INSTRUCTION FOR USE FOR 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 OF I.T.S. GMBH STERILE MEDICAL DEVICES.

Scope
This instruction leaflet refers to all supplied sterile medical devices from I.T.S. GmbH.
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 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.
- 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.

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-day) 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 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
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)
STERILE R	Sterilized using irradiation - Single sterile barrier system with protective packaging inside
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⚠	Caution! Read instructions for use! Read information on www.its-implant.com
	Consult instructions for use
	Latex Free
	Do not re-sterilize
	Do not use if package is damaged
	Keep dry
MR	MR conditional
	Manufacturer
	Manufacturing date (year/month/day)
	Expiration date (year/month/day)
MD	Medical Device
UDI	Unique device identifier