INSTRUCTION FOR USE FOR NON-STERILE I.T.S. PLATES, SCREWS, NAILS

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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 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 producttypes:
- Implant
- Instrument

Implant and instrument are only mentioned explicitly, 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.

Selection of suitable implants, duration of use
As the manufacturer, I.T.S. GmbH does not recommend a specific surgical procedure for a specific patient.
The operating surgeon is responsible for selecting the appropriate implant for the surgery.
The decision to leave the implant in place or remove it at a later date, as well as the aftercare treatment are the responsibility of the surgeon. As a rule, implants are designed to remain in place temporarily and can be removed once the bone has healed sufficiently. Implants are not intended as long-term bone replacement for intact bone material. Adequate postoperative adaptive or exercise-stable relief (e.g. splinting and/or immobilisation) must be provided, taking into account the fracture situation and the patient's willingness/ability to cooperate.
The fixation achieved by I.T.S. GmbH implants must be treated gently postoperatively until healing is complete. The surgeons post-operative care instructions must be strictly adhered to in order to avoid detrimental stress on the implant. Early load-bearing can lead to loosening, bending or fracture of the implant.

Indications
Clavicle Plates
The I.T.S. Clavicle Plates with Angular Stability is a titanium implant fracture fixation system for repairing fractures located from the middle third to the distal third of the clavicle. Indications for Use include metaphyseal and diaphyseal fracture fixation of acute fractures, malunions, and non-unions of the clavicle. Other indications include corrective osteotomy and open and closed fractures. All fractures of the clavicle in metaphyseal and diaphyseal areas. Hygienisaton of pseudo-arthroses with or without spongiosal graft. Corrective osteotomy. Open and closed fractures

Proximal Humeral Plates
The I.T.S. Humeral Head Plates with Angular Stability is a titanium implant fracture fixation system for stabilizing fractures of the proximal humerus in the shoulder. Indications for Use include fracture and fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone. All stable and unstable humerus fractures with or without shaft involvement. Fractures of the greater or lesser tuberosities. Repair of the greater tuberosity following prior fixation failure or tuberosity "escape". Delayed or nonunion of the proximal humerus. Fixation following osteotomy of proximal humeral malunion. Displaced two, three and four part fracture of the proximal humerus. Displaced anterior and posterior fractures of the proximal humerus and greater tuberosity. Nonunion of two, three and four part fractures of the proximal humerus. Nonunion of anterior and posterior fracture-dislocations of the proximal humerus and greater tuberosity. Dislocated, unstable 2, 3 and 4-segment fractures of the humeral head. Valgus-impacted 4-segment fractures of the humeral head. Non-union of the humeral head

Distal Humeral Plates
The I.T.S. Distal Humeral Plates with Angular Stability is a titanium implant fracture fixation system for stabilizing fractures of the distal humerus in the elbow of a pediatric or adult patient. Indications for Use include intra-articular fractures, supracondylar fractures, osteotomies, and non-unions of the distal humerus. Supra- & diacondylar upper-arm fractures

Olecranon Plates
The I.T.S. Olecranon Plates with Angular Stability is a titanium implant fracture fixation system for stabilizing fractures of the proximal ulna (olecranon) in the elbow. Indications for Use include fixation of complex intra- and extraarticular fractures, osteotomies, nonunions, malunions, Type I, 2, 3, & 4 simple fractures, and Type 5a, 5b, 5c, & 6 complex fractures (comminuted) of the proximal ulna (olecranon). All fractures of the olecranon

Straight Plates
The intended use of the I.T.S. Straight Plates with Angular Stability is to stabilize an osteotomy or fracture of small bones, long bones, the pelvis and the calcaneus in an adult or pediatric patient. Indications for use include communted fractures, supracondylar fractures, intra-articular and extra-articular condylar fractures, fractures in osteopenic bone, non-unions, and mal-unions, as well, a fracture or osteotomy of the tibia, fibula, femoral condyle, acetabulum, humerus, ulna, middle hand and middle foot bones. Treatment of the calcaneal; hip arthrodesis, and provisional hole fixation.

Distal Radius Plates
The I.T.S. Volar Radius Plates with Angular Stability is a titanium implant fracture fixation system for distal radius fractures of the wrist. Indications for Use include comminuted extra and intra-articular distal radius fractures, failed original fracture fixation, osteotomy and repair of a distal radius malunion, and comminuted volar shearing fractures. Complex intra-articular fractures of the distal radius. Complex extra-articular fractures of the distal radius. Osteotomies of the distal radius

Distal Ulna Plates
The Indications for Use of the I.T.S. GmbH - Distal Ulna Locking (DUL) Plate Systems is to stabilize fractures in the long bone of the distal ulna of an adult patient. Fractures of the ulnar head. Multifragmentary fracture of the ulnar head. Subcapital fractures of the ulnar head. Metaphyseal comminuted fractures of the distal ulna. Combined ulnar head and ulnar shaft fractures

Ulna Osteotomy Plates
The Indications for Use of the I.T.S. GmbH - Ulna Osteotomy Locking (UOL) Plate Systems is to stabilize osteotomies in the long bone of the mid-ulna of an adult patient. Impaction syndrome of the ulnar wrist. Symptomatic, post-traumatic ulnar malposition in the distal radio-ulnar joint (DRUJ). Degenrerative ulnar wrist. Correction of the ulnar positive relative to the unaffected other side up to a maximum of 6mm in one step or 13mm in two steps

Hand Plates
The I.T.S. Hand Locking Plate System -HLS is indicated for use in fracture fixation of: The phalanges, The metacarpal bones, The carpal bones, For arthrodesis, For corrective osteotomies and For subcapital radial head fractures

Pelvic Plates
Indications for use of the I.T.S. Pelvic Reconstruktion System (PRS Phoenix) include: Fractures involving the Posterior Wall & Posterior Column, Fractures involving the Anterior Column of the Acetabulum, Fractures involving the Quadrilateral Surface, Symphyseal Disruptions & Para-symphseal Fractures, Fractures of the ilium, Fractures of the SIJ, Dorsal neutralization plating for posterior pelvic ring fractures, Osteotomies, arthrodesis and sacroiliac joint dislocations, Revision surgery of pseudoarthroses, non-unions and mal unions

Sacral Rods
Indications for use of the I.T.S. PRS Sacral Rod System include fixation of fractures of the posterior pelvis, fixation of fractures of the posterior iliac spine, fixation of fractures of the posterior inferior iliac spine, dorsal stabilization of the posterior pelvic ring for unstable pelvic ring injuries, fixation of sacral fractures, and fracture dislocations of the sacro-iliac joint.

Distal Femur Plates
The I.T.S. LRS Locking Reconstruction System is a titanium implant fracture fixation system for stabilizing fractures in long bones of the distal femur of all pediatric patients (less than or equal to 21 years old) or adult patient. Indications for Use include distal shaft fractures, supracondylar fractures, intra-articular fractures, metaphyseal fractures, osteotomies, nonunions and malunions of the distal femur.

Proximal Tibia Plates
The I.T.S. LRS Locking Reconstruction System is a titanium implant fracture fixation system for stabilizing fractures in long bones of the proximal lateral tibia of all pediatric patients (less than or equal to 21 years old) or adult patient. Indications for Use include proximal shaft fractures, supracondylar fractures, intra-articular fractures, metaphyseal fractures, osteotomies, nonunions and malunions of the proximal tibia.

Tibia Nails
The I.T.S. CTN – Cannulated Tibia Nail System is indicated for use in long bone tibia fracture fixation which include:
Proximal, metaphyseal, epiphyseal and distal shaft fractures; Segmental, simple, compound and comminuted fractures; Transverse, oblique and spiral fractures; Surgically created defects using osteotomies, such as for leg length discrepancies or deformity; Pathologic fractures; Pseudoarthrosis, non-union, mal-union and delayed union of the tibia; Fractures involving osteopenic and osteoporotic bone; Open fractures of the tibia and; Reconstruction of the tibia after tumor resection and/or bone loss.

Pilon Plates
The I.T.S. Pilon Plates with Angular Stability is a titanium implant fracture fixation system for stabilizing fractures of the distal tibia in the leg. Indications for Use include fixation of complex intra- and extraarticular fractures, osteotomies, high medial malleollar fractures, and low boot top type rotational distal extra-articular shaft fractures of the distal tibia. Fractures of the tibial pilon of AO classification A3, especially groups C2 and C3

Fibula Plates
The I.T.S. Fibula Plate PROlock with Angular Stability is a titanium implant fracture fixation system for repairing bone fractures located from the middle to the distal third of the fibula. Indications for Use include metaphyseal and diaphyseal fracture fixation of acute fractures, mal-unions, and non-unions of the distal fibula. Other indications include corrective osteotomy and open and closed fractures. Dislocated ankle-fractures group B+C according to Weber (with or without comminuted zones)

Calcaneus Plates
The I.T.S. F.R.O.H. Calcaneus Repair System is a titanium implant fracture fixation system for repairing fractures located in the calcaneus heel bone of the foot. Indications for Use include: Intra and extra-articular fracture(s) of the calcaneus, corrective osteotomy, joint depression, non-displaced and tongue type, severely comminuted fractures, multifragmentary fractures, revision procedures, joint fusion, stabilization and fixation of fresh fractures, reconstruction of the calcaneus bones, and open and closed fractures of the calcaneus. The system can be used in both adult and pediatric patients. Complex Fractures of the Calcaneus. All intra-articular fractures with relevant joint distortion and comminution zone in which a semi-operative procedure (screws, drill wires) does not raise expectations of exact repositioning. Fractures of the sustentaculum tali

Foot Plates
The I.T.S. FLS Foot Locking Plate System is indication for use in internal fixation, reconstruction or athrodesis of small bones including the fore, mid and hind foot and ankle. Examples of these procederes may included but are not limited to replantation, lag srew techniques, joint fusions, corrective osteotomies, and treatment of fracture. Metatarsal fractures. TMT I-V Arthrodesis, MTP I-V Arthrodesis, TN, CC Arthrodesis, Corrective Osteotomies

Hallux Osteotomy Plates
The I.T.S. HOL - Hallux Osteotomy Locking Plate System is Indicated for use as an intramedullary self-locking plate for distal metatarsal osteotomies and for Hallux Valgus osteotomies up to a corrective angle of 25°. Intramedullary, self locking plate for distal metatarsal osteotomies. Hallux Valgus osteotomies up to a corrective angle of 25°

Twist-Off Screws
The I.T.S. Twist-Off Screw System is indicated for use for small bone fixation of bone fractures or for bone reconstruction. Examples include small bone fragments, Weil- Osteotomy, Mono-Cortical fixation, Osteotomies and fractures fixation in the foot and hand. For treatment of fractures, corrective osteotomies, arthrodesis and degenerative transformations of small bones

Headless Compression Screws
The I.T.S. HCS - Headless Compression Screw System for sizes of 3.5mm or smaller is indicated for use in fixation small bone fractures or for small bone reconstruction including: mono or bicorlical osteotomies in the foot or hand; distal or proximal metatarsal or metacarpal osteotomies; weil osteotomy; fusion of the first metatarsalphalangeal joint and interphalageal joint: fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.); Akin type osteotomy; distal radius fractures (articular fragments). ulnar styloid fractures, radial head fractures, capitellum fractures, humeral head fractures, glenoid fractures, intercarpal distal and proximal fusions, malleolar fractures, patellar fractures, osteochondral fractures, talonavicular fusions, tibeo-talar fusions, and cuboid fusions.
And for sizes 4.3mmn or larger is indicated for use for fractures, corrective osteotomies, pseudoarthrosis, degenerative transformations of long bones in the hindfoot and large bone intra-articular fractures of the humerus, femur and tibia. The size of the chosen compression screw should be adapted to the specific indication.

Cannulated Screws
The intended use of the I.T.S. Screw System is for corrective osteotomy or internal fracture fixation of the patella, pelvis, ankle, and long bones in an adult or pediatric patient. For the 4.0mm Cannulated Cancellous Screw indications for use are for radial and ulnar fractures, fractures of the proximal/distal humerus and of the patellas and for tendon fixation, maisonneuve injuries and disruption of the syndesmosis with bimalleolar or supramalleolar fractures and the instability of the talus centering. For the 6.5mm Cannulated Canncellous Screw, indications for use are for fractures of the femoral neck, tiblaplateau, of the sacrum and the articular cavity of the hip joint and the metaphyseal fractures of the distal femur and distal tibia, fixation of the ilio-sacal joint, and fusion of the foot and ankle.
For the 7.3mm Cannulated Cancellous Screw, indications for use are for fractures of the calcaneus, femoral neck, tiblaplateau, and of the sacrum and the articular cavity of the hip joint. Fusion of the foot and ankle, fixation of the Ilio-sacral joint, and metaphyseal fractures of the distal femur and distal tibia.

Contraindications
Clavicle Plates
Existing infections in the fracture zone and operation area. Common situations that do not allow osteosynthesis

Proximal Humeral Plates
Diaphyseal fractures

Distal Humeral Plates
Severe osteoporosis. Existing infections in the area of the fracture. Strongly reduced general condition

Olecranon Plates
Advanced osteoporosis with very soft bones. Skin and soft-part problems above the olecranon

Straight Plates
All situations that do not allow osteosynthesis

Distal Radius Plates
Existing infections in the fracture zone and operation area. Common situations that do not allow osteosynthesis

Distal Ulna Plates
Existing infections in the fracture zone and operation area. Common situations that do not allow osteosynthesis (osteoporosis). Lack of patient compliance

Ulna Osteotomy Plates
Existing infections in the fracture zone and operation area. Common situations that do not allow osteosynthesis (osteoporosis). Lack of patient compliance

Hand Plates
Existing infections in the fracture zone and operation area. Common situations that do not allow osteosynthesis. With advanced osteoporosis. Skin and soft-tissue problems which prevent a tension-free closure of the skin. Obesity. Lack of patient compliance

Pelvic Plates
Existing infections in the fracture zone and operation area. Common situations that do not allow osteosynthesis. Obesity. Lack of patient compliance

Sacral Rods
Fractures of the ala of the ilium in the posterior area. Fractures of the os sacrum in the transforaminal area with CT-verified fractured parts and fragments requiring an open revision and decompression. For the case that the relevant anatomy appears to preclude a safe positioning of the rods behind the sacral canal (rare). Existing infections in the fracture zone and operation area. Common situations that do not allow osteosynthesis. Obesity. Lack of patient compliance.

Distal Femur Plates
With advanced osteoporosis. In cases of skin and soft tissue problems above the lateral epicondyles. Obesity. Lack of patient compliance

Proximal Tibia Plates
With advanced osteoporosis. In cases of skin and soft tissue problems above the lateral epicondyles. Obesity. Lack of patient compliance

Tibia Nails
Active infection near the fracture site; Skeletally immature patients; Obesity; Osteoporosis or inadequate bone stock; Skin and soft tissue problems; Fractures that cannot be acceptably reduced by traction alone; Foreign body (material) sensitivity; Long delay after injury and patients with mental or neurological conditions who are unwilling or incapable of following postoperative care instructions.

Pilon Plates
Very advanced osteoporosis with very soft bones. Skin and soft-tissue problems which prevent a tension-free closure of the skin

Fibula Plates
Existing Infections. Common situations that do not allow osteosynthesis. Osteoporosis

Calcaneus Plates
All situations that do not allow osteosynthesis

Foot Plates
Existing infections in the fracture zone and operation area. Common situtions that do not allow osteosynthesis. With advanced osteoporosis. Skin and soft-tissue problemns which prevent a tension-free closure of the skin. Obesity. Lack of patient compliance

Hallux Osteotomy Plates
Existing bone or soft tissue infections in the operation field. Common situations that do not allow osteosynthesis. With advanced osteoporosis. Skin and soft-tissue problemns which prevent a tension-free closure of the skin. Obesity. Lack of patient compliance

Twist-Off Screws
Existing bone or soft tissue infections in the operation field. Common situations that do not allow osteosynthesis. With advanced osteoporosis. Skin and soft-tissue problemns which prevent a tension-free closure of the skin. Obesity. Lack of patient compliance

Headless Compression Screws
With advanced osteoporosis. Existing infections in the fracture zone and operation area. Common situations that do not allow osteosynthesis. Skin and soft-tissue problems which prevent a tension-free closure of the skin. Obesity. Lack of patient compliance

Cannulated Screws
All situations that do not allow osteosynthesis

Patient target group
The target group is adult patients with mature bone structure whose condition corresponds to the indications of one of the systems distributed by I.T.S. - taking into account the contraindications.

Designated users
Healthcare professionals with the appropriate training (surgeons, radiologists, operating room staff, reprocessing staff) must be authorised to perform, prepare and follow up surgical procedures in the relevant medical field and be familiar with the principles of the surgical procedure. Healthcare professionals must ensure that the use of I.T.S. GmbH medical devices is appropriate, taking into account the patient's medical condition and medical history.

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). Furthermore, all implants are non-corrosive, non-toxic in the biological environment and biocompatible.
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

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.
- 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.
- 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.
- Multidirectional locking screws can be inserted into any plate hole (except oblong holes) at an angle of +/-15°. A control criterion for adequate locking is that the screw head is flush with the top of the plate, which can be checked visually and by palpation by the surgeon. If the screw head is not flush, the locking screw must be retightened to ensure full locking.
- 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.
- Excessive loading of the affected body part and thus of the implant too early can lead to signs of fatigue and even failure of the medical device. Therefore, the healthcare professional must inform the patient about the postoperative behaviour.
- 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 product groups plates and screws 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 life time is usually determined by wear and damage caused by use.That is why functional tests and careful inspections both before cleaning and before use are essential for determining the product's life time.
- 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.
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.

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:

Cycle	Pre-vacuum steam sterilization
Temperature	132°C (270°F)
Exposure time	4 min
Minimum drying time	20-30 min
Cool-down time	60 min

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.

Disposal
The valid guidelines of the medical institution apply for disposal.
Contaminated units should be decontaminated before they are discarded.

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.

Disclaimer
- The medical device manufacturer bears no responsibility for complications arising from an incorrect diagnosis, the selection of an incorrect implant, incorrectly combined implant components or deviations from the defined reprocessing specifications.
- No liability is accepted for any complications arising from the combination of I.T.S. GmbH medical devices with implants/instruments from other manufacturers.

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
	Manufacturer
	Date of manufacture
MD	Medical Device
UDI	Unique device identifier