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EN INSTRUCTION FOR USE FOR NON-STERILE MEDICAL DEVICES

I.T.S. GmbH
Autal 28, 8301 Lassnitzhöhe, Austria
Tel.: +43 (0) 316 / 211 21 0
Fax: +43 (0) 316 / 211 21 20
office@its-implant.com
www.its-implant.com

CE 0297

ENGLISH (non USA)

THE INFORMATION BELOW SHOULD HELP WITH USING, CLEANSING, DISINFECTION, STERILIZATION AS WELL AS WITH INSPECTION OF WEAR AND TEAR OF MEDICAL DEVICES.

Scope
This instruction leaflet refers to all supplied non-sterile implants, all reusable instruments and trays from I.T.S. GmbH. All products, including those following direct delivery, must be cleaned, disinfected and sterilized before usage.
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 medical device 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. - 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 F136/ DIN ISO 5832-3) – Nails: Ti6Al4V-alloy or implant steel (according to ASTM F136/DIN ISO 5832-3, DIN ISO 5832-1). Furthermore, all implants are non-corrosive, non-toxic in the biological environment, biocompatible and enable X-ray and CT imaging practically free of artifacts.
Instruments: stainless steel, aluminum, plastics

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.
- Medical devices that have come into direct contact with a patient's blood or other bodily fluids or that have visual contamination must be cleaned and disinfected separately before they can be put back into the appropriate container.
- Medical devices that have not come into direct contact with a patient can be reprocessed.
- 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.
- No metal brushes or abrasive cleaning materials are to be used for manual cleaning purposes. The use of these materials can lead to damage of surfaces and coatings. Instead, soft brushes made of nylon should be used.
- Steam (moist heat) is the recommended sterilization method of medical products from I.T.S. GmbH.
- All the following described steps for cleaning and sterilization are made easier when contaminants (e.g. blood) are not allowed to dry beforehand.
- Medical devices supplied non-sterile must be thoroughly reprocessed in accordance with these instructions before use. The manufacturer excludes all liability in the event of non-compliance.
- It must be ensured that the selected drilling angle remains constant during the drilling process and that there is sufficient possibility of material removal. Otherwise, an increased risk of damage or health hazards must be expected.
- 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.
- To avoid damage to the drive profile of the screwdriver, compatibility and a positive connection between the screwdriver and the screw head must be ensured.
- 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.

Restrictions
- Unless otherwise stated, repeated preparation of medical devices of I.T.S. GmbH has minimal effects when following the procedures mentioned below.
- The end of the product service life is usually determined by wear and damage caused by use why functional tests and careful inspections both before cleaning and before use are essential for determining the product's life expectancy.
- Instruments containing aluminium or anodised aluminium can be damaged by alkaline (pH value > 7) cleaning agents and solutions.

Packaging
The delivery packaging (plastic pouch/ cardbox board) of non-sterile medical devices is mere for transport purposes and is not suitable for sterilisation. The medical institution is responsible for in-house procedures regarding assembly, inspection and packaging of medical devices. Packaging is carried out in accordance with the general standard packaging guidelines of relevant standards and guidelines of specialist organisations using sterile barrier systems that conform with standards.

INSTRUCTIONS FOR PROCESSING OF NON-STERILE MEDICAL DEVICES
Preparation at the location of use
- Remove surface dirt using a disposable cloth or paper towel. Rinse out the hollow parts with aqua destillata (distilled water). Saline solution (NaCl) may only be used if processing is carried out immediately afterwards - risk of corrosion!

Transport
- It is recommended that medical products are reconditioned as soon as possible after their previous use as dried dirt adhesion makes cleaning more difficult.
- The trays used by I.T.S. GmbH are not intended to be subjected to the cleaning and disinfection process defined below when loaded. I.T.S. GmbH trays are suitable and recommended for sterilization, transport and storage.
- To avoid risks of contamination, used medical devices must be transported to the reprocessing site in a closed or covered container.
- Avoid damage to the medical devices by not placing heavy products on top of delicate products, by not allowing sharp cutting edges to damage other products or by not overfilling the transport container.

Cleaning and disinfection
Only effective cleaning of the medical devices guarantees effective disinfection/sterilization. In the following, the universal manual cleaning/disinfection is described in addition to the automated machine cleaning/disinfection. Due to the lower effectiveness of manual cleaning/disinfection, mechanical cleaning/disinfection should be the method of choice. It must be ensured that fresh solutions are always used. The following documented procedures are validated procedures of I.T.S. GmbH.

Cleaning preparation
Each instrument that can be dismantled should be dismantled for cleaning after being taken out of the tray.

Pre-cleaning
I.T.S. GmbH recommends a pre-cleaning for heavily soiled medical devices. The following points must be observed:
- The disassembled instruments are cleaned under running water.
- Visible soiling of the surface, lumens and cannulations can be removed with soft brushes.
- Movable parts can be pre-rinsed under running water by back and forth movements.
- Cannulas can be cleaned with cleaning wire, syringes and cannulas.

Alternatively, the pre-cleaning of medical devices can be carried out in an ultrasonic bath. After cleaning, the medical devices must be visually checked for contamination and the steps repeated if necessary. If cleaning is not continued immediately, dry the products with a lint-free soft textile cloth to avoid oxidation.

Automatic cleaning/disinfection (recommended)
Only a washer-disinfector (WD) that conforms to standards (in accordance with EN ISO 15883) and that is regularly maintained and inspected should be used for automatic cleaning and disinfection in accordance with the manufacturer's information.

Recommended equipment: Appropriate loading trolleys to accommodate all medical devices (e.g. instrument trolleys with MIC bar, MIC trolleys); commercially available cleaning agent authorised for use with medical devices (pH value 9-11) e.g. Neodisher® Mediclean forte by Dr. Weigert. I.T.S. GmbH recommends the following validated steps for automatic cleaning and thermal disinfection. The basic device should be a Miele PG 8536 machine. Validation is carried out in accordance with EN ISO 15883 and guideline no. 3 of the Austrian Association for Sterile Services (ÖGSV).

Phase	Water quality	Tempera-ture [°C]	Time [min]*	Dosage	
				ml/L	DT [°C]
Pre-rinsing 1	SW	cold	2	-	-
Pre-rinsing 2	SW	cold	5	-	-
Cleaning**	PW	55	10*	6	45
Rinsing	SW	50	3	-	-
Thermal disinfection	PW	90	5	-	-
Drying	-	110	15	-	-

SW: Softened water; **PW:** Purified water; **DT:** Dosage temperature
Cleaning agent: **Neodisher® Mediclean forte**
* When temperature is reached
** When using highly alkaline cleaners (e.g. a neutralization step is required for Neodisher® FA)

Step 1 Jointed instruments are to be opened so that water can flow out of cannulae and blind holes. Place cannulated medical devices onto or connect them to appropriate rinsing nozzles & rinsing adapters.
Step 2 Start the relevant cycle. Adhere to the guidelines of the WD manufacturer.
Step 3 After removing the medical devices from the disinfector, check the cannulae, blind holes, etc, for visible dirt. If required, repeat cycle or clean by hand.

Manual cleaning/disinfection
Recommended equipment: Commercially available cleaning agent authorised for medical products (pH value 9-11) or combined cleaning agent and disinfectant (e.g. Sekusept® Aktiv 2% by ECOLAB); nylon brushes with soft bristles; running water.
The following table describes the manual cleaning procedure

Accessories	Gentle automatic treatment of the medical devices using lint-free soft cloths, paper towels or soft plastic brushes.
Soaking the medical devices	Fully submerge and soak the medical devices in a suitable cleaning agent and disinfectant solution. Manufacturer's information, e.g. concerning concentration, temperature and exposure time should be followed when using all agents.
Cleaning agent/ disinfectant	Use of a cleaning agent/disinfectant from the VAH list. I.T.S. GmbH recommends Sekusept® Aktiv 2% by ECOLAB. When using powdered products, it must first be checked that the powder has dissolved completely in the water before the medical devices are added. In addition, adhere to the manufacturer's information regarding material tolerance. If applicable: the cleaning agent must be suitable for ultrasound cleaning. (Non-foaming). Do not use highly alkaline or acidic additives. Recommended pH range 4.5 - 10.5. Prepare freshly every day.
Ultrasound treatment	Treatment in an ultrasound bath is carried out for 5 minutes in the abovementioned cleaning agent/disinfectant. The medical devices are then left in the solution for 15 minutes.
Rinsing/drying of the medical devices	Remove the medical devices from the solution and rinse thoroughly with running tap water until there are no visible traces of blood or other contaminants in the rinsing water. Particular attention should be paid to lumen, openings and other areas that are not easily accessible. Rubber and flexible plastics require longer rinsing times and any dirt that remains on the instruments may have to be removed manually (no metal brushes, no abrasive cleaners). Thorough final rinsing using purified water. Dry the medical devices immediately (e.g. using a lint-free disposable cloth or pressurised air gun).

After manual cleaning, the medical devices must be visually checked for contamination and the steps repeated if necessary. If only a cleaning agent has been used for the medical devices, manual disinfection must be continued immediately afterwards.

Manual disinfection
If a cleaning agent without a disinfectant effect is used, separate disinfection must be carried out after manual cleaning. (Order: Decontamination for staff protection, cleaning, disinfection). Equipment: Commercially available disinfectant authorised for use with medical products from the VAH list, purified/high purity water for rinsing. Manufacturer's information, e.g. concerning concentration, temperature and exposure time should be followed. The steps described in the table above also apply.

Drying
I.T.S. GmbH recommends the use of lint-free soft textile cloths or a compressed air gun for drying the medical products. Not dried spots can lead to oxidation and thus to functional limitations.

Checking, Maintenance and Inspection
- Each medical device is to be inspected carefully especially with regard to joints, slots and cutting points to make sure that all visible dirt has been removed. If any ingrained dirt is found, the cleaning/disinfection cycled should be repeated.
- Any instruments with an attached movable mechanism should be treated with a commercially available lubricant authorized for sterilizable surgical instruments.
- In addition to the inspection of the contamination, a functional test of the medical devices for damage and/or wear and tear must be carried out. If such damage is detected, it must be excluded or replaced.
- In general, attention must be paid to the general condition of the medical device, corrosion, damaged surfaces, splintering, scratches, cracks, etc.
- The mobility of movable parts should be checked to ensure that the planned sequence of motion can be completely carried out.
- Rotating instruments (e. g. drills) must also be checked for bending and damage.
- In the case of instruments which can be reassembled into larger units, check whether the single parts can be put together easily.

Sterilization packaging
Medical devices must be placed at the appropriate places in the I.T.S. GmbH trays and sterilized before each surgery. I.T.S. GmbH trays must be packed for sterilization in a sterile barrier system according to ISO 11607. The relevant specifications of the medical institution must be considered.
Non-sterile medical devices must be removed from their original packaging, cleaned and disinfected.
They must then be sterilized in the adequate I.T.S. GmbH trays in a sterile barrier system. The corresponding specifications of the medical institution must be considered.
- When packing the products in the I.T.S. trays, care must be taken to avoid contact with other medical devices, especially with pointed and sharp ones.
- All medical devices should be laid out in such a way that the steam can reach all the surfaces of the medical devices.
- Each instrument that can be dismantled should be taken apart for sterilization.

Sterilization
- Carry out sterilisation of the products using the fractionated pre-vacuum procedure, in accordance with EN 285 (or EN 13060), EN ISO 17665 resp. ANSI/AAMI ST79. I.T.S. GmbH recommends the following validated methods for sterilizing medical devices:

Cycle	Pre-vacuum steam sterilization - at least 3 phases
Temperature	134°C (273°F)
Exposure time	≥ 3 min (18 min*)
Minimum drying time	20-30 min
Cool-down time	60 min

* Parameters for sterilisation with steam recommended by the World Health Organisation (WHO) for recycling medical devices if contamination with Creutzfeldt-Jakob Disease (CJD) pathogens is suspected.

Storage
The sterile medical devices must be stored in a dry and dust-free environment after sterilization. Furthermore, the medical devices should be protected from vermin. The maximum storage time for sterile products is the responsibility of the medical facility.

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

Responsibility of the hospital for medical devices from I.T.S. GmbH
- Surgical instruments generally have a long service life. But their life expectancy can be quickly reduced due to misuse or insufficient protection. Instruments which no longer work correctly, whether due to wear, misuse or improper care, must be returned to I.T.S. GmbH. Problems/damage with loaned instruments must be clarified with I.T.S. GmbH.
- Medical products 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
The above instructions have been validated by the medical device manufacturer as suitable for processing a medical device before reuse.
It is the responsibility of the preparator to ensure that processing using the equipment, materials and staff available in the preparation facility achieves the desired results. For this, validation and routine inspections of the process are necessary. Likewise, any deviation from the provided instructions by the preparator should be evaluated for its efficiency and possible negative consequences.
I.T.S. GmbH does not assume any responsibility for non-compliance with the specifications for processing defined by I.T.S. GmbH!
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 ONLY	Prescription requirement
2	Single use, not reusable
LOT	Batch number
REF	Article number
MAT	Material used
QTY	Package content (no. of items)
⚠	Caution! Read instructions for use! Read information on www.its-implant.com
	Consult instructions for use www.its-implant.com
	Latex Free
NON STERILE	Non Sterile
	Do not use if package is damaged
	Keep dry
MR	MR conditional
	Manufacturer
	Date of manufacture (year/month/day)
MD	Medical Device
UDI	Unique Device Identifier