Instructions for use

Microplates and screws for single-use

VigoMed Medizintechnik GmbH
Bayernstrasse 38
97204 Höchberg
Germany
Tel.: +49 (0)931 4606703
Fax: +49 (0)931 4606704
E-mail: info@vigomed.de

Product group ideFixx LP and ULP implant system

EMDN P09120503
Osteosynthesis Screw-Plate System

BASIC-UDI-DI 42507865IFPSPK

CE 0483

With the purchase of these ideFixx bone implants, you are receiving high-quality products whose proper handling and use are described below.
Only proper handling enables optimal results. To ensure this, the following instructions for use and safety must be observed. Incorrect use can cause harm to patients, premature wear and tear and destruction of the product, as well as danger to the user, patient or third parties.

The Summary report on safety and clinical performance (SSCP) is available at the following link (after activation):
https://ec.europa.eu/tools/eudamed.
Notice:
The SSCP can be accessed on the VigoMed website www.vigomed.de under brochure downloads.

Qualification of the user
ideFixx bone implants are designed only for qualified doctors with sufficient experience in the field of neurosurgery.
Therefore, the procedures for neurosurgery are not explained in this instruction manual.

ideFixx bone implants may only be inserted by appropriately trained and qualified professionals.

Intended use / indication
Indicated for cranial osteosynthesis including:
- Revision procedures (reduction of the bone flap after a craniotomy)
- Reconstruction procedures (treatment of craniofacial bone defects, cranioplasties)

The attending physician is responsible for the selection of implants for specific applications or surgical use.
See the package label for product specific information.

The products must not be combined with products from other manufacturers!
ideFixx bone implants and instruments are designed and manufactured for common use. No component of the system should be replaced by another manufacturer's product, even if the product appears to be comparable or identical. The use of other manufacturers' products in combination may result in incalculable risks and/or contamination. The implant and instrument do not fit together, which could endanger the patient, user or third parties.
ideFixx bone screws with cross recess can be combined with the following screwdrivers from VigoMed GmbH:

Article number	Article designation	Product description
KS-5100	ideFixx KS screwdriver blade	ideFixx CR blade

Complications
Occurring risks / complications are usually not directly related to the implant. Incorrect selection, insufficient training/qualification and incorrect placement of the implant are often the cause.
Furthermore, certain risks and complications may arise during any surgical procedure. These are listed below.

Contraindications
- Active infections
- Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation
- Patients with limited blood supply, insufficient quantity or quality of bone, or latent infection
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions

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Risks / complications during treatment

- Insufficient fusion of the fracture
- Deep and/or superficial infections
- Vascular diseases such as thrombophlebitis, pulmonary embolism, haematomas and non-vascular necrosis
- Increased fibrous tissue around the implant site
- Nerve damage as a result of the surgical procedure
- Fractures
- Wound infections
- Secondary Bleeding
- Risk of loosening of the implants
- Infection of the Bone
- Circulatory disorder

MRI information

The ideFixx products are made of titanium (Ti2) or a titanium alloy (TiAl6V4). Both materials are non-ferromagnetic.

Non-clinical tests have shown that ideFixx bone implants are conditionally MR safe. Safe scanning of patients with this implant is possible in an MR system that meets the following conditions:

- Static magnetic field of 1.5 tesla (1.5 T) or 3.0 tesla (3.0 T)
- Maximum spatial gradient magnetic field of40 T/m (4,000 Gauss/cm)
- Head SAR: Maximum specific absorption rate (SAR) output and averaged by the MR system of < 2 W/kg (normal operating mode) at 1.5 T and 3.0 T
  Thoracic SAR: Maximum specific absorption rate (SAR) output and averaged by the MR system of < 1 W/kg (normal operating mode) at 1.5 T and 3.0 T
  If the nearest part of the implant is more than 30 cm from the isocenter, the control mode is allowed up to the first level.

No gradient-induced heating of more than 1°C was detected for the given implants and clinically relevant sequences.
It is likely that minor artifacts may occur in clinical MR protocols.

Application / Use

ideFixx bone implants are intended for single use.

ideFixx bone implants require careful handling / storage.

The products must never be bent or deformed, as this may cause damage or breakage and thus become a danger to the patient or user.

Only use technically flawless products. The perfect condition of each product must be ensured before each use.

Store sterile ideFixx bone implants in the unopened original packaging in a dry place.
Storage: + 7°C to + 35°C, 10% to 90% relative humidity

Do not use after the expiry date.

Store non-sterile ideFixx bone implants in a clean and dry environment.
The storage period of non-sterile products is not limited. The products are made of non-degradable material, so there is no loss of stability due to storage under the recommended conditions.

Cleaning and sterilisation

ideFixx bone implants are supplied sterile or non-sterile. Details are given on the pack label.

Non-sterile ideFixx bone implants must be cleaned and sterilised according to the following instructions.

IdeFixx bone implants supplied sterile can be reprocessed according to the following specification if they become non-sterile during surgery and have not yet been modified, have not yet been implanted and have not come into contact with body fluids, bone, etc.

The number of reprocessing cycles is limited to a maximum of 20 cycles.

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For patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants of this disease, the respective valid national regulations regarding the reprocessing of instruments must be applied.

The clinical reprocessing instructions listed below were reviewed. They comply with the requirements of the international standard DIN/EN/ISO 17664 and are designed for the forwarding of information for the reprocessing of non-sterile medical devices trip. The recommendations of the RKI (Robert Koch Institute) and the AKI (Instrument Reprocessing Working Group) must be observed.

Manual cleaning

- Prepare a fresh, clean cleaning solution according to the manufacturer's instructions (cleaning medium)
- Clean products carefully by hand
- Thoroughly rinse products (deionised water)
- Dry with a clean cloth (lint-free) (or with cleaned compressed air)

Machine cleaning (recommended method):

Pre-cleaning:	1 minute of cleaning with cold tap water
Cleaning:	5 minutes with detergent and warm tap water (55°C, +/- 5°C) (Neodisher® MediClean forte, 0.5% solution)
Neutralisation:	Rinse with warm tap water for 2 minutes with the addition of a neutralising agent (Neodisher® Z)
Rinsing:	Rinse with deionised water for at least 1 minute
Thermal disinfection:	Recommended: A0 value of 3000 according to EN ISO 15883-1, Annex A (e.g. A0 3000 = 5 minutes at 90 °C)
Drying:	30 minutes at 60°C (± 5°C)

Adequate drying must be ensured by the washer-disinfector or by other suitable measures. When removing products, check for contamination and re-clean if necessary.

Sterilisation (recommended method):

Only steam is permitted as the sterilisation medium. This must be able to come into contact with all parts of the products to ensure complete sterilisation. Sterilise the products according to the general hospital procedures for steam sterilisation. Pack each product in packaging suitable for sterilisation.

Method:	Steam sterilisation, fractionated vacuum, 2 pre-vacuum stages
Time:	5 minutes
Temperature:	134°C
Drying:	10 minutes

After completing steam sterilisation, allow the products to cool to room temperature (approx. 20°C) before opening the sterilisation packaging. Accelerated cooling is not permitted and can lead to damage / impairment.

Disposal

After use, the products must be disposed of properly.
Medical devices and their accessories may pose a potential biological hazard after use. The products used and their accessories must therefore be handled and disposed of in accordance with recognised medical procedures and in compliance with the relevant statutory regulations and local provisions.

Warranty

VigoMed GmbH is only responsible for ensuring that each individual product has been manufactured, inspected and packaged with the greatest possible care. Since VigoMed GmbH has no influence or control over indications and/or applications, VigoMed GmbH cannot be held responsible for complications or the failure of an application. The VigoMed GmbH individual products and sets are compatible with each other. Nevertheless, the user is requested to ensure the compatibility of the products with each other before use. This shall apply in particular if the user
users VigoMed products in conjunction with products from other manufacturers. Employees of VigoMed GmbH are not authorised to amend the aforementioned conditions or to extend liability or to enter into additional product-related obligations.

Repair

The repair of ideFixx bone implants is NOT intended, as this may affect the operational safety of the products and result in a potential hazard for patients.
All products are correctly prepared ex works for their later use. Therefore, any manipulation such as readjustment or re-bending is strictly prohibited, as this may impair the operational safety of the products and result in a potential hazard for users as well as patients.

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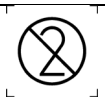
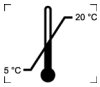
Procedure in case of serious adverse events

All serious adverse events occurred in connection with the device have to be reported to the manufacturer and the national competent authority.

Symbols for instructions for use and packaging / label

Icon	Explanation	Icon	Explanation
	Note the instruction manual		Manufacturer
	Batch code		CE mark and identification number
	Do not reuse		Attention
	Not sterile		Radiation sterilised
	Do not use if packaging is damaged		Temperature limit (+7 to +35°C)
	Store in a dry place		Protect from sunlight
	Article number		Use by
	Date of manufacture		Medical product
	Sterile packaging		Sterile barrier system with an additional inner packaging layer
	Non-sterile protective packaging with internal sterile barrier system	R_x only	Only for provision and use on the instructions of a registered medical practitioner and under the supervision of a medical practitioner