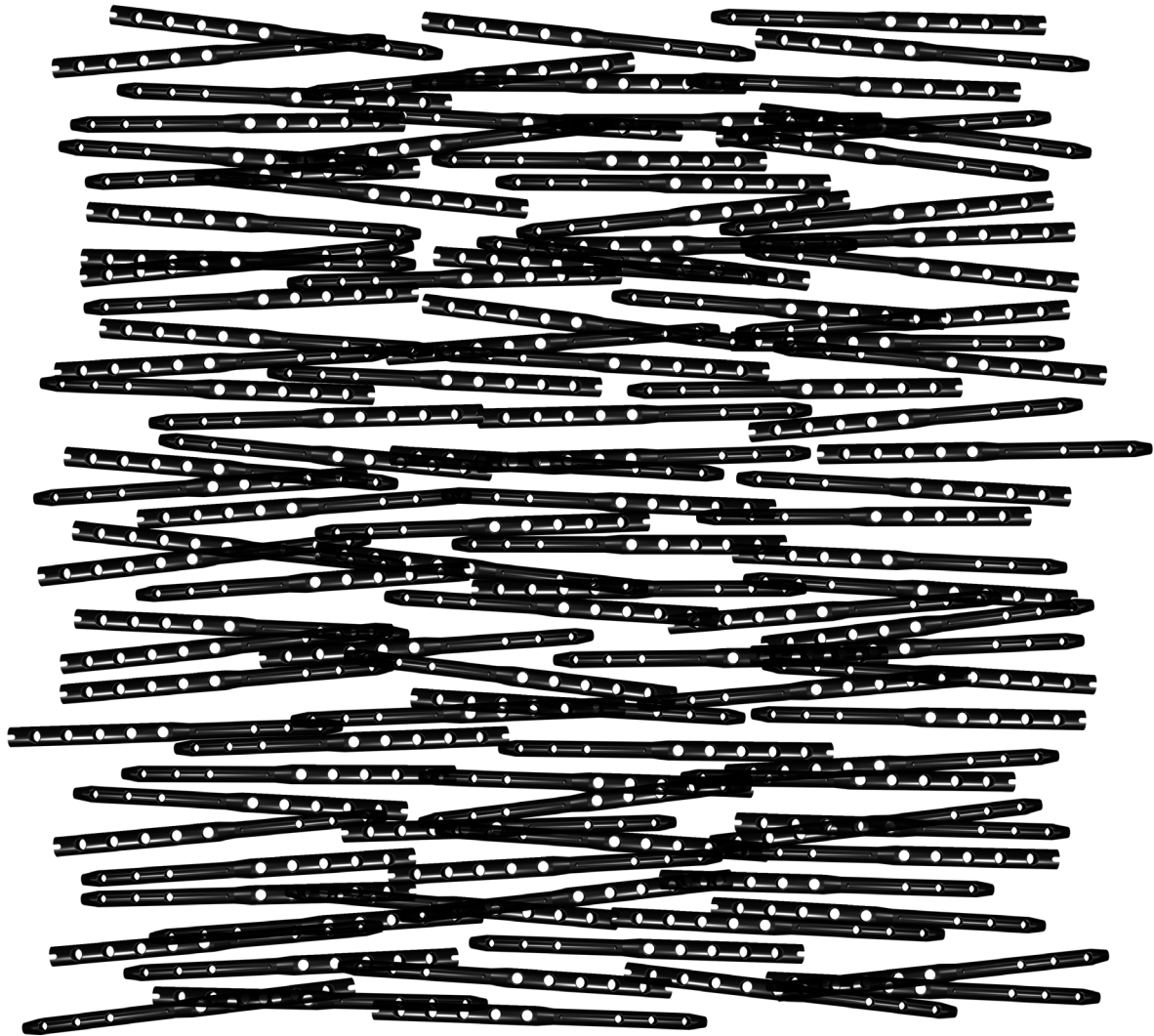


ITS.

Implants
trauma



SN

Supracondylar Nail

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Introduction



◦ Preface

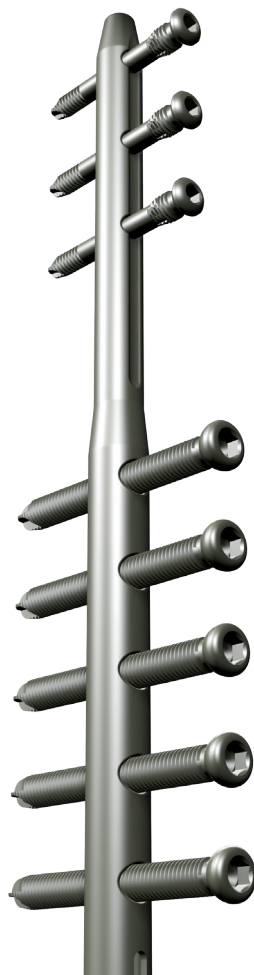
The retrograde femur nail is an excellent addition to existing methods for treating distal and diacondylar fractures of the femur, as well as of the distal epiphysis of the femur.

The challenge is in implanting and securing the nail in a minimally invasive procedure.

This technique is especially important with hip or knee endoprotheses, as in these cases the retrograde nail is the only useful option.

This nail, now available in a modified form, has 5 distal bolt holes which can be used depending on the fracture and fragment situation.

Three fixation bolts can be inserted in the proximal end of the nail.



○ Screws

3447I-XX Bolt double-thread, D=4.7mm

61386-280 Step Drill, D=3.8/4.7mm, L=280mm, AO Connector

5435I-I70 Screwdriver Shank, WS 3.5, L=170mm, Solid



3265I-XX Cortical Screw, D=6.5mm

61535-280 Drill, D=5.3mm, L=280mm, AO Connector

5450I-I70 Screwdriver Shank, WS 5.0, L=170mm



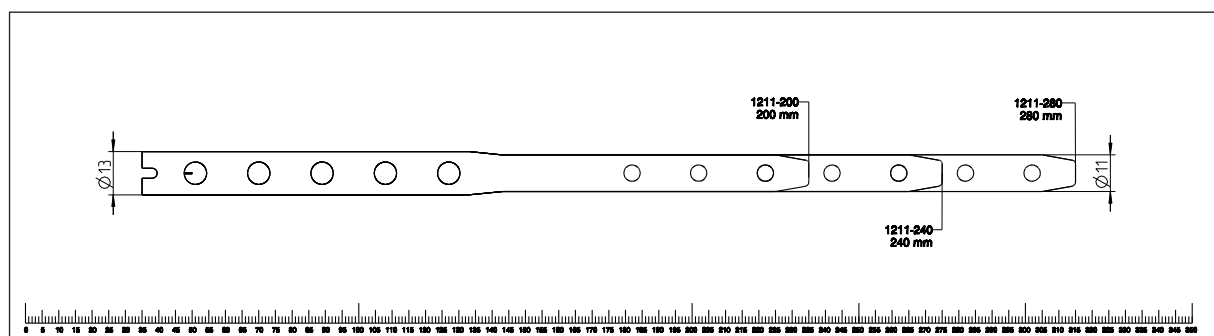
○ Properties

Properties of the material:

- ♦ Material: TiAl6V4 ELI
- ♦ Easier removal of the implant after the fracture has healed
- ♦ Improved fatigue strength of the implant
- ♦ Reduced risk of inflammation and allergy

Properties of the implant:

- ♦ External diameter D=11mm
- ♦ Lengths: 200, 240, 280mm
- ♦ 5 distal bolt holes
- ♦ 3 proximal fixation bolt holes
- ♦ Minimal invasive treatment



○ Indications & Contraindications

Indications:

- ◆ Supracondylar fractures, with or without intraarticular involvement
- ◆ Osteoporosis and nonhealing fractures
- ◆ Malpositioning and pathological fractures
- ◆ Fractures proximal to femur-knee-joint implants
- ◆ Distal femoral fractures with knee and hip endoprotheses

Contraindications:

- ◆ Open epiphyseal plate in young patients
- ◆ History of septic gonarthrosis
- ◆ Extensor contracture of the knee
- ◆ Existing infections in the fracture zone and operation area
- ◆ Common situations that do not allow osteosynthesis
- ◆ Obesity
- ◆ Lack of patient compliance

Surgical Technique

2.

◦ Preoperative planning

A preoperative x-ray of the injury extremity should be available. The length of the implant can be determined with a ruler applied to the x-ray.

The I.T.S. supracondylar nail can be used on the left or right side of the body, has a diameter of 11mm and is available in lengths of 200, 240 and 280mm.

◦ Pre-operative patient preparation

The patient lies supine with the injured extremity bent at approx. 45° on an operating table suitable for x-ray exposures.

With a dislocated, comminuted fracture or with an obese patient, it has proved to be advantageous to apply a tibial plateau extension with an extension stirrup for the surgical procedure. This makes it easy for the assisting surgeon to manipulate the distal fragment.

◦ Access

- The vertical incision can be parapatellar.
- Depending on the intra-articular situation, the incision need only be some 2.5cm long.
- Pull the patellar tendon back and to the side to obtain a good view of the joint.



○ Applying the nail

- Open the femoral canal directly before the insertion of the posterior cruciate ligament, as an extension of the axis of the marrow canal.
- To open the canal, use an awl or insert a 40cm long guide wire centrally into the femoral canal until you are above the fracture
- Drill with a step drill to open the femur to 12mm to conform to the distal diameter of the nail.
- The nail of appropriate size is placed on the screw aiming device and screwed in with the adapter.
- You should take care that the nail is firmly but not too tightly in place on the intermediate piece. Check to see that the bore hole for the nail is centric by inserting the tissue-protective cover into the screw-aiming device.
- The nail is then inserted into the opened femoral canal and pushed in 3 - 5mm retrograde under the surface of the joint, either by hand or with gentle taps with a hammer.

○ Distal interlocking

- On the distal end of the nail there are five holes for D=6.5mm cortical screws.
- To apply the first screw, push the protective cover system through the chosen hole in the aiming device.
- Push the drill bit for the D=5.3mm drill through the protective cover and drill through to the contracortex.
- You can immediately read the correct length of screw on the calibrated drill.
- Remove the drill cover and apply the self-cutting D=6.5mm cortical screw through the protective cover with the WS 5.0mm hexagonal screw driver. Follow this procedure for all the remaining screws.
- Before the implant is secured, the surgeon decides on the basis of the individual case which and how many bolt holes should be used.
- It should be noted that at least two proximal and two distal holes should be used.
- Check the rotation and axis of the femur before the implant is secured proximally.

◦ Proximal interlocking

- On the proximal end of the nail there are three holes for D=4.7mm securing bolts. The screw aiming device can be used for closure for all lengths of nails.
- Insert the protective cover through one of the proximal holes, corresponding to the length of the attached nail (the aiming device shows the respective lengths).
- Insert the drill bit for the D=3.8/4.7mm step drill through the protective cover. Then drill through to the contact cortex. You can immediately read the suitable screw length from the calibrated drill.
- Then apply the D=4.7mm securing bolts with the WS 3.5mm hexagonal screwdriver. Repeat this procedure for the remaining screws.
- Do not apply pressure to the aiming device as this could change the axis of the femur.
- Check the fracture position and fixation with an x-ray. Remove the intermediate piece and the aiming device, then screw the end cup onto the distal end of the nail.
- Close the wound as usual.
- Fix the end cup firmly to the nail so that it cannot become detached.
- The long end cup is an additional fixation for the distal screw. It must be removed before the most distal screw is removed.
- The long end cup is an additional fixation for the distal screw. It must be removed before the most distal screw is removed.

○ Postoperative treatment

- Position the patient in a slight knee band and bedrest
- After reduction of swelling, beginning of the passive mobilization
 - Partial weight bearing with crutches
 - Encourage active motion of all joints (hip, knee, ankle and toes)
 - Full weight bearing after radiographic verification of the healed bone
- Clinical and radiological follow-up after 2, 6 and 12 weeks

○ Explantation

If desired by the patient, the implant can be removed.

Removal should be performed at the earliest 1 1/2 years later or after radiographic verification of the healed bone.

The problem of cold welding was resolved by using a special surface treatment (for further information see page 13).

○ Case studies



Information

3.

◦ Dotize®

Chemical process - anodization in a strong alkaline solution*

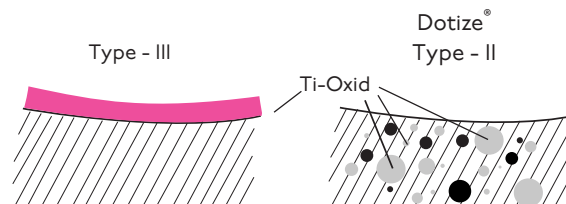
Type III anodization

- ♦ Layer thickness 60-200nm
- + Different colors
- Implant surface remains sensitive to:
Chipping
Peeling
Discoloration

Dotize

Type II anodization

- ♦ Layer thickness 2000-10 000nm
- + Film becomes an interstitial part of the titanium
- No visible cosmetic effect



Anodization Type II leads to following benefits*

- ♦ Oxygen and silicon absorbing conversion layer
- ♦ Decrease in protein adsorption
- ♦ Closing of micro pores and micro cracks
- ♦ Reduced risk of inflammation and allergy
- ♦ Hardened titanium surface
- ♦ Reduced tendency of cold welding of titanium implants
- ♦ Increased fatigue resistance of implants
- ♦ Improved wear and friction characteristics

◦ Order list

Supracondylar Nail, D=11mm, L=200mm	1211-200
Supracondylar Nail, D=11mm, L=240mm	1211-240
Supracondylar Nail, D=11mm, L=280mm	1211-280

Targeting Jig, Supracondylar Nail	1280
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Jig Adaptor, Supracondylar Nail	1281
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Sheath, 6.5mm Screw	1282
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Drill Guide, 5.3mm Drill	1283
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Sheath, 4.7mm Locking Bolt	1182
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Drill Sleeve, 5.3mm, 3.8/4.7mm Step Drill	1183
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Screwdriver Shank, WS 3.5, L=170mm, Solid	54351-170
Screwdriver Shank, WS 5.0, L=170mm	54501-170

Step Drill, D=3.8/4.7mm	61386-280
Drill, D=5.3mm, L=280mm	61535-280

T-Handle, Cannulated	53022
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Screwdriver, 3.5mm, Socket Key with Clamping Piece	56351
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Guide Wire, Steel, D=3.2mm, L=400mm, RR	35325-400
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Endcap for Supracondylar Nail, Short	1241
Endcap for Supracondylar Nail, Long	1242

Trochar	1184
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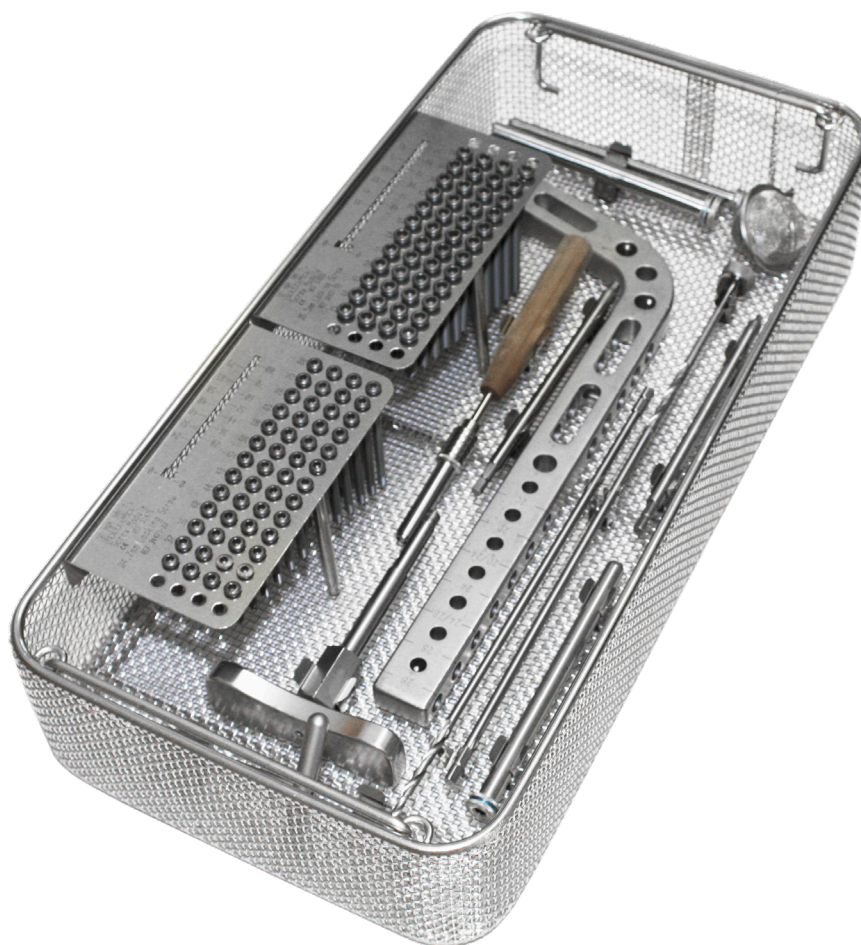
Double Thread Bolt, D=4.7mm, L=28mm	34471-28
Double Thread Bolt, D=4.7mm, L=32mm	34471-32
Double Thread Bolt, D=4.7mm, L=36mm	34471-36
Double Thread Bolt, D=4.7mm, L=40mm	34471-40
Double Thread Bolt, D=4.7mm, L=44mm	34471-44
Double Thread Bolt, D=4.7mm, L=48mm	34471-48
Double Thread Bolt, D=4.7mm, L=52mm	34471-52
Double Thread Bolt, D=4.7mm, L=56mm	34471-56
Double Thread Bolt, D=4.7mm, L=60mm	34471-60

Double Thread Bolt, D=4.7mm, L=65mm	3447I-65
Double Thread Bolt, D=4.7mm, L=70mm	3447I-70
Double Thread Bolt, D=4.7mm, L=75mm	3447I-75
Double Thread Bolt, D=4.7mm, L=80mm	3447I-80

Cortical Screw, D=6.5mm, L=35mm	3265I-35
Cortical Screw, D=6.5mm, L=40mm	3265I-40
Cortical Screw, D=6.5mm, L=45mm	3265I-45
Cortical Screw, D=6.5mm, L=50mm	3265I-50
Cortical Screw, D=6.5mm, L=55mm	3265I-55
Cortical Screw, D=6.5mm, L=60mm	3265I-60
Cortical Screw, D=6.5mm, L=65mm	3265I-65
Cortical Screw, D=6.5mm, L=70mm	3265I-70
Cortical Screw, D=6.5mm, L=75mm	3265I-75
Cortical Screw, D=6.5mm, L=80mm	3265I-80
Cortical Screw, D=6.5mm, L=85mm	3265I-85
Cortical Screw, D=6.5mm, L=90mm	3265I-90

Sterilization Tray, Supracondylar Nail	5012I
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Tray



◦ Sterilization guidelines

The following remarks should serve as a guideline in the sterilization of medical products.

IMPORTANT INDICATIONS FOR DOCTORS AND OPERATING THEATRE PERSONNEL

This instruction leaflet refers to all supplied non-sterile implants and all reusable instruments from ITS GmbH. Detailed information for the identification of the product (such as system classification, cat. no.) can be found in the product identification code and/ or on the packaging label. Make sure that you are familiar with the possible application, combinability and correct handling of the product. Please note that product systems can undergo modifications which can affect the combinability of the implant with other implants or instruments. Detailed user information can be found in the respective surgical instructions.

Intended Use of the Implant

The implant temporarily stabilises bone segments until bony consolidation has taken place. After this, the implant has no more use and can be removed.

Indications and Contra-Indications of the Implant

Indications and contra-indications are determined by current medical practice.

Side Effects of the Implant

Up to now, no allergic reactions have been identified with titanium implants. Allergic reactions to steel implants cannot be ruled out.

Warnings and Preventive Measures

- Pay attention to the instructions on the packaging.
- Implants are only to be used once.
- Always treat implants carefully to avoid surface damage or geometric alterations.
- Any alterations to the design of implants from ITS 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 implants from different producers. The materials used are stated in the product catalogue or on the label.
- 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.
- In the case of magnetic resonance imaging (MRI), it is generally recommended to check back with the manufacturer of the MR scanner. The use of MRI with steel implants is prohibited by ITS GmbH, and in such cases the user must contact the manufacturer of the MRI scanner.
- 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 (damp heat) is the recommended sterilization method of medical products from ITS GmbH.
- All the following described steps for cleaning and sterilization are made easier when contaminants (e.g. blood) are not allowed to dry beforehand.

Restrictions

- Unless otherwise stated, repeated preparation of re-usable instruments of ITS GmbH has minimal effects on them when following the procedures mentioned below.
- The end of the product service life is usually determined by wear and damage caused by use.
- Instruments containing aluminium or anodised aluminium are damaged by alkaline (pH > 7) cleaning agents and solutions.

INSTRUCTIONS FOR RECONDITIONING

Preparation at the Location of Use

- Remove surface dirt using a disposable cloth or paper towel.

Storage and Transport

- No special requirements.
- It is recommended that medical products are reconditioned as soon as possible after their previous use.

Cleaning/ Disinfection/ Drying

Cleaning automatic

Recommended equipment: commercially available disinfectant authorized for use with medical products, with tested efficiency; commercially available cleaning agent authorized for use with medical products (alkaline – with pH value < 11).

- Step 1 Each instrument that can be dismantled should be taken apart for cleaning. Jointed instruments are to be opened so that water can flow out of the cannulae and blind holes.
- Step 2 Set the cycle. Adhere to the guidelines of the manufacturer of the disinfectant.
- Step 3 After removing the instruments from the disinfectant, check the cannulae, blind holes, etc. for visible dirt. If required, repeat cycle or clean by hand.

Cleaning manual

Recommended equipment: commercially available cleaning agent authorized for medical products (alkaline – with a pH value < 11); soft brushes made of nylon; running water

- Step 1 Each instrument that can be dismantled should be taken apart for cleaning. Rinse off surface dirt from instrument.
- Step 2 Apply cleaning agent solution to all surfaces using a brush. Make sure that jointed instruments are cleaned in both open and closed positions. N.B.: A suitable brush must be used for cleaning cannulae and blind holes so that every part can be reached. The concentration and residence time as stated by the cleaning agent manufacturer must be adhered to without exception.
- Step 3 Rinse the medical product for a minimum of 1 minute with clean water. Openings and other areas which are not easily accessible should be thoroughly rinsed.

Disinfection

Equipment: Commercially available disinfectants authorized for use with medical products e.g. MEDICLEAN FORTE) can be used (but only according to the instructions of the disinfectant producer).

In the case of automatic cleaning, a final rinse cycle at 90 °C for 5 minutes can be carried out at the end to provide thermal disinfection.

Drying

Drying as part of the cleaning/ disinfection cycle should not exceed 110 °C.

Checking, Maintenance and Inspection

- Each instrument or implant is to be inspected carefully to make sure that all visible dirt has been removed. If any ingrained dirt is found, the cleaning/ disinfection cycle should be repeated.
- Any instruments with an attached movable mechanism should be treated with a commercially available lubricant authorized for sterilisable surgical instruments.
- The mobility of movable parts should be checked to ensure that the planned sequence of motion can be completely carried out.
- In the case of instruments which can be reassembled into larger units, check whether the single parts can be put together easily.

Package

The delivery package is purely for transport use and not suitable for sterilization.

Sterilization

- The hospital is responsible for in-house procedures regarding assembly, inspection and packaging of instruments. Furthermore, the hospital should recommend protective measures covering sharp or potentially dangerous parts of the instruments.
- All instruments and implants should be laid out in such a way that the steam can reach all the surfaces.
- Each instrument that can be dismantled should be taken apart for sterilization.
- Sterilization by means of heat/ steam is the preferred method for instruments and implants from ITS GmbH.
- The manufacturer's recommendations regarding sterilization appliances should always be followed. When several instruments are sterilised in one sterilization cycle, care must be taken not to exceed the maximum amount of items to be sterilized in the appliance as stated in the manufacturer's instructions.

Cycle	Duration of sterilization	Temperature	Pressure	Duration of drying
Prevacuum	4 minutes	132°C 270°F	3.04 bar 27 psi	60 minutes
Prevacuum ²	18 minutes	134°C 273 °F	3 bar 28.5 psi	30 minutes

² From the World Health Organization's (WHO) recommended disinfection/ steam sterilization parameters for the reconditioning of instruments when there is a risk of TSE/CJD contamination

Disposal

The valid guidelines of the hospital operator apply for disposal.

Patient Information

Implantation has consequences for the discomfort, mobility and general life circumstances of the patient. For this reason, the patient should be given instructions about appropriate behaviour to adopt after implantation, and it should be explained to him or her 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.
















Responsibility of the Hospital for Instruments lent by ITS 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, have to be disposed of.
- Medical products which are returned to ITS GmbH must undergo cleaning, disinfection, inspection and a final sterilization. Products returned to ITS GmbH must be accompanied by a confirmation of the decontamination they were subjected to.

Important Note

- The above-mentioned instructions have been validated by the medical products manufacturer for the preparation of a medical product where re-use is deemed SUITABLE. It is the responsibility of the reconditioner to ensure that any reconditioning carried out using the equipment, materials and staff in the preparation facility achieves the desired results. For this, validation and routine inspections of the preparation process are usually necessary. Likewise, any deviation from the instructions provided by the preparer should be evaluated for its efficiency and possible disadvantageous consequences.
- In the case of questions or problems, please contact us at the address above.

Symbols

	Prescription
	Single use
	Expiry date (year/month)
	Charge number
	Sterilization by steam
	Sterilization by radiation
	Sterilization by ethylene oxide
	Order number
	Material used
	Package content (no. of items)
	Size
	Pay attention to instructions
	Latex Free
	Non Sterile
	Do not use if package is damaged

 0297
RL 93/42/EWG
ÖNORM EN ISO 13485
ISO 17664

Notes

This image shows a full page of blank handwriting practice paper. It features 20 evenly spaced horizontal blue lines across the entire page, providing a guide for letter height and placement. The lines are consistent in color and thickness throughout.



ITS. 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

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