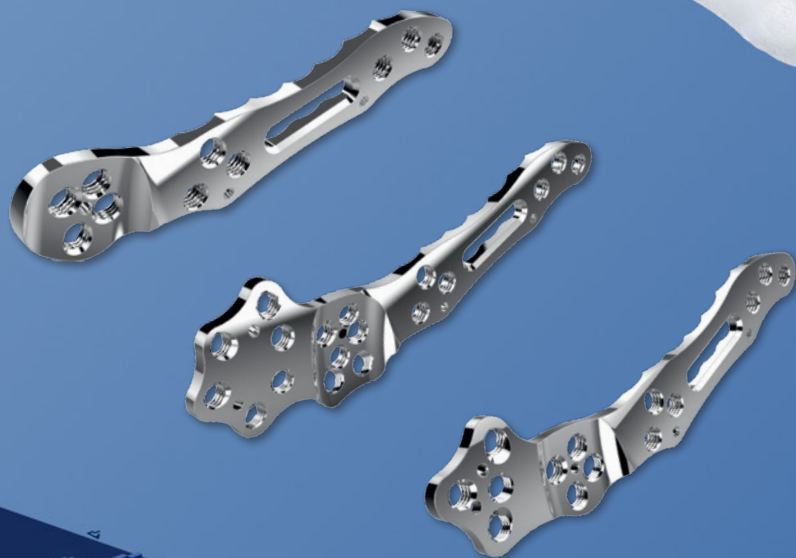
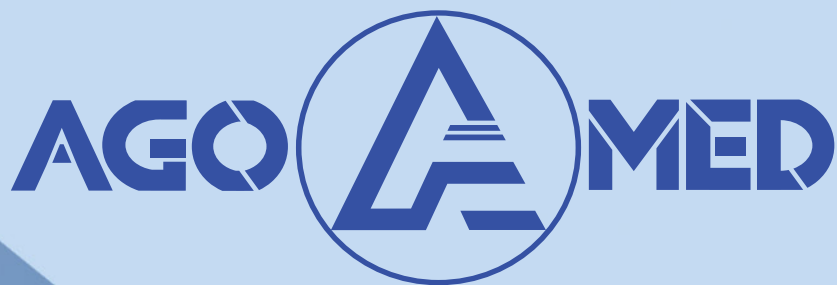


SURGICAL
TECHNIQUE GUIDE

INCLUDING



**AGOFIX 4.0
SYSTEM**

Made in Germany

EN Working with AGOMED means working with a company committed to excellence. Our products are German engineered, biocompatible, and cutting-edge. Our team members collectively bring decades of medical technology experience to the table.

We're reliable. We're flexible. We're inventive.

AGOMED collaborates with distributors, hospitals, and doctors worldwide to create and develop exacting, state-of-the-art solutions. We work closely with specialists to insure that our implants for trauma and extremities improve the patient's quality of life.

Patient safety is always our number one priority.

DE Mit AGOMED zu arbeiten, bedeutet mit einem Unternehmen zu arbeiten, dass sich zur Exzellenz und Hochleistung verpflichtet.

Unsere Produkte werden von deutschen Ingenieuren entwickelt, sind biokompatibel, innovativ und auf dem neuesten Stand der Technik. Unser Team hat jahrzehntelange Erfahrung im Bereich der Medizintechnik.

Wir sind zuverlässig. Wir sind flexibel. Wir sind innovativ.

AGOMED arbeitet weltweit mit Unternehmen, Krankenhäusern und Ärzten zusammen, um anspruchsvolle, hochmoderne Lösungen zu entwickeln. Wir arbeiten eng mit Spezialisten zusammen, um sicherzustellen, dass unsere Implantate für Traumatologie und Extremitäten die Lebensqualität der Patienten verbessern.

Die Sicherheit der Patienten steht bei uns immer an erster Stelle.

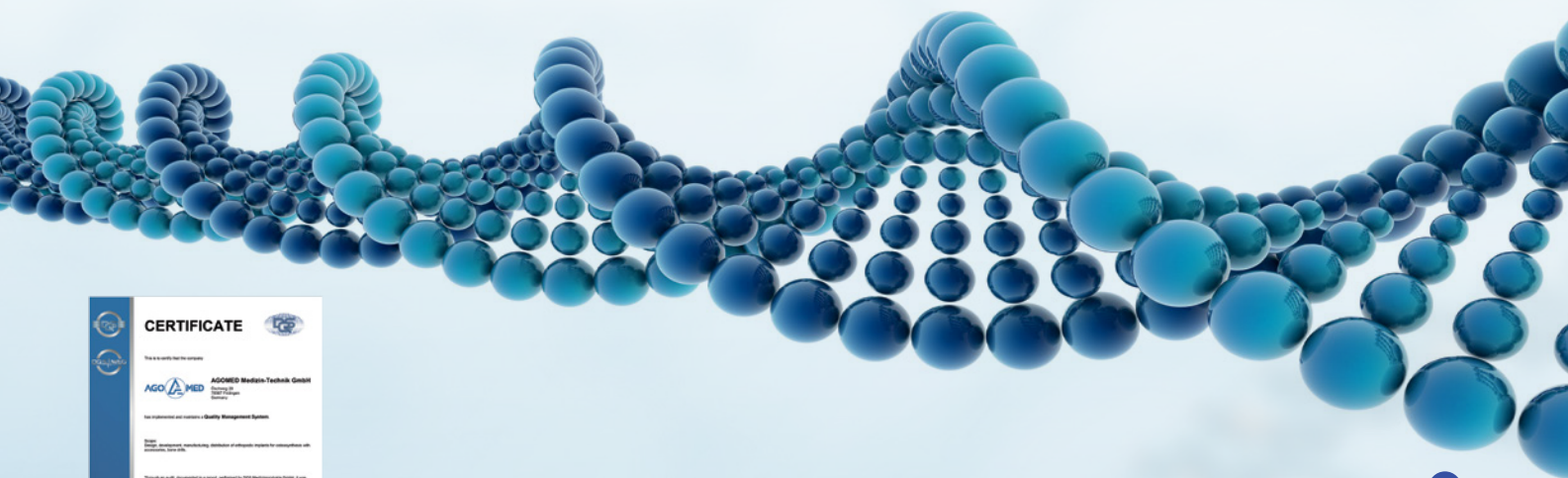
ES Trabajar con AGOMED significa trabajar con una empresa comprometida con la excelencia. Nuestros productos son diseñados en Alemania, biocompatibles y de vanguardia. Los miembros de nuestro equipo aportan, de manera colectiva, décadas de experiencia en tecnología médica.

Somos fiables. Somos flexibles. Somos innovadores.

AGOMED colabora con distribuidores, hospitales y doctores a nivel mundial con el objetivo de crear y desarrollar soluciones rigurosas y con lo último de la tecnología. Cooperamos estrechamente con especialistas para garantizar que nuestros implantes para trauma y extremidades mejoren la calidad de vida de los pacientes.

La seguridad de los pacientes siempre es nuestra prioridad.

QUALITY IS PART OF OUR DNA



DIN EN ISO 13485

AGOMED MEANS QUALITY. WE EXCEED ISO 13485 STANDARDS AND HAVE CE CERTIFICATION.

AGOMED BEDEUTET QUALITÄT. WIR SIND ZERTIFIZIERT NACH ISO 13485 UND HABEN DIE CE ZERTIFIZIERUNG

AGOMED ES SINÓNIMO DE CALIDAD. SUPERAMOS LOS ESTÁNDARES ISO 13485 Y CONTAMOS CON CERTIFICACIÓN CE.



CE CERTIFICATE



**EXTERNAL COMPRESSION DEVICE /
EXTERNAL COMPRESSIONS GERÄT /
DISPOSITIVO DE COMPRESIÓN EXTERNO**



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SURGICAL TECHNIQUE

Patient Positioning

- Place the patient in the supine position with an ipsilateral pelvic sand bag or midlateral position.

STEP 1

Incision for AgoFix Plates (TT Fusion)

- Using a lateral approach, make a straight incision to enable the best view of the lateral talar and calcaneal walls. Mobilize the peroneal tendons.

Incision for AgoFix Plus Plates (TTC Fusion)

- Using a lateral approach, make a straight incision longer than the TT fusion incision to allow access to the subtalar joint. Mobilize the peroneal tendons and retract them posteriorly.

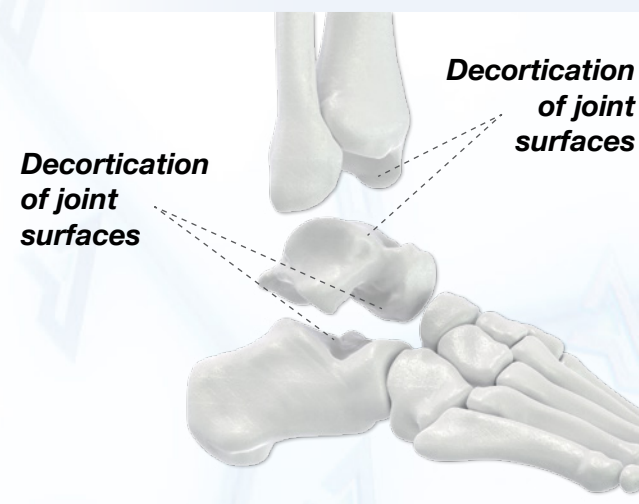
STEP 2

Fibular Resection

- Resect approximately 8 cm-10 cm of the distal fibula, depending on the patient's anatomy and according to the plate dimension. The fibula may be morselized for additional bone graft after removing the periosteum and all soft tissue.



STEP 3



Bone Preparation

- Prepare the joint in the usual manner. Use burs, curettes, and osteotomes (such as a Charcot chisel or special osteotomes for joint surface preparation) to decorticate the involved joint surfaces until subchondral bone is fully exposed on each side. Ensure that the joint surfaces are prepared congruently.



Note: Care should be taken to maintain the desired position of the arthrodesis throughout the procedure. In particular, when the compression is applied to the arthrodesis, the surgeon should prevent the hindfoot drifting into excessive valgus alignment.



STEP 4

Temporary Positioning of the Arthrodesis

- Temporarily position and fix the ankle alignment with 2 mm K-wires.

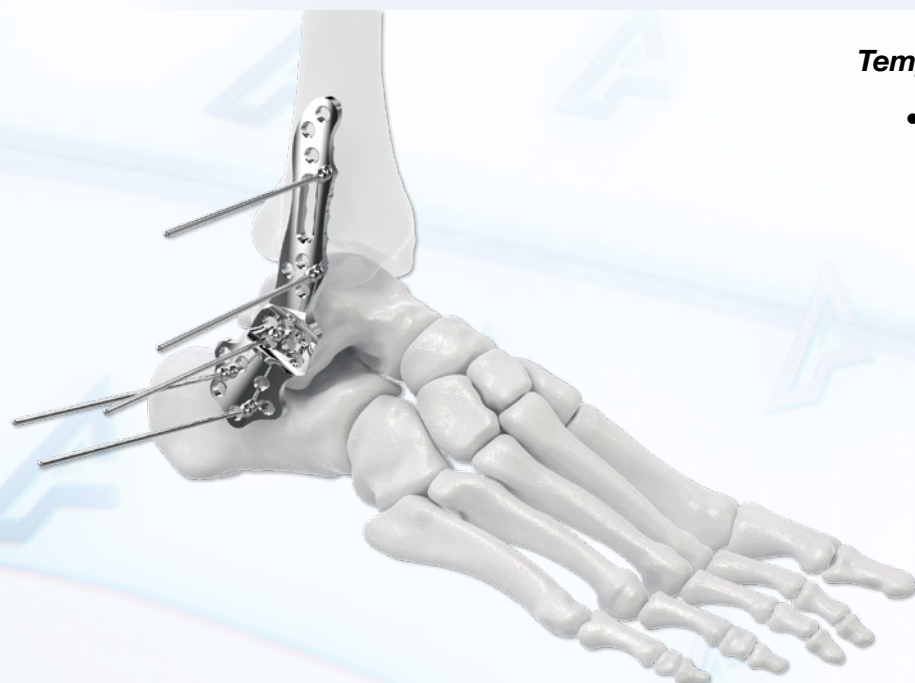
- Optional:** With the fibula removed, there is easy access to the posterolateral aspect of the tibial metaphysis. A K-wire can be placed from the postero-lateral tibia into the neck of the talus over which a cannulated single- and partial threaded screw (with or without a washer) can be applied to provide compression across the arthrodesis. Ensure the screw is of sufficient strength and does not lock the arthrodesis in the direction in which compression will be applied by the Compression/Distraction Device later on in Step 12. The AgoFix plate is then used to neutralize the fixation.



STEP 5

Temporary Fixation of the Plate

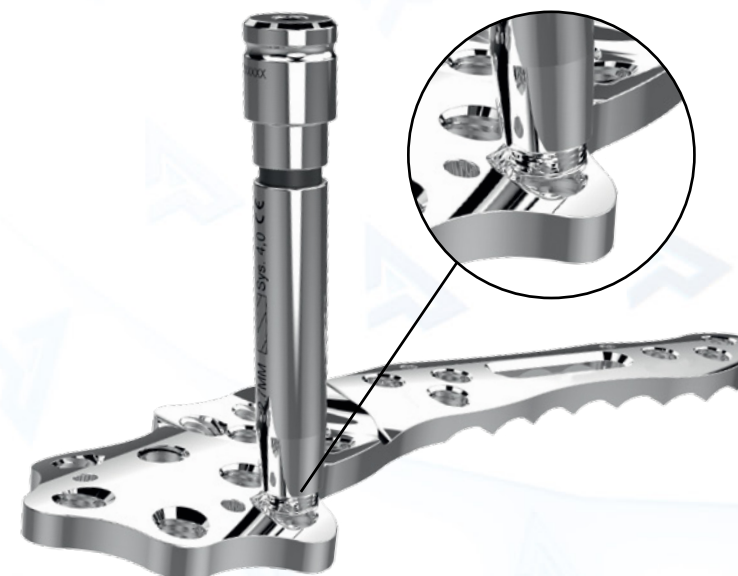
- Select the appropriate anatomical plate side and size (see pages 10-11), according to the patient's bony anatomy and chosen procedure (TT or TTC fusion). Apply the plate to the bone surface and temporarily hold it with 2 mm K-wires while using image intensification to ensure that it is correctly positioned. Some contouring of the tibial incisura may be required to seat the plate flush with the bone.



STEP 6

Drilling the Distal Screw Holes

- Drill distal screw holes accordingly to each specific plate: AgoFix – drill only the talus screw holes AgoFix Plus – drill only the calcaneus screw holes
- Bicortically drill the distal screw holes (calcaneus/talus) through the holes in the plate, using the 2.7 mm Twist Drill (black mark). Use as many screw holes as possible to ensure stable fixation. For locking screws, the corresponding 2.7 mm threaded-tip Drill Guide (black mark) **must** be used to avoid damaging the threads and to ensure correct drill direction. While not required, the Drill Guide is also recommended for standard screws to help minimize wear on the drill bit and damage to the threads on the plate.



Note: Because of the plate contours, a threaded screw will not always engage the screw hole at a 90° angle to that portion of the plate's surface that surrounds the hole. For proper threading of the Drill Guide into the hole, ensure that the Drill Guide is aligned with the direction of the threads in the hole (see illustration). Then tighten it gently.

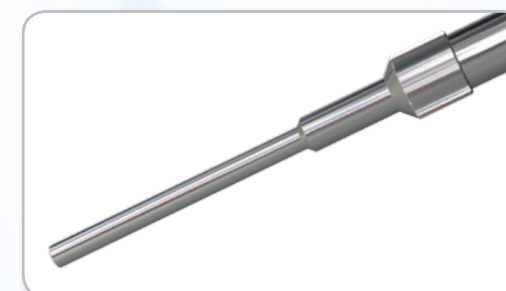
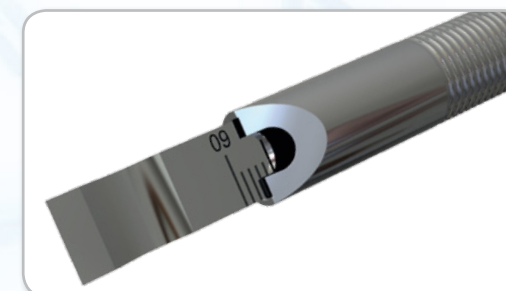
STEP 7

Depth Measurement for Distal Screws

- Position the Depth Gauge on the plate hole and advance the probe into the predrilled hole until it penetrates the opposite cortex. Read the length directly from the Depth Gauge.



Note: If the drill hole does not penetrate the opposite cortex, measure where the probe bottoms out. Read the length directly from the gauge and subtract 1 mm to determine the appropriate screw length. (The screw length includes the length of the head.)





STEP 8

Distal Screw Insertion

- Use as many screws as possible to ensure stable fixation.
- Attach the screwdriver blade to the handle by pulling back on the coupling, inserting the blade into the shaft, and releasing the coupling. Pull on the blade to ensure that it is locked into the handle. The screwdriver has a ratchet function to simplify screw insertion. Insert the screws bicortically, if possible. The screwdriver can be used to facilitate removal of the screws from the tray by pushing the tip of the blade firmly into the screw head in a vertical direction to achieve a secure grip.

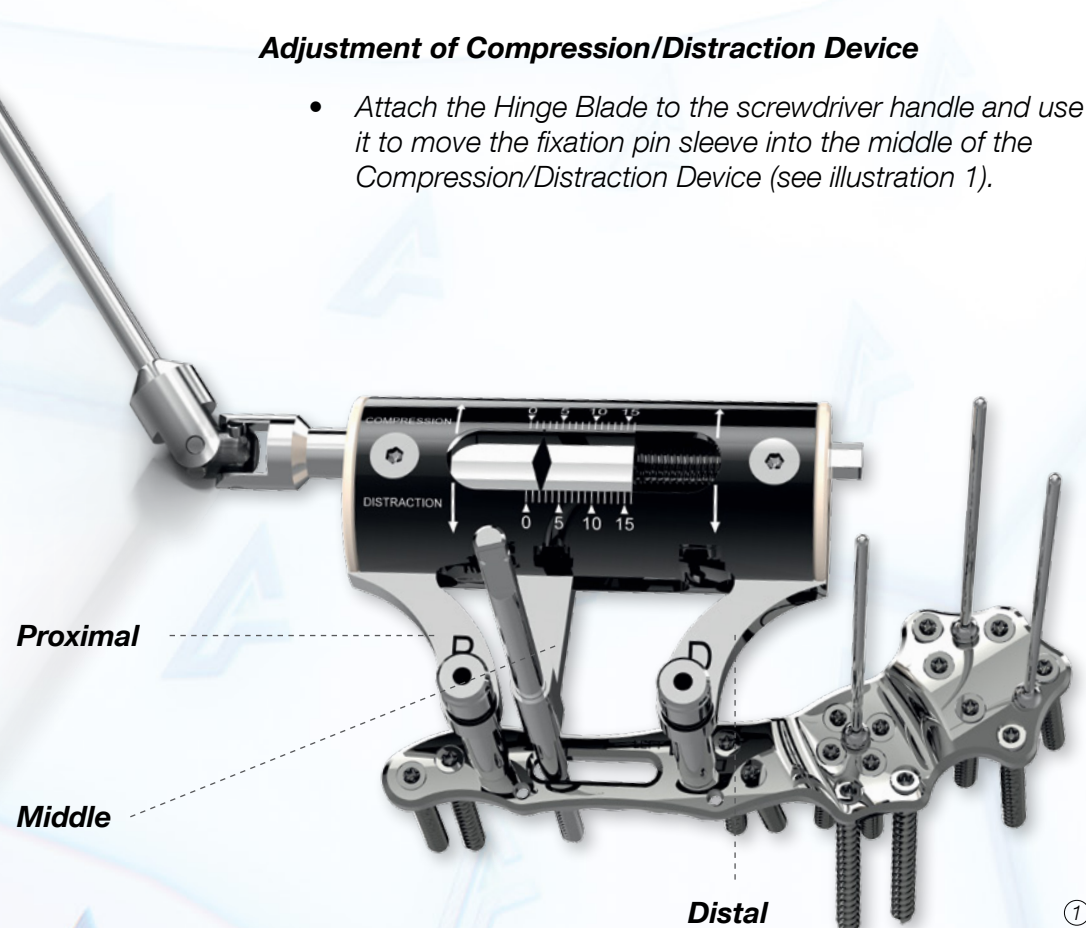


Note: Use only the screwdrivers available with the AgoFix System. Inserting the screws with inappropriate instruments may damage the screw threads. Do not use damaged screws.

STEP 9

Adjustment of Compression/Distraction Device

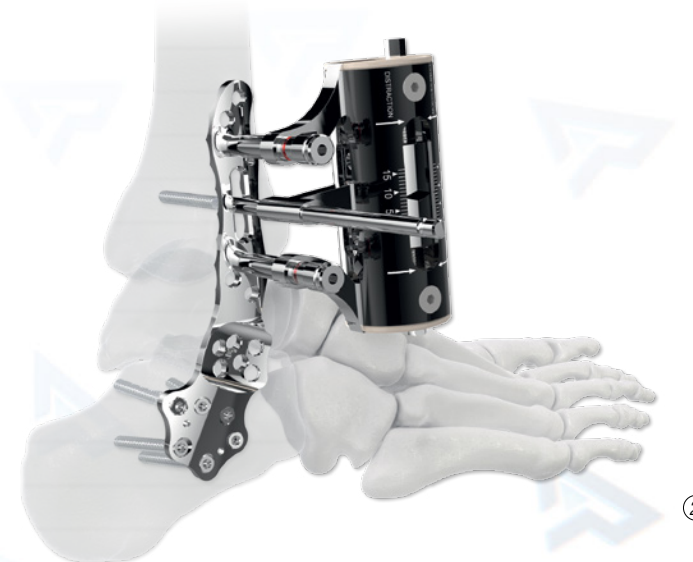
- Attach the Hinge Blade to the screwdriver handle and use it to move the fixation pin sleeve into the middle of the Compression/Distraction Device (see illustration 1).



STEP 10

Application of Compression/Distraction Device

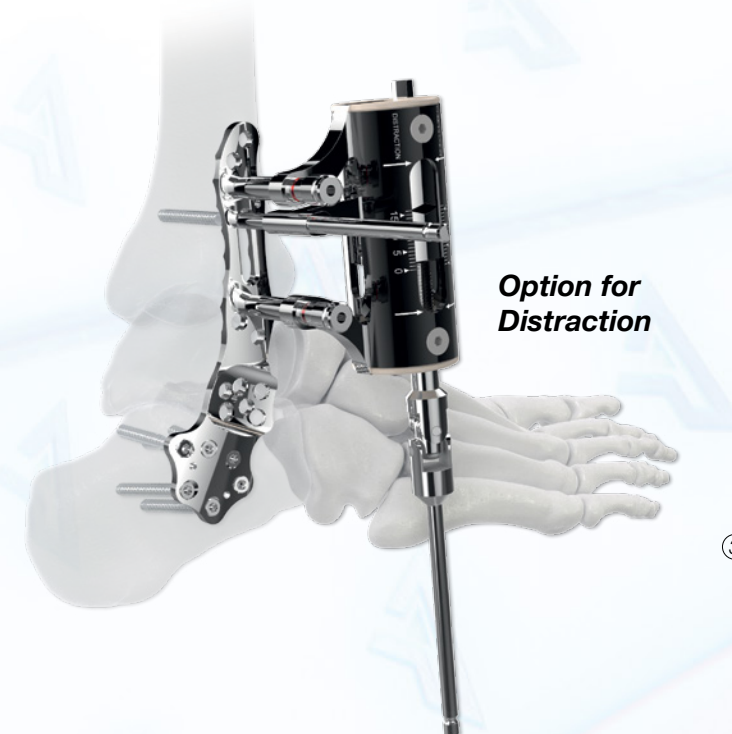
- Remove any K-wires that were used for temporary plate or bone positioning.
- While holding the device in a proximal/distal direction as marked on the device (see illustration 1), insert the two 3.2 mm Threaded Drill Guides (with red markings) through the holes in the proximal and distal arms of the Compression/Distraction Device, and thread the guides into the plate holes directly above and below the slotted hole (see illustration 2).



STEP 11

Fixation Pin Insertion

- Insert a 4.0 threaded fixation pin (1300513) into the middle of the slotted hole on the tibial part of the plate (see illustration 2) until bicortical fixation is achieved.

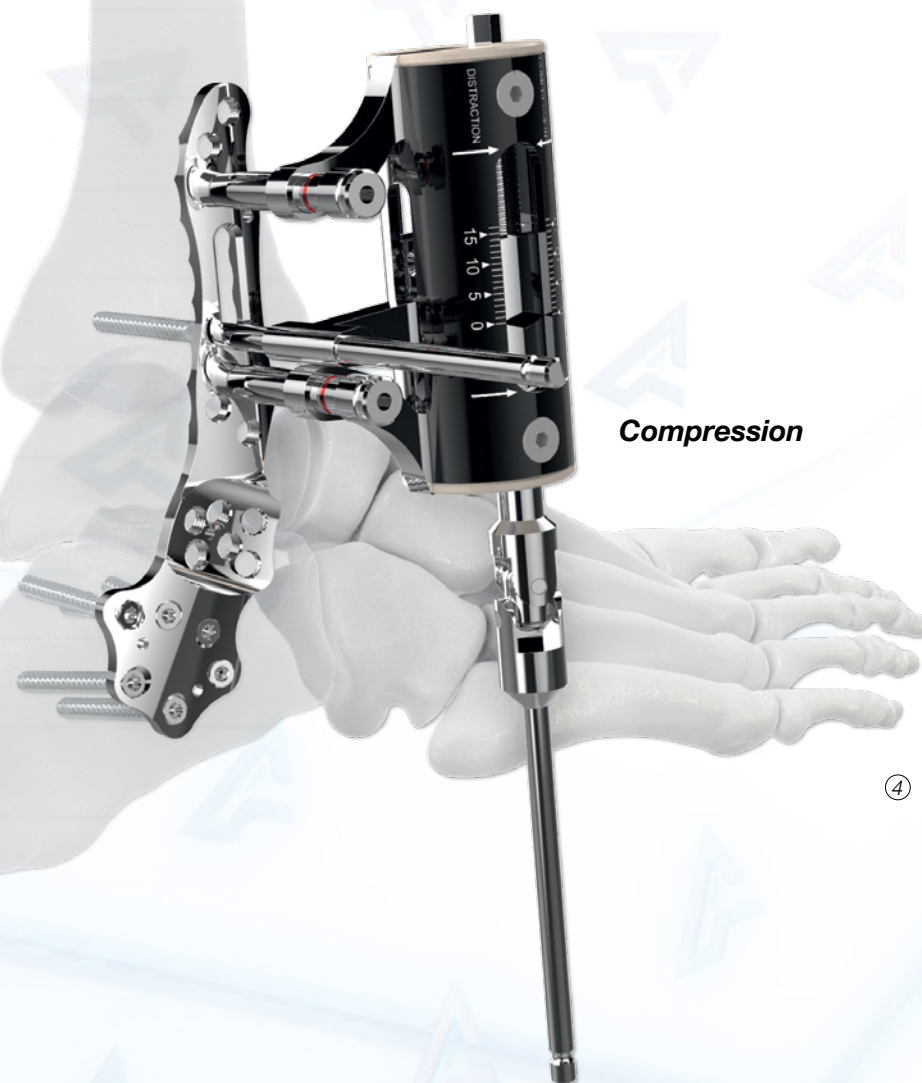




STEP 12

Joint Compression

- Compress the joint by using the Hinge Screwdriver to turn the bolt clockwise on the distal end of the Compression/Distracton Device (see illustration 3/4). Use image intensification to assess the progress of the compression.



Note: Be careful to ensure that the desired position of the arthrodesis is maintained during compression. In particular, avoid drifting of the hindfoot into excessive valgus which may create a valgus orientation in the construct. Congruent preparation of the joint surfaces will aid in maintaining the desired position.

Note: The middle pin position provides the possibility to distract prior to compression, which allows additional joint preparation if necessary.



STEP 13

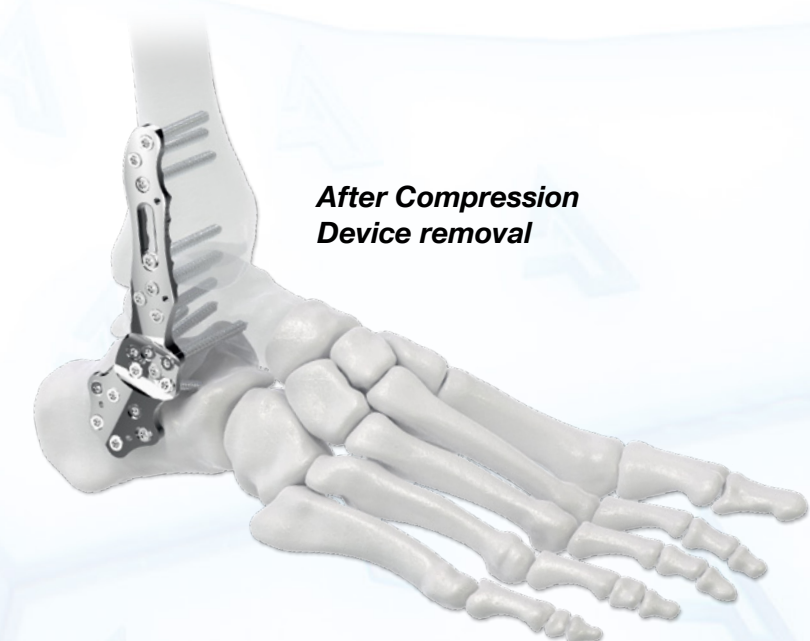
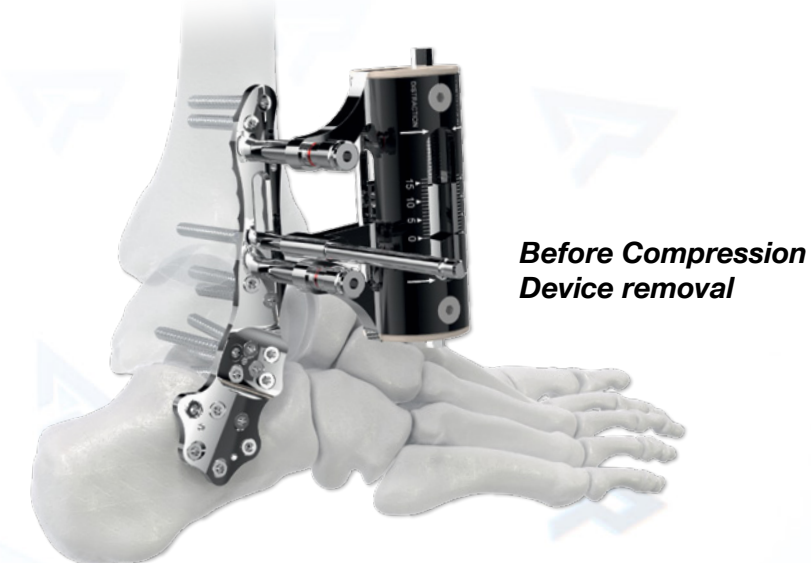
Proximal Screw Fixation

- Once adequate compression has been achieved, drill, measure, and insert locking screws in the plate in the same manner as with the distal screws for:

AgoFix – insert screws in the tibial part

AgoFix Plus – insert screws in the talus and tibial part

For tibial screws, use the 3.2 mm instruments (with red markings).



- After achieving adequate fixation, remove the fixation pin and the Compression/Distracton Device. Then insert locking screws into the remaining tibial holes. For improved stabilization, always insert a standard screw in the fixation pin hole.



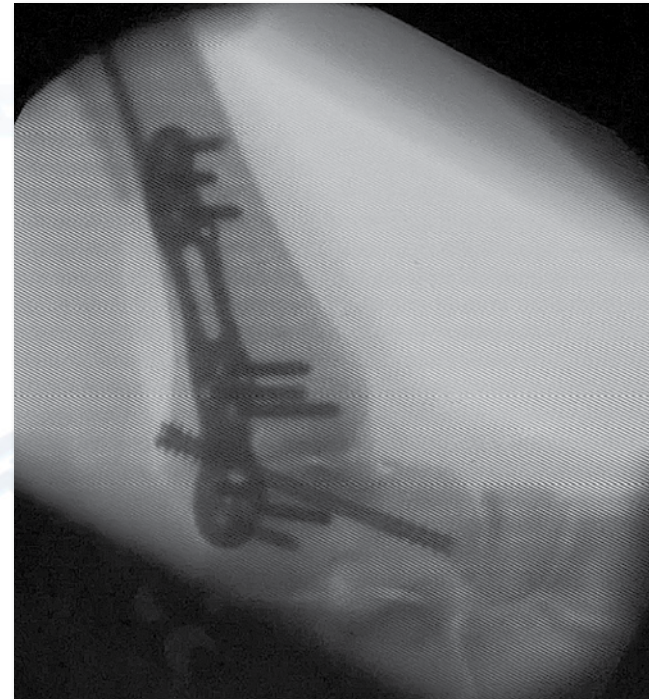
Note: Only standard screws may be used in the slotted hole.



STEP 14

Wound Closure and Dressing

- Use image intensification to confirm adequate plate and screw placement. Then close the wound in layers, and apply a cast in the usual manner.



Postoperative Treatment

- Postoperatively the limb is elevated in a back slab plaster cast for the first two weeks.
- A wound check is performed at two weeks, and if the wound is healing, a new cast or boot is applied with the patient allowed to partially weight bear as dictated by the strength of the bone and the fixation at the time of the surgery.
- At 6-8 weeks post-op, the cast is removed (an X-ray may be performed at this stage depending on surgeon preference), and the patient may then commence full weight bearing in a removable boot or cast.
- At 12 weeks post-op, an X-ray is taken, and if healing is established, the patient may fully weight bear without support.

Implant Removal

- There is no need to routinely remove the implant or any screws once bony consolidation is confirmed. If the hardware is causing tendon or soft tissue irritation, then removal may be carried out, but care must be taken to confirm that the underlying joint is completely consolidated with bone. This step may require a CT scan. If there is no irritation, then the plate and screws should remain in the bone indefinitely.

TITANIUM AGOFIX PLATES

TITANIUM AGOFIX TT PLATES



LEFT 3.0 mm

RIGHT 3.0 mm



4001196
Standard, pack/1



4001197
Standard, pack/1



4001198
Large, pack/1



4001199
Large, pack/1



TITANIUM AGOFIX TTC PLATES



LEFT 3.0 mm

RIGHT 3.0 mm



4001200
Plus standard, pack/1

4001201
Plus standard, pack/1



4001202
Plus large, pack/1



4001203
Plus large, pack/1

TITANIUM SCREWS



L	Ø 4.0 mm	Ø 4.0 mm	Pack
18 mm	5004018	5004118	5
20 mm	5004020	5004120	5
22 mm	5004022	5004122	5
24 mm	5004024	5004124	5
26 mm	5004026	5004126	5
28 mm	5004028	5004128	5
30 mm	5004030	5004130	5
32 mm	5004032	5004132	5
34 mm	5004034	5004134	5
36 mm	5004036	5004136	5
38 mm	5004038	5004138	5
40 mm	5004040	5004140	5
42 mm	5004042	5004142	5
44 mm	5004044	5004144	5
46 mm	5004046	5004146	5
48 mm	5004048	5004148	5
50 mm	5004050	5004150	5
55 mm	5004055	5004155	5

Drill-ø 3.2 mm





INSTRUMENTS AND TOOLS

1301048 AgoFix agopaq system 4.0 instrument tray



1000150 Agopaqx4 tray for implant modules w/4 lids, w/o implant modules



1301049 Agopaqx4 AgoFix plate-tray system 4.0, w/o implants



1301050 Agopaqx4 AgoFix-plus plate-tray system 4.0, w/o implants



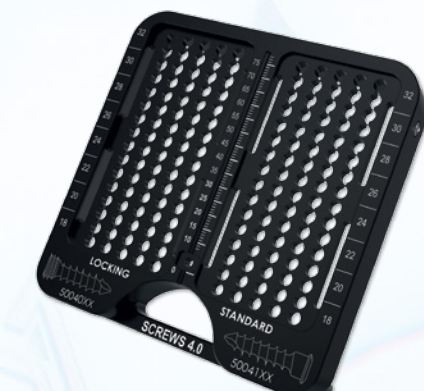
1301051 Agopaqx4 AgoFix screw tray 34-55 mm locking, system 4.0, w/o implants



1301052 Agopaqx4 AgoFix screw tray 34-70 mm standard, system 4.0, w/o implants



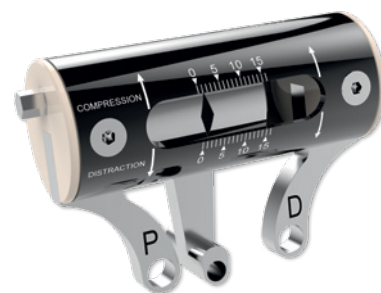
1301038 Agopaqx4 screw tray system 4.0 w/o implants





1300511

AgoFix compression/distraction device, 0 - 15 mm



1300980

Silicone ratchet T-handle, AO-shaft right / left / fixed, 13 cm, cannulated, black



1300977

Silicone ratchet handle, AO-shaft right / left / fixed, 15 cm, non-cannulated, black



1300512

Hinge blade hex 5, AO, 112 mm for 1300511



1300513

Pin w/screw thread 4.0, AO 140 mm, for 1300511



1101270

Kirschner wires trocar/trocar 2 x 150 mm, pack/10



1201114

AgoFix drill-guide f. drill 2.7 sys. 4.0, screwable, black marking, 45 mm



1201115

AgoFix drill-guide f. drill 3.2 sys. 4.0, screwable, red marking, 65 mm



1001010

Screwdriver blade TX 10 non-cannulated, interchangeable, AO-shaft



1201064

Twist drill 2.7 x 125 mm, ao 50 mm thread, black marker



1201101

Twist drill 3.2 x 145 mm, AO-shaft 50 mm thread, red marker



1002527

Plate- /screwholding forceps angled, 15cm/6"





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