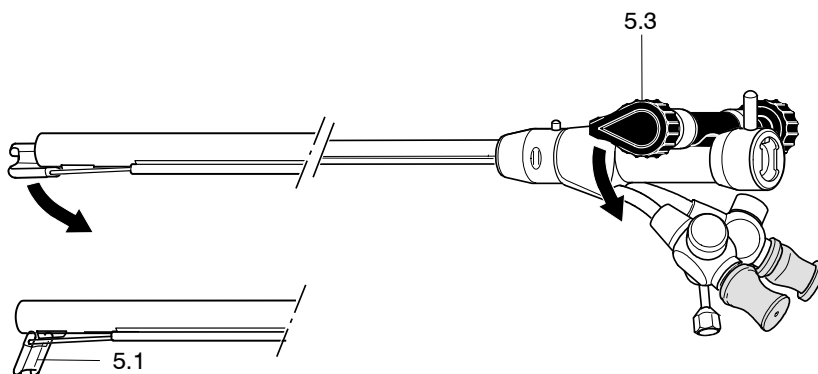


Fig. 13

8 Reprocessing and maintenance



IMPORTANT!

Follow the current **"Notes and instructions on the reprocessing of R. Wolf products, accessories and devices"**, order no.: GA-J 020.

Do not use disinfectants containing peracetic acid without corrosion protection agents, phenols or chlorine components for the reprocessing of R. Wolf products.

Do not exceed the maximum exposure time specified by the manufacturer of the disinfectants used.

8.1 Manual reprocessing

- ◇ Wet preparation at the point of use
- ◇ Disassembly before cleaning
 - ◆ Remove sealing cap (5.7) (Fig. 14).

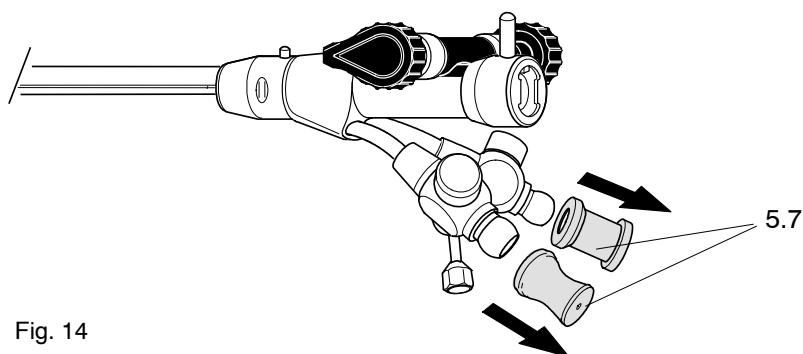


Fig. 14

- ◇ Manual cleaning with approved enzymatic cleaner.

8.2 Machine reprocessing

- ◇ Dry preparation at the point of use
- ◇ Disassembly before cleaning: section 8.1
- ◇ Machine cleaning with approved enzymatic cleaner.

8.3 Checks

- ◇ see chapter 7

8.4 Sterilization

- ◇ Before sterilization, oil joint of Albarran's lever (5.1) (Fig. 15)

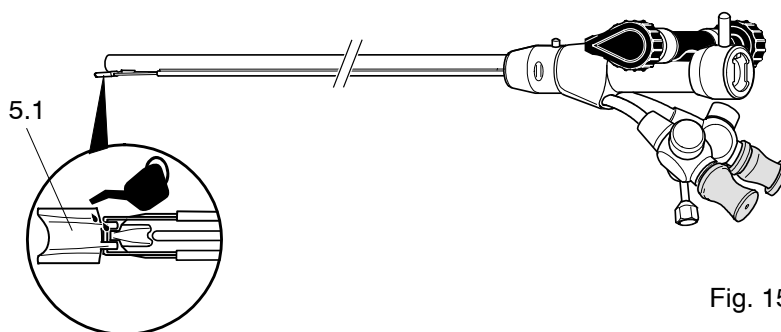


Fig. 15

8.5 Sterilization

8.5.1 Steam sterilization

- ◇ Steam sterilization at 132°C (270°F) using a Pre-Vac process/cycle at an exposure time of 4 minutes with 20 minutes dry time.



8.5.2 Gas sterilization

- ◇ Gas sterilization using ethylene oxide (EtO).

9 Technical data and order data

See chapter: 4.1 "Overview of Cysto- Urethroscope 8650.xxx
4.2 "Overview of Urethro- Cystoscope 8652.xxx
4.3 "Overview of small- calibre Cysto- Urethroscope 8860.xxx"

10 Spear parts and accessories

| Illustration | Order no. | Designation, Technical data |
|---|-----------|---|
|  | 88.01 | Rubber cap, red- orange for auxiliary instruments up to Fr. |
| | 88.02 | Rubber cap, sky blue for auxiliary instruments from 8 to 10 Fr. |
| | 88.04 | Rubber cap, fern green for 5 mm instruments. |
|  | 886.00 | Luer lock tube connector |

The products can be combined as required provided the relevant technical data and intended use is observed. For the general overview please refer to the current catalogue sheets and brochures or contact Richard Wolf GmbH or your Wolf 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 avoid damage during the transport or shipment of the products, we recommend using the original packaging material.

11.1 Disposal of the product, packaging material and accessories

For the disposal follow the relevant regulations and laws valid in your country.
➤ 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.