

ITS.

Implants
trauma



CTN

Cannulated Tibia Nail

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Introduction



○ Preface

The newly developed **CTN - Cannulated Tibia Nail** enables the surgical treatment of various fractures of the tibia.

Stable, ridged fixation of fractures can be achieved, with the advantage of early weight bearing due to intramedullary insertion.



○ Screw

32475-XX Cortical Screw, D=4.7mm

61423-350 Spiral Drill, D=4.2mm, L=350mm, AO Connector

61427-140 Spiral Drill, Angledrilled, D=4.2mm, L=140mm

54353-230SH Screwdriver Shank, PRS, Solid, WS 3.5,
L=230mm, AO Connector



○ Properties

Properties of the material:

- ♦ Nail material: TiAl6V4 ELI
- ♦ Material of screw: TiAl6V4 ELI
- ♦ Easier removal of the implant if necessary
- ♦ Improved fatigue strength of the implant
- ♦ Reduced risk of inflammation and allergy

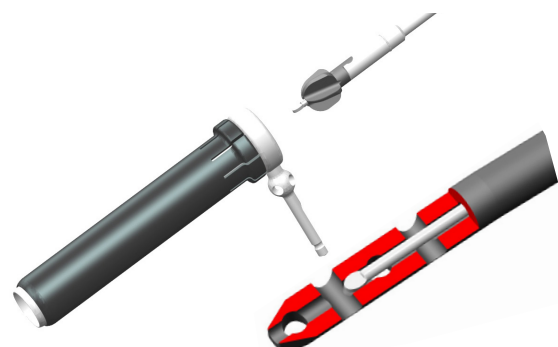
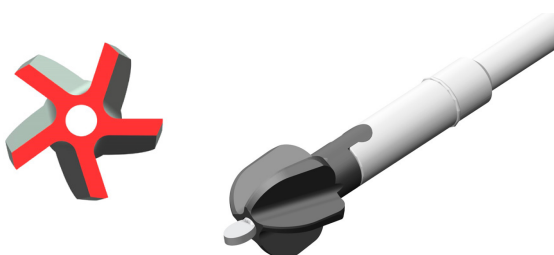
Properties of the implant:

- ♦ Anatomically shaped
- ♦ Radiolucent insertion guide
- ♦ Intramedullary insertion allows early weight bearing
- ♦ Multi-direction proximal Locking
- ♦ Dynamic interlock options to allow for fracture compression on axial loading without sacrificing rotational stability
- ♦ The most distal hole is inclined 15° posteriorly in the AP direction with respect to the shaft axis in order to resist shear forces in the tibia fracture

○ Reamer (optional)

Properties:

- ♦ Nitinol shaft with large AO-Connector, easy to clean
- ♦ Reamer heads available from 8.0 to 14mm in 0.5 increments
- ♦ 5 Reamer blades with 67% free clearance space for low intramedullary pressure and temperature
- ♦ Ball tipped guide wire for reaming fits through nail (no change of wire)
- ♦ Radiolucent and lightweight tissue protection sleeve with AO Connector and K-wire holes for fixation



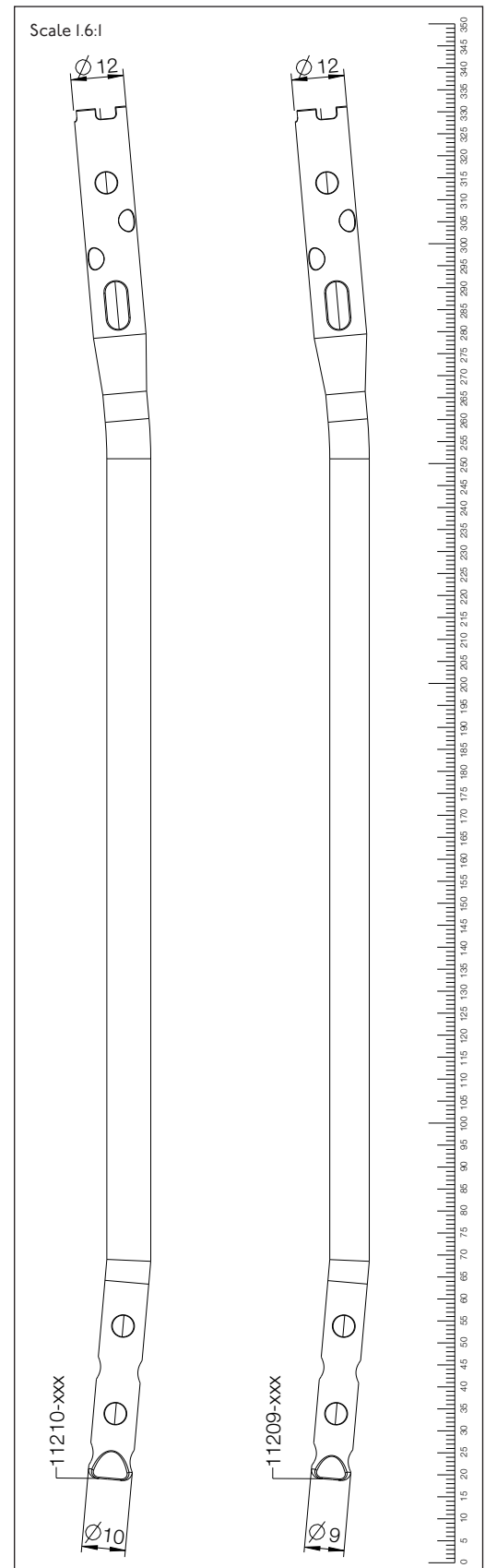
○ Measurement of nail length

1. Determine the nail length with the template (see right) and a X-Ray

Attention: Scale 1.6:1

2. Determine the nail length with the X-Ray ruler (**59205**).

3. Insert the calibrated D=2.5mm guide wire with ball tip (**35257-800**), attach the nail length gauge (**59206**) and advance it to the tibial cortex. Then read off the required nail length at the end of the gauge.



◦ Indications, Contraindications

Indications:

- ♦ Proximal, metaphyseal, diaphyseal and distal metaphyseal fractures
- ♦ Simple, segmental and comminuted fractures
- ♦ Open fractures of the tibia
- ♦ Surgical correction of non-unions, mal-unions and delayed unions
- ♦ Pathological fractures
- ♦ Fractures involving osteopenic and osteoporotic bone

Contraindications:

- ♦ Active infection near the fracture site
- ♦ Skeletally immature patients
- ♦ Severe osteoporosis or inadequate bone stock
- ♦ Skin and soft tissue problems
- ♦ Foreign body (material) sensitivity
- ♦ Obesity
- ♦ Lack of patient compliance

Surgical Technique

2.

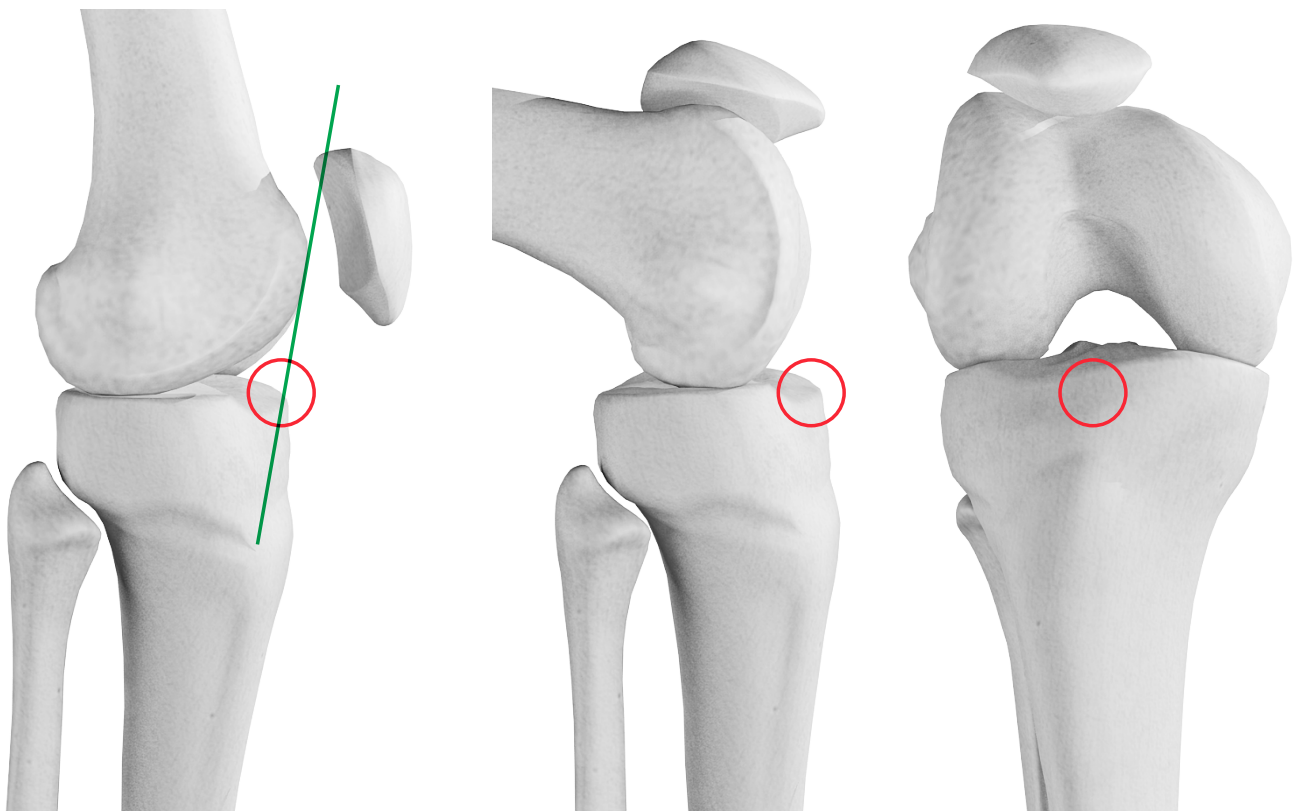
◦ Pre-operative patient planning

- Surgical planning depends on the operative technique individually preferred.
- In most cases, the patient should be placed supine on a standard radiolucent operating room table.

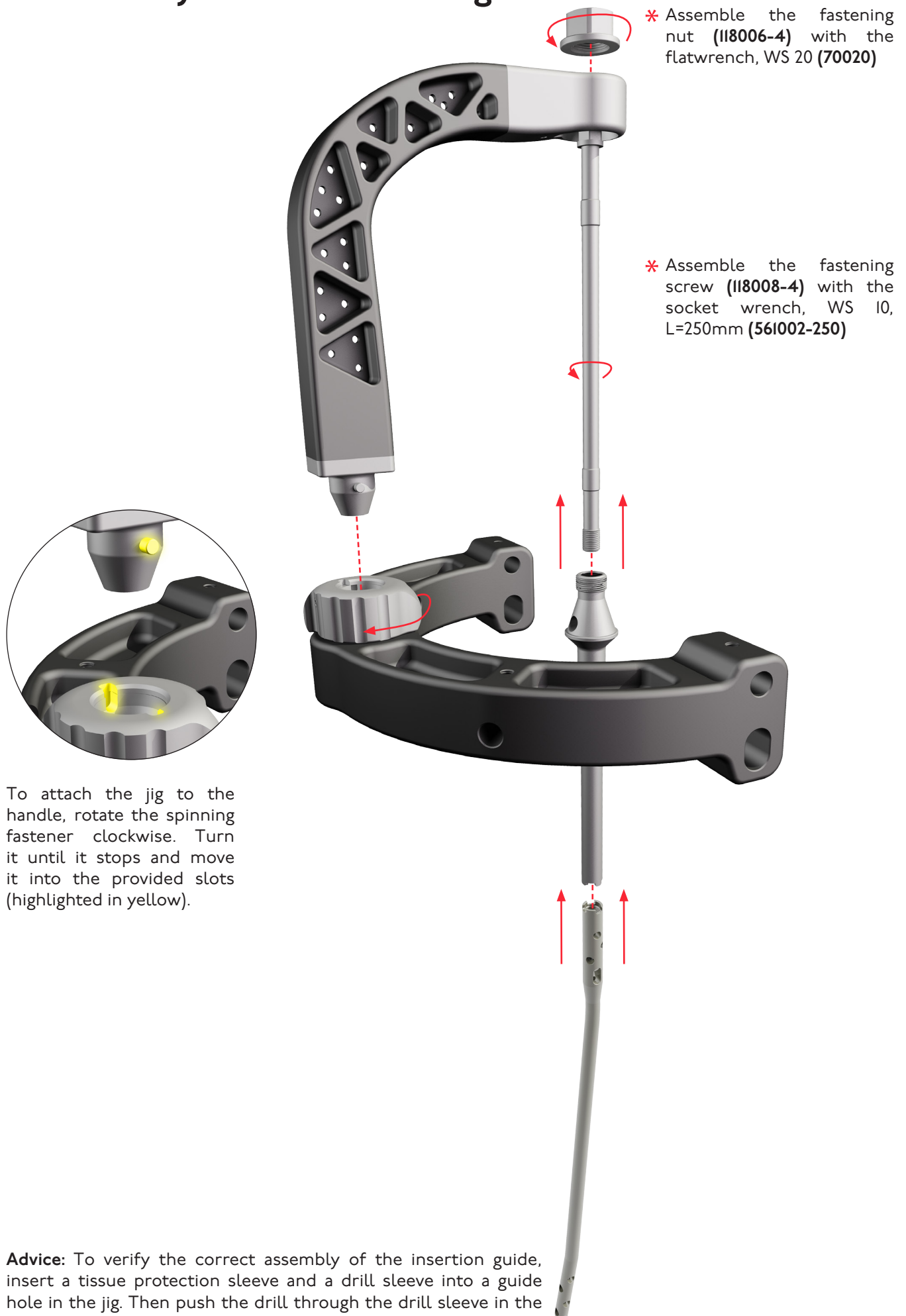
◦ Incision

Entry point depends on the surgeon's preference:

- Suprapatellar (green line) - usage of the protection sleeve is recommended
- Medial to the patellar ligament
- Through the patellar ligament
- Lateral to the patellar ligament



○ Assembly of the insertion guide



◦ Locating entry portal



- ♦ The entry portal for the insertion of a tibial nail is very important.
- ♦ The individual anatomy should be carefully evaluated.
- ♦ The insertion point should be in line with the medullary canal on the AP fluoroscopy view (just medial to the lateral tibial eminence) and just on the anterior roll over of the tibia plateau on the lateral fluoroscopy view.
- ♦ Open the medullary canal with the required drill, awl or gimlet to the desired diameter.
- ♦ If no reaming will be executed, introduce the D=2.5mm guide wire (**35251-800**). When using the optional available reamer, introduce the D=2.5mm guide wire with ball tip (**35257-800**), down to the level of the fracture, reduce the fracture and pass the guide wire distally under fluoroscopic guidance.

◦ Optional Reaming



- ♦ If appropriate, the canal should be reamed in a sequential manner starting with the smallest reamer and increasing size in 0.5mm increments to 1.0 to 1.5mm over the desired diameter of the nail.
- ♦ Additional proximal reaming is recommended to facilitate insertion - proximal nail diameter is 12mm.
- ♦ For suprapatellar approach the usage of the protection sleeve is recommended.

Note: Reamer heads available from 8.0 to 14mm in 0.5 increments

Note: Ball tipped guide wire will stop the reamer head.

◦ Nailing



- Attach the CTN to the insertion guide and pass the nail over the guide wire as far as possible into the medullary space by hand.
- When the nail will no longer advance by hand, the impactor screw (**II8006-II**) or the impaction/retraction rod (**II8006-2I**) can be gently tapped with the slotted hammer (**I-1920**) while watching the nail for advancement across the fracture under fluoroscopy.
- The ideal position of the tibia nail should be 1cm proximal to the tibiotalar joint or the level of the distal epiphyseal scar.
- If the CTN has been inserted too distally, it can be repositioned manually or back-slapped by using the impaction/retraction rod (**II8006-2I**) and the slotted hammer (**I-1920**).

Note: Circumferential indentations (visible under fluoroscopy) in 5mm increments at the distal end of the adapter facilitates the determination of the correct depth.

Attention: Manipulate the nail gently to avoid penetration of the anterior cortex. Please do not hit the insertion guide directly with the hammer (because of material damage)!

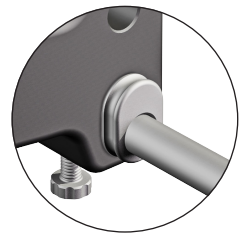
Advice: If you lock the nail distally first, it is possible to compress the fracture gap by using the impaction/retraction rod and the slotted hammer to impact the fracture.

○ Proximal Locking

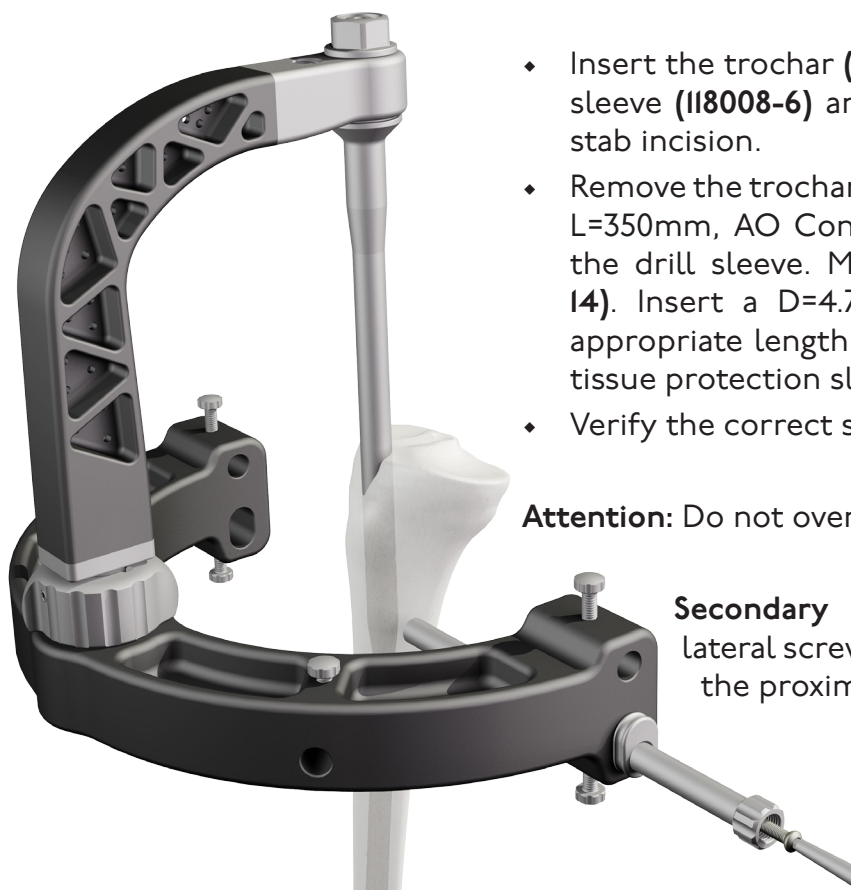
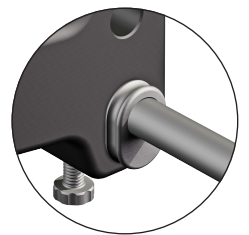


- For proximal locking, the jig is attached to the handle with the spinning fastener (see page 10).
- The circular holes on the handle provide static locking with rotational and axial stability.
- Dynamic compression can be carried with a single proximal screw in the oblong hole, which provides rotation stability with axial compression on weight bearing.

Static Locking:
eccentric hole distal



Dynamic Locking:
eccentric hole proximal



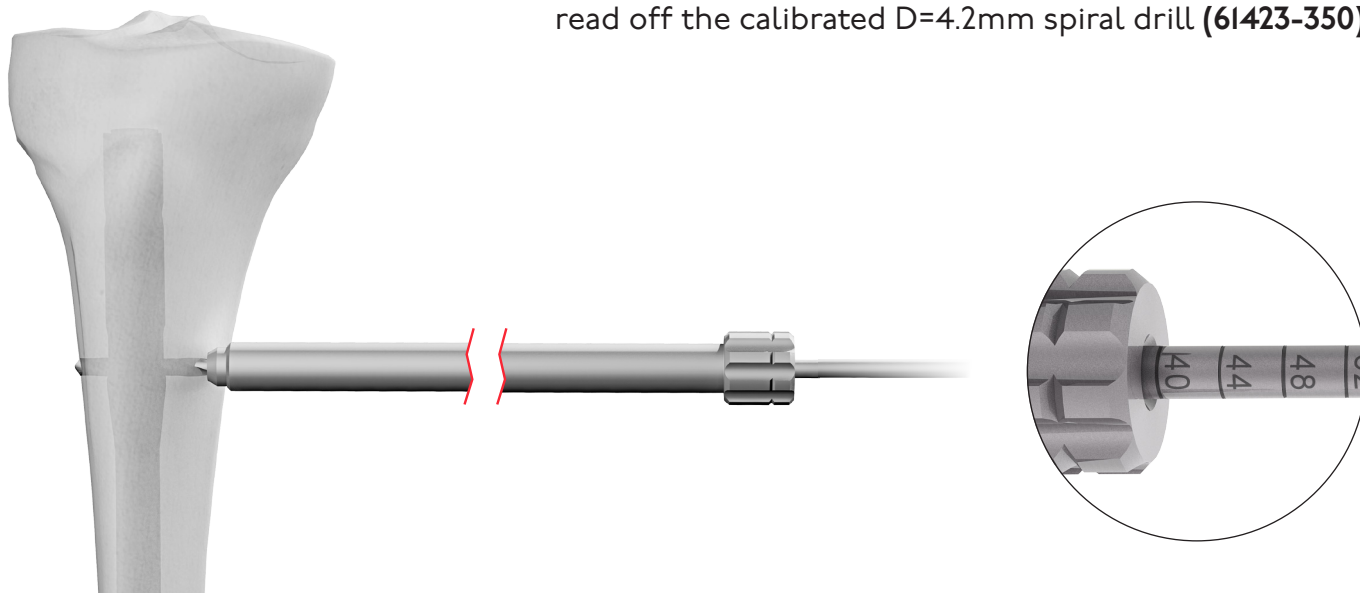
- Insert the trochar (**118008-8**) through the D=4.3mm drill sleeve (**118008-6**) and advance to the cortex through a stab incision.
- Remove the trochar and insert the spiral drill, D=4.2mm, L=350mm, AO Connector (**61423-350**) to drill through the drill sleeve. Measure the screw length (**see page 14**). Insert a D=4.7mm cortical screw (**32475-XX**) of appropriate length determined previously through the tissue protection sleeve.
- Verify the correct screw position under fluoroscopy.

Attention: Do not overtighten the screws.

Secondary dynamization: Insert both medial/lateral screws. If compression is desired, remove the proximal medial/lateral screw.

◦ Measuring of proximal screw length

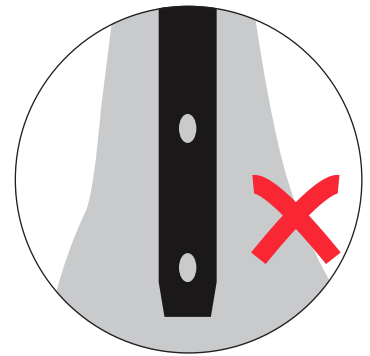
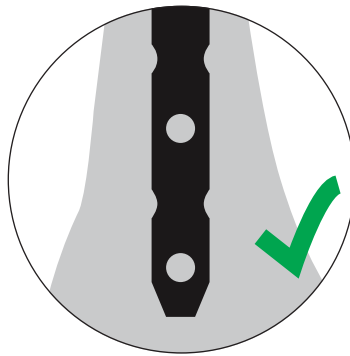
Drilling of the screw holes under fluoroscopy can be done. Once the far cortex is drilled the length can be read off the calibrated D=4.2mm spiral drill (61423-350).



◦ Distal Locking



- Distal locking is carried out using fluoroscopy and perfect circle technique.
- Before locking, the correct reduction should be verified.

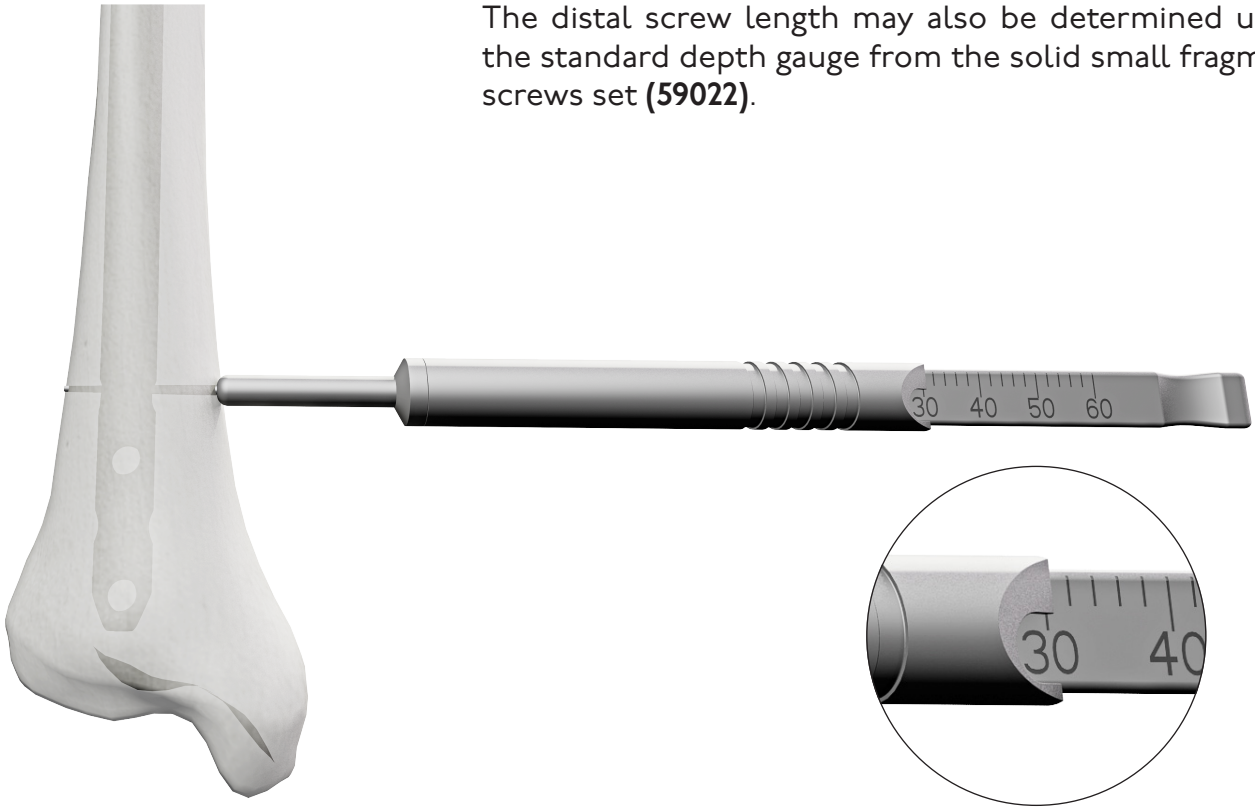


- The spiral drill, angledrived, D=4.2mm, L=140mm, AO Connector (**61427-140**), is used to drill through the near and far cortex.
- Measure the screw length.
- Insert a D=4.7mm cortical screw (**32475-XX**) of appropriate length determined previously.
- Verify the correct screw position under fluoroscopy.

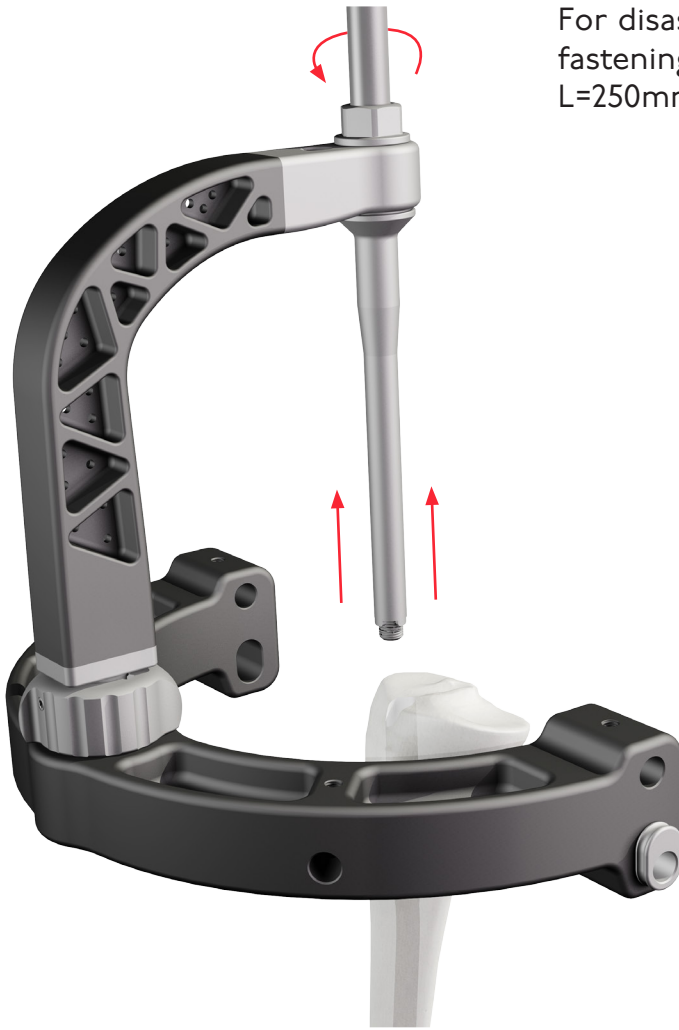
Attention: Do not overtighten the screws.

◦ Measuring of distal screw length

The distal screw length may also be determined using the standard depth gauge from the solid small fragment screws set **(59022)**.



◦ Removal of the insertion guide

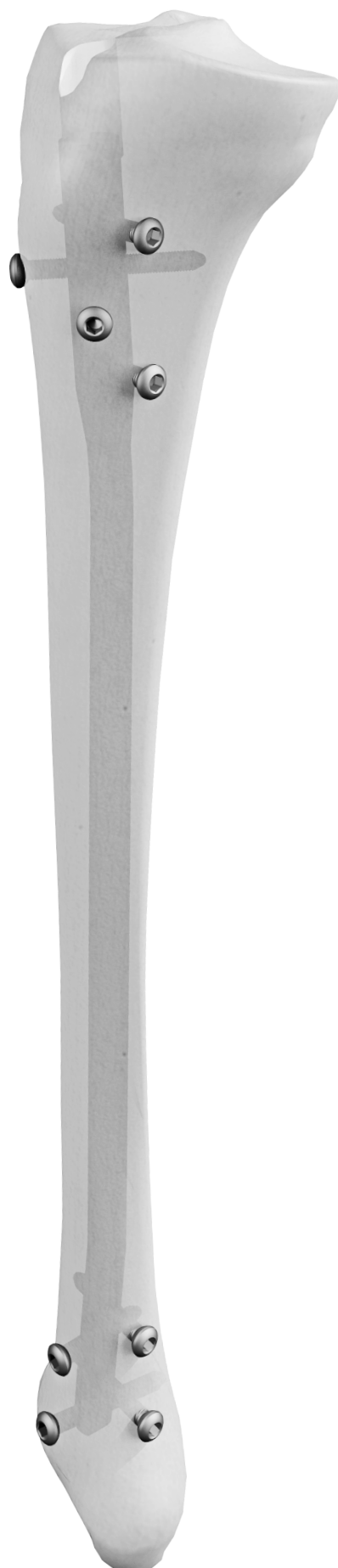


For disassembly of the insertion guide (**118008**) release the fastening screw (**118008-4**) with the socket wrench, WS 10, L=250mm (**561002-250**) and remove it.

◦ Endcap insertion

Finally screw the endcap with the screwdriver shank, PRS, solid, WS 3.5mm, L=230mm, AO Connector (**54353-230SH**) 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.

Final verification of nail position under fluoroscopy.



○ Postoperative treatment

- Standard postoperative protocols for management of tibia fractures apply.
- Weight bearing status and range of motion will be determined by the surgeon for the individual needs of the patient.

○ Nail removal

- Removal is possible, if necessary or desired by the patient. The situation is facilitated by the fact that cold welding never occurs.
- Implant removal is performed after radiographic verification of the healed fracture.
- Skin incision over the previous surgical site.
- Remove the endcap and all screws with the screwdriver shank, PRS, solid, WS 3.5mm, L=230mm, AO Connector **(54353-230SH)**.

- Finally, the extraction rod **(118008-9)** is screwed into the nail using the flatwrench, WS 17 **(70017)**.
- Using light taps with the slotted hammer **(1-1920)** to remove the nail from the medullary space.
- The problem of cold welding was resolved by using a special surface treatment (for further information see page 21).



Information

3.

◦ Dotize®

Chemical process - anodization in a strong alkaline solution*

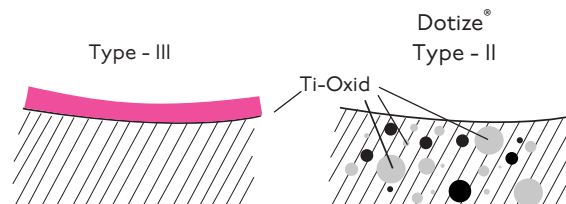
Type III anodization

- ♦ 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

Cannulated Tibia Nail, D=9mm, L=285mm	11209-285	
Cannulated Tibia Nail, D=9mm, L=300mm	11209-300	
Cannulated Tibia Nail, D=9mm, L=315mm	11209-315	
Cannulated Tibia Nail, D=9mm, L=330mm	11209-330	
Cannulated Tibia Nail, D=9mm, L=345mm	11209-345	
Cannulated Tibia Nail, D=9mm, L=360mm	11209-360	
Cannulated Tibia Nail, D=9mm, L=375mm	11209-375	
Cannulated Tibia Nail, D=9mm, L=390mm	11209-390	
Cannulated Tibia Nail, D=9mm, L=405mm	11209-405	
Cannulated Tibia Nail, D=9mm, L=420mm	11209-420	
Cannulated Tibia Nail, D=10mm, L=285mm	11210-285	
Cannulated Tibia Nail, D=10mm, L=300mm	11210-300	
Cannulated Tibia Nail, D=10mm, L=315mm	11210-315	
Cannulated Tibia Nail, D=10mm, L=330mm	11210-330	
Cannulated Tibia Nail, D=10mm, L=345mm	11210-345	
Cannulated Tibia Nail, D=10mm, L=360mm	11210-360	
Cannulated Tibia Nail, D=10mm, L=375mm	11210-375	
Cannulated Tibia Nail, D=10mm, L=390mm	11210-390	
Cannulated Tibia Nail, D=10mm, L=405mm	11210-405	
Cannulated Tibia Nail, D=10mm, L=420mm	11210-420	
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	
Handle, 25mm, AO Connector	53011	
Screwdriver Shank, PRS, Solid, WS 3.5mm, L=230mm, AO Connector	54353-230SH	
Depth Gauge, Solid Small Fragment Screws	59022	   
X-Ray Ruler, Cannulated Tibia Nail	59205	
Depth Gauge, for Cannulated Tibia- & Femur Nail	59204	
Nail Length Gauge,	59206	
Spiral Drill, D=4.2mm, L=350mm, AO Connector	61423-350	 
Spiral Drill, angledrived, D=4.2mm, L=140mm	61427-140	
Guide Wire, Steel, D=2.5mm, L=800mm	35251-800	  
Guide Wire, Steel, with ball tip, D=2.5mm, L=800mm	35257-800	
Guide Wire, Steel, D=3.2mm, L=228mm	35324-228	

Impactor Screw, CNS	118006-11	
Socket Wrench, WS 10, L=250mm	561002-250	
Extraction Rod, Cannulated Tibia Nail	118008-9	
Impaction/Retraction Rod, CNS	118006-21	
Slotted Hammer	1-1920	
Endcap, Standard, Cannulated Tibia Nail	118008-10	
Endcap, +5mm, Cannulated Tibia Nail	118008-11	
Endcap, +10mm, Cannulated Tibia Nail	118008-12	
Endcap, +15mm, Cannulated Tibia Nail	118008-13	
Endcap, +20mm, Cannulated Tibia Nail	118008-14	
Endcap, +25mm, Cannulated Tibia Nail	118008-15	
Endcap, +30mm, Cannulated Tibia Nail	118008-16	
Flat Wrench, WS 10	70010	
Flat Wrench, WS 17	70017	
Flat Wrench, WS 20	70020	
Outer Protection Sleeve, D=17.0mm, Radiolucent, Suprapatellar	118008-29	
Trochar, Cannulated, Suprapatellar	118008-27	
Protection Sleeve, D=15.0mm, AO Connector	118008-28	
Awl	1-1902	
Awl, 16cm	9-1456	
Gimlet, Cannulated	1-1906	
Sterilization Tray, Cannulated Tibia Nail	50268	
Insertion Guide, Cannulated Tibia Nail	118008	
Spare Parts List Insertion Guide / Optional (on request)		
Handle, Cannulated Tibia Nail	118008-1	
Jig, Cannulated Tibia Nail	118008-2	
Fastening Nut, CNS	118006-4	
Adapter, Cannulated Tibia Nail	118008-3	
Fastening Screw, Cannulated Tibia Nail	118008-4	

Order list

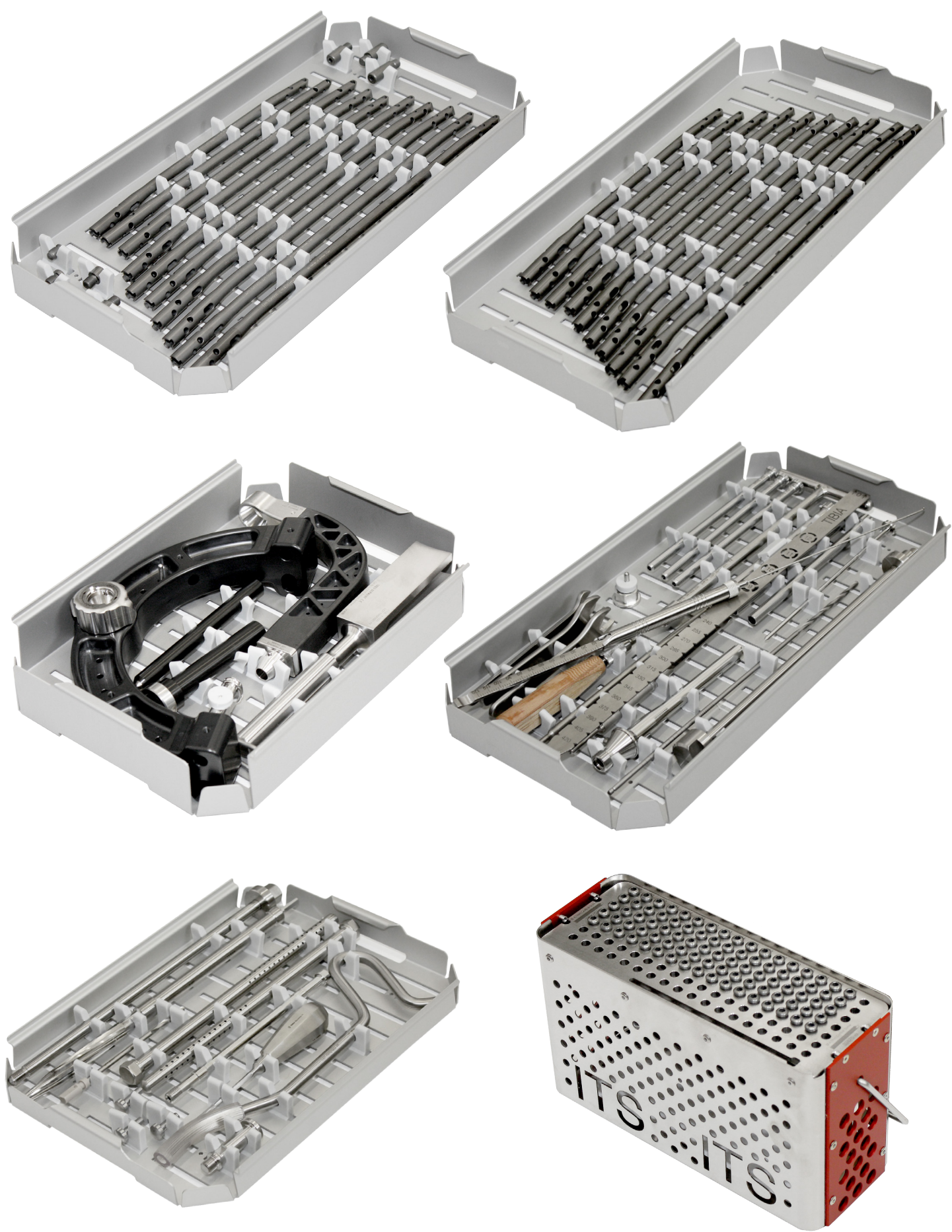
Tissue Protection Sleeve, Cannulated Tibia Nail	118008-5	
Drill Sleeve, D=4.3mm, Cannulated Tibia Nail	118008-6	
Sleeve, Eccentric	118008-7	
Trochar, Cannulated Tibia Nail	118008-8	
Clamping Screw	118003-12	

Special instruments optional on request *

Nitinol Reamer Shaft, D=5.0mm, L=473mm, AO Connector	63500-473	
Convex Reamer Head, D=8.0mm	63501-080	
Convex Reamer Head, D=8.5mm	63501-085	
Convex Reamer Head, D=9.0mm	63501-090	
Convex Reamer Head, D=9.5mm	63501-095	
Convex Reamer Head, D=10.0mm	63501-100	
Convex Reamer Head, D=10.5mm	63501-105	
Convex Reamer Head, D=11.0mm	63501-110	
Convex Reamer Head, D=11.5mm	63501-115	
Convex Reamer Head, D=12.0mm	63501-120	
Convex Reamer Head, D=12.5mm	63501-125	
Convex Reamer Head, D=13.0mm	63501-130	
Convex Reamer Head, D=13.5mm	63501-135	
Convex Reamer Head, D=14.0mm	63501-140	

For detailed cleaning and sterilization instructions, please refer to package insert.

Tray setting



Notes



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