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EN INSTRUCTION FOR USE FOR STERILE MEDICAL DEVICES

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ENGLISH (non USA)

THE INFORMATION BELOW SHOULD HELP WITH USING OF I.T.S. GMBH MEDICAL DEVICES.

Scope
This instruction leaflet refers to all supplied sterile medical devices from I.T.S. GmbH. The term medical device is summarized below for the following products:
- Implant
- Instrument

The products are only mentioned by name, when the procedure differs.

IMPORTANT INDICATIONS FOR SURGEONS AND SURGICAL STAFF
Detailed information for the identification of the medical device (such as system classification, art. no., material) can be found in the product identification code and/ or on the packaging label. As a general rule, the user must be informed in detail about the intended applications, combination possibilities and correct handling before using the medical devices and must be qualified by appropriate training. Changes to product systems can also affect the compatibility of certain medical devices with each other. Before the user uses the I.T.S. GmbH medical device, all available documents must be read carefully. Detailed user information can be found in the respective surgical instructions.

Intended purpose
The implant and the needed instruments temporarily stabilises bone segments until bony consolidation has taken place. After this, the implant has no more use and can be removed. The surgeon in charge decides when to explant the implant. I.T.S. GmbH recommends the explantation of the implant after full bone recovery – as far as it is possible and applicable for the individual patient. Detailed user information can be found in the respective surgical instructions.

Indications and Contraindications
Indications and contra-indications are determined by current medical practice. Indications and contraindications of each Implant can be gathered from the respective surgical instructions.

Patient target group
The target group comprises persons whose condition corresponds to the indications of one of the systems distributed by I.T.S. GmbH - taking into account the contraindications.

Designated users
The intended users are limited to medical personnel with appropriate product training by the medical product consultants or knowledge of the surgical procedure to be applied.
The medical staff must ensure that the use of I.T.S. GmbH medical devices is appropriate, taking into account the medical condition and medical history of the patient.

Used material
Plates and Screws: commercially available, pure titanium (CP) or Ti6Al4V-alloy (according to ASTM F67/DIN ISO 5832-2, ASTM FI36/ DIN ISO 5832-3) – Nails: Ti6Al4V-alloy or implant steel (according to ASTM FI36/DIN ISO 5832-3, DIN ISO 5832-I). Furthermore, all implants are non-corrosive, non-toxic in the biological environment, biocompatible and enable X-ray and CT imaging practically free of artifacts.

Side Effects of the Implant
- Implant failure due to wrong implant selection and/or overloading of the implant
- Allergic reactions due to material incompatibility
- Delayed healing due to vascular defect
- Pain caused by the implant

Allergic reactions to steel implants cannot be ruled out.

Warnings and Preventive Measures
- Pay attention to the instructions on the packaging.
- Medical devices are for single use.
- Always treat medical devices carefully to avoid surface damage or geometric alterations.
- Any alterations to the design of medical devices from I.T.S. GmbH are prohibited.
- Regular postoperative follow-up examinations (e.g. X-ray check-ups) are to be carried out.
- For metallurgical, mechanical and design reasons, never combine medical devices from different manufacturers. The materials used are stated in the product catalogue or on the label. I.T.S. GmbH assumes no liability for possible complications resulting from the combination of I.T.S. GmbH medical devices with implants/ instruments from other manufacturers.
- The length, angle and right or left version of a particular type of implant can differ.
- The precise positioning and fastening of a properly made connection between the implant and instrument must be repeatedly checked during the course of an operation.
- Medical devices marked with the Symbol ② on the label are for single use and thus, must not be reused.
- Implants that have been inserted and removed from a patient must be disposed of according to local requirements. They must not be reprocessed, as the reuse of disposable products creates a risk of contamination, for example through the transmission of germs from patient to patient. This may result in injury and/or illness of the patient and/or user.
- Staff who come into contact with contaminated or potentially contaminated medical products should follow the generally recognised preventive measures. Due care is to be taken when handling medical products with sharp points or edges.
- Appropriate protective measures must be taken to ensure safe handling when dealing with contaminated or potentially contaminated medical products (e.g. gloves, etc.)
- In countries with stricter safety requirements regarding recycling medical products, these safety requirements apply and are to be adhered to.
- Excessive shaping / deformation, notching or scratching of the implant should be avoided, as it can lead to damage to the surface or even failure of the medical device.
- Placing excessive strain too early where the product was implanted can lead to symptoms of fatigue or even failure of the medical device. Therefore, the medical staff must inform the patient about postoperative behavior.

MRI Safety Information

MR

Non-clinical testing has demonstrated that I.T.S. GmbH implantable medical devices - except „flexible children nail" are MR conditional.
Note: Significant SAR restrictions apply.

Parameter	Condition of Use / Information
Static Magnetic Field Strength (B_0)	1.5 T, 3 T
Static Magnetic Field (B_0) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient (SFG)	30 T/m (3000 G/cm)
RF Polarization (Note: formerly called RF Excitation)	1.5 T: Circularly Polarized (CP) 3 T: Circularly Polarized (CP)
RF Transmit Coil	Integrated Whole Body Transmit RF coil
RF Receive Coil	Any receive RF coil may be used
MR System (RF) Operating Modes or Constraints	"Normal Operating Mode"
Whole Body Averaged SAR	≤ 2 W/kg
Head SAR	≤ 3.2 W/kg
Patient Position in Scanner	Supine
Scan Duration and Wait Time & Anatomy at Isocenter	Scan for 15 minutes of continuous RF exposure with one or more MR imaging pulse sequences (scans or series) Scan Regions: 1.5 T: Place isocenter at least 30cm from the implant 3 T: Place isocenter at least 22.5cm from the implant Or Scan for 1 hour of continuous RF exposure with one or more MR imaging pulse sequences (scans or series) Scan Regions: 1.5 T: Place isocenter at least 35cm from the implant 3 T: Place isocenter at least 30cm from the implant
MR Image Artifact	The presence of the item may produce an MR image artifact. Imaging protocol modifications may be necessary to compensate for the MR image artifact.

Patient Information
Implantation has consequences for the discomfort, mobility and general life circumstances of the patient. For this reason, the necessity and the importance of reporting negative changes in the area of the implant as well as any falls and accidents which may appear not to have damaged the implant or the site of the operation should be explained to the patient. Patients who are not able to follow the surgeons instructions due to a mental or neuromuscular disorder should note that the risk of postoperative complications (e. g. B. implant failure) is higher.

Package and Sterilisation
The medical device is supplied in a sterile condition. Please find the used sterilisation process on the label. Before usage, always verify that the packaging did not suffer any damage, because this will compromise the item's sterility, and check out the expiry date (year-month) printed on the label. In the case of not warranted sterility, please contact the manufacturer or return the implant. The manufacturer cannot guarantee sterility if the package seal is broken or if the package is improperly opened, and assumes no liability in such instances.

Storage
The sterile medical devices must be stored in a dry and dust-free environment. Furthermore, temperature fluctuations and high humidity should be avoided and the medical devices should be protected from direct sunlight and vermin.

Disposal
The valid guidelines of the medical institution apply for disposal.

Responsibility of the hospital for medical devices from I.T.S. GmbH
Medical devices which are returned to I.T.S. GmbH must undergo cleaning, disinfection, inspection and a final sterilization. Products returned to I.T.S. GmbH must be accompanied by a confirmation of the decontamination they were subjected to.

Important information
If you have any questions or problems, please contact the address mentioned in this manual!
All serious incidents which have occurred must be reported to the manufacturer and to the national competent authority of the country in which the user and/or patient is established.
SSCP - Report (short report on safety and clinical performance) is available on https://ec.europa.eu/tools/eudamed

Symbols

Rx	Prescription	⚠	Caution! Read instructions for use! Read information on www.its-implant.com
②	Single Use	LATEX	Latex free
LOT	Charge Number	STERILIZE	Do not re-sterilize
REF	Article Number		Do not use if package is damaged
MAT	Material Used		Manufacturer
QTY	Package Content (no. of items)		Manufacturing date (year/month/day)
	Consult instructions for use www.its-implant.com		Expiration date (year/month/day)
STERILE R	Sterilized using irridiation	MR	MR conditional
	Keep dry	MD	Medical Device
UDI	Unique Device Identifier		