INSTRUCTION FOR USE FOR NON-STERILE I.T.S. INS PROXIMAL FEMUR NAIL

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

ENGLISH

CAUTION: USA LAW RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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 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 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
The indications for the I.T.S. Intramedullary Nailing System (INS) - Proximal Femur include intramedullary treatment of fractures, revisions and tumour stabilisation in the area of the proximal femur, as well as combinations that additionally affect the shaft area using the long nails.

The indications for use of the I.T.S. INS Proximal Femur include:

All Nails:
- Stable and unstable pertrochanteric fractures
- Intertrochanteric fractures
- Combinations of fractures listed above

Additionally for Long Nails:
- Subtrochanteric fractures
- Proximal fractures as listed above associated with shaft fractures
- Pathological fractures in regions as listed above
- Nonunions and malunions in regions as listed above

Contraindications
Contraindications generally exist in the case of growth plates that have not yet been fused and in special constellations such as marked local inflammation. The treatment of typical medial femoral neck fractures in the elderly with intramedullary force carriers is not recommended to date in accordance with the literature. Before choosing the implant certain precautions regarding preexisting and fracture related conditions have to be taken into account As for most intramedullary implants, the I.T.S. INS Proximal Femur is designed to stabilize fractures temporarily until bony healing and therefore depends on the patient's bone quality for adequate fixation. Conditions such as compromized vascularity, excessive stresses on bone and implant such as severe obesity or degenerative diseases have to be considered as well as every interfering systemic condition such as infection, demonstrated allergy or foreign body sensivity to any of the implant materials. The decision whether to use I.T.S. INS Proximal Femur in these conditions must be made by the physician taking into account risks versus benefits.

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
Nails, Screws and Endcaps: Ti6Al4V-alloy (according to ASTM F136/DIN ISO 5832-3). 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, 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.
- Implants 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 ⊗ 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.
- Any supplied non-sterile medical products must be thoroughly prepared according to these instructions before use.
- 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.
- 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.
- 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

Non-clinical testing has demonstrated that I.T.S. GmbH implantable medical devices of the I.T.S. INS Proximal Femur Nail are MR conditional. Note: Significant SAR restrictions apply.
Magnetically Induced Torque and Displacement: Non-clinical testing in a 1.5 T and 3 T MRI system did not reveal any relevant torque or displacement of the I.T.S. INS Proximal Femur Nail at a maximum spatial gradient of 30 T/m.
Image artifacts: In non-clinical testing the image artifacts extended up to 29.8 mm from the implant with a gradient echo sequence and a 3 T MRI system.
Radio-frequency induced heating: Please note landmark restrictions below for SAR. Imaging of the patient when the device is inside the RF coil is not safe and could lead to tissue injury. Imaging may be performed safely when the end of the implanted device is at least 35cm away from the center of the RF coil. The center of the RF coil is also the location on the body where the patient is landmarked for imaging.
Maximum whole body averaged specific absorption rate (SAR) for imaging landmarks in the allowed zones: 1 W/kg for 60 minutes of continuous scanning. Maximum head SAR: 3.2 W/kg for 60 minutes of continuous scanning.

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.

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.
Trays must not be stacked within the sterilization container or sterilization wrap and in the autoclave during sterilization as doing so may negatively impact ventilation and sterilization.

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. Automated cleaning and disinfection is mandatory. 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 before cleaning/disinfection after being taken out of the tray. All sleeves must be dismantled and removed from their guides. Specifically, the master sleeve (PF Proximal Master Sleeve) must be removed from the targeting module (TPF Targeting Module 120°, 125° or 130°) by turning the locking leaver upwards. Then, the PF Tissue Protection Sleeve Superior & Inferior and the PF K-Wire Sleeve Superior & Inferior are removed from the master sleeve.

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.
- Remove visible soiling of the surface, lumens and cannulations with soft brushes.
- Pre-rinse movable parts under running water by back and forth movements.
- Clean cannulas with cleaning wire, syringes and cannulas.

The pre-cleaning of medical devices is 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
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 carts to accommodate all medical devices (e.g. instrument carts with rinsing ports); commercially available cleaning agent authorised for use with medical devices (pH value 9-11) such as Neodisher® Mediclean forte by Dr. Weigert (take note of the instructions provided by the cleaning detergent manufacturer for correct handling and use of the product). I.T.S. GmbH recommends the following validated steps for automatic cleaning and thermal disinfection. Use a legally marketed washer-disinfector (WD) with fundamentally approved efficiency (such as CE mark or FDA approval according to ISO 15883 series), properly installed, qualified and regularly subjected to maintenance and testing.

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

SW: Softened water; **CW:** Critical Water per AAMI TIR34; **DT:** Dosage temperature; **ml/L:** amount of detergent in milliliter per liter of critical water
* When temperature is reached
** take note of the instructions provided by the cleaning detergent manufacturer for correct handling and use of the product

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 and 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 cannula, blind holes, etc., for visible dirt. If required, Repeat cycle or dean by hand if dirt or visible sign of contamination is present.

Drying
I.T.S. GmbH recommends the use of lint-free soft textile cloths or a compressed air gun for drying the medical products. Moisture remaining on the device may result in malfunction or compromised function.

Checking, Maintenance and Inspection
- Each medical device has to be inspected carefully especially with regard to joints, slots and cutting points to make sure that all visible soil has been removed. If any visible soil is found, the cleaning/disinfection cycles should be repeated until no visible soil remains on the device.
- 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.
- All devices must be thoroughly cleaned and inspected prior to sterilization.

The following guidelines should be applied to all I.T.S. GmbH instruments which are labeled for multiple use.
All functional checks and inspections described below also cover the interfaces with other instruments or components.
The failure modes below may be caused by end of life of the medical device, improper use or improper maintenance.
Potential failure modes:
- Depth Gauges: broken needle, bent needle, biological residuals, discoloration, otherwise damaged - in case of failure, device must be replaced.
- Drills: cracked, blunt tip, dull cutting flutes, biological residuals, discoloration, otherwise damaged - in case of failure, device must be replaced.
- Screwdrivers: deformed, broken tip, worn tip, biological residuals, discoloration, otherwise damaged - in case of failure, device must be replaced.
- Drill guides, sleeves: deformed, bent, dents on the tip, scratches, biological residuals, discoloration, otherwise damaged - in case of failure, device must be replaced.
- Insertion guides, accessories: deformed, cracked, broken, deformed connection parts, dents, biological residuals, discoloration, otherwise damaged - in case of failure, device must be replaced.

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 wrapped for sterilization in a FDA cleared sterilization wrap. 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 an appropriate 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.
- The medical devices shall be sterilized in the mounting condition in the dedicated brackets, holders or recessions in the tray.
- Each instrument that can be dismantled should be taken apart for sterilization.

Sterilization
- Carry out sterilization 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:

	Worldwide*	**USA**
Cycle	Pre-vacuum steam sterilization	
Temperature	134°C (273°F)	132°C (270°F)
Exposure time	3 min (18 min**)	4 min
Minimum drying time	20-30 min	20-30 min
Cool-down time	60 min	60 min

* except USA
** 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, temperature fluctuations and high humidity should be avoided and the medical devices should be protected from direct sunlight and vermin. The maximum storage time for sterile products is the responsibility of the medical facility.

Functional check of the targeting device
Before the device is used ensure that the targeting module chosen (TPF Targeting Module 120°, 125° or 130°) is in compliance with the nail. Therefore, fully tighten the nail to the targeting arm with the retaining screw (PF Nail Holding Bolt) and attach the appropriate targeting module. Insert the master sleeve (PF Proximal Master Sleeve), the PF Tissue Protection Sleeve Superior & Inferior and pass the step drill (PF Step Drill Lag Screw) through the nail. If there are no interferences, the check for compliance with the femoral neck angle of the targeting device and the nail is positive.

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.

Symbols

Rx ONLY	Prescription requirement
	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
	Latex Free
NON STERILE	Non Sterile
	Do not use if package is damaged
	Keep dry
MR	MR conditional
	Manufacturer
	Date of manufacture
MD	Medical Device
UDI	Unique device identifier