I.T.S.

# TNC TIBIA NAIL CONNEXX

emergency team for broken bones®

# Contents

## Preface:

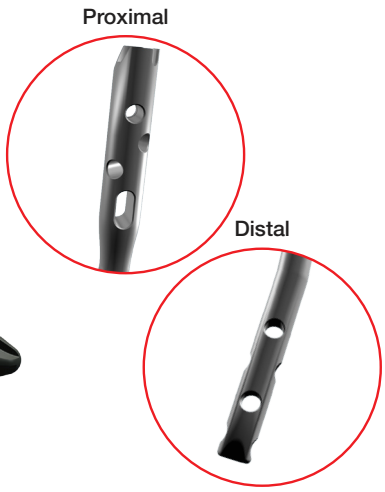
The Connexx intramedullary nail for the tibia is a further development of the I.T.S. intramedullary nail for the tibia, of which several thousand items have been successfully implanted since its introduction in 1998. The Connexx intramedullary nail for the tibia marks the successful development of a locking intramedullary nail.
By locking we mean a fixed, rigid connection which does not allow any movement between nail and locking screws.
This innovative tibia nail offers a variety of novel features on both the proximal and distal ends.

# Tibia Nail CONNEXX

32475-XX **Cortical Screw, D=4.7mm**

61423-280 **Spiral Drill, D=4.2mm, L=280mm, AO Connector**

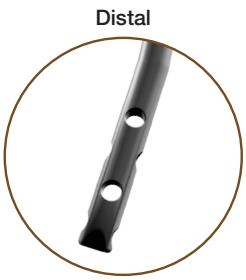
56352-SH **Screwdriver, WS 3.5, conic, self-holding**

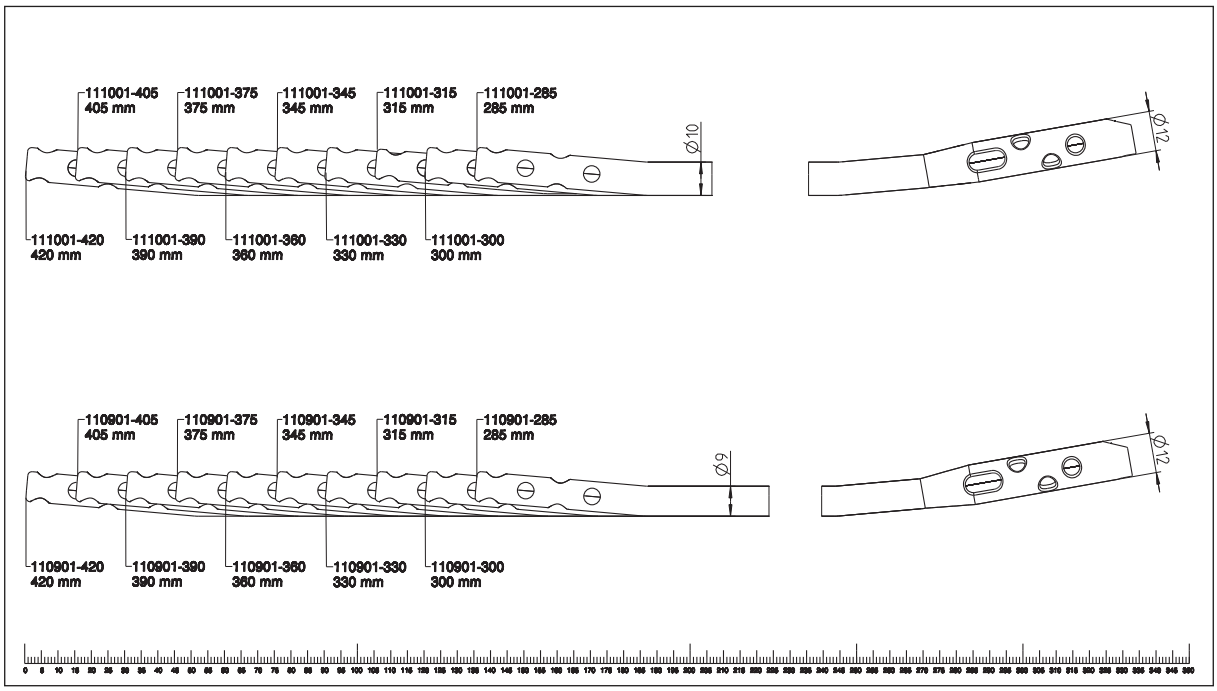



34471-XX **Bolt double-thread, D=4.7mm**

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

56352-SH **Screwdriver, WS 3.5, conic, self-holding**


All I.T.S. locking plates are anatomically pre-contoured. In the unlikely event that the plate has to be formed to the bone please notice that slight contouring is possible.

ATTENTION: Significant **bending** at the locking holes will reduce locking effectiveness and if **bend more than once** in both directions it might weaken the titanium plate strongly.

# Properties

## Properties of the material:

- Nail material: Titanium Grade 2
- Material of screws: TiAl6V4 ELI
- Easier removal of implant after fracture has healed
- Improved fatigue strength of implant
- Reduced risk of inflammation and allergy

## Properties of the implant:

- Anatomically shaped
- Radiolucent aiming arm
- Axial attached implant to bear loads early
- Proximal end is chamfered to prevent impairments of the patella tendon and soft parts after implantation
- The surgeon can decide in favour of a angle-stable or non angle-stable locking device right up until the „last“ implantation step (attaching the endcap to the nail)
- The Connexx tibia nail offers the possibility of dynamic locking. An axial flexibility is possible despite of rotation stability. This kind of dynamization allows micro-movements which again support the bone growth.
- The most distal hole is inclined 15° posteriorly in the AP direction with respect to the shaft axis in order also to fixate bone fragments caused by shear fractures of the tibia margin.
- Solid cross section (no clearance volume) reduces danger of infection (osteomyelitis)

# Indications

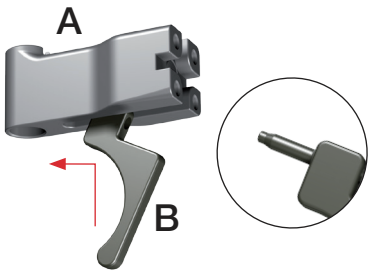
## Indications:

- Proximal and distal fractures from the 1st to the 5th fifth
- Bone transport
- Open fractures
- Corrective fractures
- Pathologic fractures
- Pseudoarthrosis of tibial shaft
- Nonunion/malunion
- Metaphyseal and epiphyseal fractures
- Transverse fractures
- Oblique and spiral fractures
- Segmental fractures
- Comminuted fractures
- Fractures with bone loss

# Assembling of the insertion guide

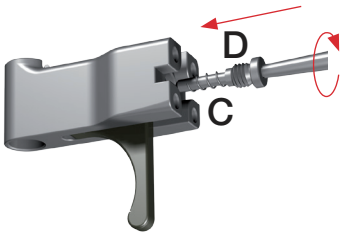
## Step 1:

- To ensure smooth functioning of the aiming arm, the slot of the aiming-device arm **A** in which the sliding handle moves **B** should be sprayed with a commercially available spray oil for medical instruments after washing and during assembly. The sliding handle **B** (118001-2) is introduced over the slot in the aiming-device arm **A** (118001-1) in such a way that the cylindrical plug of the sliding handle is inserted inside the drill hole in the interior of the slot.



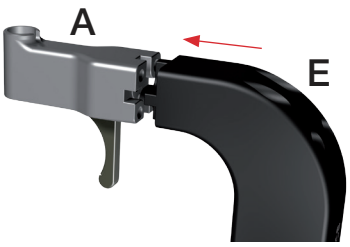

## Step 2:

- The pressure spring **C** (118001-4) is slid into the holding screw **D** (118001-3) and then screwed into the rear part of the aiming arm **A** with the help of the screwdriver, WS 3.5 (56352-SH) until the limit stop is reached. The head of the holding screw forms a flat surface with the cross-shaped recess in the aiming arm.



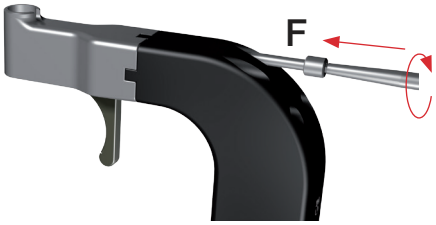

## Step 3:

- Then the X-ray transparent aiming arm **E** (118001-6) is plugged into the cross-shaped recess on the aiming-device arm **A**.



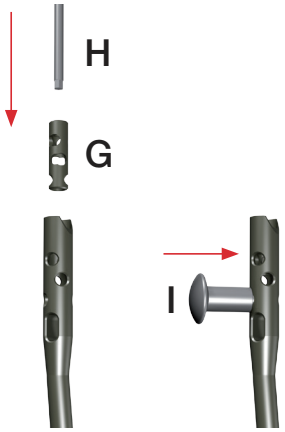

## Step 4:

- The X-ray transparent aiming arm is screwed together with the aiming-device arm by using 4 anchor screws **F** (118001-5) in the provided drill holes with the help of the screwdriver, WS 3.5 (56352-SH)



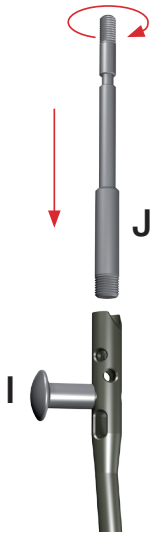
## Step 5:

- Attach the locking bolt **G** (110901-1) at the proximal end of the nail using the locking key wrench **H** (56353-170). Align until the holes are congruent. Introduce the locatin pin **I** (115600) and remove locking key wrench.



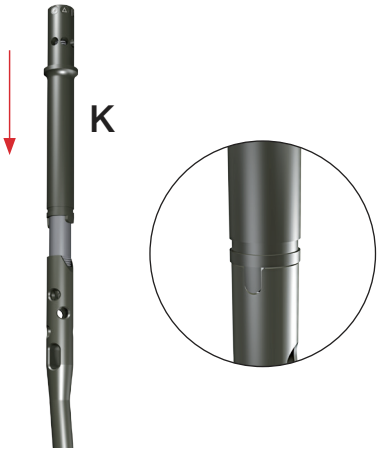

## Step 6:

- The impactor rod **J** (118001-8) is then manually screwed in (short thread) at the proximal end of the Connexx. If necessary, the screwdriver WS 3.5 at the front end of the compactor rod can be used for tightening purposes. After removal of the location pin **I**, the compactor rod now secures the clamping bolt.



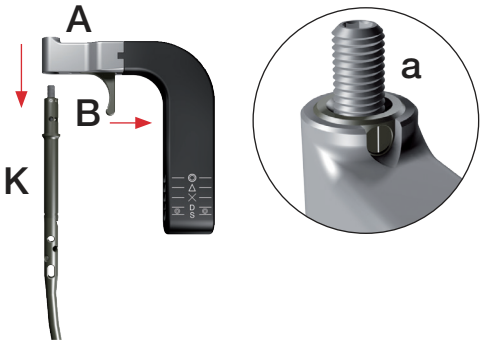

## Step 7:

- Slide the adaptor **K** (118001-7) over the compactor rod, making sure that the clip of the adaptor fits into the groove on the Connexx.
- The aiming device is slid over the adaptor **B** until the limit stop **K** by simultaneous pulling back the sliding handle**.**




## Step 8:

- The aiming device is twisted in relation to the nail until the “vertical line” can be seen at the adaptor **K** in the upper recess **a** of the aiming-device arm **A** This “vertical line” symbolises the “zero position”. On letting go of the sliding handle, the latter snaps into place in the adaptor, so that the aiming arm can no longer be swivelled.




## Step 9:

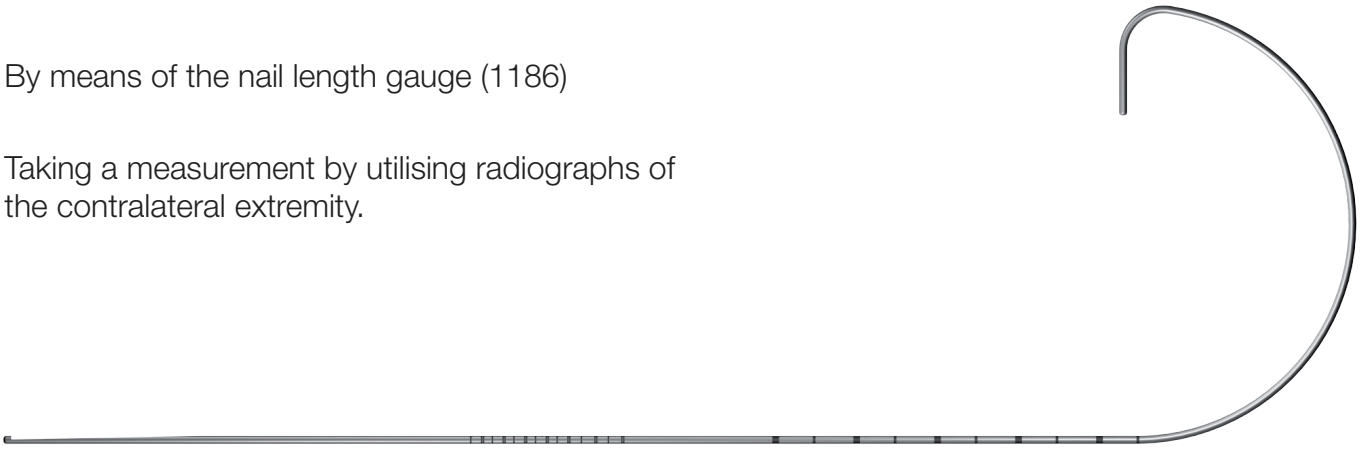
- After this, the nut, WS 17 (118001-9) or the nut, WS 17 with 2 threads **L** (118001-11) is screwed onto the compactor rod and tightened by means of the flat wrench WS 17 **M** (70017).

## Postitioning of the patient

- Actually the positioning of a patient depends on the operation technique individually preferred.
- In case of open fractures the patient should be placed supine on a standard radiolucent operating room table. The knee should be flexed at least 90° to allow for easy insertion of the Tibianail.

## Determining of nail length

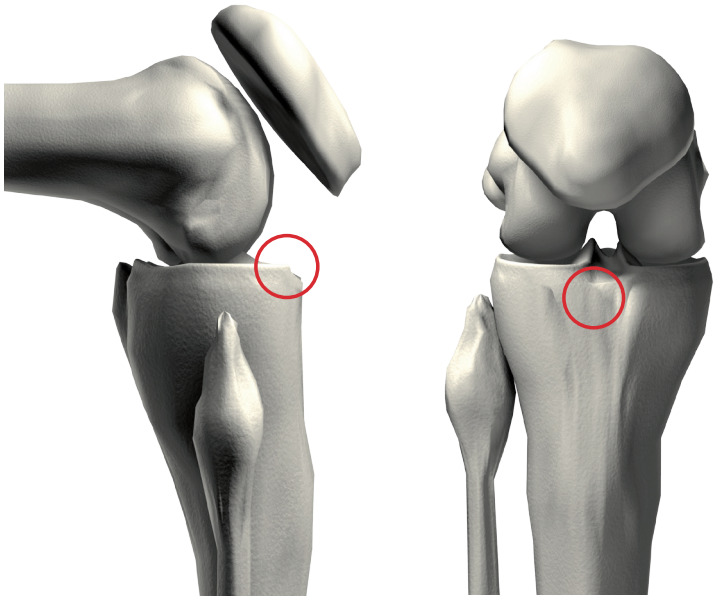
- By means of the nail length gauge (1186)
- Taking a measurement by utilising radiographs of the contralateral extremity.



## Entry point

Most of the time the entry point depends on the kind of fracture:

- Medial to the ligamentum patellae
- Through the ligamentum patellae
- Lateral to the ligamentum patellae



## Medullary canal

- In order to ease the insertion of the tibianail, the right choice of the insertion point is very important.
- Individual anatomy should be carefully evaluated.
- It is important that the starting hole is in line with the medullary canal of the tibia shaft.
- Additional a slightly more proximal insertion site on the flat surface of the anterosuperior tibial surface should be selected.

## Nailing

- The Connexx intramedullary nail for the tibia is now introduced as far as possible into the medullary space by hand using the tightly screwed together jig.
- If this no longer possible, the nut, WS 17 (118001-9) of the tibia nail can be carefully tapped with a hammer while carefully observed through the image converter.
- This procedure can also optionally be carried out using the slip weight (115400) in combination with the impactor rod (115300).
- The passing through the fracture should be controlled by the C-arm. Ideally the position of the tibianail should be 1 cm proximal to the tibiotalar joint.
- The jig must not be driven into the metaphysis.

## Proximal locking

- For proximal locking use the D=4.7mm locking screw (32475-XX) with the spiral drill D=4.2mm, L=280mm, AO Connector (61423-280).
- The locking screws are positioned by means of the jig. The drill sleeve (118083) is screwed together with the tissue protection sleeve (118082) and the trocar (118084) is inserted into the drill sleeve. The tissue protection sleeve is subsequently inserted into the drill of the aiming arm.
- The symbol on the aiming arm on which the tissue protection sleeve is positioned is adjusted by retracting the sliding handle and subsequently swivelling the arm at the adaptor.
- The tissue protection sleeve and the drill sleeve with the trochar should be guided through a stab incision to the cortical.

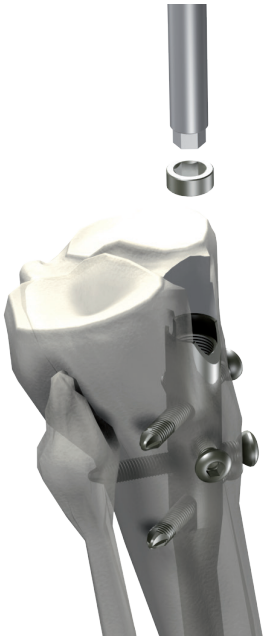
- Remove the trochar and drill through the cortical and through the far cortical with the spiral drill, D=4.2mm, L=280mm, AO Connector (61423-280).
- The length of the required screw is measured directly on the drill or, optionally, by means of the separate length measuring device (1186).
- After removing the drill sleeve, the D=4.7mm locking cortical screw is screwed through the tissue protection sleeve.
- Only add 2 mm to the length to account for the thickness of the far cortex when selecting the appropriate screw.
- **Do not strip the screws.**
- The circular holes for static interlocking guarantee rotation-stability as well as axial stability.
- The long hole for dynamic interlocking ensures rotation stability.

# Distal locking

- The D=4.7mm locking cortical screw (32475-XX) with the spiral drill, D=4.2mm, L=280mm, AO Connector (61423-280) is to be used for distal locking.
- Distal locking is carried out unguided using an image converter or possibly a navigation system.
- The right position of the incision should be found out by positioning the image converter as long as the distal nail hole appears perfectly round.
- After drilling through the medial and the lateral cortex with the spiral drill, D=4.2mm and after determination of the screw length (59022), the D=4.7mm cortical screws can be inserted.
- Additionally the screw should rise above the lateral cortex at least 2 mm. **Do not overwind the screws.**

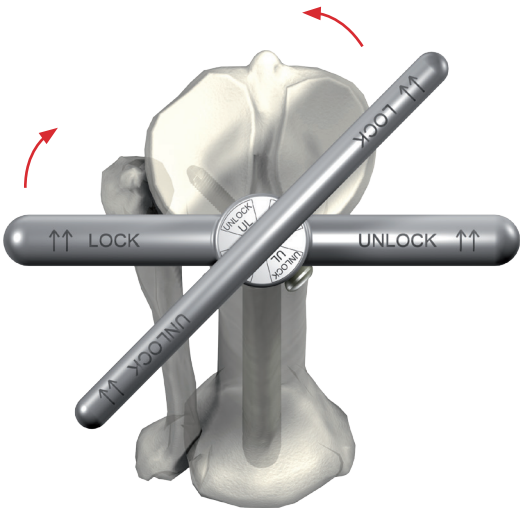
## Non angle-stable locking

- Finally screw an endcap (110901-2) with the locking key wrench, WS 6 (56603-150) into the proximal end of the nail, which will protect the internal thread of the tibia nail against tissue growth, thus facilitating removal of the implant at a later date.



## Angle-stable locking

- First, screw the endcap (110901-2) onto the proximal end of the nail using the cannulated locking key wrench WS 6 (56603-150) until it comes to rest against the locking bolt (no further rotation possible). Then, retract the endcap very slightly (so that the end cap no longer rests on the locking bolt).
- Now, insert the WS 3.5 (56353-170) locking key wrench into the cannulated locking key wrench WS 6, so that the latter grips against the locking bolt. While doing this and for easier manipulation, the handle of the WS 3.5 locking key wrench should cover the field indicated **“Lock”** on the upper part of the WS 6 locking key wrench.
- Then, screw both spanners against each other until they cannot be turned any more.
- With this procedure, the locking bolt in the nail is turned in such a way that it clamps all the locking screws. At the same time, the end cap is screwed into the nail until it presses tightly against the locking bolt so that the locking bolt and locking screws are jammed together.
- Finally, both locking key wrench are removed.
- The proximal locking screws are now jammed against the nail and allow no movement at all.

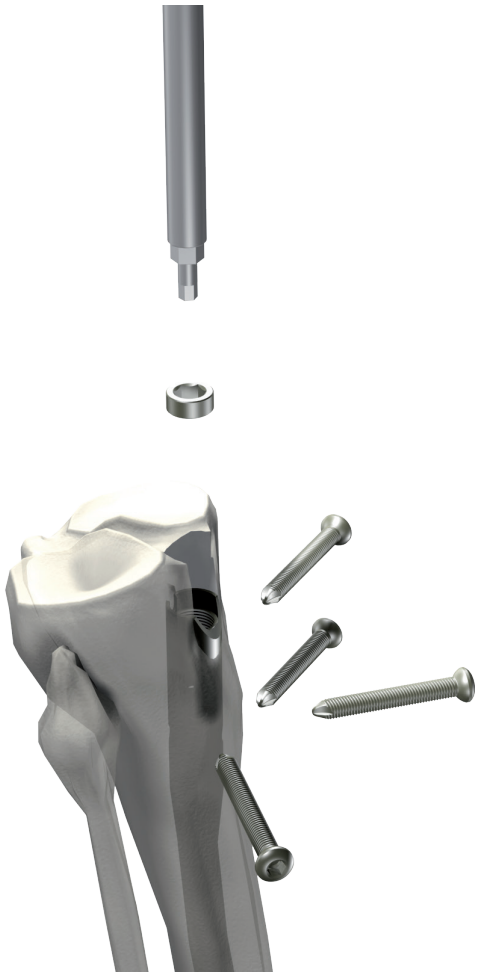


## Postoperative treatment

- Position the patient in a slight knee bend and bedrest
- After reduction of swelling, beginning of the passive mobilisation
  - Partial weight bearing with crutches
  - Encourage active motion of all joints (hip, knee, ankle and toes)
  - Full weight bearing after sufficient bone healing (callus forming)
- Clinical and radiological follow-up after 2, 6 and 12 weeks.

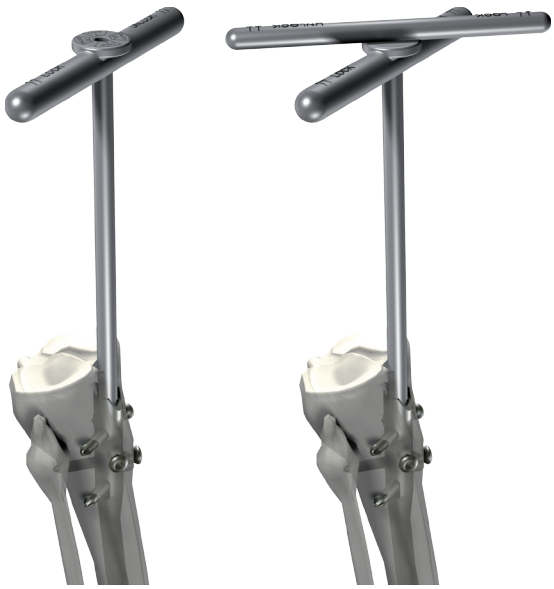
## Explantation of a non angle-stable system

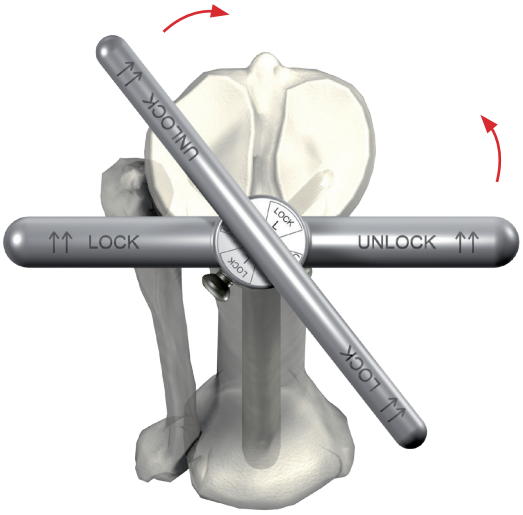
- If the tibia nail was not locked in an angle-stable way, the endcap (110901-2) can be removed with the WS 6 (56603-150) locking key wrench and all the locking screws with the WS 3.5 screwdriver (56352-SH).
- Finally, the impactor rod (115300) and the slip weight (115400) is screwed together with the nail. Using light taps with the slip weight, the nail can be removed from the medullary space.



# Explantation of the angle-stable system

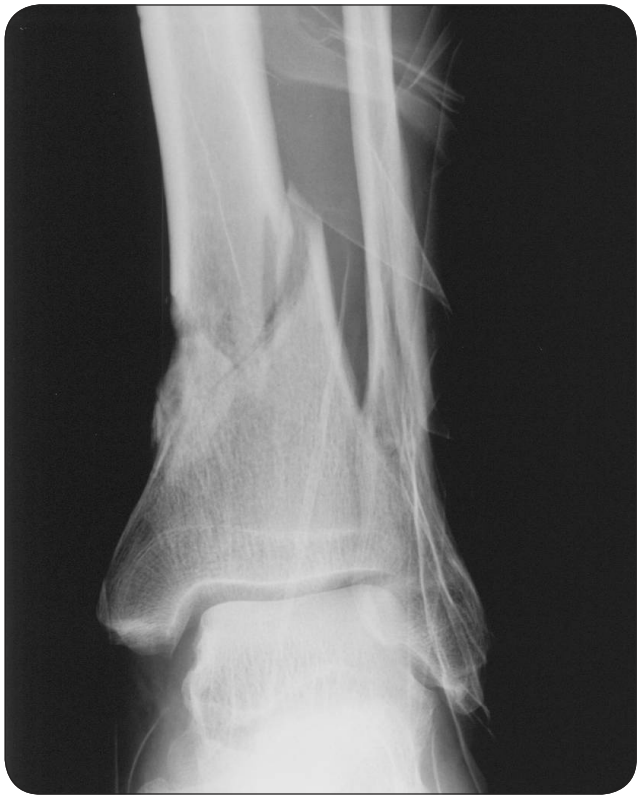
- To release it, attach the pair of locking key wrench (WS 3.5 + WS 6) to the endcap (110901-2) and the locking bolt (110901-1) and turn them against each other.
- The turning direction is indicated with an arrow on the marking **“Unlock”** on the handle of the spanner.
- Now the endcap can be removed with the WS 6 locking key wrench and all the locking screws with the WS 3.5 screwdriver (56352-SH).
- Finally, the impactor rod (115300) and the slip weight (115400) is screwed together with the nail. Using light taps with the slip weight, the nail can be removed from the medullary space.

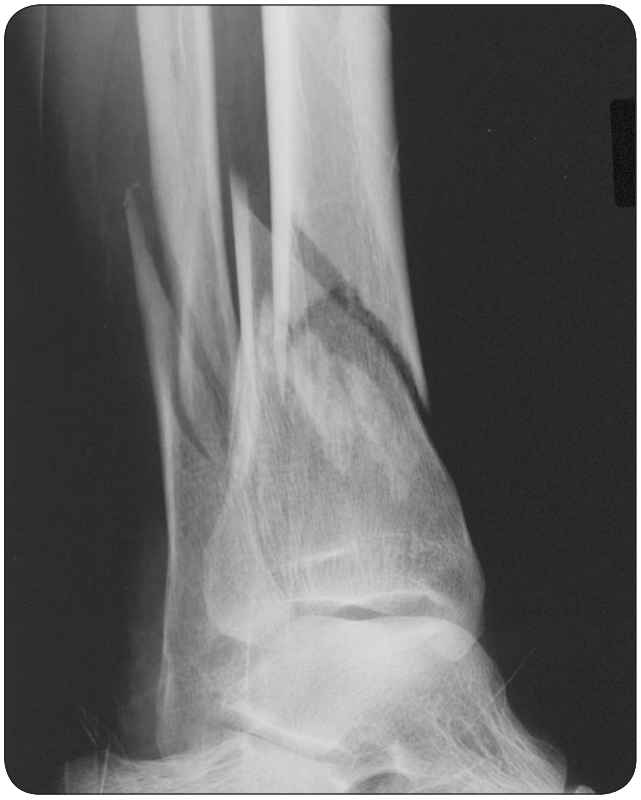


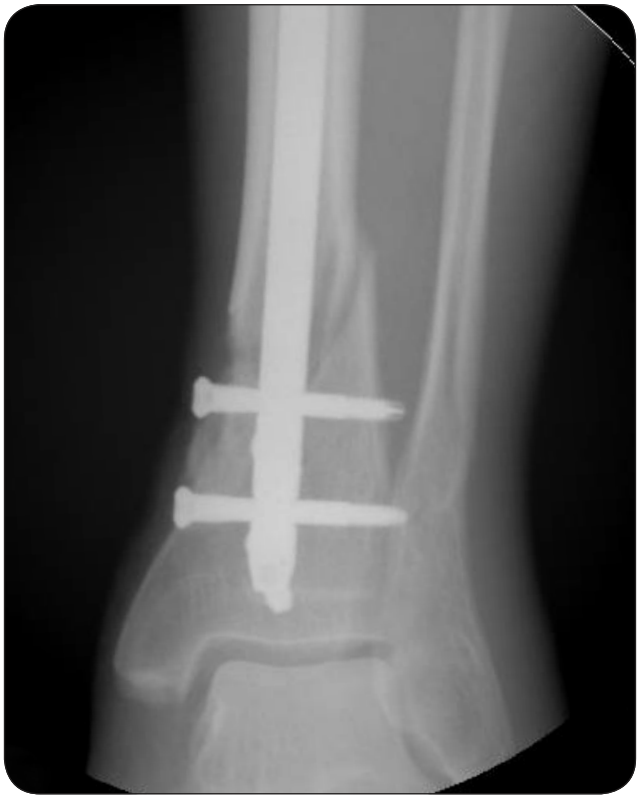



## Case 1:

Pre- and postoperative radiographs following locking intramedullary fixation of a spiral fracture in the distal area of the tibia shaft (fracture classification AO 42 A1).







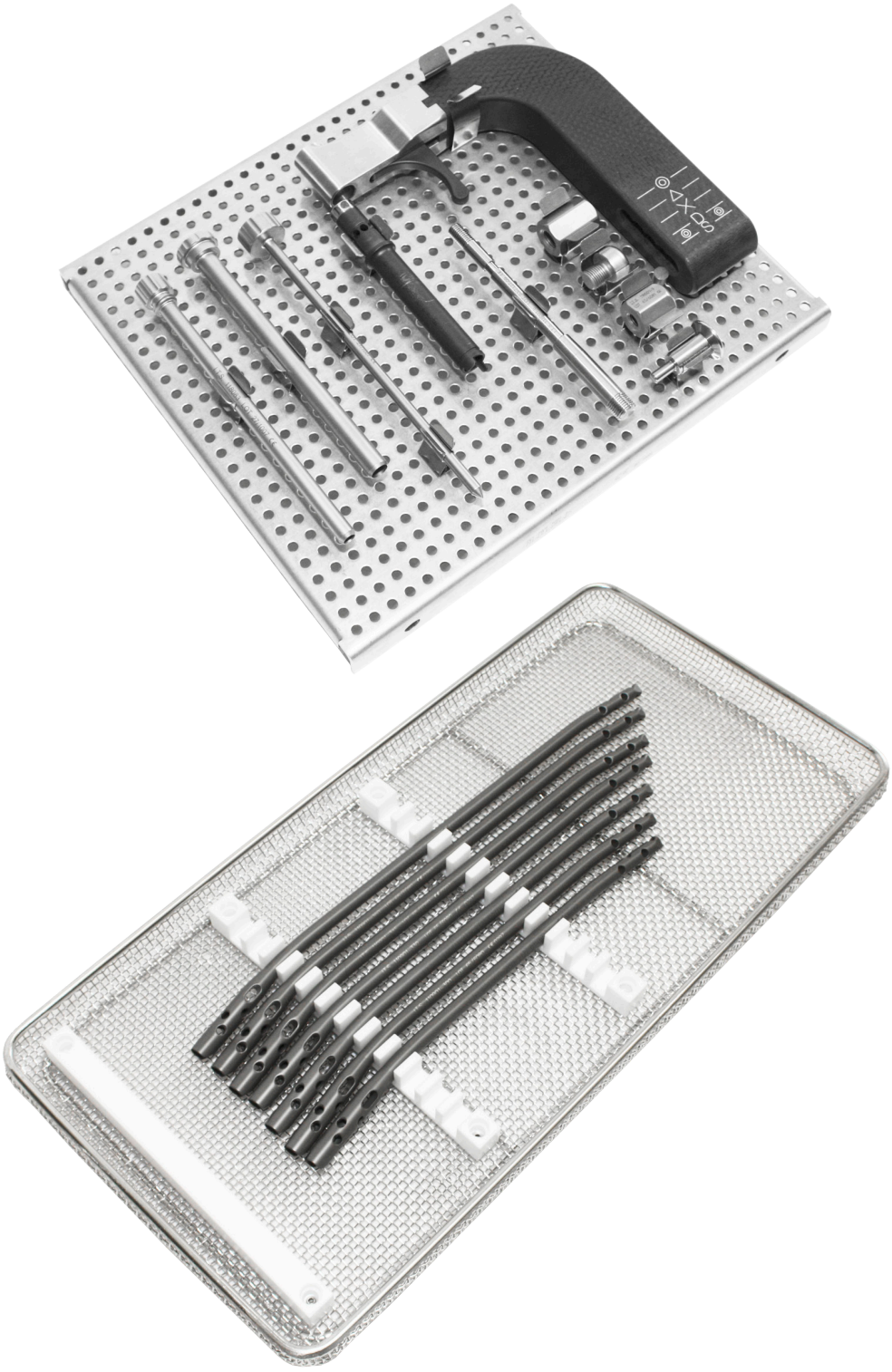
# Order information

| | |
|---|---|
| Jig, 7 Parts | 118001 |
| Aiming-Device Arm | 118001-1 |
| Sliding Handle | 118001-2 |
| Holding Screw | 118001-3 |
| Pressure Spring | 118001-4 |
| 4x Anchor Screw, M4x38 | 118001-5 |
| Aiming arm for Connexx Tibia Nail | 118001-6 |
| Adaptor for Connexx Tibia Nail | 118001-7 |
| Impactor Rod, Tibia Nail, Connexx | 118001-8 |
| Nut, WS 17 | 118001-9 |
| Nut, WS 17, with 2 Threads | 118001-11 |
| Protective Cap | 118001-10 |
| Tissue Protection Sleeve, Connexx | 118082 |
| Drill Sleeve, Connexx | 118083 |
| Trochar, Connexx | 118084 |
| Location Pin, Tibia Nail, Connexx | 115600 |
| Tibia Nail, Connexx, D=9.0mm, L=285mm | 110901-285 |
| Tibia Nail, Connexx, D=9.0mm, L=300mm | 110901-300 |
| Tibia Nail, Connexx, D=9.0mm, L=315mm | 110901-315 |
| Tibia Nail, Connexx, D=9.0mm, L=330mm | 110901-330 |
| Tibia Nail, Connexx, D=9.0mm, L=345mm | 110901-345 |
| Tibia Nail, Connexx, D=9.0mm, L=360mm | 110901-360 |
| Tibia Nail, Connexx, D=9.0mm, L=375mm | 110901-375 |
| Tibia Nail, Connexx, D=10.0mm, L=315mm | 111001-315 |
| Tibia Nail, Connexx, D=10.0mm, L=330mm | 111001-330 |
| Tibia Nail, Connexx, D=10.0mm, L=345mm | 111001-345 |
| Tibia Nail, Connexx, D=10.0mm, L=360mm | 111001-360 |
| Tibia Nail, Connexx, D=10.0mm, L=375mm | 111001-375 |
| Tibia Nail, Connexx, D=10.0mm, L=390mm | 111001-390 |
| Tibia Nail, Connexx, D=10.0mm, L=405mm | 111001-405 |
| Tibia Nail, Connexx, D=10.0mm, L=420mm | 111001-420 |

## Special lengths (on request)

| | |
|---|---|
| Tibia Nail, Connexx, D=9.0mm, L=390mm | 110901-390 |
| Tibia Nail, Connexx, D=9.0mm, L=405mm | 110901-405 |
| Tibia Nail, Connexx, D=9.0mm, L=420mm | 110901-420 |
| | |
| Tibia Nail, Connexx, D=10.0mm, L=285mm | 111001-285 |
| Tibia Nail, Connexx, D=10.0mm, L=300mm | 111001-300 |

| | |
|---|---|
| Sterilisation Tray, Connexx Nail | 50193 |



# Order information

| | |
|---|---|
| Cortical Screw, D=4.7mm, L=28mm | 32475-28 |
| Cortical Screw, D=4.7mm, L=30mm | 32475-30 |
| Cortical Screw, D=4.7mm, L=32mm | 32475-32 |
| Cortical Screw, D=4.7mm, L=34mm | 32475-34 |
| Cortical Screw, D=4.7mm, L=36mm | 32475-36 |
| Cortical Screw, D=4.7mm, L=38mm | 32475-38 |
| Cortical Screw, D=4.7mm, L=40mm | 32475-40 |
| Cortical Screw, D=4.7mm, L=42mm | 32475-42 |
| Cortical Screw, D=4.7mm, L=44mm | 32475-44 |
| Cortical Screw, D=4.7mm, L=48mm | 32475-48 |
| Cortical Screw, D=4.7mm, L=52mm | 32475-52 |
| Cortical Screw, D=4.7mm, L=56mm | 32475-56 |
| Cortical Screw, D=4.7mm, L=60mm | 32475-60 |
| Cortical Screw, D=4.7mm, L=65mm | 32475-65 |
| Cortical Screw, D=4.7mm, L=70mm | 32475-70 |
| Cortical Screw, D=4.7mm, L=75mm | 32475-75 |
| Cortical Screw, D=4.7mm, L=80mm | 32475-80 |
| Locking Key Wrench, WS 3.5, L=170mm | 56353-170 |
| Locking Key Wrench, WS 6, L=150mm | 56603-150 |
| Nail Length Gauge, Tibia Nail | 1186 |
| Screw Driver, WS 3.5, Conic, Self Holding | 56352-SH |
| Extraction Rod, Tibia Nail, Connexx | 115300 |
| Flatwrench, WS 17 | 70017 |
| Slip Weight, Tibia Nail Connexx | 115400 |
| Depth Gauge, Solid Small Fragment Screws | 59022 |
| Spiral Drill, D=4.2mm, L=280mm, AO Connector | 61423-280 |
| Drill, Angledrived, D=4.2mm, L=140mm, AO Connector | 61427-140 |
| Locking Bolt, Connexx | 110901-1 |
| Endcap, Connexx | 110901-2 |
| Sterilization Tray Connexx, Instruments | 50192 |

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 I.T.S. 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 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 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 I.T.S. 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 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.

**Restrictions**

- Unless otherwise stated, repeated preparation of re-usable instruments of I.T.S. 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 disinfector 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 disinfector.

Step 3 After removing the instruments from the disinfector, 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 cycled 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 I.T.S. 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 | Tempera-ture | Pressure | Duration of drying |
|---|---|---|---|---|
| Prevacuum | 4 minutes | 132°C 270°F | 3.04 bar 27 psi | 60 minutes |
| Prevacuum² | 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

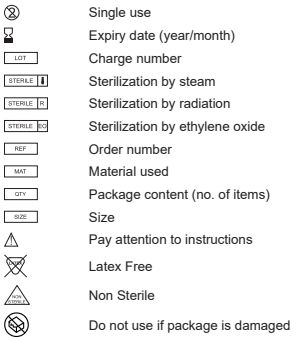
**Disposal**
The valid guidelines of the hospital operator apply for disposal.

**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 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, have to be disposed of.
- 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 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**




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

# Dotize®

**Chemical process - anodization in a strong alkaline solution***

**Type III anodization**

Layer thickness 60-200nm

+ Different colors

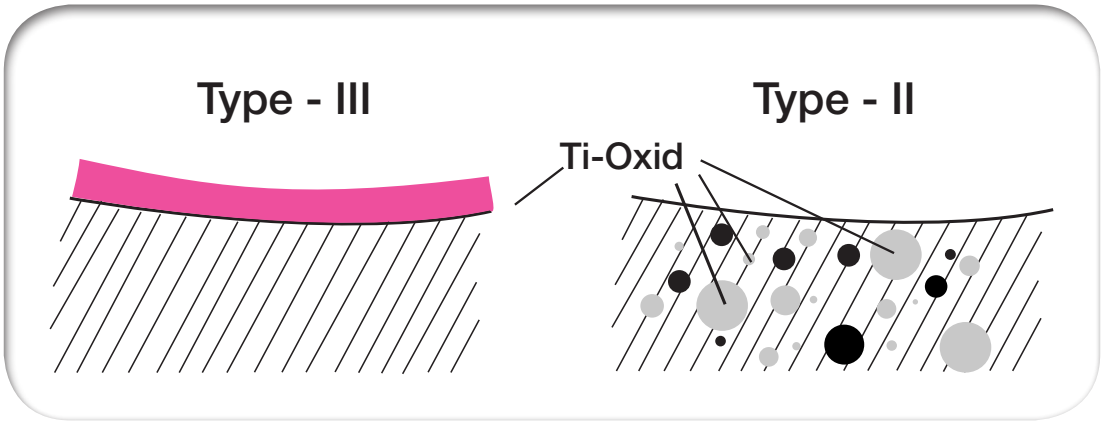
- Implant surface remains sensitive to:
  Chipping
  Peeling
  Discoloration

**Type II anodization**

Layer thickness 2000-10 000nm

+ Film become an interstitial part of the titanium

- No visible cosmetical 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

* White Paper: Ti6Al4V with Anodization Type II: Biological Behavior and Biomechanical Effects; Axel Baumann, Nils Zander

# Notes

I.T.S. GmbH
part of the MED-HOLD GROUP
Autal 28, 8301 Lassnitzhöhe, Austria

Tel.: +43 | 316 | 211 21 0
Fax: +43 | 316 | 211 21 20
office@its-implant.com
www.its-implant.com

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