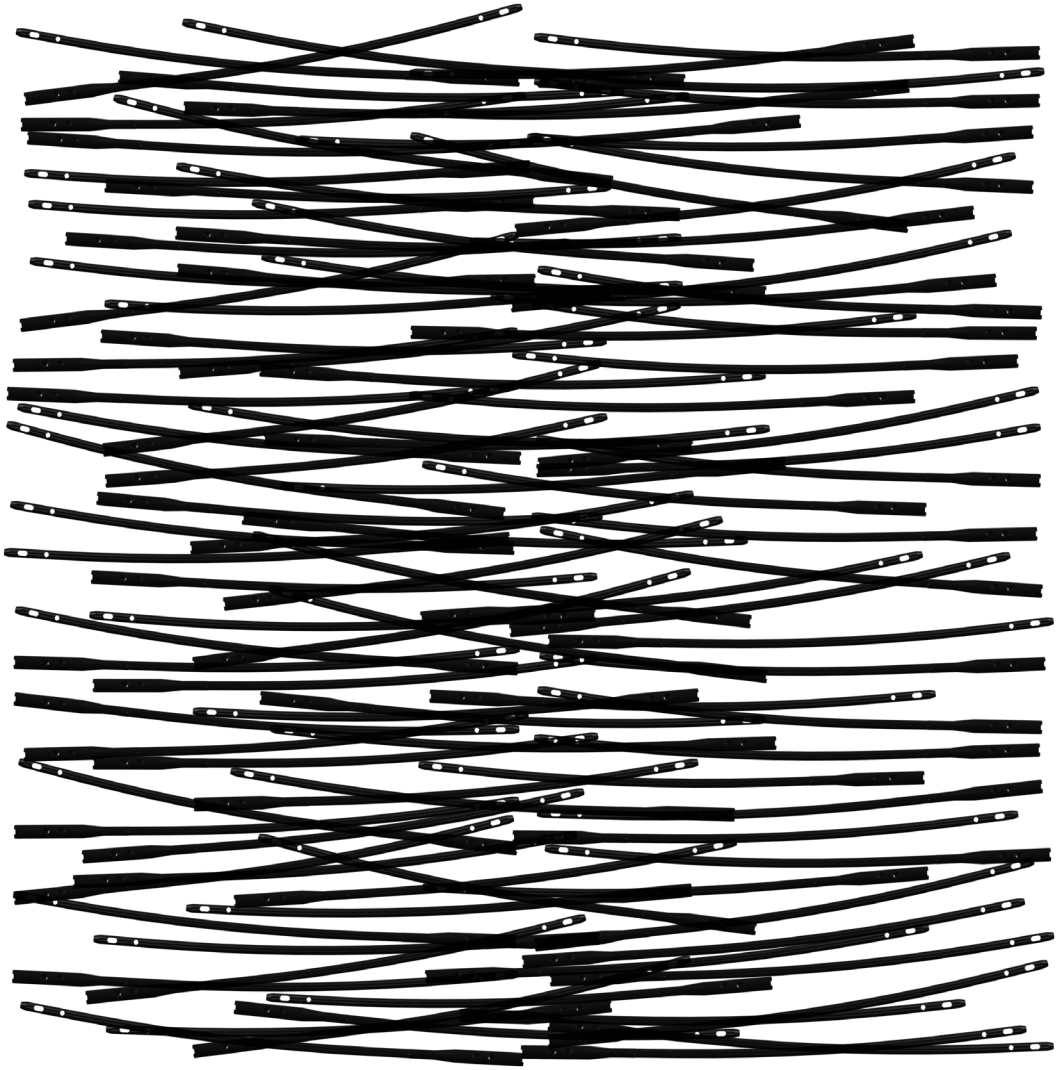
ITS.

Implants
trauma



# CFN

## Cannulated Femur Nail

**CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a board certified physician.

**WARNING:** If there is no sufficient bone healing, wrong or incomplete postoperative care, implant might break.

Contents

## 1. Introduction



## 2. Surgical Technique



## 3. Information

# Introduction

1.

# Preface

The newly developed **CFN - Cannulated Femur Nail** enables the surgical treatment of various fractures of the femur.

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

# Screws

**32652-XXX** Cortical Screw, D=6.5mm

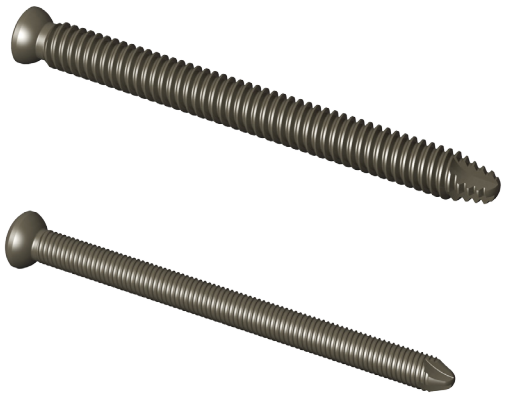
**61502-350** Spiral Drill, D=5.0mm, L=350mm, AO Connector

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

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

**61427-140** Spiral Drill, Angledrived, D=4.2mm, L=140mm

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



# Properties

## Properties of the material:

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

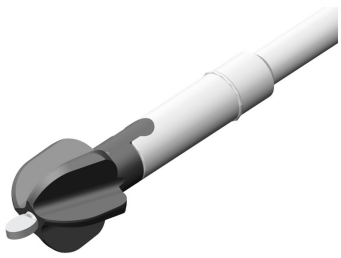
## Properties of the implant:

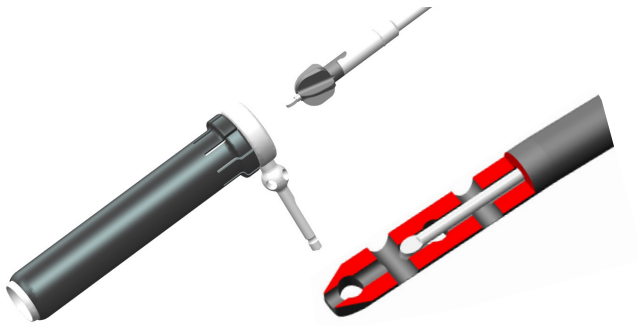
- Anatomically shaped
- Single radiolucent insertion guide for left and right sides
- Intramedullary insertion allows early weight bearing
- Multi-direction proximal Locking
- Dynamic interlock options to allow for fracture compression on axial loading without sacrificing rotational stability
- Left and right sided nails

# Reamer (optional)

## Properties:

- Nitinol shaft with large AO-Connector
- 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





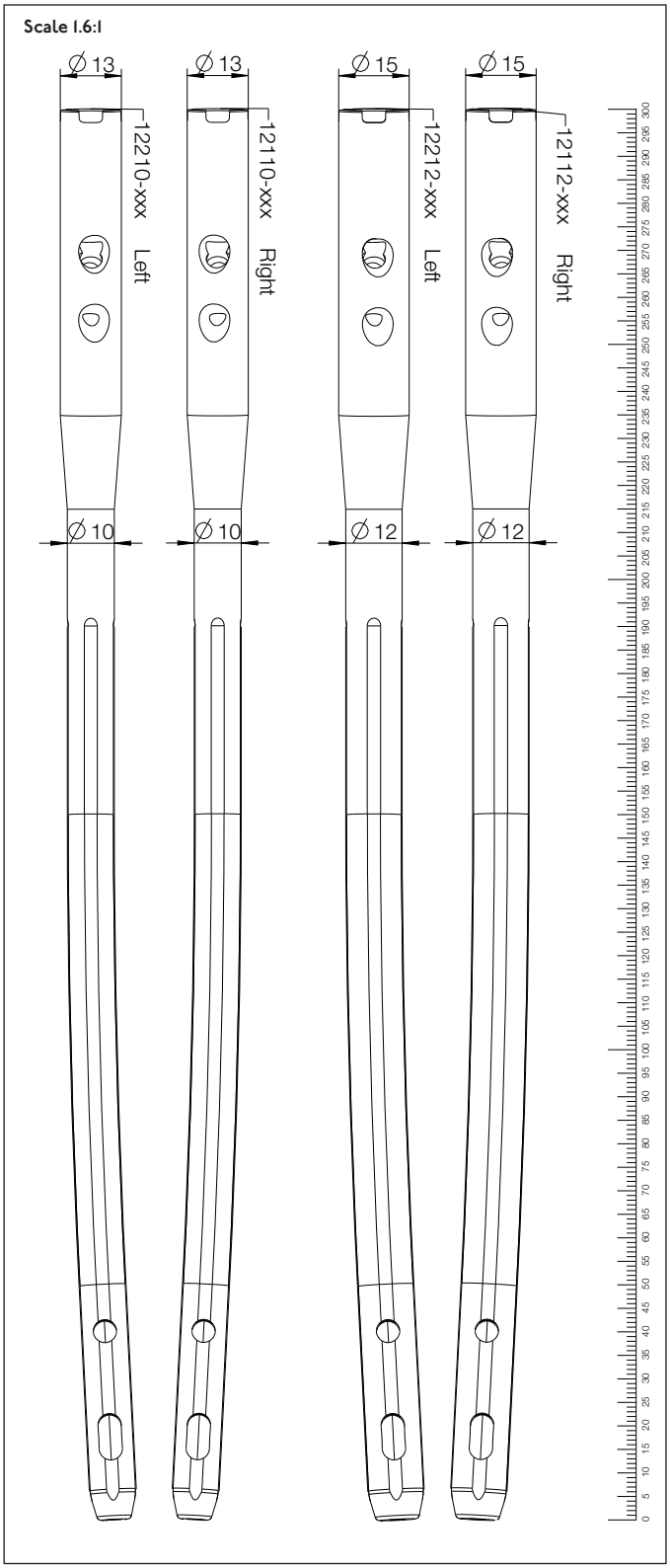
# Preoperative identification of nail length

**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 **(59203)**.

**3.** Insert the calibrated D=2.5mm guide wire with ball tip **(35258-800)** attach the nail length gauge **(59206)** and advance it to the cortex. Then read off the required nail length at the end of the gauge.

## Indications, Contraindications

### Indications:

- Open and closed metaphyseal and diaphyseal fractures
- Subtrochanteric and supracondylar fractures
- Segmental fractures
- Non-unions, mal-unions and delayed union fractures
- Pathological fractures, impending pathological fractures and tumor resections
- Fractures proximal to a total knee arthroplasty

### Contraindications:

- Active infection
- 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

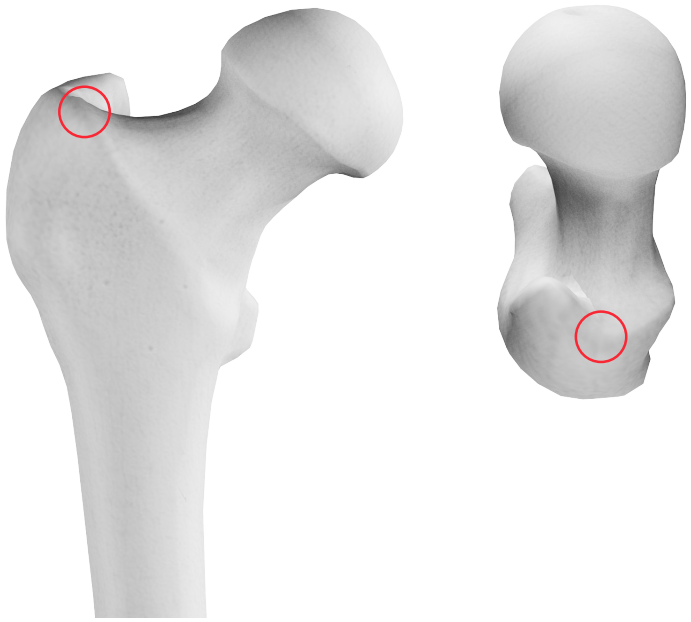
# 2.

## Pre-operative patient planning

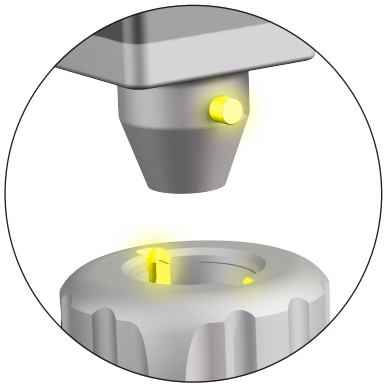
- Surgical planning depends on the operative technique individually preferred.
- Recommended position supine on a standard radiolucent operating room table with traction through the injured extremity (AP and lateral fluoroscopic imaging should be confirmed).

## Incision

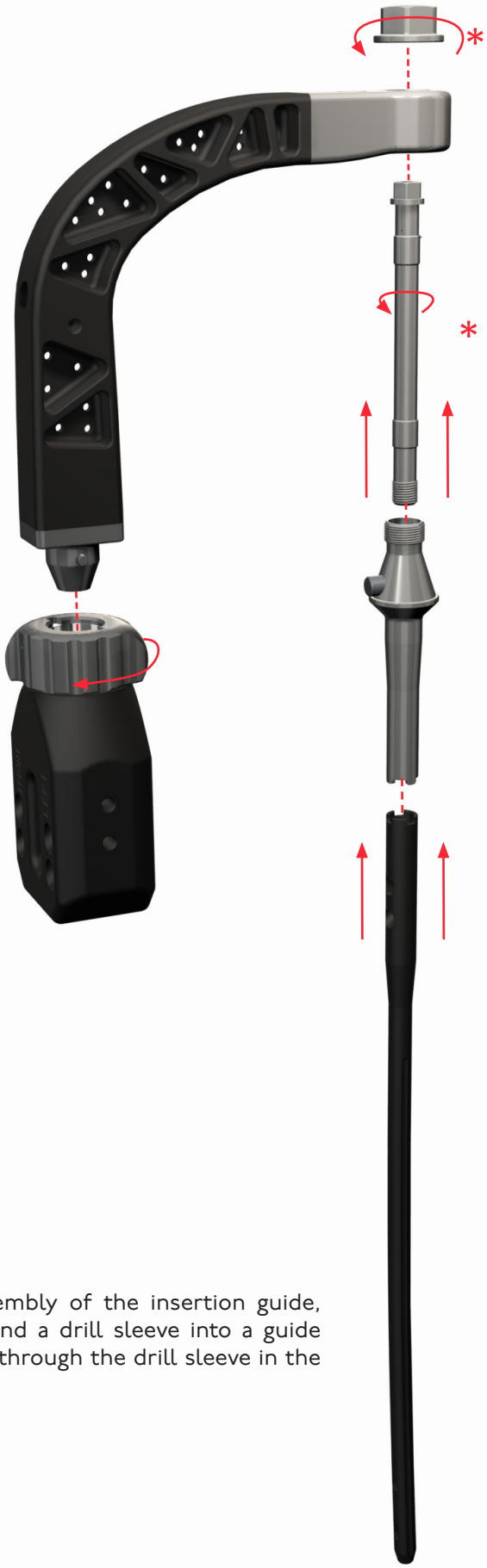
- Incision 2 - 3cm proximal to the greater trochanter in line with the longitudinal axis of the femur.
- Longitudinally split the fascia and use a trochar or finger palpation to identify the greater trochanter.



# Assembly of the insertion guide



To attach the jig to the handle, rotate the spinning fastener clockwise. Turn it until it stops and move it into the provided slots (highlighted in yellow).



* Assemble the fastening nut **(118006-4)** with the flatwrench, WS 20 **(70020)**

* Assemble the fastening screw **(118007-4)** with the socket wrench, WS 10, L=250mm **(561002-250)**

**Advice:** To verify the correct assembly of the insertion guide, insert a tissue protection sleeve and a drill sleeve into a guide hole in the jig. Then push the drill through the drill sleeve in the appropriate nail interlock hole.

## Locating entry portal

- Identification of the insertion portal is extremely important. The drill tip, guide wire or awl should be inserted at the medial edge of the greater trochanter on the AP fluoroscopic view and in line with the longitudinal axis of the femur on the lateral fluoroscopic view.
- Open the proximal medullary canal with the required drill, awl or gimlet to the desired diameter with the appropriate soft tissue protector in place.
- Introduce the D=3.0mm guide wire with ball tip **(35301-800)** when using the optional available reamer down to the level of the fracture, reduce the fracture and pass the guide wire distally under fluoroscopic guidance. The canal should then be reamed in a sequential manner starting with the smallest reamer and increasing size in 0.5mm increments to 1 to 1.5mm over the desired diameter of the nail.

## 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.
- The usage of the protection sleeve is recommended to avoid injuries of soft tissue.

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

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

# Nailing

- Remove the guide wire with ball tip and insert the D=2.5mm guide wire **(35251-800)**.
- Attach the CFN to the insertion guide and pass the nail over the guide wire as far as possible into the medullary canal by hand.
- When the nail will no longer advance by hand, the impactor screw **(118006-11)** or the impaction/retraction rod **(118006-21)** of the CFN can be gently tapped with the slotted hammer **(1-1920)** while watching the nail for advancement across the fracture under fluoroscopy.
- If the CFN has been inserted too distally, it can be repositioned manually or back-slapped by using the impaction/retraction rod **(118006-21)** and the slotted hammer **(1-1920)**.

**Attention:** The insertion guide must not be driven into the metaphysis. 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 / Femoral neck

- For proximal locking into the femoral neck the screw alignment guide is attached to the handle with the spinning fastener (see page 11).
- Insert the trochar **(118007-8)** through the D=5.1mm drill sleeve **(118007-7)** and advance to the cortex through a stab incision.
- Remove the trochar and insert the spiral drill, D=5.0mm, L=350mm, AO Connector **(61502-350)** to drill through the drill sleeve.
- Measure the screw length (see page 15).

- Insert a D=6.5mm cortical screw **(32652-XXX)** of appropriate length determined previously through the tissue protection sleeve.
- Verify the correct screw position under fluoroscopy.

**Attention:** Do not overtighten the screws.

# Proximal Locking / Greater to lesser trochanter

- For the proximal Locking into the lesser trochanter the tissue protection sleeve **(118007-5)** is inserted directly on the handle **(118007-1)**
- Insert the trochar **(118003-12)** through the D=5.1mm drill sleeve **(118007-7)** and advance to the cortex through a skin incision.

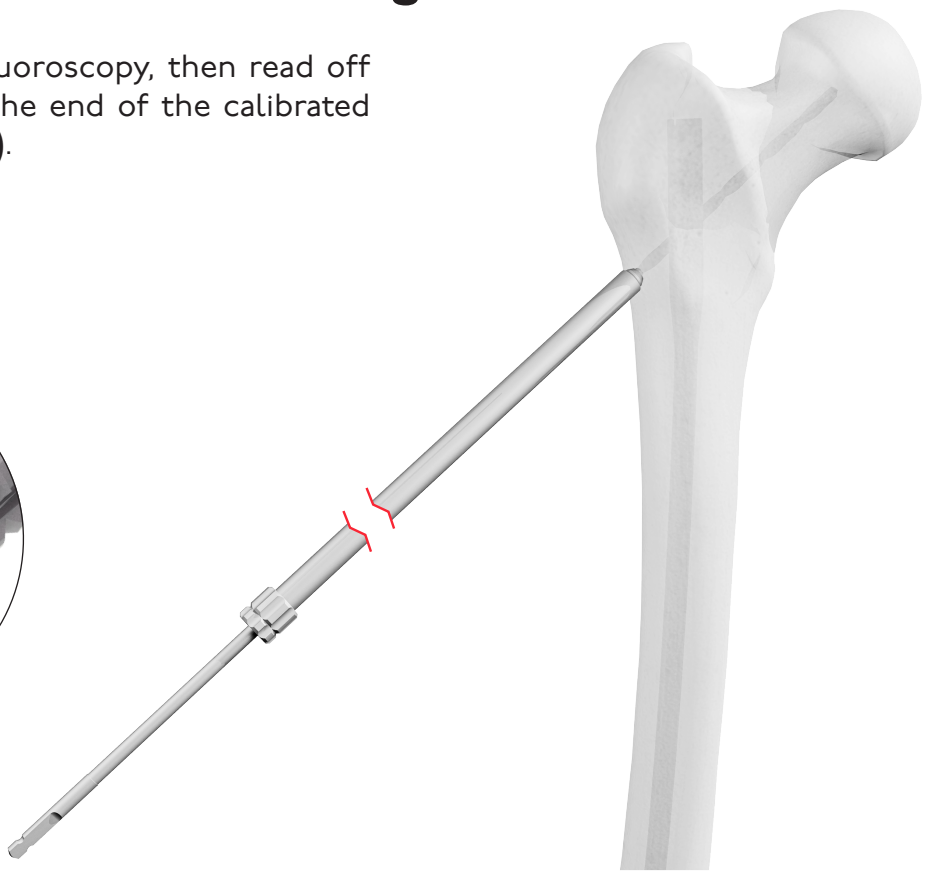
- Remove the trochar and insert the spiral drill, D=5.0mm, L=350mm, AO Connector **(61502-350)** to drill through the drill sleeve.
- Measure the screw length (see page 15).

- Insert a D=6.5mm cortical screw **(32652-XXX)** of appropriate length determined previously through the tissue protection sleeve.
- Verify the correct screw position under fluoroscopy.

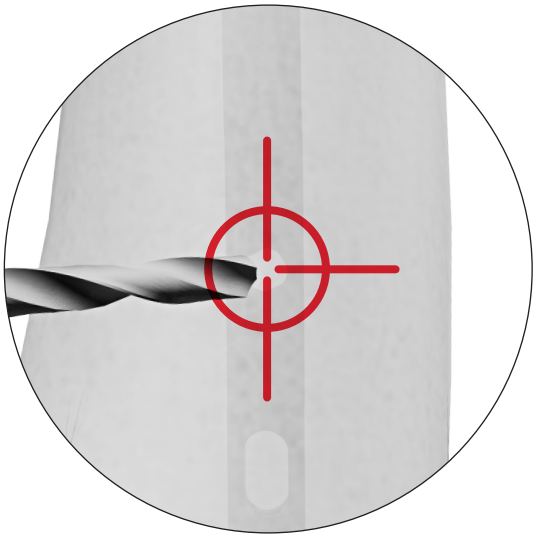
**Attention:** Do not overtighten the screws.

# Measuring of proximal screw length

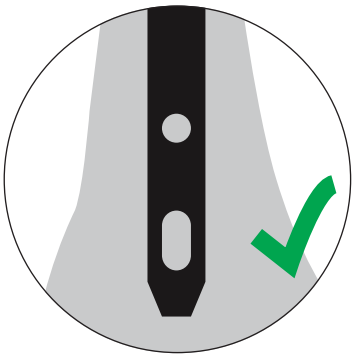
Drill the screw holes under fluoroscopy, then read off the required screw length at the end of the calibrated D=5.0mm spiral drill **(61502-350)**.

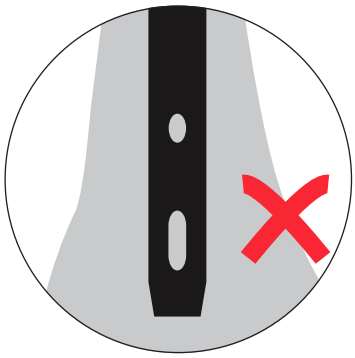



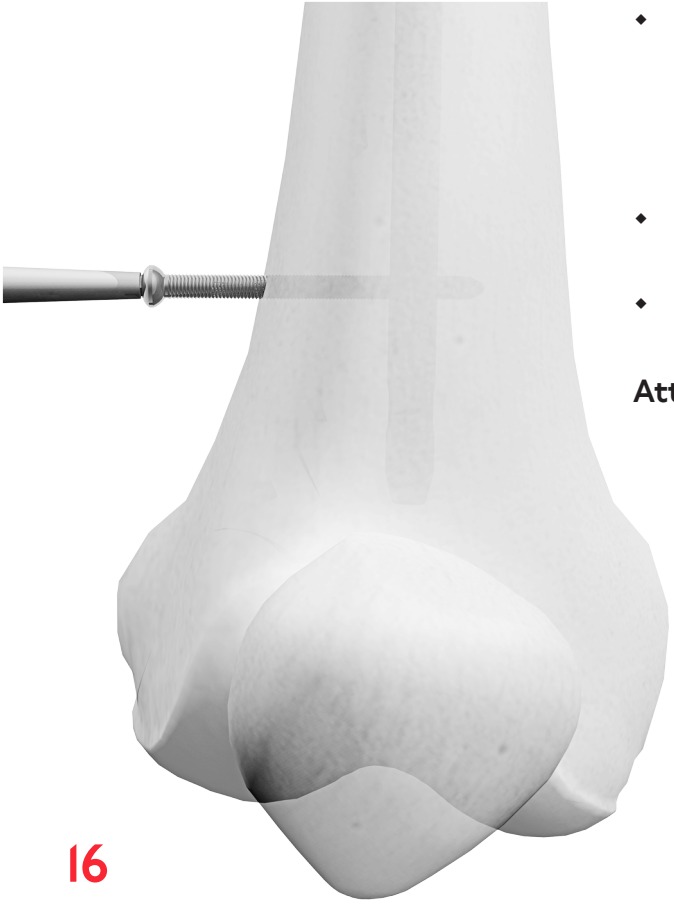

# Distal Locking



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





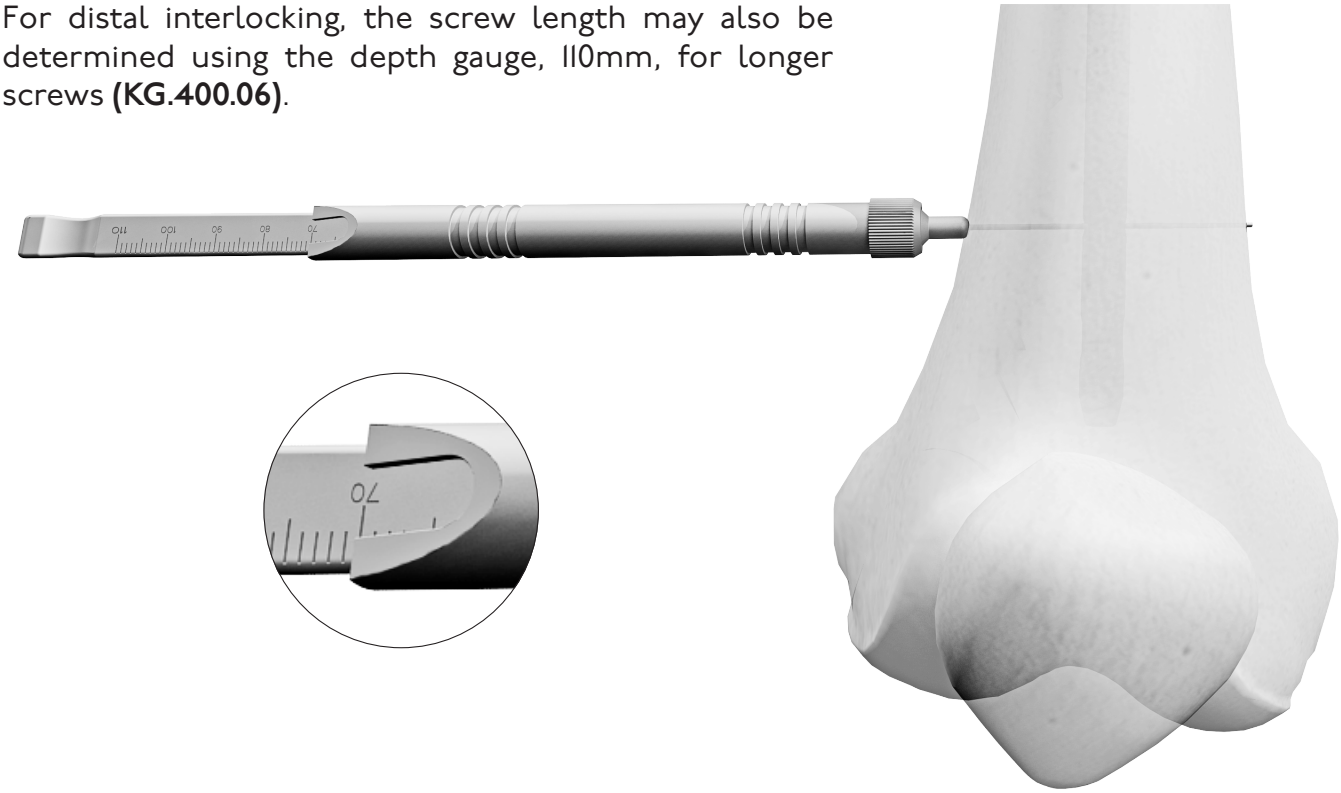


- The spiral drill, angledrived, D=4.2mm, L=140mm **(61427-140)** is used to drill through the medial and lateral cortex. Measure the screw length using the depth gauge **(KG.400.06)**. Insert a D=4.7mm cortical screw **(32475-XX)** of appropriate length determined previously.
- Additionally, the screw should rise above the lateral cortex at least 2mm
- Verify the correct screw position in the fluoroscopy.

**Attention:** Do not overtighten the screws.

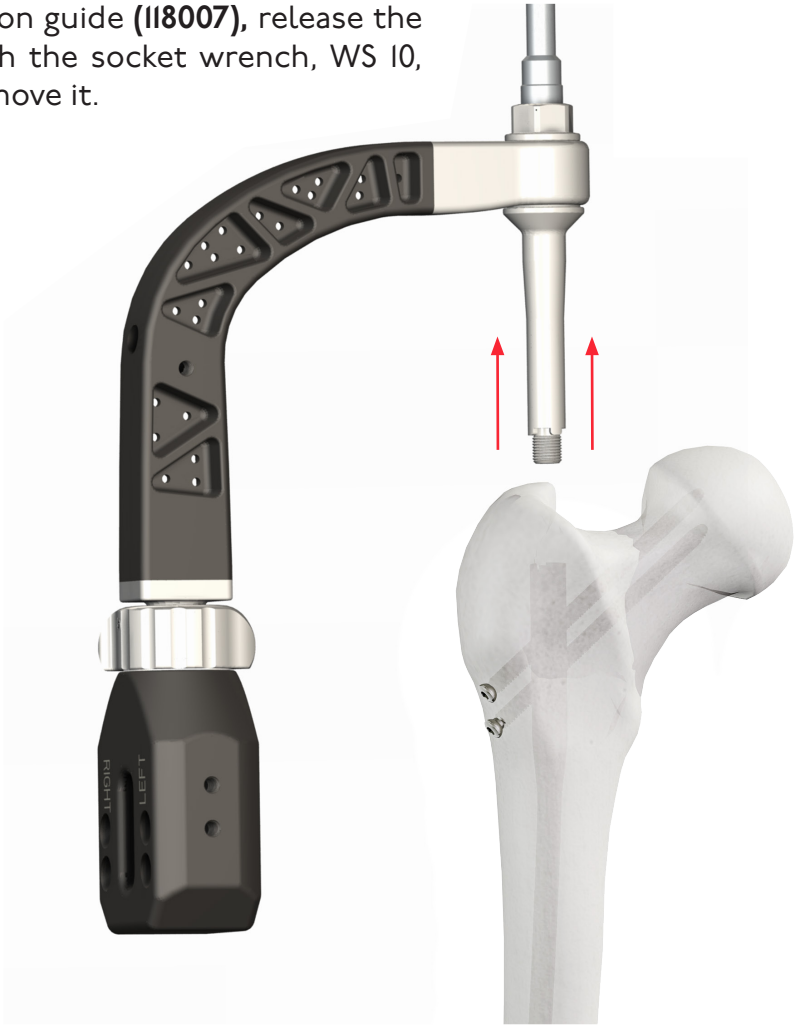
# Measuring of distal screw length

For distal interlocking, the screw length may also be determined using the depth gauge, 110mm, for longer screws **(KG.400.06)**.



## Removal of the insertion guide

For disassembly of the insertion guide **(118007),** release the fastening screw **(118007-4)** 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 femur nail against tissue growth, thus facilitating removal of the implant at a later date.

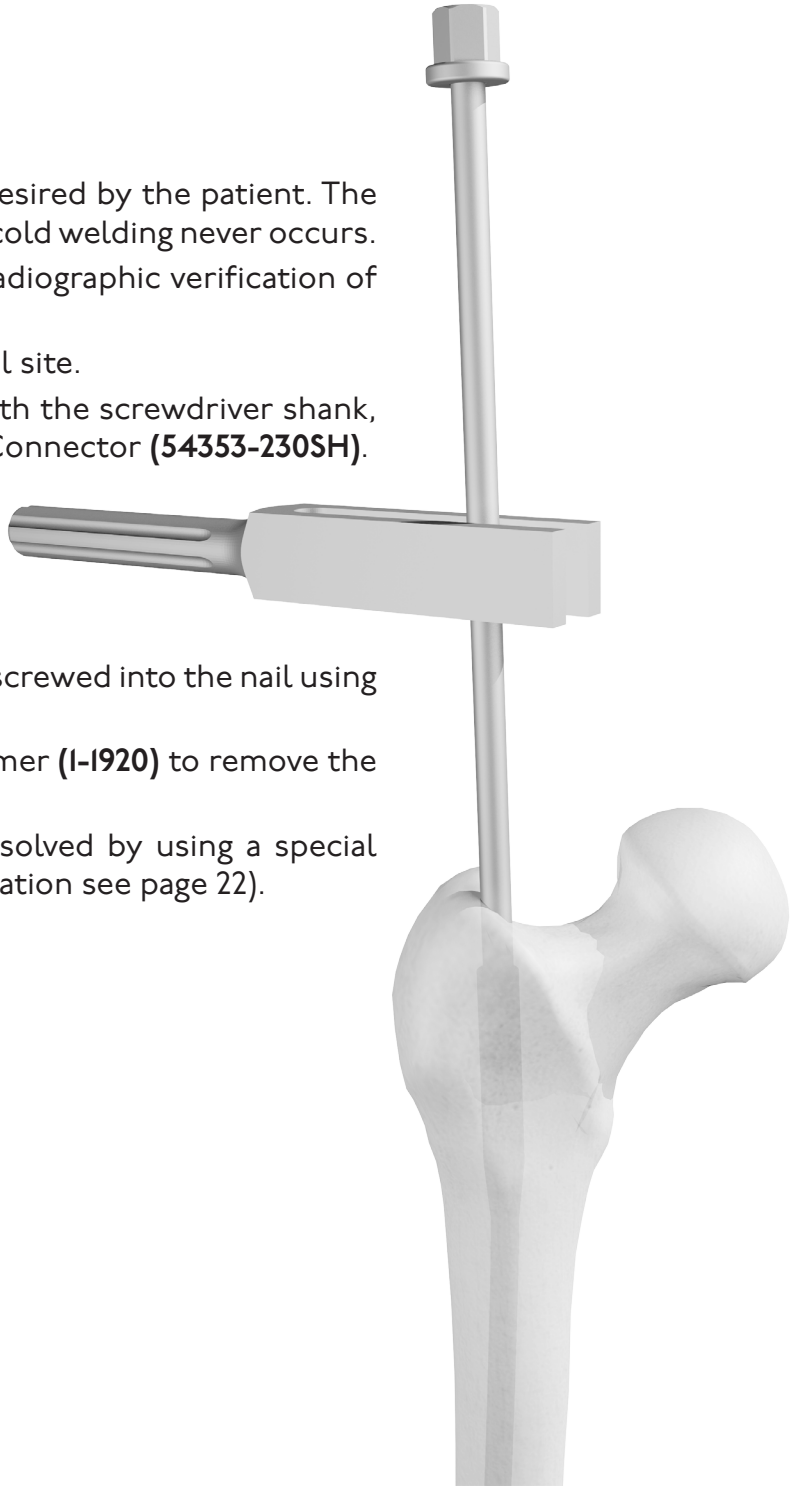
Final verification of nail position under fluoroscopy.

## Postoperative treatment

- Standard postoperative protocols for management of femur 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 **(118007-9)** 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 22).

# Information

# 3.

# Dotize®

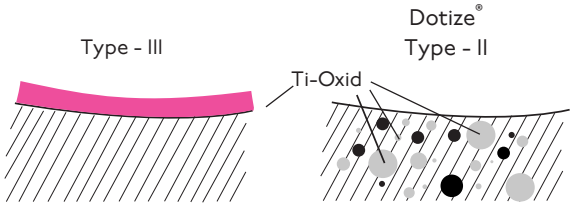
## Chemical process - anodization in a strong alkaline solution*

### 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



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

# Order list

| | |
|---|---|
| Cannulated Femur Nail, D=10mm, L=300mm, Right | 12110-300 |
| Cannulated Femur Nail, D=10mm, L=320mm, Right | 12110-320 |
| Cannulated Femur Nail, D=10mm, L=340mm, Right | 12110-340 |
| Cannulated Femur Nail, D=10mm, L=360mm, Right | 12110-360 |
| Cannulated Femur Nail, D=10mm, L=380mm, Right | 12110-380 |
| Cannulated Femur Nail, D=10mm, L=400mm, Right | 12110-400 |
| Cannulated Femur Nail, D=10mm, L=420mm, Right | 12110-420 |
| Cannulated Femur Nail, D=10mm, L=440mm, Right | 12110-440 |
| Cannulated Femur Nail, D=10mm, L=460mm, Right | 12110-460 |
| Cannulated Femur Nail, D=10mm, L=480mm, Right | 12110-480 |

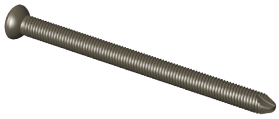
| | |
|---|---|
| Cannulated Femur Nail, D=10mm, L=300mm, Left | 12210-300 |
| Cannulated Femur Nail, D=10mm, L=320mm, Left | 12210-320 |
| Cannulated Femur Nail, D=10mm, L=340mm, Left | 12210-340 |
| Cannulated Femur Nail, D=10mm, L=360mm, Left | 12210-360 |
| Cannulated Femur Nail, D=10mm, L=380mm, Left | 12210-380 |
| Cannulated Femur Nail, D=10mm, L=400mm, Left | 12210-400 |
| Cannulated Femur Nail, D=10mm, L=420mm, Left | 12210-420 |
| Cannulated Femur Nail, D=10mm, L=440mm, Left | 12210-440 |
| Cannulated Femur Nail, D=10mm, L=460mm, Left | 12210-460 |
| Cannulated Femur Nail, D=10mm, L=480mm, Left | 12210-480 |

| | |
|---|---|
| Cannulated Femur Nail, D=12mm, L=300mm, Right | 12112-300 |
| Cannulated Femur Nail, D=12mm, L=320mm, Right | 12112-315 |
| Cannulated Femur Nail, D=12mm, L=340mm, Right | 12112-340 |
| Cannulated Femur Nail, D=12mm, L=360mm, Right | 12112-360 |
| Cannulated Femur Nail, D=12mm, L=380mm, Right | 12112-380 |
| Cannulated Femur Nail, D=12mm, L=400mm, Right | 12112-400 |
| Cannulated Femur Nail, D=12mm, L=420mm, Right | 12112-420 |
| Cannulated Femur Nail, D=12mm, L=440mm, Right | 12112-440 |
| Cannulated Femur Nail, D=12mm, L=460mm, Right | 12112-460 |
| Cannulated Femur Nail, D=12mm, L=480mm, Right | 12112-480 |

| | |
|---|---|
| Cannulated Femur Nail, D=12mm, L=300mm, Left | 12212-300 |
| Cannulated Femur Nail, D=12mm, L=320mm, Left | 12212-320 |
| Cannulated Femur Nail, D=12mm, L=340mm, Left | 12212-340 |
| Cannulated Femur Nail, D=12mm, L=360mm, Left | 12212-360 |
| Cannulated Femur Nail, D=12mm, L=380mm, Left | 12212-380 |
| Cannulated Femur Nail, D=12mm, L=400mm, Left | 12212-400 |
| Cannulated Femur Nail, D=12mm, L=420mm, Left | 12212-420 |
| Cannulated Femur Nail, D=12mm, L=440mm, Left | 12212-440 |
| Cannulated Femur Nail, D=12mm, L=460mm, Left | 12212-460 |
| Cannulated Femur Nail, D=12mm, L=480mm, Left | 12212-480 |

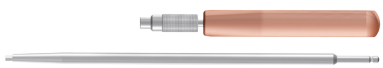
# Order list

| | |
|---|---|
| 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 |

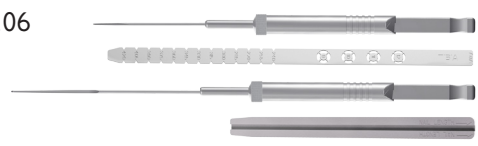


| | |
|---|---|
| Cortical Screw, D=6.5mm, L=40mm | 32652-40 |
| Cortical Screw, D=6.5mm, L=44mm | 32652-44 |
| Cortical Screw, D=6.5mm, L=48mm | 32652-48 |
| Cortical Screw, D=6.5mm, L=52mm | 32652-52 |
| Cortical Screw, D=6.5mm, L=56mm | 32652-56 |
| Cortical Screw, D=6.5mm, L=60mm | 32652-60 |
| Cortical Screw, D=6.5mm, L=64mm | 32652-64 |
| Cortical Screw, D=6.5mm, L=68mm | 32652-68 |
| Cortical Screw, D=6.5mm, L=72mm | 32652-72 |
| Cortical Screw, D=6.5mm, L=76mm | 32652-76 |
| Cortical Screw, D=6.5mm, L=80mm | 32652-80 |
| Cortical Screw, D=6.5mm, L=84mm | 32652-84 |
| Cortical Screw, D=6.5mm, L=88mm | 32652-88 |
| Cortical Screw, D=6.5mm, L=92mm | 32652-92 |
| Cortical Screw, D=6.5mm, L=96mm | 32652-96 |
| Cortical Screw, D=6.5mm, L=100mm | 32652-100 |
| Cortical Screw, D=6.5mm, L=105mm | 32652-105 |
| Cortical Screw, D=6.5mm, L=110mm | 32652-110 |
| Cortical Screw, D=6.5mm, L=115mm | 32652-115 |
| Cortical Screw, D=6.5mm, L=120mm | 32652-120 |

| | |
|---|---|
| Handle, 25mm, AO Connector | 53011 |
| Screwdriver Shank, PRS, Solid, WS 3.5mm, L=230mm, AO Connector | 54353-230SH |



| | |
|---|---|
| Depth Gauge, 110mm, for longer screws | KG.400.06 |
| X-Ray Ruler, Cannulated Femur Nail | 59203 |
| Depth Gauge, for Cannulated Tibia & Femur Nail | 59204 |
| Nail Length Gauge | 59206 |



| | |
|---|---|
| Spiral Drill, Angledrived, D=4.2mm, L=140mm | 61427-140 |
| Spiral Drill, D=5.0mm, L=350mm, AO Connector | 61502-350 |

| | | |
|---|---|---|
| Guide Wire, Steel, D=2.5mm, L=800mm<br>Guide Wire, Steel, Femur, D=2.5mm, L=800mm, Ball Tip<br>Guide Wire, Steel, D=3.2mm, L=228mm | 35251-800<br>35258-800<br>35324-228 |  |
| Impactor Screw, CNS | 118006-11 |  |
| Socket Wrench, WS 10, L=250mm | 561002-250 |  |
| Extraction Rod, Cannulated Femur Nail | 118007-9 |  |
| Impaction/Retraction Rod, CNS | 118006-21 |  |
| Slotted Hammer | 1-1920 |  |
| Endcap, Standard, Cannulated Femur Nail<br>Endcap, +5mm, Cannulated Femur Nail<br>Endcap, +10mm, Cannulated Femur Nail<br>Endcap, +15mm, Cannulated Femur Nail<br>Endcap, +20mm, Cannulated Femur Nail<br>Endcap, +25mm, Cannulated Femur Nail<br>Endcap, +30mm, Cannulated Femur Nail | 118007-11<br>118007-12<br>118007-13<br>118007-14<br>118007-15<br>118007-16<br>118007-17 |  |
| Flat Wrench, WS 10<br>Flat Wrench, WS 17<br>Flat Wrench, WS 20 | 70010<br>70017<br>70020 |  |
| Awl<br>Perthes Awl, 16cm<br>Gimlet, Cannulated | 1-1902<br>9-1452<br>1-1906 |  |
| Sterilization Tray, Cannulated Femur Nail | 50245 | |
| Insertion Guide, Cannulated Femur Nail | 118007 |  |

# Order list

## Spare Parts List Insertion Guide / Optional (on request)

| | | |
|---|---|---|
| Handle, Cannulated Femur Nail | 118007-1 |  |
| Jig, Cannulated Femur Nail | 118007-2 |  |
| Fastening Nut, CNS | 118006-4 |  |
| Adapter, Cannulated Femur Nail | 118007-3 |  |
| Fastening Screw, Cannulated Femur Nail | 118007-4 |  |
| Tissue Protection Sleeve, Cannulated Femur Nail | 118007-5 |  |
| Drill Sleeve, D=4.3mm, Cannulated Femur Nail<br>Drill Sleeve, D=5.1mm, Cannulated Femur Nail | 118007-6<br>118007-7 |  |
| Trochar, Cannulated Femur Nail | 118007-8 |  |
| Clamping Screw | 118003-12 |  |

## Special instruments optional on request *

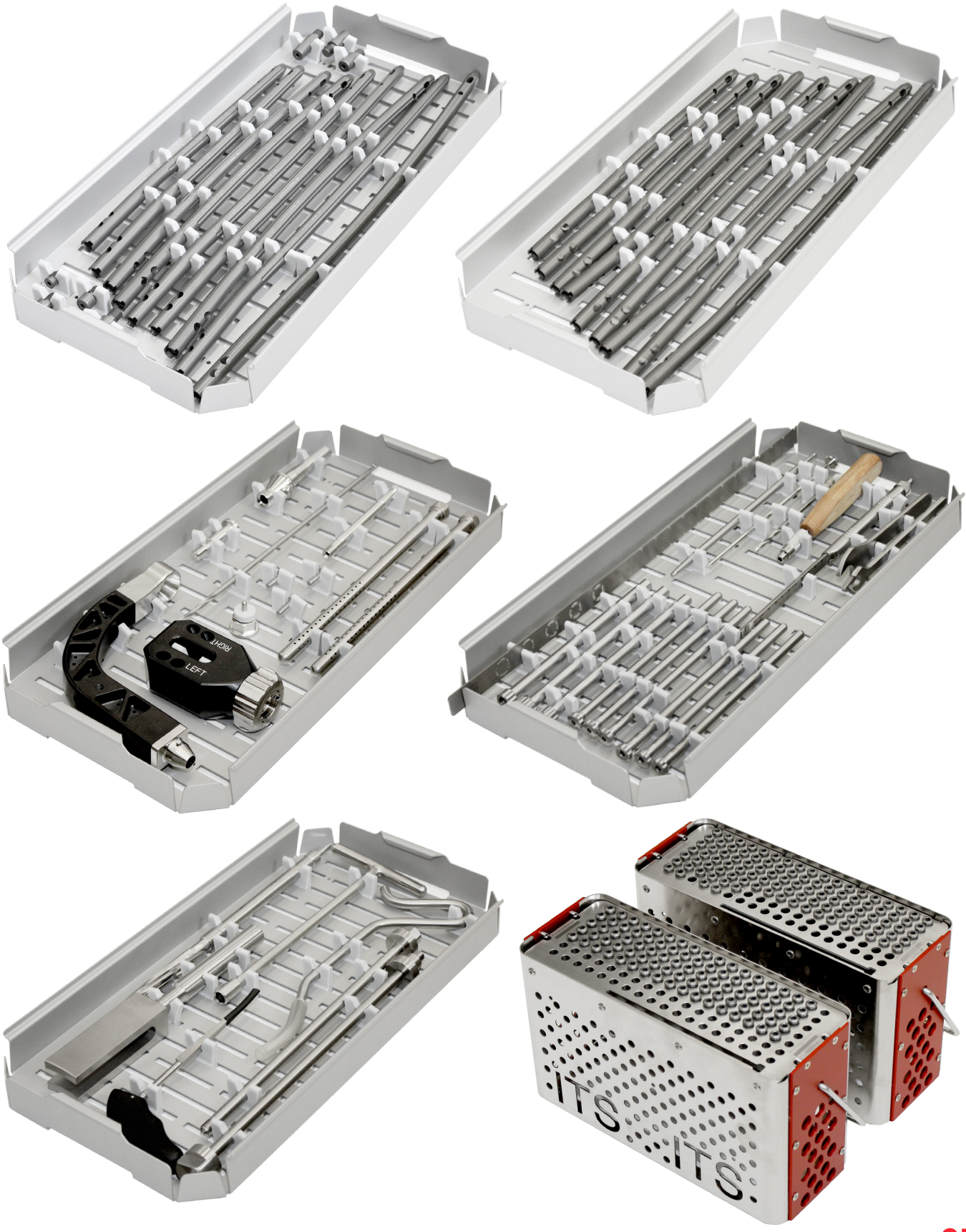
| | | |
|---|---|---|
| Nitinol Reamer Shaft, D=5.0mm, L=473mm, AO Connector | 63500-473 |  |
| Convex Reamer Head, D=8.0mm | 63501-080 |  |
| Convex Reamer Head, D=8.5mm | 63501-085 | |
| Convex Reamer Head, D=9.0mm | 63501-090 | |
| Convex Reamer Head, D=9.5mm | 63501-095 | |
| Convex Reamer Head, 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 | |
| Outer Protection Sleeve, D=17.0mm, Radiolucent | 118008-29 |  |
| Trochar, Cannulated | 118008-27 | |
| Protection Sleeve, D=15.0mm, AO Connector | 118008-28 | |

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



* Delivery times, prices & minimum quantities may vary from standard

## Tray setting



# Notes

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