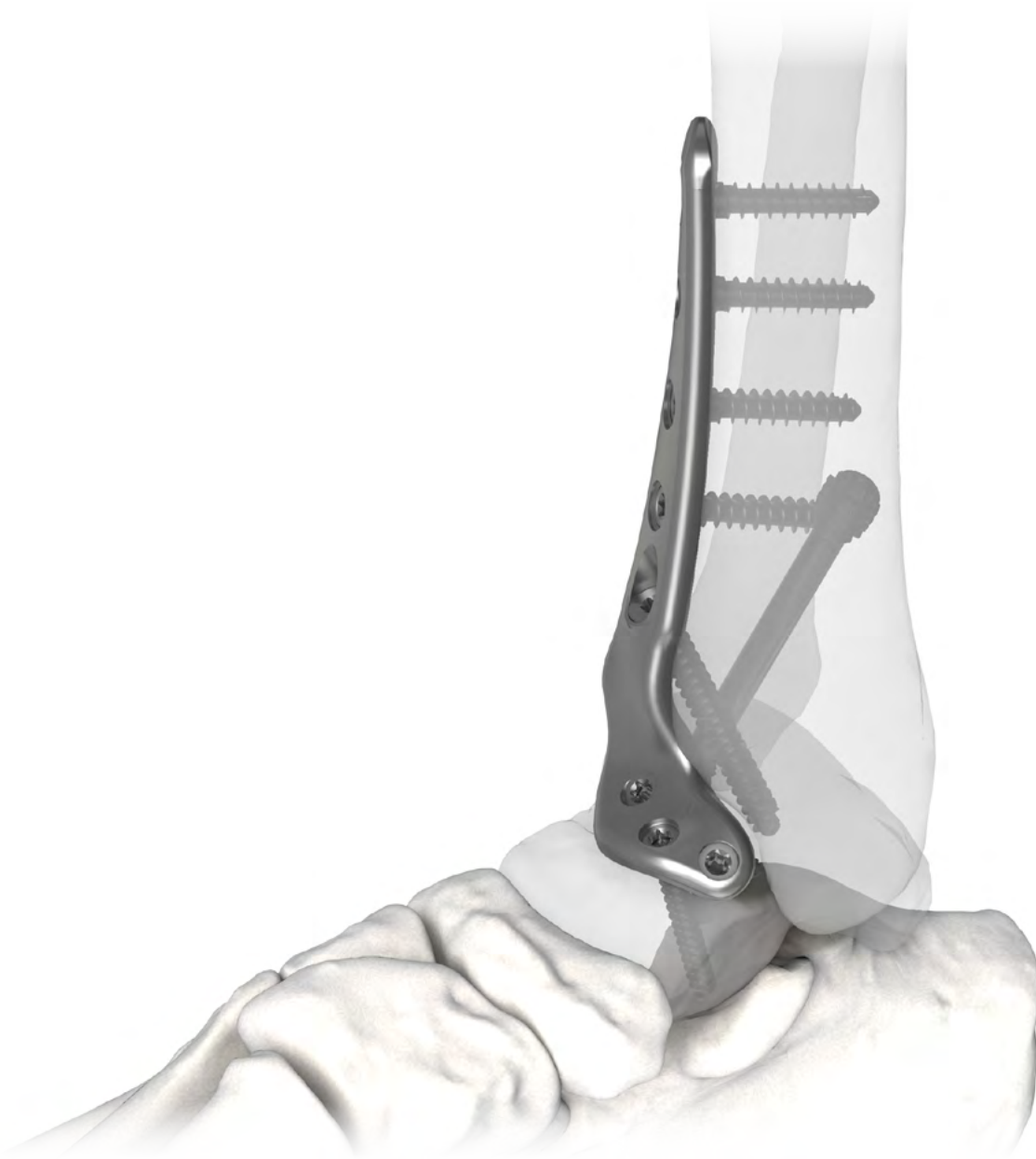


Neofuse

ANKLE FUSION SYSTEM



A GLOBAL EXTREMITY COMPANY

TABLE OF CONTENTS

Indications	3
Product introduction	4
Surgical technique	6
Ordering informations	22
Regulatory informations	26

IMPORTANT NOTE TO READ BEFORE ANY SURGERY

NeoFuse plates are temporarily available without the tibial oblong hole. This surgical technique describes the steps to implant the NeoFuse plate with the tibial oblong hole.

Please note, that the tibial fixation described from page 7 to 8 cannot be realized with the current version and that these steps must be done during the tibial fixation starting page 18 with other tibial screws. Therefore, the tibial fixation must be done after the talar fixation and the joint compression with the IBS screw.

NeoFuse plates with tibial oblong hole will be shortly available.

INDICATIONS

The In2Bones Ankle Fusion plating system is indicated for anterior fixation of ankle arthrodesis and fractures, including the distal tibia, talus and calcaneus. The addition of a compression screw through the tibiotalar joint (for example IBS™ 6.5mm screw) is necessary in order to ensure the closure of the posterior hinge and reinforce the stability of the arthrodesis.

CONTRA-INDICATIONS

The device should not be used in a patient who has currently, or who has history of:

- Acute or chronic, systemic inflammations,
- Active infections,
- Sensitivity/allergies to the implant materials
- Bone pathologies that may compromise the rigidity of the implant fixation (examples include: osteoporosis, acute cystic developments, acute osteopenia, bone tumor, etc...)

Neofuse®

ANKLE ARTHRODESIS PLATING SYSTEM

UNIFORM COMPRESSION AND STABILITY

- Anatomically designed low-profile plate
- Right and left anterolateral plate for tibio-talar fusion
- Multiple points of fixation with divergent axis in the Talus provide rotational stability.
- Locking screws system with caps to offer a solid anchorage.
- Transarticular screw to close posterior gap.
- MedioLateral compression screw



NEOFUSE® PLATE

- One single anterolateral plate system
- Contoured anatomic to fit the anatomy
- Right and left versions
- Material: Titanium (Ti6Al4V)



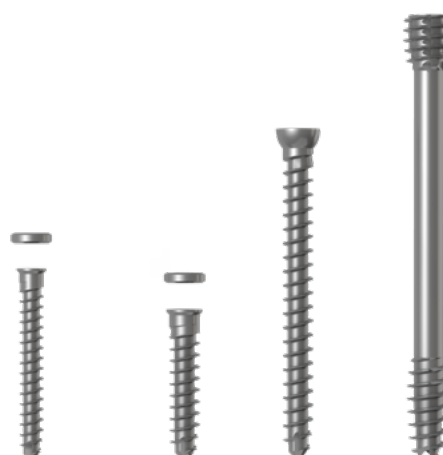
NEOFUSE® SCREWS

Fixed angle locking screws

- 3 talar screws: diam 3.5mm Lg 12-50mm
- 4 tibial screws: diam 4.5mm Lg 18-50mm
- 1 transarticular screw through the plate: diam 4.5mm Lg 40-95mm

Compression screw

- 1 medio-lateral IBS Compression 6,5mm screw



Neofuse®

ANKLE ARTHRODESIS TARGETING SYSTEM

- Targeting guide to facilitate placement of a medio-lateral compression screw
- Calculated screw trajectory, avoiding talar and transarticular screws
- Optimized medial to lateral screw placement by targeting the lateral process of the talus
- Universal targeting guide for left/right foot



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SURGICAL TECHNIQUE

In2Bones® as the manufacturer of this device, does not practice medicine. The surgeon who performs any implants procedure is responsible for determining and using the appropriate surgical techniques for implanting the device in each patient. This surgical technique manual is furnished for information purposes, as an aid to use properly the device and its dedicated instruments.

1 - Joint preparation and compression of the joint

Osteophytes should be removed.

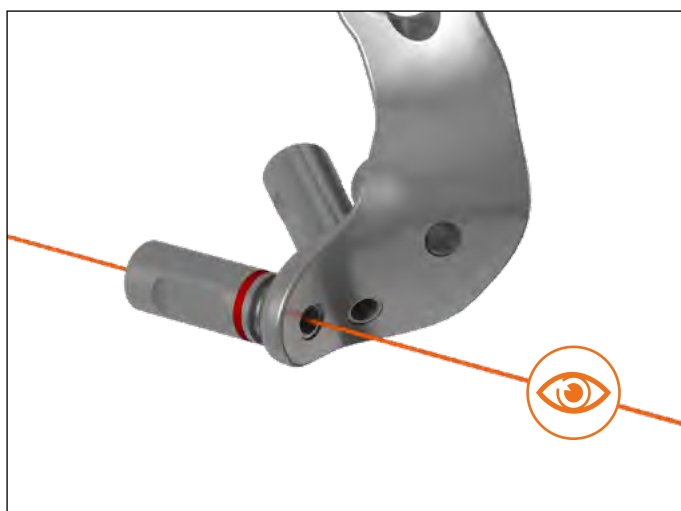
Preparation of the ankle joint surfaces may be performed with flat cuts or resurfacing cuts. Temporary fixation of the bones may be obtained using 2.5mm diam. K-wires.

Control using fluoroscopy is recommended for each step of the procedure.

2 - Talar Drill Guides assembly over the plate



Using the T8 screwdriver, assemble the three talar drill guides (red line) to the plate, on the back table.



Proper positioning of the Drill Guides may be confirmed by flipping over the plate.

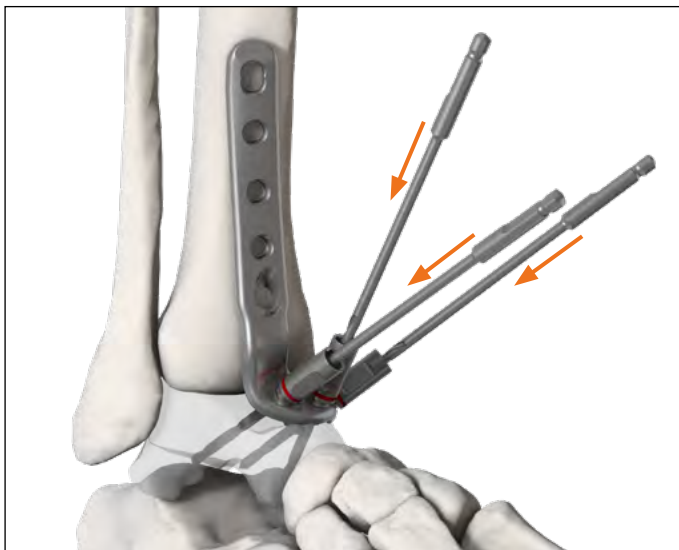
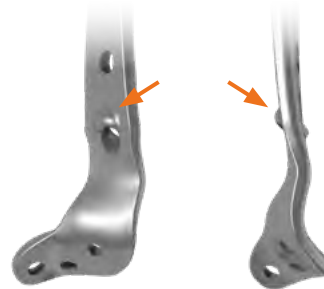
The cannulas of the Drill Guides should be in the same axis as the holes in the plate.

3 - Plate positioning and fixation



Position the plate on the anterolateral aspect of the ankle joint.

Bone preparation of the anterior wall of the tibia should be performed using standard surgical instruments to fit with the internal protrusion of the plate.



Drill the three talar holes with the 2.7mm Drill Bits.

The Drill Guides should be utilized to ensure appropriate trajectory.

The fixed trajectory holes in the plate have been designed to prevent hardware collision between the screws and offer a multiple angles anchorage.

Talar screws can be inserted in the most appropriate order according to the case.



Fix the plate to the tibia in the oblong hole.

The tibial oblong hole screw is meant to maintain the plate in place during the insertion of the compression screw in the joint line. It will keep the plate aligned on the tibia during this future step.

Insert the Tibial Drill Guide (blue line) with the T15 screwdriver (blue handle) in the tibial oblong hole.

Make sure to screw the Drill Guide in the proximal part of the oblong hole.



Drill the tibial oblong hole.

Using the 3.2mm diam. short drill, drill the tibial oblong hole until the 2nd cortical wall.

Remove Drill Guide from the plate using the T15 screwdriver.

4 – Proximal tibial screw insertion



Measure screw length with the depth gauge.

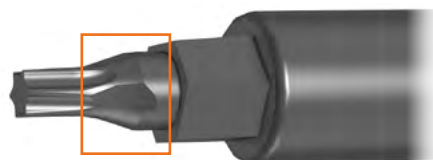
It is critical that the tip of the depth gauge sits at the bottom of the plate.

Make sure the gauge and the shaft are assembled properly. The shaft should indicate depth gauge.



Insert tibial screw.

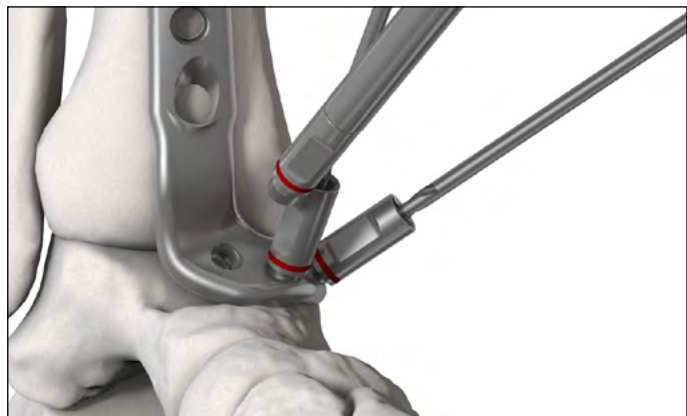
The screw head should be driven until it sits at the bottom of the hole. It is mandatory to countersink the near cortex in case of hard bone, with the tip of the screwdriver.



Insert the tibial screw using the T15 screwdriver or the T15 screwdriver axis.

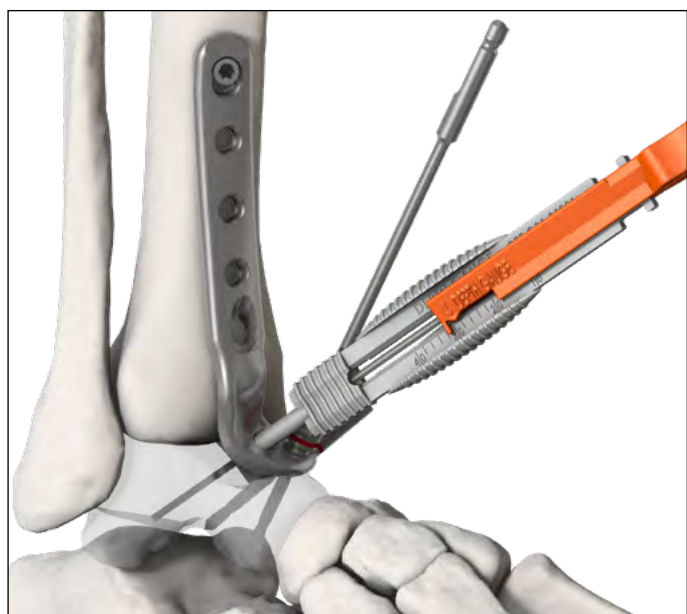
This screw shouldn't be completely inserted at this step. The screw will be tightened and locked after compression will be achieved, at a later step.

5 – Talar screws insertion



Remove the talar Drill Guide with the T8 screwdriver.

Other drills may be left in place while inserting one screw to secure the plate in the desired position.

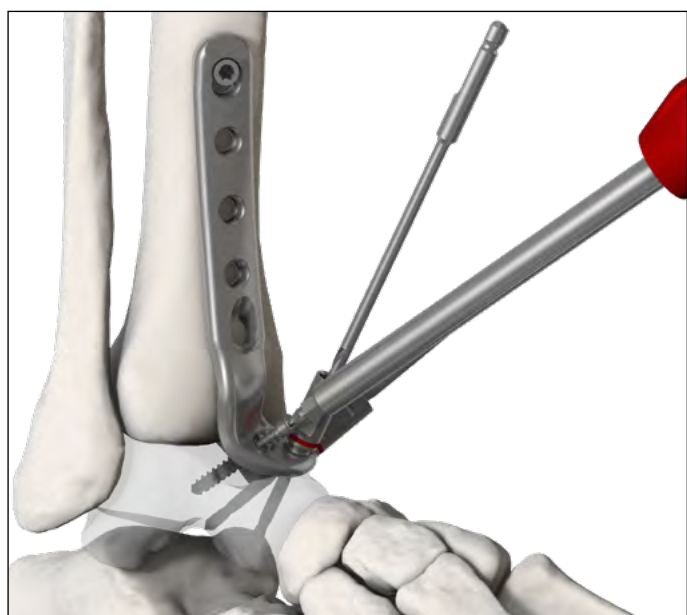


Measure screw length with the depth gauge.

It is critical that the tip of the depth gauge sits at the bottom of the plate.

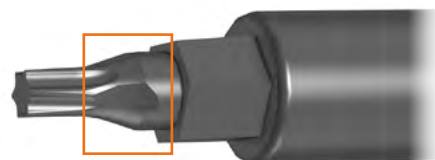
It is recommended to withdraw 1mm to the measure read.

Make sure the gauge and the shaft are assembled properly. The shaft should indicate depth gauge.

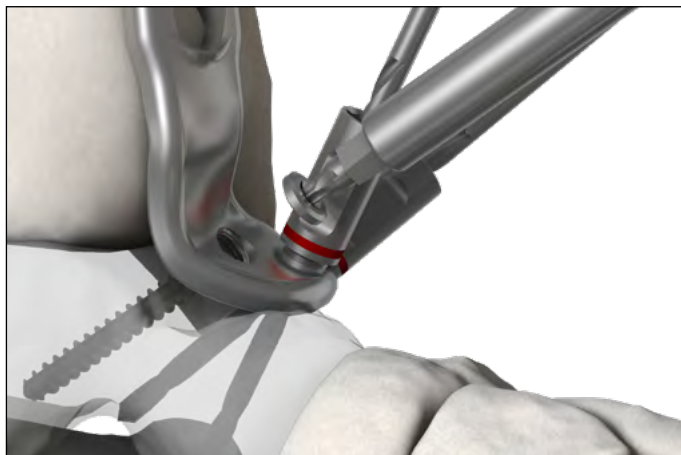


Insert the 3.5 mm diam. talar screw.

The screw head should be driven until it sits at the bottom of the hole. It is mandatory to countersink the near cortex in case of hard bone, with the tip of the screwdriver.



Insert the 3.5 mm diam. screw using T8 screwdriver or the T8 screwdriver axis.



Insert the cap on the screw.

Lock the screw with the cap.

Caps must be inserted right after the screw insertion.

Care must be taken to insert the cap in the same axis of the screw hole to prevent cold fusion between the cap and the plate.

If the cap cannot be inserted, remove the 3.5mm diam. screw and countersink the near cortex with the screwdriver tip, once again.



Repeat previous steps for the 2nd and 3rd screws.

6 – Compression screw insertion

The compression screw can either be inserted with the Targeting Guide or free hand according to surgeon's preference.

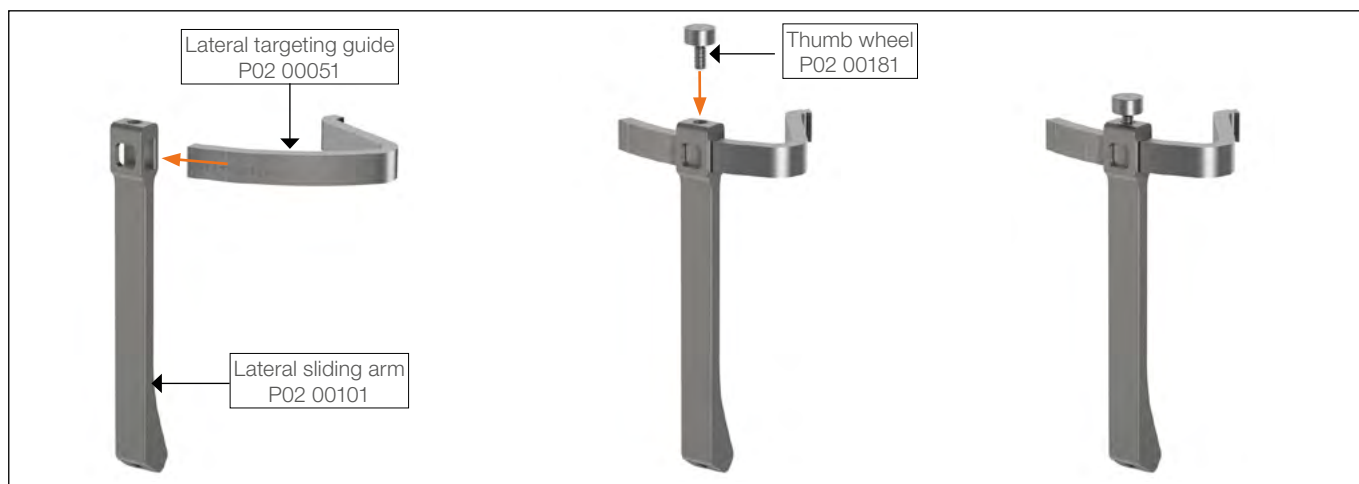
6·A WITH THE TARGETING GUIDE · · · · · 11

6·B FREE HAND · · · · · 16

6-A – Compression screw insertion with the Targeting Guide

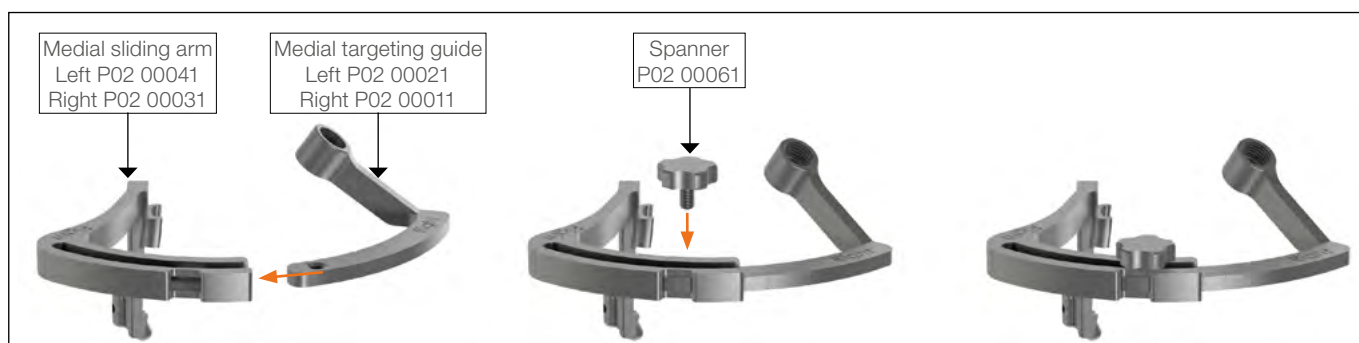
Targeting guide Assembly (on the back table)

Step 1 : Assemble talus lateral process aiming arm to lateral arm.

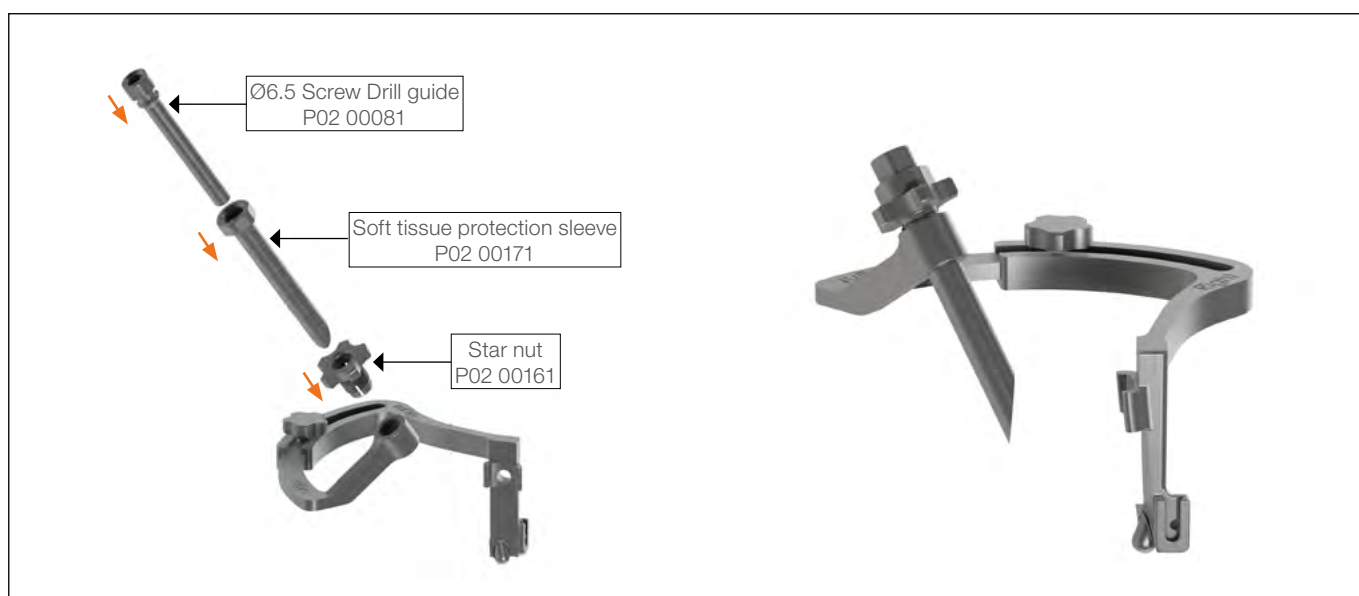


Step 2 : Assemble medial arm extension to medial arm.

Care must be taken to the side.



Step 3 : Assemble guides to medial arm.

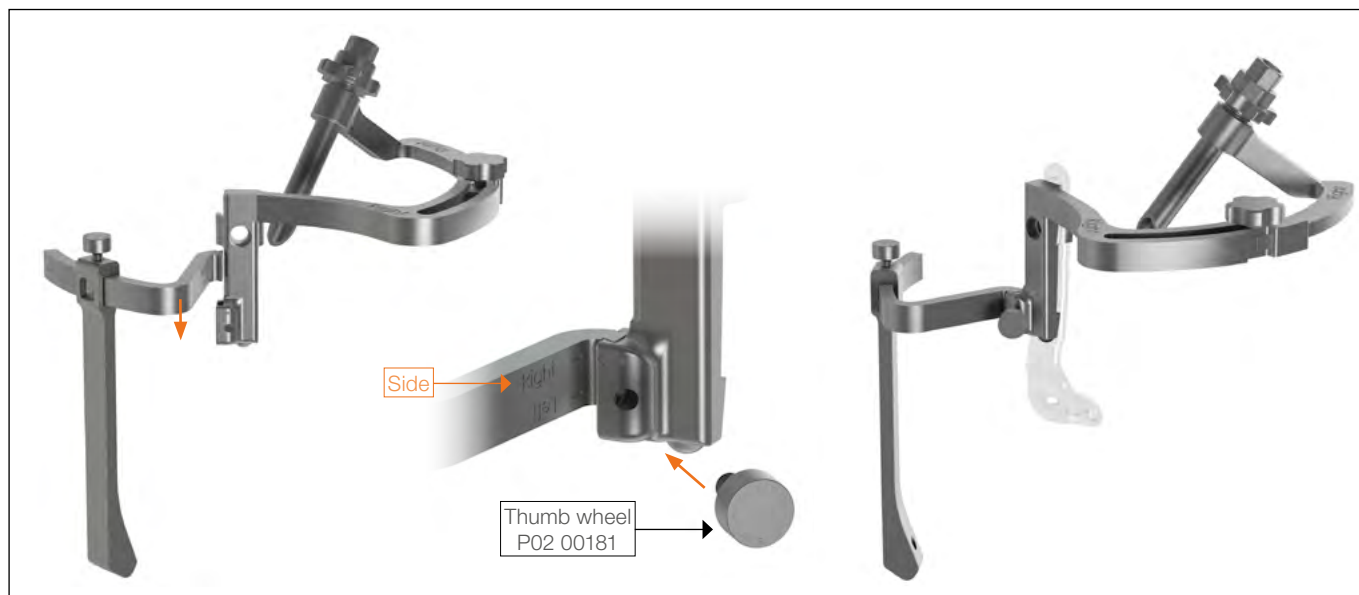


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Step 4 : Assemble the Lateral assembly to the Medial assembly.

Care must be taken to the side



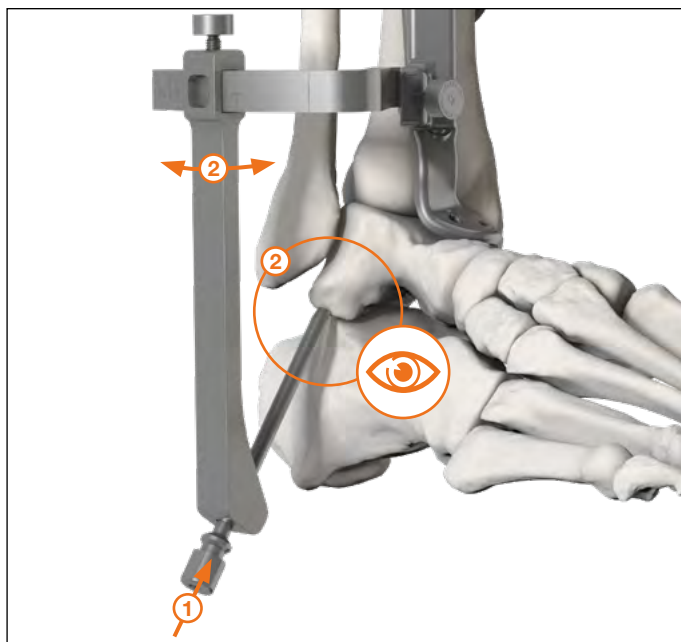
Targeting Guide assembly fixation to the plate.

Position the Targeting Guide assembly on the plate by sliding the assembly over the plate (ramp) and by inserting the pad into the transarticular screw hole (distal tibial screw hole).



Lock the Targeting Guide to the plate using a Tibial Drill Guide. Insert the Tibial Drill Guide with the T15 screwdriver.

The Tibial Drill Guide must be locked into the plate. Make sure that the Targeting Guide assembly is well fixed to the plate.



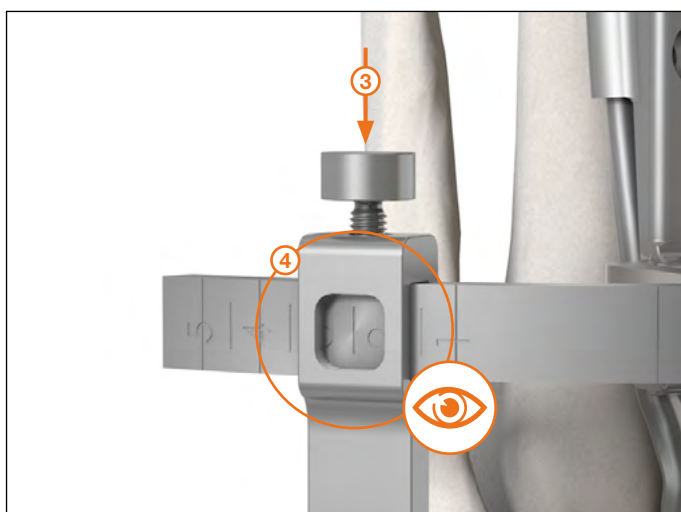
Targeting Guide assembly adjustment.

Slide the K-wire Guide in the dedicated Lateral Sliding Arm. ①

The K-wire Guide is used against the skin to confirm the lateral process of the talus position.

The Kwire Guide cannot be secured in the Lateral Sliding Arm. Care should be taken during this step to maintain the Kwire Guide by hand in order to avoid the fall of the instrument.

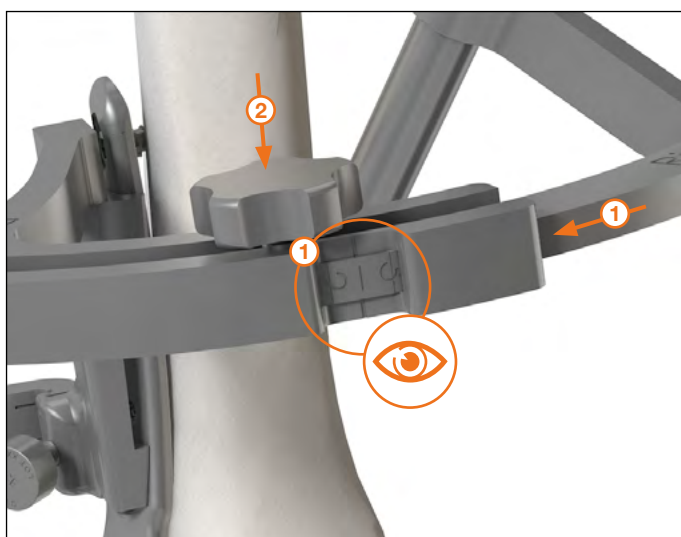
Point the lateral process of the talus with the K-wire Guide. ②



Lock the position of the lateral arm by tightening the thumbwheel. ③

Note the index number associated to this position of the lateral arm ④

If the mark is in between two index, it is recommended to reproduce the same position on the medial index.

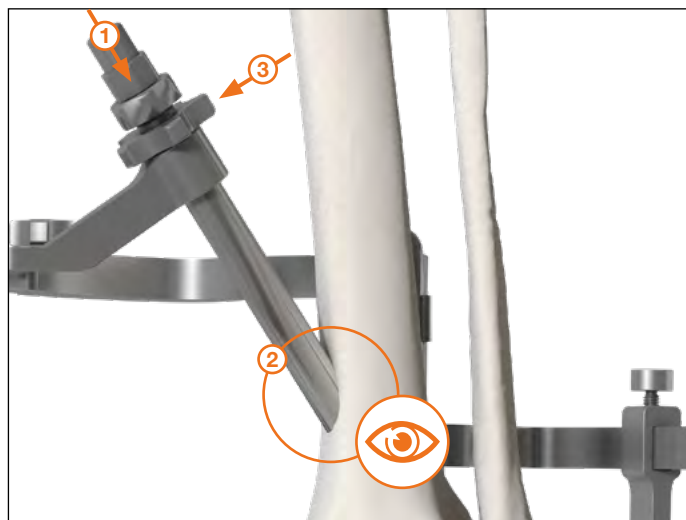


Position and lock the targeting guide on the plate

Slide the medial arm until the same index number appears on the ruler ①. Lock the medial arm with the thumbwheel ②.

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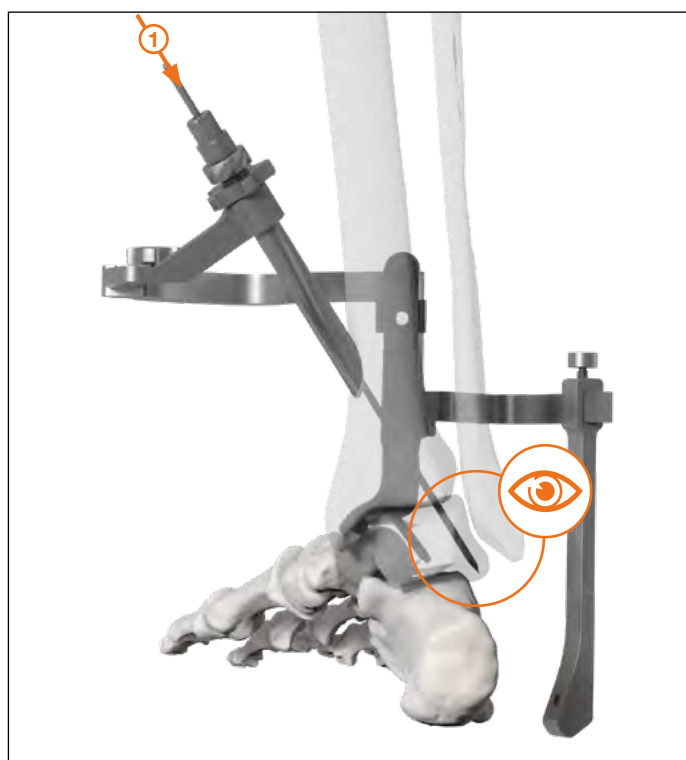


Once the index is confirmed on the medial and lateral sides, and the jig secured, remove the K-wire guide from the lateral arm.

Insert the K-wire guide into the targeting guide (1) and lock the soft tissue protecting sleeve against the bone (2) using the thumbwheel (3).

A small stab incision should be performed to allow the soft tissue protector sleeve to be in contact with the bone.

Make sure that the soft tissue protector is in contact with the bone (2).



Insertion of the 6.5mm IBS Compression screw

Position the diam. 2.0mm K-wire

Insert the diam. 2.0mm K-wire in the targeting guide from medial to lateral up to the cortical wall of the lateral process of the talus.

Care must be taken to stop the K-wire insertion before it passes the cortical.

There are 2 different K-wires available in the set:

- The 2.0mm diam. 225mm length K-wire will be used in conjunction with the guide.
- The 2.0mm diam. 200mm length K-wire will be used when the 6.5mm IBS Compression screw is targeted free hand.

Be careful when you select the K-wire.

Fluoroscopy should be used to ensure proper trajectory and location of the guide wire



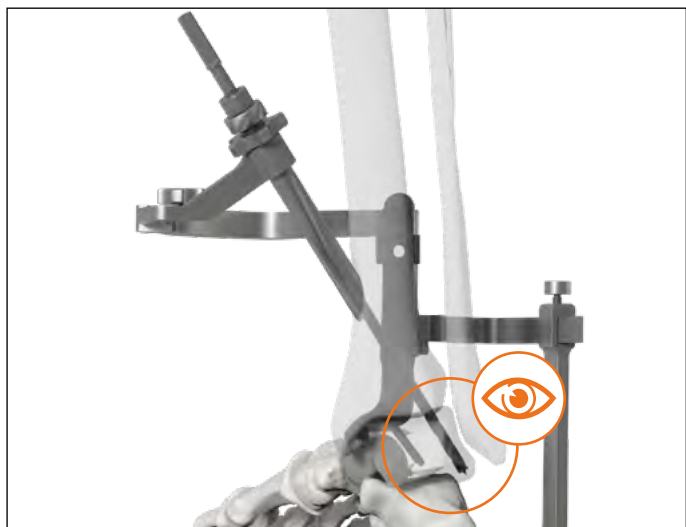
Measure

Remove the K-wire guide. Slide the measurer onto the K-wire until it reaches the tibia

Make sure that the measurer is against the bone.



Read the length indicated with the tip of the K-wire on the measurer.

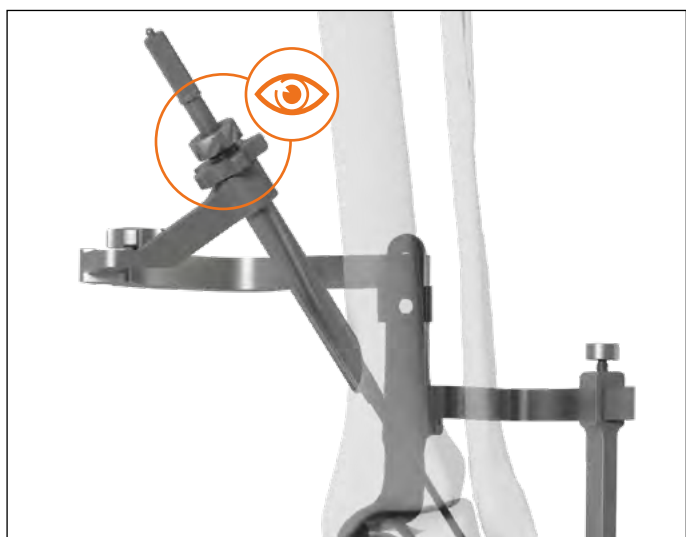


Drill to the appropriate depth.

With the 4.3mm x 203mm Cannulated Drill, drill over the K-wire.

The screw length can be confirmed directly over the drill. Use the laser marking near the mention « over the drill guide ».

Make sure to drill through the 2 tibial cortical walls and the first talar cortical wall only.

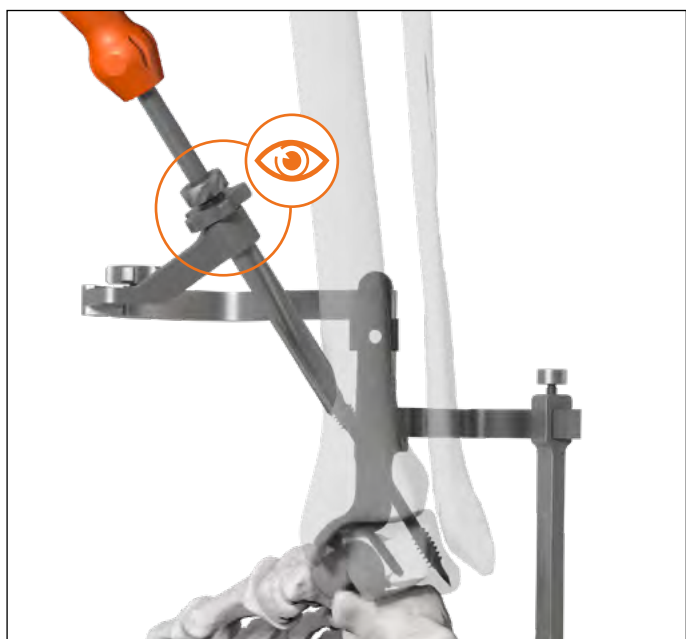
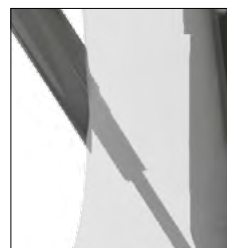
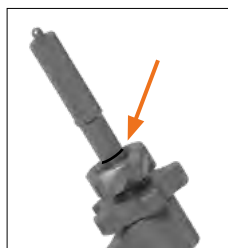


Prepare the bone for the screw head.

Remove the 6.5mm screw drill guide.

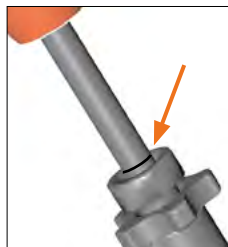
Insert the 2in1 cannulated drill up to the laser mark.

The laser mark should be flush with the soft tissue protecting sleeve.



Insert the 6,5mm screw

The 6.5mm screw is inserted directly in the protector sleeve over the k-wire.



The T25 screwdriver should be inserted until the laser mark is flush with the sleeve's collar

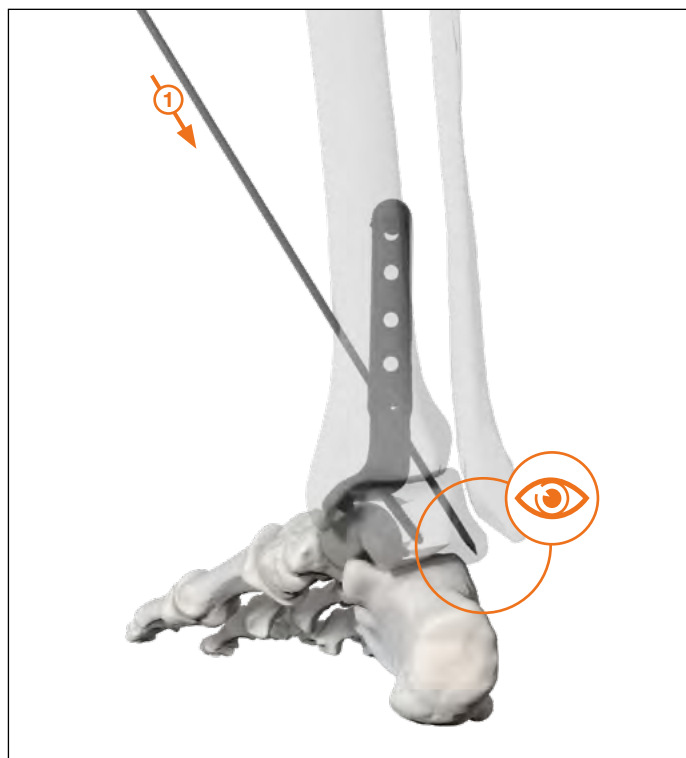
indicating that the screw head is fully inserted into the cortical bone.

Fluoroscopy should be used to ensure proper positioning of the 6,5mm screw.

Remove the targeting guide and the K-wire, once proper positioning has been confirmed.

NEXT STEP: PAGE 18

6-B – Compression screw insertion free hand



Insertion of the 6.5mm IBS Compression screw

Position the 2.0mm diam. 200mm length K-wire

Insert the 2.0mm diam. 200mm length K-wire in the bone from medial to lateral up to the cortical wall of the lateral process of the talus.

Care must be taken to stop the K-wire insertion before it passes the cortical.

There are 2 different K-wires available in the set:

- The 2.0mm diam. 225mm length K-wire will be used in conjunction with the guide.
- The 2.0mm diam. 200mm length K-wire will be used when the 6.5mm IBS Compression screw is targeted free hand.

Be careful when you select the K-wire.

Fluoroscopy should be used to ensure proper trajectory and location of the guide wire



Measure

Slide the measurer onto the K-wire until it reaches the tibia

Make sure that the measurer is against the bone.



Read the length indicated with the tip of the K-wire on the measurer.



Drill to the appropriate depth.

With the 4.3mm x 203mm Cannulated Drill, drill over the K-wire.

The screw length can be confirmed directly over the drill at the bone level.

Make sure to drill through the 2 tibial cortical walls and the first talar cortical wall only.



Prepare the bone for the screw head.

Insert the 2in1 cannulated drill over the K-wire to countersink the bone. Check good insertion of the 2in1 cannulated drill over the bone.



Insert the 6,5mm screw

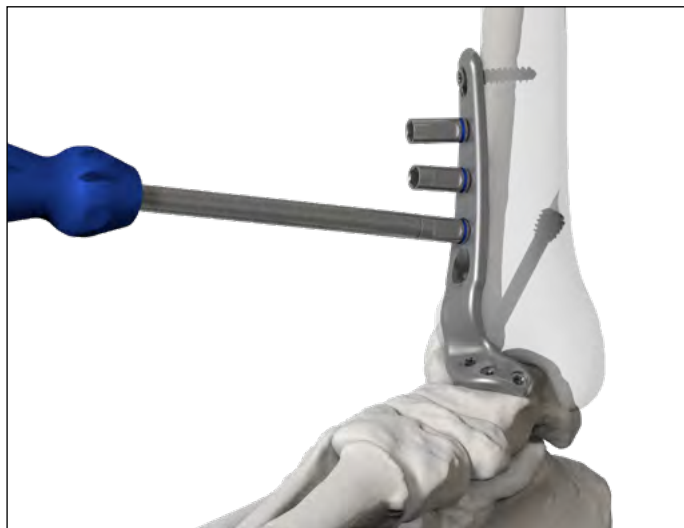
The 6.5mm screw is inserted directly over the K-wire with the T25 screwdriver.

Make sure that the screw is well inserted in the bone.

Remove the K-wire once proper positioning has been confirmed.

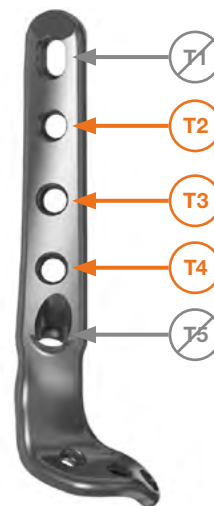
Fluoroscopy should be used to ensure proper positioning of the 6.5mm screw.

7 - Fixation of the tibial Screws T2, T3 and T4.



Insert tibial drill guides

Insert the three drill guides with the T15 screwdriver on T2, T3 and T4.



Drill the tibial holes

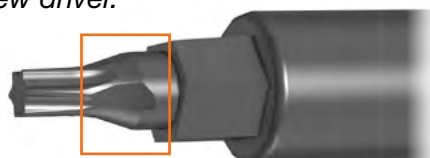
Using the short 3.2mm diam. drill, drill the tibial holes until the 2nd cortical wall.



Insert T2, T3 and T4 screws

Remove drill guides with the T15 screwdriver.
Measure screw length with the depth gauge.

The screw head should be driven until it sits at the bottom of the hole. It is recommended to prepare the near cortex in case of hard bone, with the tip of the screw driver.





insert the tibial screws with the T15 screwdriver or the T15 screwdriver axis.

Insert the caps on the screws.



Finalize the tibia fixation by tightening T1 screw with the T15 screwdriver and insert the cap in the distal part of the oblong hole.

8 - Insert transarticular screw



Position the transarticular screw drill guide into the transarticular screw hole in the plate.

If the positioning of the IBS 6,5mm screw was made with graduation line 1 to 3, it is highly recommended to position the drilling guide closer to the tibial axis (more vertical) to avoid a potential conflict with the Medio Lateral screw.

Drill the transarticular screw hole with the long 3,2mm diam. Drill.

Read the screw length directly on the drill bit in contact with the drill guide.

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Using the T15 screwdriver, insert the transarticular 4,5mm screw until its head is fully embedded into the plate.

Confirm hardware placement with antero-posterior and lateral X-rays.



The wound is closed in layers and the patient is treated with additional fixation if appropriate.

The patient should remain non-weight-bearing for six weeks or until there is early radiographic evidence of consolidation at the arthrodesis sites.

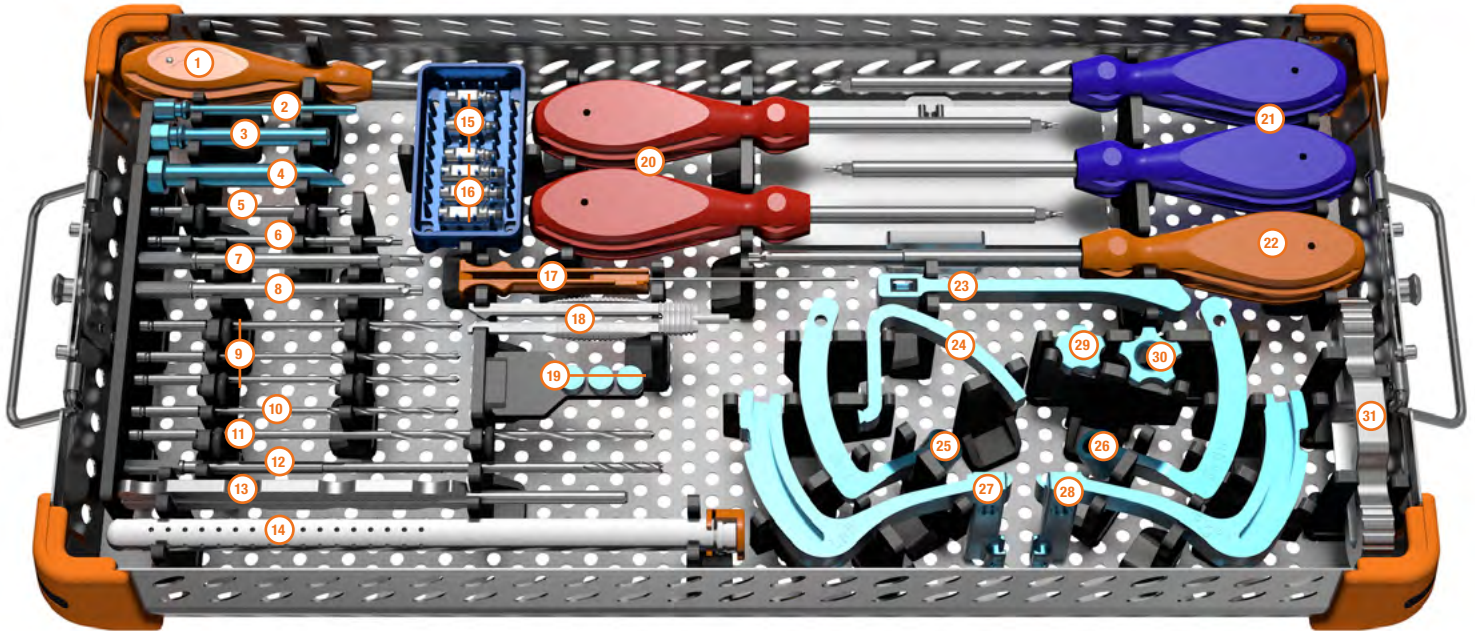
Further protection with a walking boot or brace may help ease the transition to weight bearing.

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ORDERING INFORMATION

INSTRUMENTS SET

(optional targeting device instruments are framed in blue)



1	P02 00191	4.5mm Diam. Transfocal Screw Drill guide	15	P02 00141	Diam 3,5mm screw Drill guide
2	P02 00071	6.5mm Diam. Screw K-wire guide (optional – targeting device)	16	P02 00151	Diam 4,5mm screw Drill guide
3	P02 00081	6.5mm Diam. Screw Drill guide (optional – targeting device)	17	G01 00901	Depth gauge NEOSYS
4	P02 00171	Soft Tissue Protection Sleeve (optional – targeting device)	18	P02 00201	Hindfoot Measurer
5	G01 00261	Screwdriver tip T8 Non cannulated AO Quick coupling	19	P02 00181	Thumb wheel (optional – targeting device)
6	G01 00351	Screwdriver tip T15 Non cannulated AO Quick coupling	20	G01 01571	Screwdriver - T8
7	G01 00031	Drill 2in1 Diam. 4.3/5.8 L120mm non sterile cannulated 2.0mm	21	G01 01561	Screwdriver - T15
8	G01 00381	Screwdriver tip T25 - AO Quick coupling	22	G01 00411	Cannulated screwdriver T25
9	P02 00281	2.7mm Diam. drill - AO Attachement - Non Sterile lg 120mm with graduation	23	P02 00101	Lateral Sliding Arm (optional – targeting device)
10	2100-3.2-130	3.2mm Diam. drill bit - AO Attachement - Non Sterile lg 130mm*	24	P02 00051	Lateral Targeting Guide (optional – targeting device)
11	P02 00131	3.2mm Diam. drill bit - AO Attachement - Non Sterile lg 200mm	25	P02 00041	Medial Sliding Arm – Left (optional – targeting device)
12	P02 00291	4.3mm x 203mm Cannulated Drill (optional – targeting device)	26	P02 00031	Medial Sliding Arm – Right (optional – targeting device)
or	G01 01181	Cannulated drill S65	27	P02 00021	Medial targeting guide – Left (optional – targeting device)
13	G01 00181	Measurer S65-80	28	P02 00011	Medial targeting guide – Right (optional – targeting device)
14	G01 40031	Tube for K-Wire,	29	P02 00061	Spanner (optional – targeting device)
14	K10 NS251	K-wire 2.5mm diam. Length 100mm	30	P02 00161	Star Nut (optional – targeting device)
14	K10 NS200	K-Wire Diam 2.0mm Length 200mm 1 Sharp tip	31	G01 01391	T Handle (Medium size)
or	K10 NS225	K-Wire Diam 2.0mm Length 225mm 1 Sharp tip (optional – targeting device)			

* Drills supplied by Auxein (CE0434)

IMPLANTS



Ankle Fusion Plate

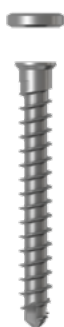
P20 ST110

Ankle Fusion Plate - Right

P20 ST210

Ankle Fusion Plate - Left

IMPLANTS



Talar Screw & Cap Diameter 3.5mm

V35 ST512	Screw & Cap Diam3.5 Lg12mm T8
V35 ST514	Screw & Cap Diam3.5 Lg14mm T8
V35 ST516	Screw & Cap Diam3.5 Lg16mm T8
V35 ST518	Screw & Cap Diam3.5 Lg18mm T8
V35 ST520	Screw & Cap Diam3.5 Lg20mm T8
V35 ST522	Screw & Cap Diam3.5 Lg22mm T8
V35 ST524	Screw & Cap Diam3.5 Lg24mm T8
V35 ST526	Screw & Cap Diam3.5 Lg26mm T8
V35 ST528	Screw & Cap Diam3.5 Lg28mm T8
V35 ST530	Screw & Cap Diam3.5 Lg30mm T8
V35 ST532	Screw & Cap Diam3.5 Lg32mm T8
V35 ST534	Screw & Cap Diam3.5 Lg34mm T8
V35 ST536	Screw & Cap Diam3.5 Lg36mm T8
V35 ST538	Screw & Cap Diam3.5 Lg38mm T8
V35 ST540	Screw & Cap Diam3.5 Lg40mm T8
V35 ST542	Screw & Cap Diam3.5 Lg42mm T8
V35 ST544	Screw & Cap Diam3.5 Lg44mm T8
V35 ST546	Screw & Cap Diam3.5 Lg46mm T8
V35 ST548	Screw & Cap Diam3.5 Lg48mm T8
V35 ST550	Screw & Cap Diam3.5 Lg50mm T8



Tibial Screw & Cap Diameter 4.5mm

V45 ST518	Screw & Cap Diam4.5 Lg18mm T15
V45 ST520	Screw & Cap Diam4.5 Lg20mm T15
V45 ST522	Screw & Cap Diam4.5 Lg22mm T15
V45 ST524	Screw & Cap Diam4.5 Lg24mm T15
V45 ST526	Screw & Cap Diam4.5 Lg26mm T15
V45 ST528	Screw & Cap Diam4.5 Lg28mm T15
V45 ST530	Screw & Cap Diam4.5 Lg30mm T15
V45 ST532	Screw & Cap Diam4.5 Lg32mm T15
V45 ST534	Screw & Cap Diam4.5 Lg34mm T15
V45 ST536	Screw & Cap Diam4.5 Lg36mm T15
V45 ST538	Screw & Cap Diam4.5 Lg38mm T15
V45 ST540	Screw & Cap Diam4.5 Lg40mm T15
V45 ST542	Screw & Cap Diam4.5 Lg42mm T15
V45 ST544	Screw & Cap Diam4.5 Lg44mm T15
V45 ST546	Screw & Cap Diam4.5 Lg46mm T15
V45 ST548	Screw & Cap Diam4.5 Lg48mm T15
V45 ST550	Screw & Cap Diam4.5 Lg50mm T15



Transfocal Screw Diameter 4.5mm

V45 ST140	TFL Screw Diam4.5 Lg40mm T15
V45 ST142	TFL Screw Diam4.5 Lg42mm T15
V45 ST144	TFL Screw Diam4.5 Lg44mm T15
V45 ST146	TFL Screw Diam4.5 Lg46mm T15
V45 ST148	TFL Screw Diam4.5 Lg48mm T15
V45 ST150	TFL Screw Diam4.5 Lg50mm T15
V45 ST155	TFL Screw Diam4.5 Lg55mm T15
V45 ST160	TFL Screw Diam4.5 Lg60mm T15
V45 ST165	TFL Screw Diam4.5 Lg65mm T15
V45 ST170	TFL Screw Diam4.5 Lg70mm T15
V45 ST175	TFL Screw Diam4.5 Lg75mm T15
V45 ST180	TFL Screw Diam4.5 Lg80mm T15
V45 ST185	TFL Screw Diam4.5 Lg85mm T15
V45 ST190	TFL Screw Diam4.5 Lg90mm T15
V45 ST195	TFL Screw Diam4.5 Lg95mm T15



**I.B.S.™ Compression Screw - Sterile
Ti6al4v - Diam 6.5mm**

S65 ST140	I.B.S.™ Compression screw diam 6.5 mm lg 40 mm
S65 ST145	I.B.S.™ Compression screw diam 6.5 mm lg 45 mm
S65 ST150	I.B.S.™ Compression screw diam 6.5 mm lg 50 mm
S65 ST155	I.B.S.™ Compression screw diam 6.5 mm lg 55 mm
S65 ST160	I.B.S.™ Compression screw diam 6.5 mm lg 60 mm
S65 ST165	I.B.S.™ Compression screw diam 6.5 mm lg 65 mm
S65 ST170	I.B.S.™ Compression screw diam 6.5 mm lg 70 mm
S65 ST175	I.B.S.™ Compression screw diam 6.5 mm lg 75 mm
S65 ST180	I.B.S.™ Compression screw diam 6.5 mm lg 80 mm
S65 ST185	I.B.S.™ Compression screw diam 6.5 mm lg 85 mm
S65 ST190	I.B.S.™ Compression screw diam 6.5 mm lg 90 mm
S65 ST195	I.B.S.™ Compression screw diam 6.5 mm lg 95 mm

RECOMMENDATION

It is recommended to carefully read the instructions for use available in the package insert.

REIMBURSEMENT

Reimbursement may vary from countries to countries. Check with local authorities.

MANUFACTURER

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DOCUMENT

Reference : ST-DIG-NEOFUSE-EN-052019-TEMPORARY

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

Always refer to the appropriate instructions for use for complete clinical instructions.

Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of a physician.

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- Implant: CE Class IIb - CE2797
- Instruments connected to a power driver: Class IIa - CE2797
- Instruments with measuring function: Class Im - CE2797
- Other instruments: Class I - CE



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