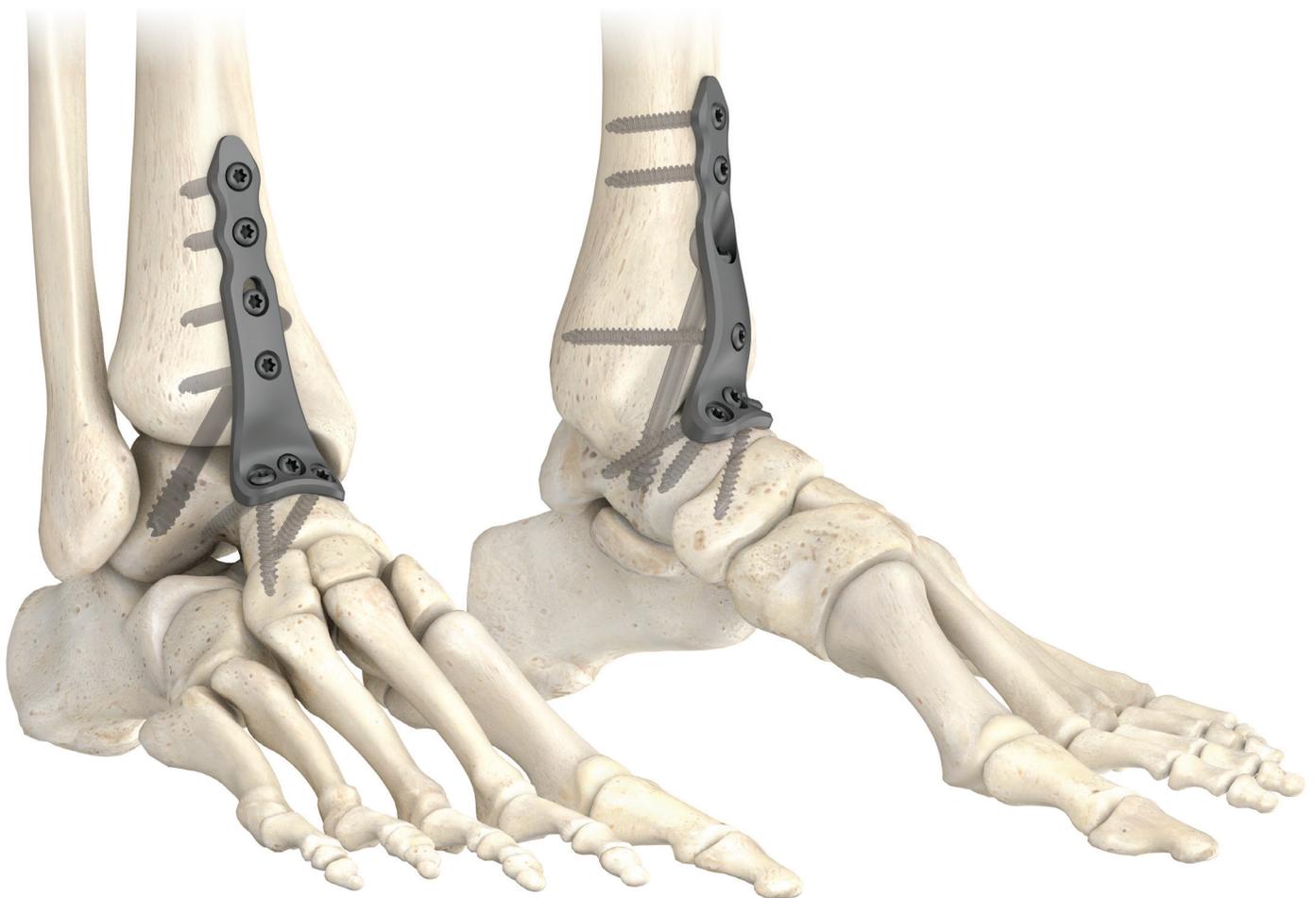


AxSOS 3[®] Ti Platform

Ankle Fusion System

Operative technique

AxSOS 3 Ankle Fusion System



AxSOS 3® Ti Platform

Ankle Fusion Plate

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to performing surgery with these implants.

▲ WARNING

Follow the instructions provided in our cleaning and sterilization guide (OT-RG-1).

▲ WARNING

All non-sterile devices must be cleaned and sterilized before use. Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.

Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

Consult Instructions for Use (IFU V15246, V15247, V15020 or www.ifu.stryker.com) for a complete list of potential adverse effects, contraindications, warnings and precautions.

▲ WARNING

- The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.
- The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.
- Removal or revision of the device may be required sometime in the future due to medical reasons.

Acknowledgments:

Stryker acknowledges the following surgeons for their support in the development of this technique guide:
Michael J. Coughlin, M.D. and Keith L. Wapner, M.D.

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Introduction

The AxSOS 3 Ankle Fusion System is indicated for arthrodesis of the ankle, which includes tibi-talo-calcaneal, tibio-talar, and tibio-calcaneal arthrodesis, in possible conjunction with osteotomies and fractures of the distal tibia, talus, and calcaneus. This operative technique contains a step-by-step procedure for the implantation of ankle fusion plates using the ORIF instrumentation.

Plates and Screws used in this Operative Technique Guide:

Tibiotalar Plates

AxSOS 3 Titanium Ankle Fusion Plates

Anterior Standard Plate



Anterolateral Standard Plate



Anterior CP Plate



Anterolateral CP Plate



Screws

AxSOS 3 Titanium Screws

All of the AxSOS 3 screws below have a T15 screw head interface.

4.0mm
Locking



4.0mm
Cancellous
Partial Thread



4.0mm
Cancellous
Full Thread



3.5mm
Cortex



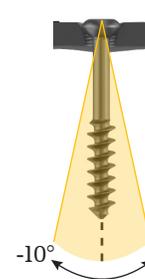
4.0mm
Cortex



Locking



Cancellous



Cortex



-10° +10° -10° +10°

The 6.5mm cannulated screws below have a T30 screw head interface.

6.5mm Cannulated
16mm Thread



6.5mm Cannulated
32mm Thread



Material

Please note that AxSOS 3 Titanium is a titanium alloy (Ti6Al4V) and is not compatible with any stainless-steel plates or screws.

Indications, precautions & contraindications

Indications for use

The AxSOS 3 Ankle Fusion System is indicated for arthrodesis of the ankle, which includes tibio-talo-calcaneal, tibio-talar, and tibio-calcaneal arthrodesis, in possible conjunction with osteotomies and fractures of the distal tibia, talus, and calcaneus.

Precautions

MRI safety information



Non-clinical testing has demonstrated the Stryker AxSOS 3 Ankle Fusion System is MR Conditional.

A patient with these devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T or 3.0T
- Maximum spatial field gradient of 3000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg

Under the scan conditions defined above, the Stryker AxSOS 3 Ankle Fusion system is expected to produce a maximum temperature rise of less than 7.3°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 21 mm from the Stryker AxSOS 3 Ankle Fusion System when imaged with a gradient echo pulse sequence and a 3.0T MRI system.

⚠ CAUTION

The MRI safety information provided above is based on testing which did not include other implants. Other implants (i.e. plates, screws, wires, prosthesis, etc.) present within 3 cm of the AxSOS 3 Ankle Fusion System could result in significant heating and possible tissue damage, and therefore scanning is not recommended.

Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity, unless used with a compatible system that may also be used in obese patients. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

Detailed information is included in the instructions for use.

See instructions for use for a complete list of potential adverse effects and contraindications. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient.

General information

Plate Bending

In most cases, the pre-contoured plate will fit without the need for further bending. If additional bending of the plate is required, the bending irons (705007) are supplied with the AxSOS 3 Ankle Fusion system.

The bending irons are designed to be used as a pair, using two of the same instrument. Please note, this is different from bending of other AxSOS plates. The open slots of the bending irons are designed to bend the proximal aspect of the ankle fusion plates. If desired, the slots on either side of the instrument can be used, see bending iron (705007) image. See Step 3 for detailed instruction.



Bending Iron (Type 2)
(705007)



⚠ CAUTION

Bending of the plate in the region of the universal holes may affect the ability to correctly seat the locking screws into the plate and is therefore not permitted. Also do not overbend the plate and do not bend back and forth as this may weaken the plate.

Non-Locking Screw Technique

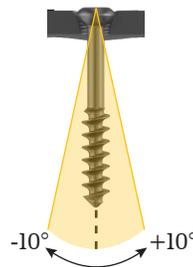
To seat a non-locking cortex or cancellous screw, use the drill guide (705022) or polyaxial drill sleeve (705824) and non-locking drill bit (705025), and drill through both cortices for bi-cortical screw fixation or to the desired depth.

The appropriate screw length is determined by reading directly off the drill bit with the drill guide only (705022), or with the depth gauge (705012). Tapping is optional as the screws are self-tapping.

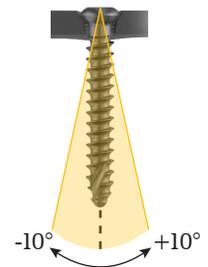
Non-locking screws of appropriate length are inserted into the plate using the T15 screwdriver bit (705015) with the AO handle + handle insert (703920 + 703922).

If inserting non-locking screws under power make sure to use a low speed drill setting to avoid potential thermal necrosis. In hard bone, it is advised to use the Ø4.0mm cortical tap (705829) or Ø3.5mm (702804) for cortex screws or the cancellous tap (702805) for cancellous screws before screw insertion. See page 7 for a detailed table of compatible instruments for non-locking screws.

Cancellous Screw



Cortex Screw



Polyaxial Drill Sleeve
(705824)



Drill Guide
(705022)



AO handle + handle insert
(703920 + 703922)

T15 screwdriver bit
(705015)

General information

Locking Screw Technique

The orange color on the Drill Sleeve 3.1mm Locking (705004) represents the color code for the 4.0mm locking system.

To seat a locking screw, use the Drill Sleeve 3.1mm Locking (705004) and the locking drill bit (705031), and drill to the desired depth.

The appropriate screw length is determined by reading directly off the locking drill bit with the locking screw drill sleeve, or with the depth gauge (705012). Tapping is optional as the screws are self-tapping.

Locking screws of appropriate length are inserted into the plate using the T15 screwdriver bit (705015) with the AO handle (703920) + handle insert (703922) + 2.5Nm torque limiter (702760).

If inserting locking screws under power using the T15 screwdriver bit (705015), make sure to use a low speed drill setting to avoid damage to the screw plate interface and potential thermal necrosis. In hard bone, it is advised to use the locking tap Ø4.0mm (702772) before screw insertion.

See page 7 for a detailed table of compatible instruments for locking screws.



AO handle + handle insert
(703920 + 703922/703923)

2.5Nm Torque limiter
(702760)

T15 screwdriver bit
(705015)

▲ CAUTION

Always use the locking drill sleeve when drilling for locking screws.

▲ CAUTION

Ensure that the screwdriver tip is fully seated in the screw head, but do not apply axial force during final tightening.

▲ CAUTION

Always perform final tightening of the locking screws by hand using the 2.5Nm torque limiter (702760). This prevents overtightening of locking screws and also ensures that these screws are properly tightened with a torque of 2.5Nm. The device will click when the torque reaches 2.5Nm. This procedure is repeated for all locking screws.

▲ CAUTION

The torque limiters require routine maintenance. Refer to the instructions for maintenance of torque limiters (V15020).

General information

Compatible instruments for Ankle Fusion screw implantation

The AxSOS 3 Ankle Fusion system has a unique drill and tap for the cancellous, cortex, locking and cannulated screw options. The table below outlines the compatible instruments for each screw type. See the AxSOS 3 Ankle Fusion system component sheet for a complete list of standard screw sizes included in the standard set.

Step	Locking screw	Non-locking screw		Cannulated screw
Screw selection	 4.0mm Locking (661014-661095)	 4.0mm Cancellous Full thread (607310-607400) Partial thread (607410-607500)	 4.0mm Cortex (666110-666220) 3.5mm Cortex (661410-661520)	 6.5mm Cannulated 16mm thread (666435-666515) 32mm thread (666675-666740)
Drill guide	 Drill Sleeve 3.1mm Locking (705004)	 Drill Sleeve Polyaxial Ø2.5mm (705824) Drill Guide 2.5mm Non-Locking (705022) Compression Drill Guide (705817) - not pictured		 CP Double Wire Guide for Ø3.2mm Wires (705804)
Optional K-wire	 K-Wire Ø2.0x150m (390192)	 K-Wire Ø2.0x150m (390192)		 Guide Wire Ø3.2x300mm (702463)
Drill	 Drill Bit 3.1x216mm Locking (705031)	 Drill Bit 2.5x216mm Non-Locking (705025)		 Cannulated Drill Ø4.9mm (705809)
Depth gauge	 Depth Gauge 0-120mm (705012) -or- Drill Bit + Drill Sleeve 3.1mm Locking (705004)	 Depth Gauge 0-120mm (705012) -or- Drill Bit + Drill Guide 2.5mm Non-Locking (705022)		 Direct Measuring Gauge, Ø3.2x300mm (705808)
Tap	 Locking 4.0mm (702772)	 Cancellous 4.0mm (702805)	 Cortex 4.0mm (705829) Cortex 3.5mm (702804) Not Standard in Set	 Cannulated Tap Ø6.5mm (705810)
Screw insertion	 AO Handle (703920) & Handle Insert (703922/703923) & Torque Limiter, 2.5Nm (702760) & Screwdriver Bit T15 (705015)	 AO Handle (703920) & Handle Insert (703922/703923) & Screwdriver Bit T15 (705015)		 Delta Handle, Modified Trinkle (2351-0140) & Cannulated/Solid Screwdriver T30 (705812/705813)

Screw measurement on the screw rack

The screw is placed with the tip on the end of the measuring slot. The length can be read off the scale of the rack.



Pre-operative planning

Back table layout

Other items needed:

- Power system (that accepts AO and Modified Trinkle Adapters)
- Pin Driver/Drill
- Modified Trinkle Adapter
- AO Adapter

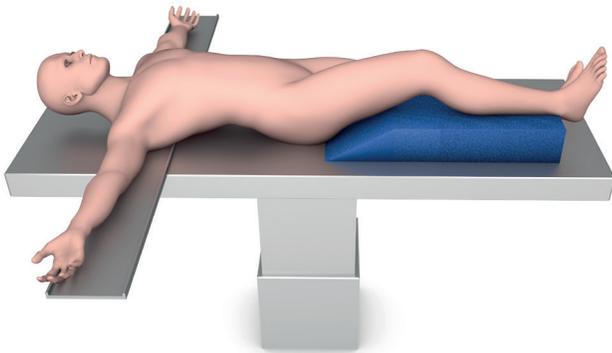
Joint preparation instruments including, but not limited to:

- Lamina spreaders
- Osteotomes (6mm to 16mm)
- Angled curette
- Rongeurs

Before the patient is in the operating room, check the AxSOS 3 Ankle Fusion set to be sure all required instruments and implants are available.

Patient positioning

Position the patient supine with option to elevate the leg over a leg support above the contralateral limb. Visualization of the ankle joint under fluoroscopy in both the lateral and AP views is necessary. A small bump is placed beneath the ipsilateral hip to rotate the ankle so that the line of the medial malleolus is perpendicular to the operating table.



▲ WARNING

After the foot and ankle have been correctly positioned, the leg is elevated for about two minutes. The lower limb is exsanguinated with an esmark bandage, and a thigh high tourniquet is inflated with an appropriate amount of pressure for the size of the patient's leg and foot.

Approach

A longitudinal incision is centered over the ankle immediately lateral to the anterior tibial tendon. The incision is deepened to the ankle joint while retracting the extensor hallucis longus and the neurovascular bundle laterally. The superficial branch of the peroneal nerve in the foot is visible and must be retracted carefully to the lateral aspect of the ankle.

It is frequently necessary to sacrifice one small branch of this nerve that innervates the great toe. The tendon sheath of the extensor hallucis longus is now incised in line with the skin incision. Be sure the incision size is appropriate to avoid excessive soft tissue irritation.

Plate selection

Selection of Anterior or Anterolateral Plate

The AxSOS 3 Ankle Fusion Plates are all designed from Stryker's SOMA database to be highly conforming with minimal bending adjustments required.

Selection of Standard or CP Plate

The AxSOS 3 Ankle Fusion Plates are designed with either a CP (cross plate) hole or a standard compression slot to help achieve tibiotalar compression.

Operative steps

Implantation of Standard or CP Plate

Step 1

Distraction, joint prep, positioning and provisional fixation

1.1 Joint distraction

Based upon the patient's bone quality, joint distraction can be achieved using one of three techniques.

A. Transverse pin technique

Place the first transverse Ø3.2mm pin (702463) medially in the central talus just below the medial malleolus and drive laterally to exit the talus anterior to the fibula. Palpate to ensure the pin insertion is above the posterior tibial tendon, flexor digitorum tendon, and neurovascular bundle. (Figure 1.1a)

Place the medial joint distractor over the talar pin and align the distractor's (705820) proximal arm so the tibial pin is placed several centimeters above the joint line, while leaving sufficient throw (minimum 1cm) to allow for distraction. Position to place the tibial transverse pin in the center of the tibial shaft to ensure the tibial transverse pin does not intersect with the plate's compression screw placement. (Figure 1.1b; Figure 1.1c)

Using the joint distractor as a pin guide, insert a second transverse pin medially, parallel to the talar pin and exiting the tibia anterior to the fibula. Position both the distractors (705820) medially and laterally over the pins and ratchet to achieve tibiotalar distraction for joint preparation. (Figure 1.1c; Figure 1.1d; Figure 1.1e)

The locking knob on the distractor can be engaged to prevent accidental disengagement of the ratchet mechanism. The distractor ratchet mechanism has sharp edges, take care to avoid catching gloves while releasing the ratchet mechanism.

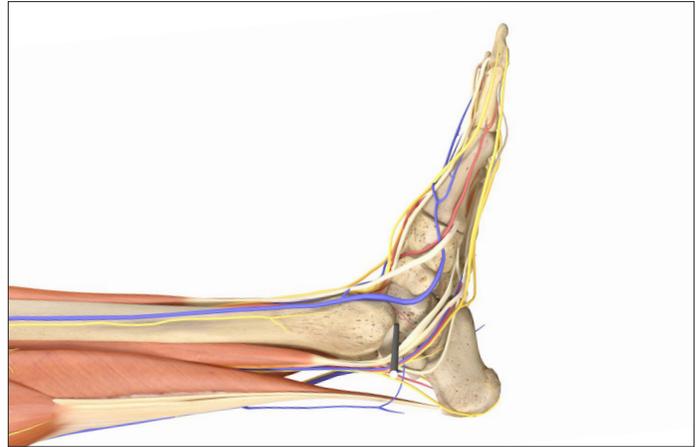


Figure 1.1a

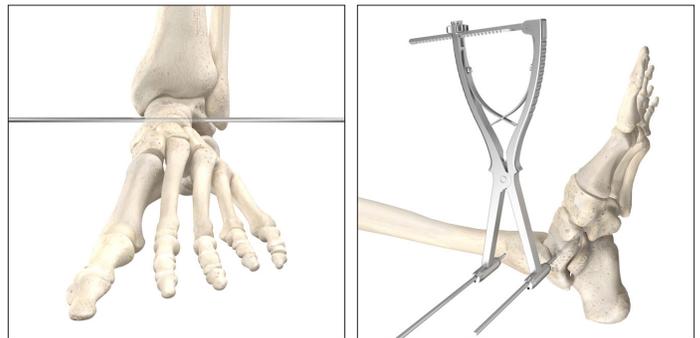


Figure 1.1b

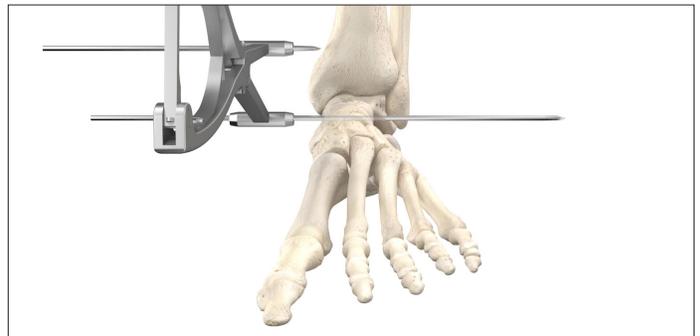


Figure 1.1c

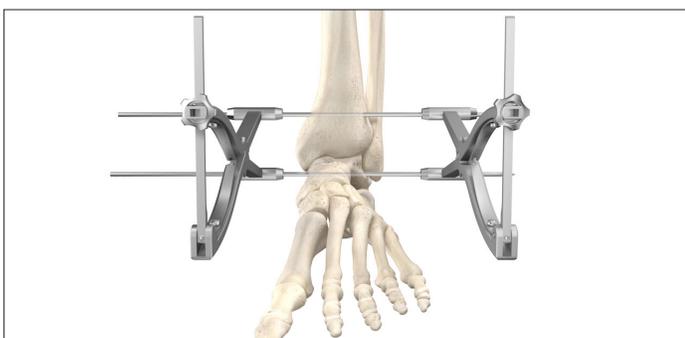


Figure 1.1d

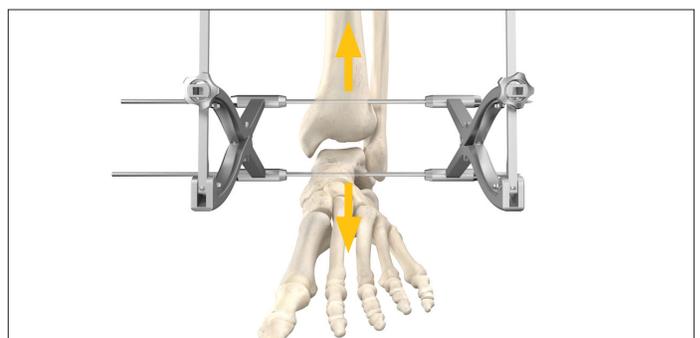


Figure 1.1e

B. Anterior pin technique

Insert two anterior pins (705801) into the talus, one medial and one lateral. Take care to avoid damage to critical structures, interfering with the final plate positioning and limiting access to joint surfaces to be prepared. (Figure 1.1f)

Place the medial and lateral joint distractor over the talar pin and align the distractor's (705820) proximal arm so the tibial pin is placed several centimeters above the joint line, while leaving sufficient throw (minimum 1cm) to allow for distraction. (Figure 1.1g)

Using the joint distractor as a pin guide, insert the tibial pins, one medial and one lateral. Take care to avoid damage to critical structures, interfering with the final plate positioning and limiting access to joint surfaces to be prepared. (Figure 1.1h)

Position both the distractors (705820) medially and laterally over the pins and ratchet to achieve tibiotalar distraction for joint preparation. (Figure 1.1i)

The locking knob on the distractor can be engaged to prevent accidental disengagement of the ratchet mechanism.

⚠ CAUTION

Be sure to fully insert the compression/distraction instruments over the pins, but just off the skin for best performance.

⚠ CAUTION

Insufficient ankle joint distraction may decrease access for joint preparation.

⚠ CAUTION

The ratchet mechanism on the compressor and distractor has sharp edges, take care to avoid catching any gloves while releasing the ratchet mechanism.

C. Lamina spreaders

Insert lamina spreaders into the joint space, alternating between medial and lateral placement to allow sufficient access for joint preparation.



Figure 1.1f

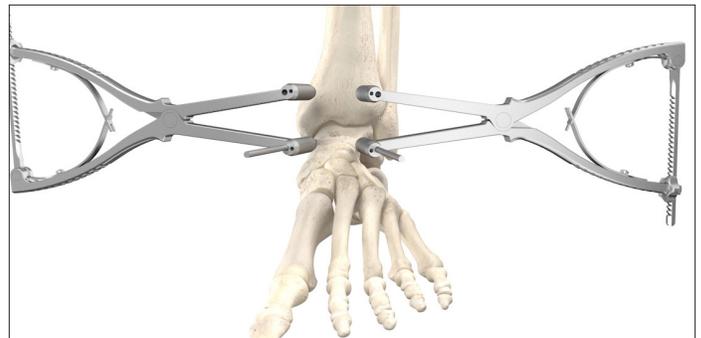


Figure 1.1g



Figure 1.1h

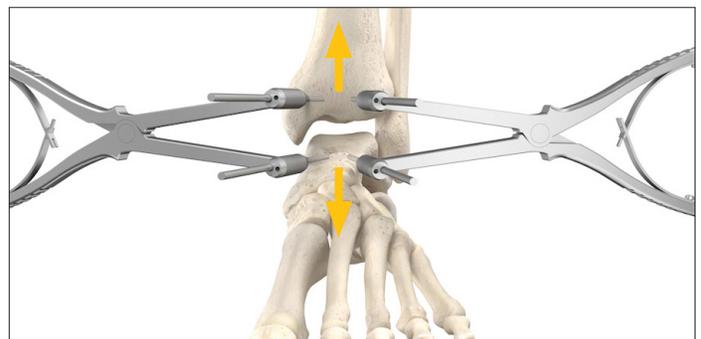


Figure 1.1i

1.2 Joint preparation

During the procedure, take care to avoid damage to critical structures. Be sure the incision size is appropriate to avoid excessive soft tissue irritation.

Prepare tibial and talar joint surfaces using the Stryker F1 System or more traditional techniques (rasp, osteotome, curette). Remove cartilage and subchondral bone from the articular surfaces exposing cancellous bone. Remove sclerotic bone and osteophytes from the anterior tibia and talar neck. Increase the subchondral joint surface area and blood flow by drilling holes (microfracture) or feathering the joint contacting surfaces with a saw blade. (Figure 1.2a; Figure 1.2b)

Once the joint surfaces are adequately prepared, remove the distractors while leaving the pins in place. If distraction is done via anterior pins, remove pins.

⚠ CAUTION

Insufficient joint preparation may decrease the chances of a successful fusion.

1.3 Tibio-talar positioning

For all procedures, it is essential that the bone is correctly reduced and compressed prior to template and implant placement.

The optional 90° Ankle Guide (705821) is intended to approximate 90° and is provided to aid in proper foot positioning prior to fixation. Slide the long end of the Ankle Guide under the posterior aspect of the leg, until the heel and forefoot contact the plate to approximate 90°. Place a bump under the distal tibia to prevent posterior translation of the talus. If there is a concern about the amount of sagittal plane dorsiflexion/plantarflexion, the angle can be confirmed with a goniometer and adjusted with padding beneath the leg, if necessary. Confirm desired positioning radiographically before provisional fixation with A/P and lateral fluoroscopy imaging. If necessary, intraoperative pads can be applied to achieve desired position. Take care not to bend the Ankle Guide during positioning. (Figure 1.3a)

If not already in place, two transverse pins can be placed (see Step 1.1A) to assist in compression and proper foot positioning.

Joint compressors (705819) are placed over the transverse pins on the medial and lateral sides of the ankle. (Figure 1.3b)

⚠ CAUTION

Be sure to fully insert the compression/distraction instruments over the pins, but just off the skin for best performance.

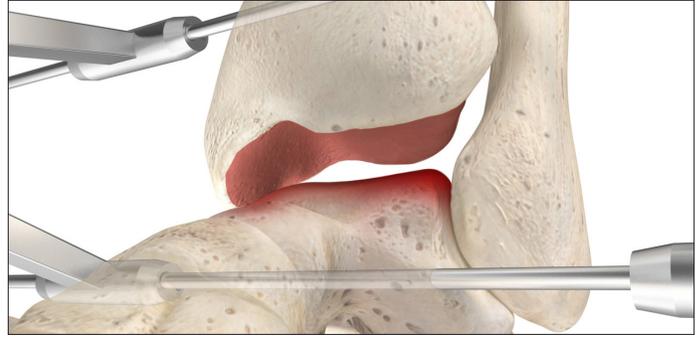


Figure 1.2a



Figure 1.2b

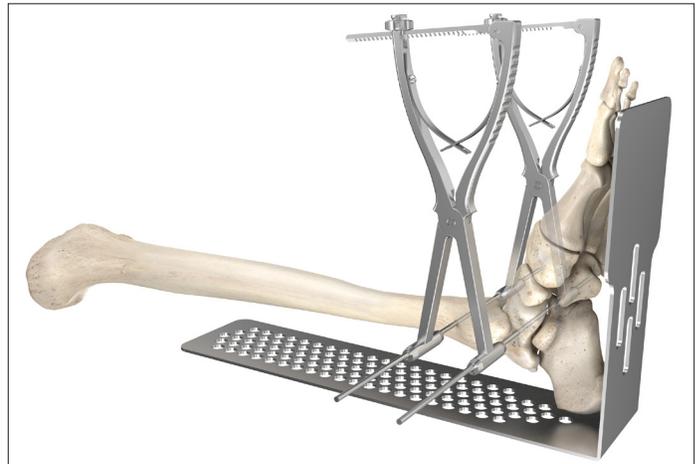


Figure 1.3a

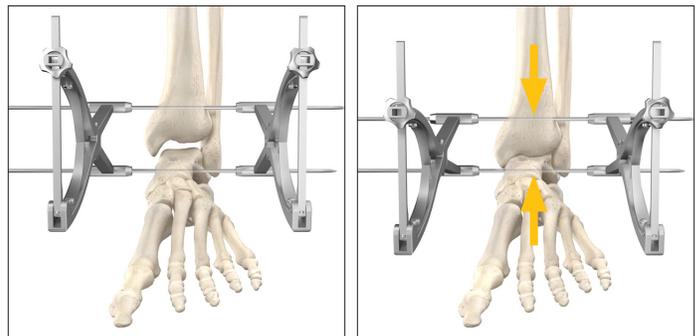


Figure 1.3b

Figure 1.3c

Position the compressors at least 1cm off the skin to provide adequate clearance of the ratchet from the forefoot. (Figure 1.3c)

Compressor handles can be used as dual steering levers for slight adjustments in rotation and A/P position. Evenly activate compressors to ensure proper varus/valgus alignment as the foot is reduced into the desired position.

Prior to provisional fixation, ensure proper foot alignment:

- Dorsiflexion / plantarflexion
90° to the tibia, neutral
- A/P Translation
Talus centered under the tibia
- Medial / lateral shift
Centered in the mortise
- Rotation
Mirror the contralateral limb, (typically 5-15° external rotation in reference to the patella)
- Varus / Valgus
Position the calcaneus in 5° valgus for a neutral foot

A forefoot deformity may make it more difficult to achieve the final position for ankle fusion.

After properly aligning the foot, apply final compression prior to provisional fixation.

▲ CAUTION

Avoid excessive dorsiflexion or plantarflexion of the foot. Correct preparation, reduction and compression are fundamental to achieving a good outcome.

1.4 Provisional fixation options

Once proper positioning of the foot is achieved and the tibiotalar joint has been adequately compressed, insert a 3.2mm pin through the optional ankle guide into the plantar aspect of the foot through the center of the talus and into the center of the distal tibia to hold proper tibiotalar position during plating. (Figure 1.4a; Figure 1.4b)

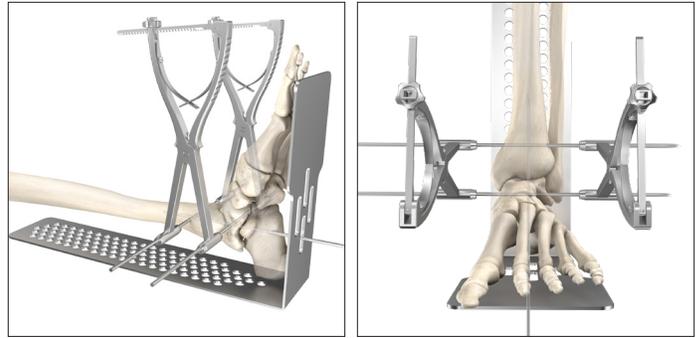


Figure 1.4a

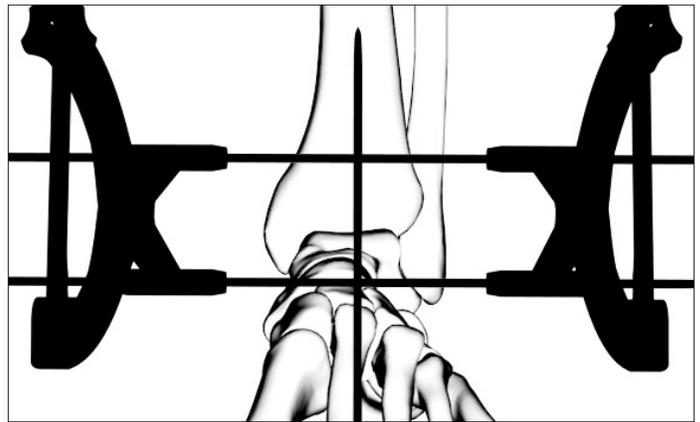


Figure 1.4b

Alternately, insert a K-wire from above the medial malleolus, posterior to the tibial transverse pin, through the center of the medial third of the talar dome and terminating in the lateral process. Use the CP double wire guide (705804) as a tissue protection sleeve for K-wire insertion. If using a standard plate, this K-wire can be used for independent screw fixation (see Step 5). (Figure 1.4c; Figure 1.4d)

Confirm final positioning after provisional fixation with an A/P and lateral fluoroscopy shot.

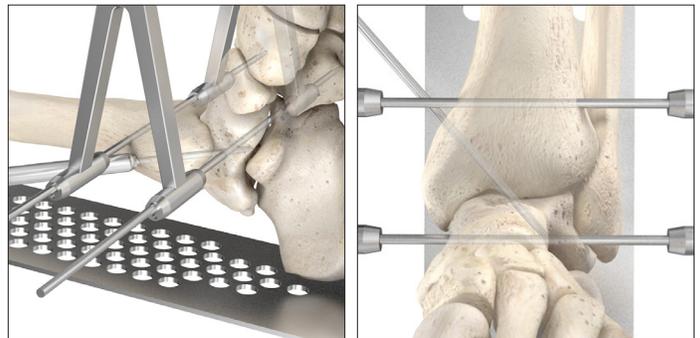


Figure 1.4c

CAUTION

Ensure proper compression and provisional fixation with K-wires to avoid movement of bones during plate fixation.

The provisional fixation k-wire is omitted from subsequent images, for clarity.

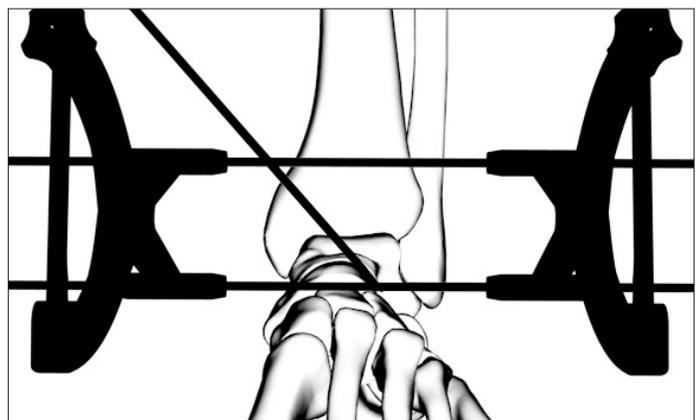


Figure 1.4d

Step 2

Plate positioning

Standard Plate

2.1 Plate positioning

Select the desired standard plate, anterior (630101, 630102) or anterolateral (630111, 630112). The use of the template is not required for the standard plate.

Screw the Drill Sleeve 3.1mm Locking (705004) into the plate's most distal tibial screw hole, and place the plate on the bone. Assess implant position and identify if the bone or plate needs to be contoured for optimal fit. (Figure 2.1 Standard)

Remove prominent tibial or talar bone to achieve a more anatomic fit.

If plate bending is required proceed to Step 3, otherwise proceed to Step 4 for provisional fixation.

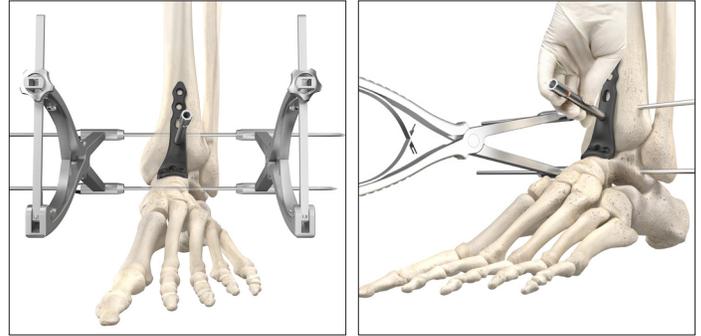


Figure 2.1 Standard

CP Plate

2.1 Template positioning

The use of a template (705781, 705782, 705783, 705784) is essential for CP plates in order to define the correct reaming position of the CP pocket.

Select the appropriate template based on the desired final implant. Screw the Drill Sleeve 3.1mm Locking (705004) into the template's tibial screw hole and position the plate on the bone. Assess implant fit and identify if bone or plate needs to be contoured for optimal fit. (Figure 2.1 CP)

Remove prominent tibial or talar bone to achieve a more anatomic fit.

The template may be temporarily fixated with olive K-wires (705800).

2.2 CP K-wire insertion

The K-wire acts as a guide for the CP pocket reamer. Insert the K-wire sleeve (705003) into the Drill Sleeve 3.1mm Locking (705004) on the template. Drive a Ø2.0 K-wire (390192) through the locking drill sleeve (705003 + 705004) and 20mm into the bone. (Figure 2.2 CP)

⚠ CAUTION

Be sure the template is positioned correctly as this will determine the final implant position.

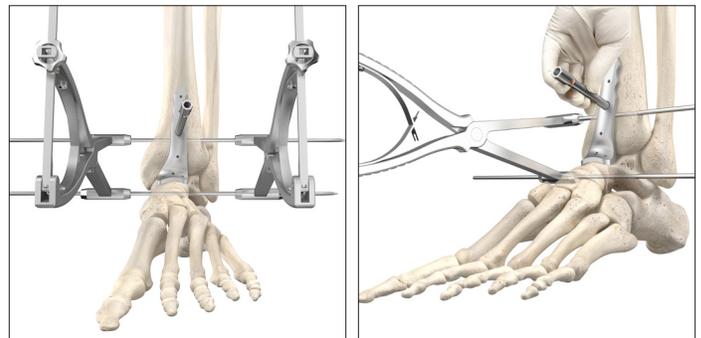


Figure 2.1 CP

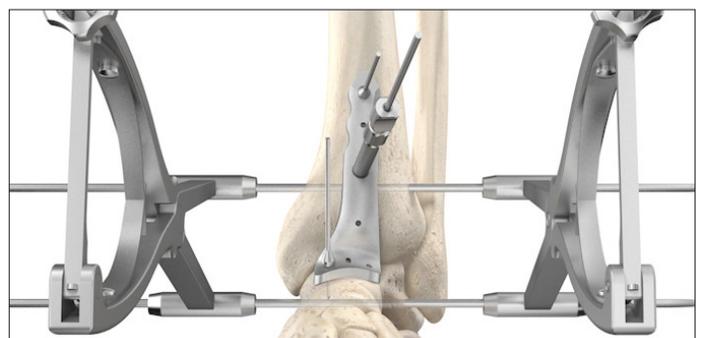


Figure 2.2 CP

NOTICE

Use K-wire insertion sleeve to avoid deflection of K-wire during insertion.

NOTICE

Be sure the guidewire is inserted at least 20mm into the tibia to maintain reamer alignment during reaming.

⚠ WARNING

Stop insertion of the guidewire before perforation of the posterior cortex to avoid damage to soft tissue structures.

2.3 Reaming the CP pocket

Remove the template and drill sleeve over the K-wire, leaving the K-wire in place. Insert the reamer (705803) over the K-wire under power. (Figure 2.3a CP)

Depth of the CP pocket

The correct reaming depth has been achieved when the full circumference of the upper edge of the reamer's head is flush or below the surface of the bone. If proximal end of CP plate is bent, ensure that the bone is reamed deep enough to seat the CP dome. (Figure 2.3c CP)

Remove the reamer and guidewire.

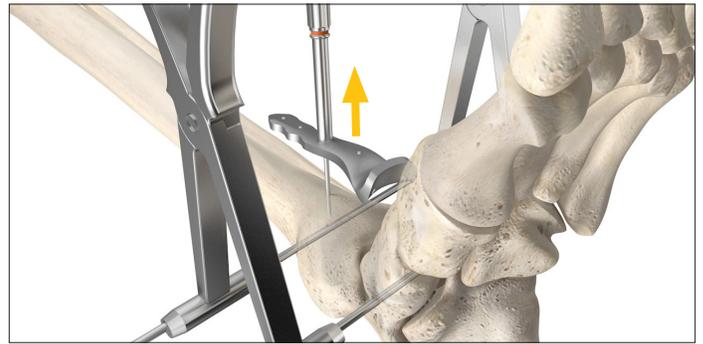


Figure 2.3a CP



Figure 2.3b CP



Figure 2.3c CP



Figure 2.3d CP

⚠ CAUTION

Be sure to ream to the proper depth (to the upper edge of the reamer head) as a shallow pocket will cause the plate to sit off the bone.

⚠ CAUTION

The reamer cutting design is aggressive and removes bone quickly.

⚠ CAUTION

Be careful not to push in the guidewire during reaming.

Step 3

Plate bending

Plate bending is best performed with two people. The first person holds the bending irons (705007) with slots face up and the second person then positions and secures the plate within the largest bending iron slot. (Figure 3.1)

▲ CAUTION

Bending of the plate in the region of the universal holes may affect the ability to correctly seat the locking screws into the plate and is therefore not permitted. Also do not overbend the plate and do not bend back and forth as this may weaken the plate.

Pull the handles apart to bend the plate in the desired direction. Reposition the plate and bending irons as necessary throughout bending to ensure the universal screw holes are not positioned outside of the bending iron groove. Refer to the standard and CP plate specific bending positions below. If desired, the slots on either end of the bending irons can be used. (Figure 3.2)

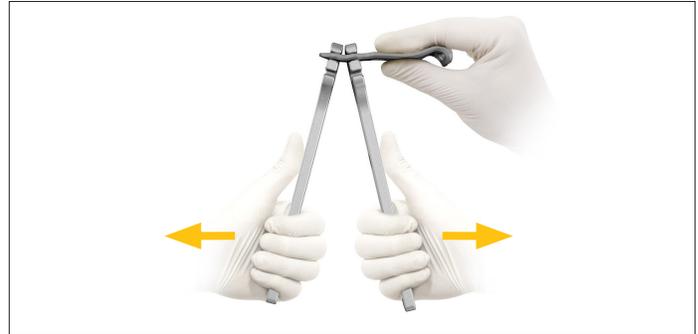


Figure 3.1

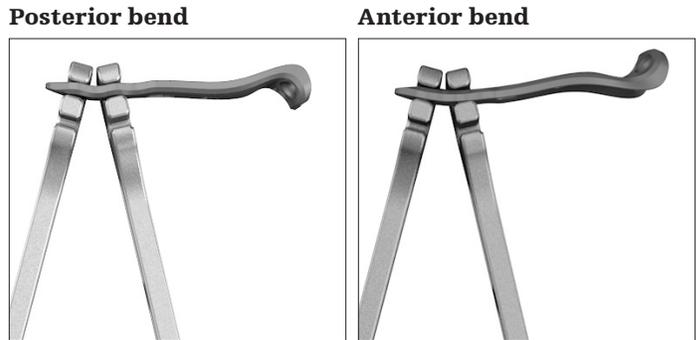


Figure 3.2

Standard Plate

Bending of the standard plate can only be performed on the proximal tibial section, in the two positions indicated in Figure 3.3 Standard.

Place the distal bending iron just superior to the compression screw hole, and the proximal bending iron over the adjacent tibial screw hole.

Place the distal bending iron just over the compression screw hole, and the proximal bending iron over the adjacent tibial screw hole.



Figure 3.3a Standard



Figure 3.3b Standard

CP Plate

Bending of the CP plate can only be performed on the proximal tibial section, in the position indicated in Figure 3.4 CP.

▲ CAUTION

Bending of the plate through the CP hole may allow the CP screw to slip through the hole if it is deformed and may weaken the plate.

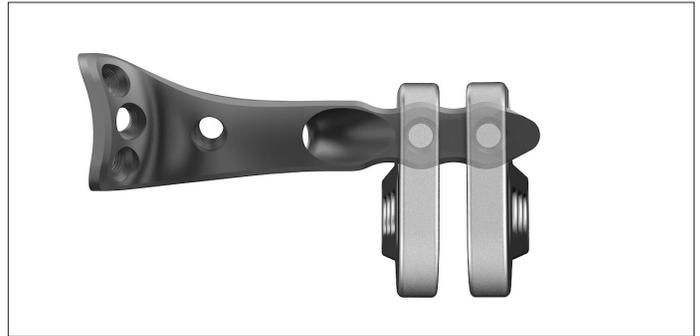


Figure 3.4 CP

Step 4

Plate talar fixation

4.1 Provisional plate fixation

Ensure the compressor locking knobs are tightened to avoid accidental disengagement of the ratchet mechanism. (Figure 4.1b)

⚠ CAUTION

Confirm correct implant selection with markings directly on the implant.

Provisionally fixate the plate with two Ø1.6mm Olive K-wires (705800), one in the tibia and one in the talus. Remove the tibial drill guide. (Figure 4.1a)

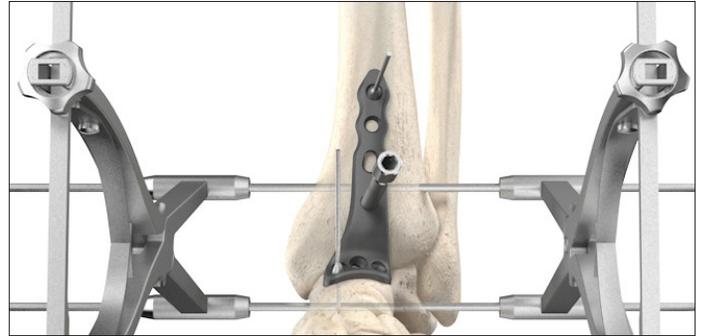


Figure 4.1a

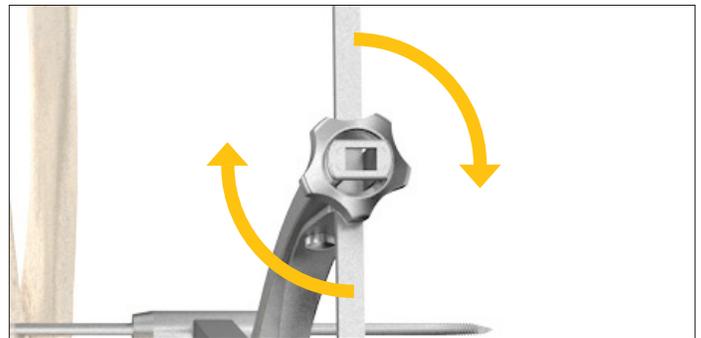


Figure 4.1b

4.2 Screw selection

Choose the desired screw from the available system options:

Non-locking

3.5 / 4.0 mm Cortex

4.0 mm Cancellous (Partial or Full Thread)

Locking (Fixed Angle)

4.0 mm

NOTICE

Always insert all non-locking screws in a bone before you use locking screws.

Final talar screw placement

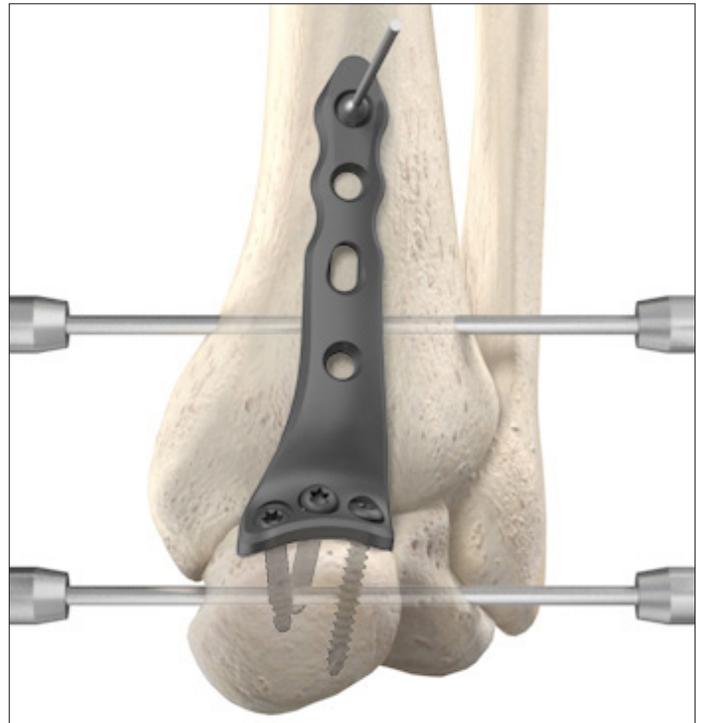


Figure 4.2

4.3 Drill

Screw or place the desired drill guide into the threaded talar screw holes for each screw preparation. An optional K-wire (390192) may be inserted first to confirm trajectory. The polyaxial drill sleeve (705824) can be inserted into any of the universal holes. It allows predrilling with the Ø2.5mm drill, for a Ø3.5mm or 4mm non-locking screw, up to a 10° cone. (Figure 4.3a; Figure 4.3b)

Drill up to the far cortex or preferred depth using the appropriate drill bit.

⚠ CAUTION

Always use the locking drill sleeve when drilling for locking screws.

⚠ CAUTION

Always use the appropriate drill guide when predrilling for a screw: Drill Sleeve 3.1mm Locking (705004) for locking screws or for straight insertion of a bone screw; Drill Sleeve Polyaxial Ø2.5mm (705824) or Drill Guide Ø2.5mm Non-Locking (705022) for bone screws; Drill Guide for Compression, Ø2.5mm (705817).

⚠ WARNING

When using the drill and/or tap, be sure to stop once through the far cortex to avoid damaging soft tissue structures.

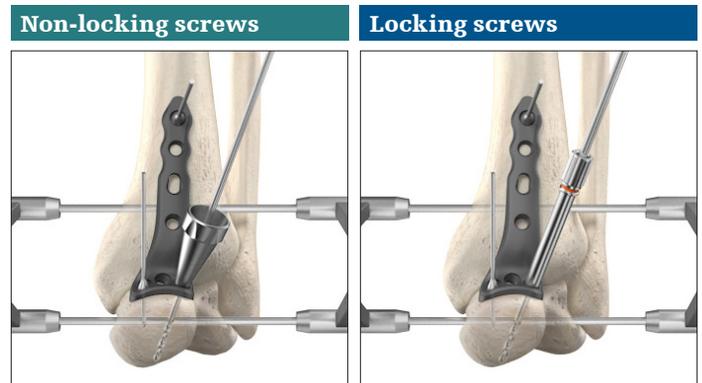


Figure 4.3a

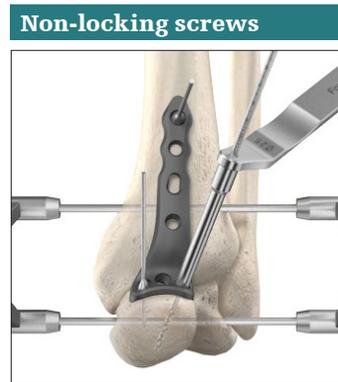


Figure 4.3b

4.4 Tap

Tapping is optional as the screws are self-tapping. Tap, if desired, using the appropriate tap. (Figure 4.4)

Non-locking screw taps

- Cancellous 4.0mm (702805)
- Cortex 4.0mm (705829)
- Cortex 3.5mm (702804)

Locking screw tap

- Locking 4.0mm (702772)

⚠ CAUTION

It is advisable to tap hard (dense) cortical bone before inserting screw.

⚠ WARNING

When using the drill and/or tap, be sure to stop once through the far cortex to avoid damaging soft tissue structures.

4.5 Measure

The appropriate screw length can be measured off the drill or with the depth gauge (705012). (Figure 4.5a; Figure 4.5b)

Appropriate screw length selection is important for the stability of the fixation. Measurements follow the principle of “what you read is what you get.” This means that the measured value in millimeters on the depth gauge (705012) or the drill bit is the exact value of the screw selected.

⚠ CAUTION

In case a self-tapping screw is intended to be positioned bi-cortically, make sure the tip is slightly sticking out on the far cortex (1-3mm) in order to allow for good cortical purchase.

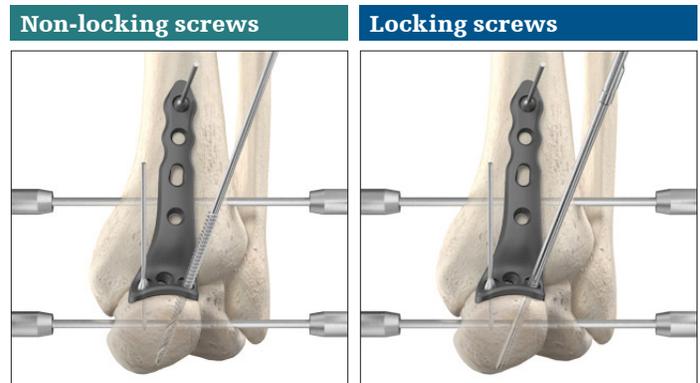


Figure 4.4

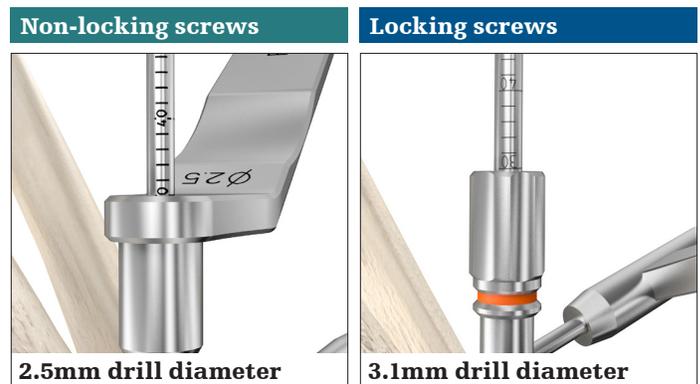


Figure 4.5a



Figure 4.5b

4.6 Screw insertion

Insert the selected talar screw with the handle (703920), handle insert (703922) and screwdriver bit T15 (705015). If using a locking screw, perform final tightening with the handle (703920), handle insert (703922), torque limiter, 2.5Nm (702760) and screwdriver bit T15 (705015). (Figure 4.6a)

⚠ CAUTION

Always measure the screw length before insertion and ensure correct screw length and position with fluoroscopy.

⚠ CAUTION

Fluoroscopy is required to ensure correct length and position.

⚠ CAUTION

Always start inserting the screw manually to ensure proper alignment in the plate thread and core hole. It is recommended to start inserting the screw using “the three finger technique” on the handle. Avoid any angulations or excessive force on the screwdriver, as this could cross-thread the screw.

⚠ CAUTION

If inserting locking screws under power, make sure to use a low speed drill setting to avoid damage to the screw / plate interface and bone necrosis.

⚠ CAUTION

Do not over-tighten as this might cause stripping of the threads in the bone and affect the construct stability.

⚠ CAUTION

Always perform final tightening of the locking screws by hand using the 2.5Nm torque limiter (702760). This prevents overtightening of locking screws and also ensures that these screws are properly tightened with a torque of 2.5Nm. The device will click when the torque reaches 2.5Nm. This procedure is repeated for all locking screws.

⚠ CAUTION

Use low speed only and do not apply axial pressure if power screw insertion is selected. Stop power insertion approximately 1cm before engaging the screw head in the plate.

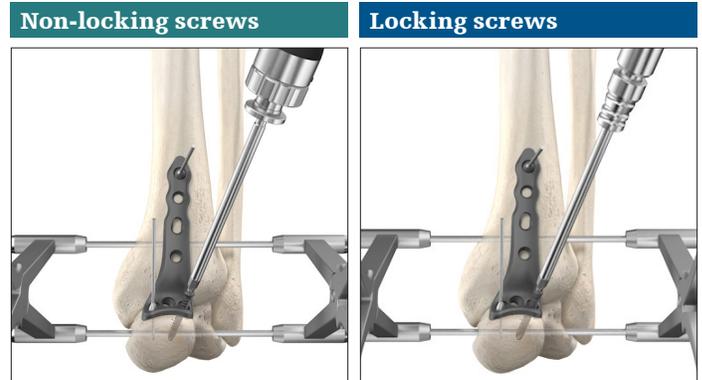


Figure 4.6a

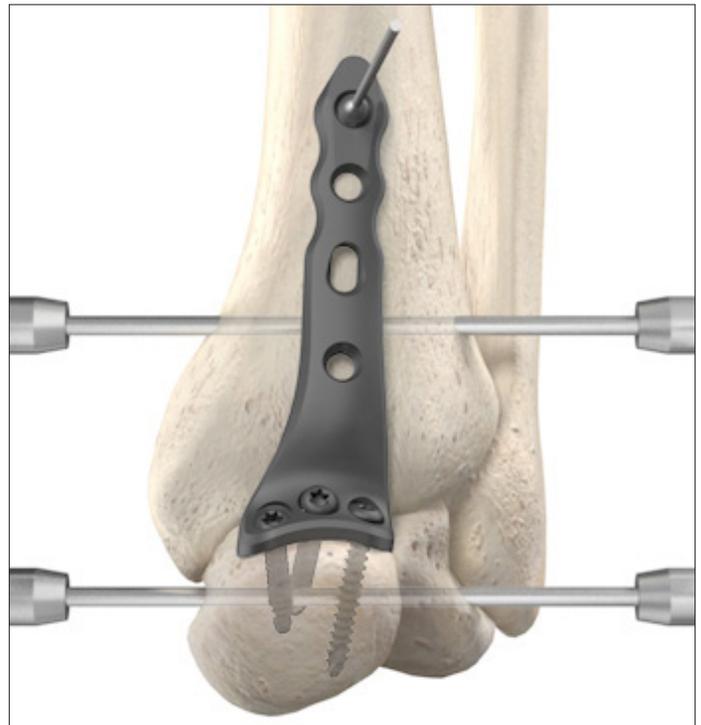


Figure 4.6b

Step 5

Cannulated screw

Standard Plate

5.1 Independent cannulated screw placement

Use the CP double wire guide (705804) as a tissue protector. Insert a Ø3.2mm K-wire (702463) from above the medial malleolus, posterior to the tibial transverse pin, through the center of the medial third of the talar dome and terminating in the lateral process. (Figure 5.1)

Confirm K-wire position and depth with fluoroscopy.

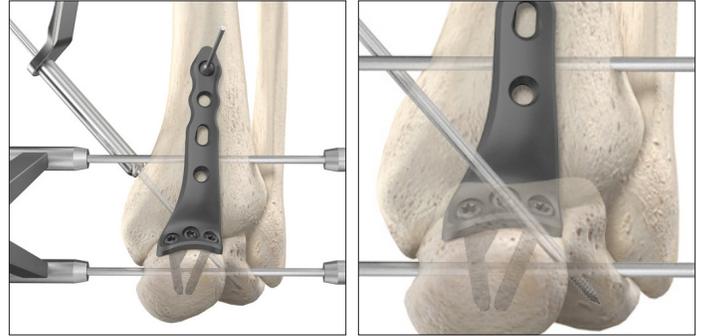


Figure 5.1 Standard

5.2 Drilling

Pre-drilling is optional as the cannulated screws are self-drilling and self-tapping. Use the soft tissue protector (705816) and drill (705809) to the proper depth. (Figure 5.2)

CAUTION

Be careful not to advance the guidewire during drilling.

WARNING

When using the drill and/or tap, be sure to stop once through the far cortex to avoid damaging soft tissue structures.

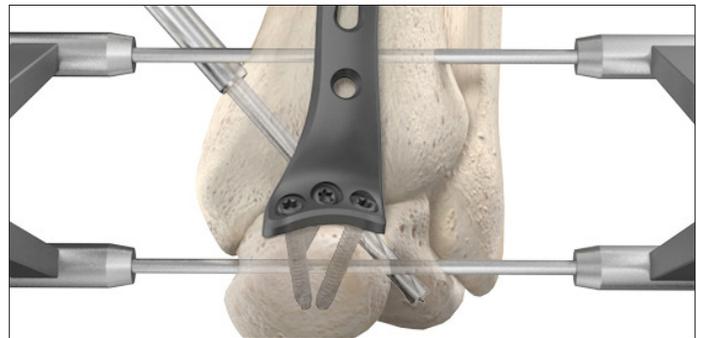


Figure 5.2 Standard

5.3 Tapping

Tapping is optional; the cannulated screws are self-tapping. Use the double protection sleeve (705816) and tap (705810) to the proper depth. (Figure 5.3)

CAUTION

Be careful not to advance the guidewire during tapping.

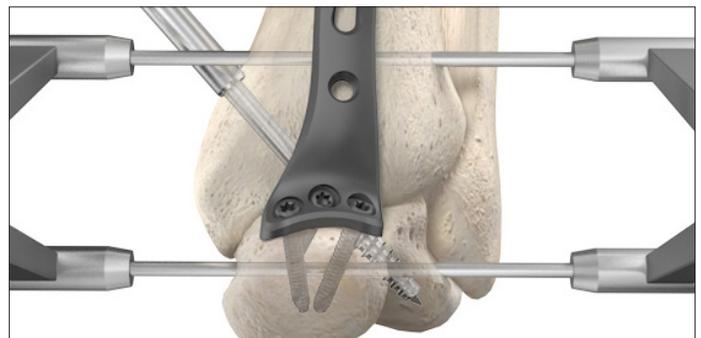


Figure 5.3 Standard

5.4 Countersinking

Where soft tissue coverage is minimal, use of the countersink (705811) may be beneficial to further recess the low-profile screw head. The double protection sleeve (705816) can also be optionally used during countersinking. The appropriate depth of countersinking is indicated with the notch. (Figure 5.4a)

⚠ CAUTION

Be careful not to advance the guidewire during countersinking.

In poor quality bone, washers (619904) can be applied in place of countersinking, to spread the load of the screw head over a greater area to avoid loss of compression due to head penetration.

⚠ CAUTION

Be sure to countersink to the proper depth as a shallow pocket will cause the screw to sit proud and a deep pocket will allow the screw head to penetrate the cortex reducing fixation.

⚠ CAUTION

The countersinking is always done manually.



Figure 5.4a Standard

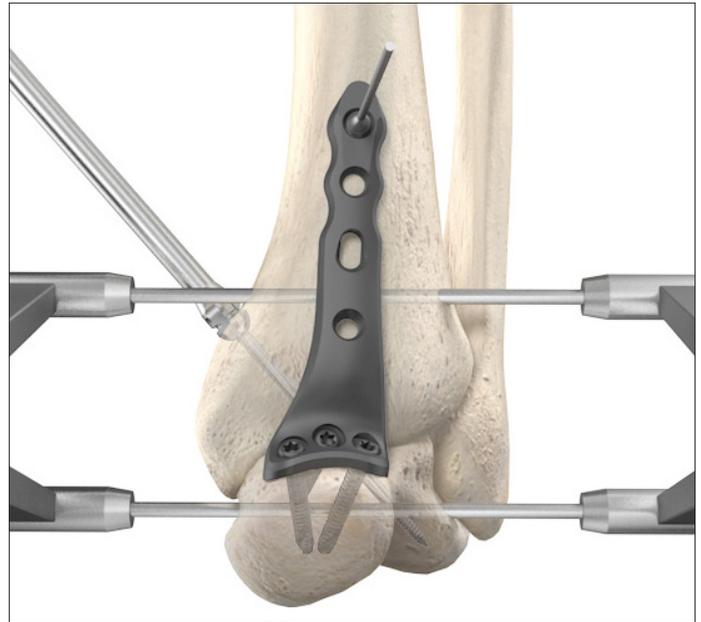


Figure 5.4b Standard

5.5 Measuring

Measure the proper cannulated screw length with the direct measuring gauge (705808). The instrument is guided over the Ø3.2mm K-wire (702463) and pushed down to the bone. The end of the K-wire indicates the desired screw length. The direct measuring gauge can only be used with Ø3.2mm x 300mm K-wires. (Figure 5.5)

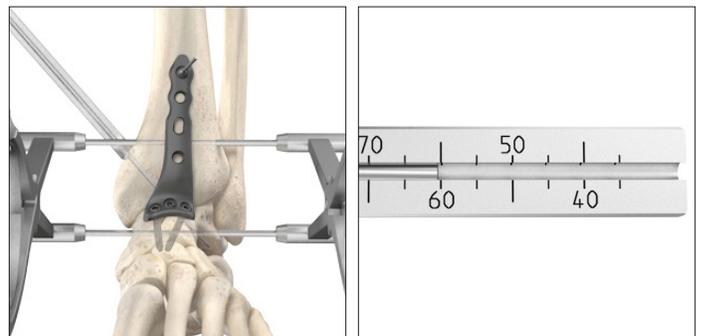


Figure 5.5 Standard

5.6 Screw insertion

Insert the screw over the K-wire and tighten the screw with the cannulated screwdriver (705812) and delta handle (2351-0140). (Figure 5.6)

⚠ CAUTION

Do not over-tighten as this might cause stripping of the threads in the bone and affect the construct stability.

⚠ CAUTION

Be careful not to advance the guidewire during screw insertion.

⚠ CAUTION

Always measure the screw length before insertion and ensure correct screw length and position with fluoroscopy.

Remove the K-wire after screw insertion. Additionally, remove the provisional fixation 3.2mm pin that is located through the center of the talus and distal tibia.

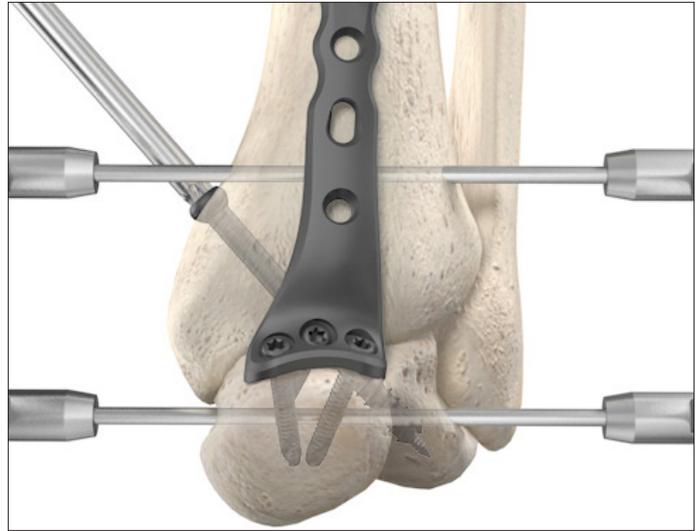


Figure 5.6 Standard

CP Plate

5.1 CP cannulated screw placement

After the three screws in the talus are set, the CP double wire guide (705804) is used to insert the K-wire with a fixed angle or variable angle. (Figure 5.1a CP)

The conical side of the guide is used for centered insertion of the Ø3.2mm K-wire (702463), the cylindrical side can be angulated in a 7.5° cone.

The CP screw should enter the talus just anterior to the apex of the talar dome and extend centrally into the body of the talus stopping short of the inferior talar surface. (Figure 5.1b CP)

Confirm K-wire position and depth with fluoroscopy.

⚠ WARNING

The CP screw should not violate the tarsal canal or the subtalar joint.

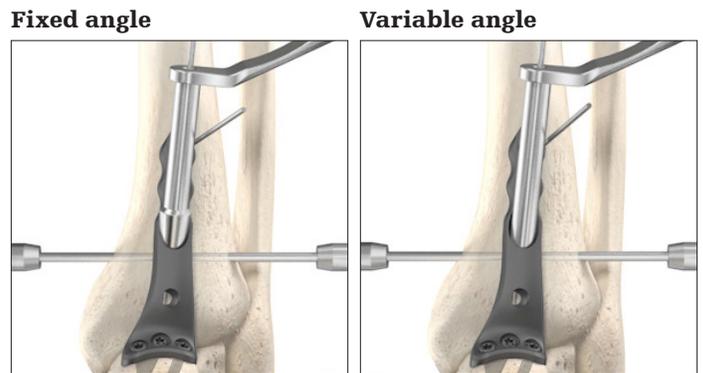


Figure 5.1a CP

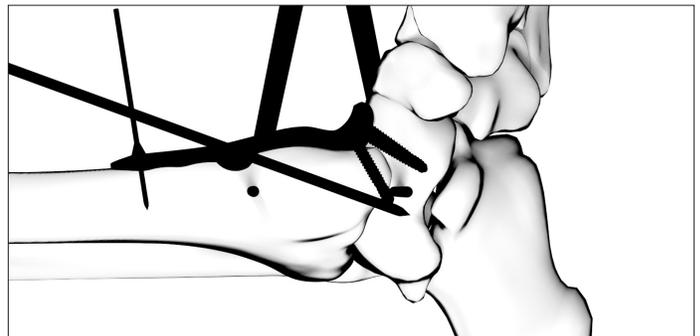


Figure 5.1b CP

5.2 CP screw drilling

Pre-drilling is optional; the screws are self-drilling.

The drill has a modified Trinkle Connection and can be used with the Delta handle (2351-0140). The cannulated drill (705809) is inserted over the Ø3.2mm K-wire (702463) and advanced to the preferred depth. Confirm drill position and depth with fluoroscopy. (Figure 5.2 CP)

⚠ CAUTION

Be careful not to advance the guidewire during drilling.

⚠ CAUTION

It is recommended to perform a pre-drilling before screw insertion to avoid excessive torque.

⚠ WARNING

When using the drill and/or tap, be sure to stop once through the far cortex to avoid damaging soft tissue structures.

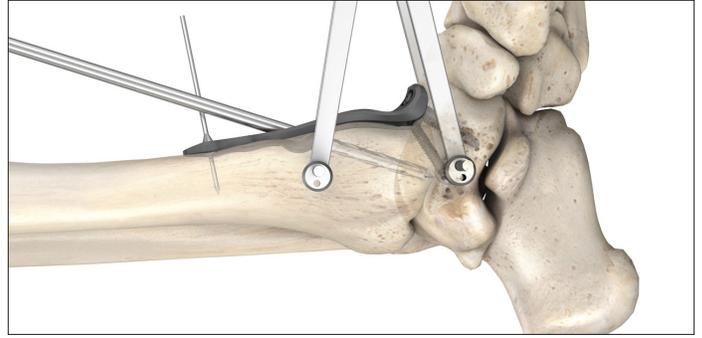


Figure 5.2 CP

5.3 CP tapping

Tapping is optional; the screws are self-tapping.

The tap has a modified Trinkle Connection and is used with the Delta handle (2351-0140).

The cannulated tap (705810) is inserted over the Ø3.2mm K-wire (702463) and advanced to the preferred depth. (Figure 5.3 CP)

⚠ CAUTION

Be careful not to advance the guidewire during tapping.

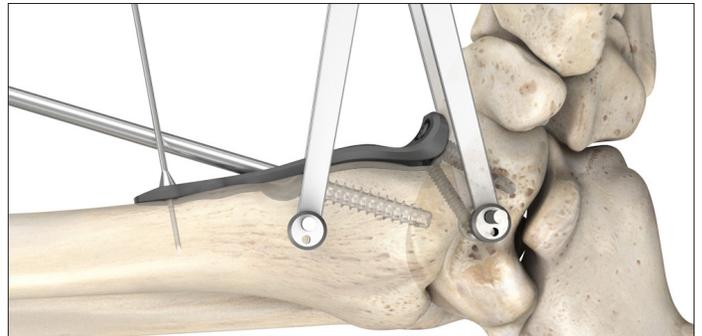


Figure 5.3 CP

5.4 CP screw measurement

Measure the proper cannulated screw length with the direct measuring gauge (705808). The instrument is guided over the K-wire and pushed onto the plate. The end of the K-wire indicates how deep the wire is in the bone. (Figure 5.4 CP)

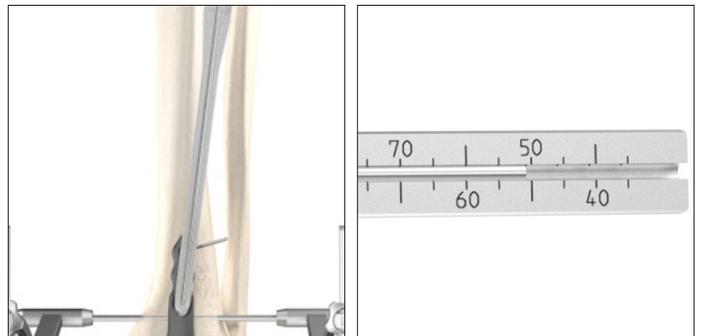


Figure 5.4 CP

Step 6

Plate compression screw insertion

Standard Plate

6.1 Alignment of compression drill guide

If additional compression is desired, the compression screw must be the first screw used in the proximal portion of the plate. (Figure 6.1a)

If the screw is inserted in buttress position (with the arrow pointing away from the joint), the order of insertion does not matter as the buttress insertion does not apply any compression. (Figure 6.1b)

Select the desired alignment of the compression drill guide (705817), buttress or compression. The sleeve can be rotated in the handle. The arrow on top of the sleeve should point towards the joint if compression is desired and away from the joint if the screw shall be inserted in buttress position, without compression.

The sleeve must fit securely in the plate hole and perpendicular to the plate. (Figure 6.2)



Figure 6.1a Standard Compression



Figure 6.1b Standard Buttress

6.2 Compression slot screw selection

Choose the desired compression slot screw from the available system options:

3.5 or 4.0 mm Cortex

4.0 mm Cancellous (Partial or Full Thread)

NOTICE

Compression drill guide must be used in the compression hole (in compression or buttress orientation).



Figure 6.2 Standard

6.3 Drill

An optional K-wire (390192) may be inserted first to confirm trajectory. Remove the optional K-wire before drilling. Drill through the far cortex or preferred depth using the non-locking drill bit (705025). (Figure 6.3)

⚠ WARNING

When using the drill and/or tap, be sure to stop once through the far cortex to avoid damaging soft tissue structures.



Figure 6.3 Standard

6.4 Tap

Tap if desired using the appropriate tap. (Figure 6.4)

- Non-locking screw taps
- Cancellous 4.0mm (702805)
- Cortex 4.0mm (705829)
- Cortex 3.5mm (702804)

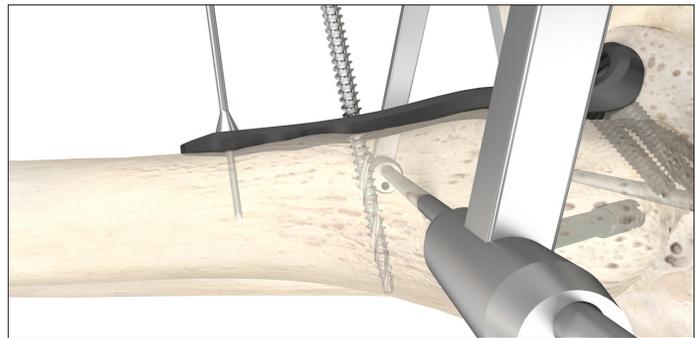


Figure 6.4 Standard

6.5 Measure

The appropriate screw length can be measured off the drill or with the depth gauge (705012). (Figure 6.5)

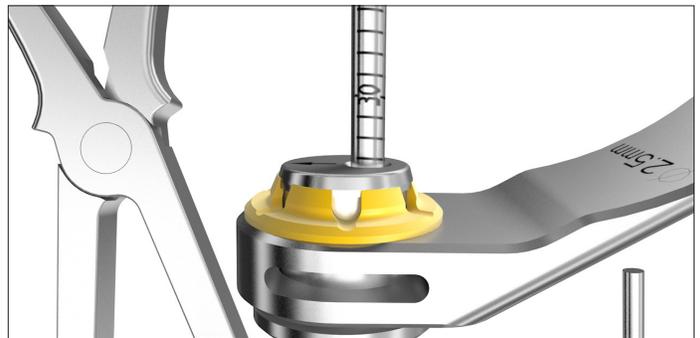


Figure 6.5 Standard

6.6 Compression slot screw insertion

Insert the selected talar screw with the T15 screwdriver (705015, AO handle 703920). (Figure 6.6)

NOTICE

All K-wires need to be removed from the tibia part of the plate before tightening the compression screw.

NOTICE

Only non-locking screws can be used in the compression hole.



Figure 6.6 Standard

⚠ CAUTION

Do not over-tighten as this might cause stripping of the threads in the bone and affect the construct stability.

⚠ CAUTION

Always measure the screw length before insertion and ensure correct screw length and position with fluoroscopy.

Additional independent cannulated screws may be implanted to improve construct stability and joint compression, if desired (see Step 5).

CP Plate

6.1 CP screw insertion

Only the 6.5mm cannulated screws from the set can be used in the CP hole (16mm thread 666435-666515 and 32mm thread 666675-666740). Insert the screw over the K-wire and tighten the screw with the cannulated screwdriver (705812) and delta handle (2351-0140). The CP screw should enter the talus just anterior to the apex of the talar dome and extend centrally into the body of the talus stopping short of the inferior talar surface. (Figure 6.1b CP)

Leave all compression instruments in place until all tibial screws are inserted.

An additional solid screwdriver shaft (705813) is included in the set.

⚠ WARNING

The CP screw should not violate the tarsal canal or the subtalar joint.

⚠ CAUTION

Be careful not to advance the guidewire during screw insertion.

⚠ CAUTION

Always measure the screw length before insertion and ensure correct screw length and position with fluoroscopy.

⚠ CAUTION

Do not over-tighten as this might cause stripping of the threads in the bone and affect the construct stability.

Remove the K-wire after screw insertion. Additionally, remove the provisional fixation Ø3.2mm pin that is located through the center of the talus and distal tibia.

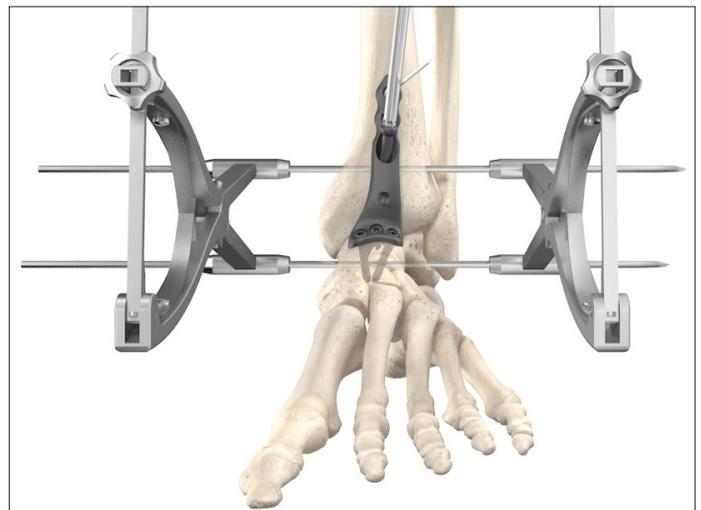


Figure 6.1a CP

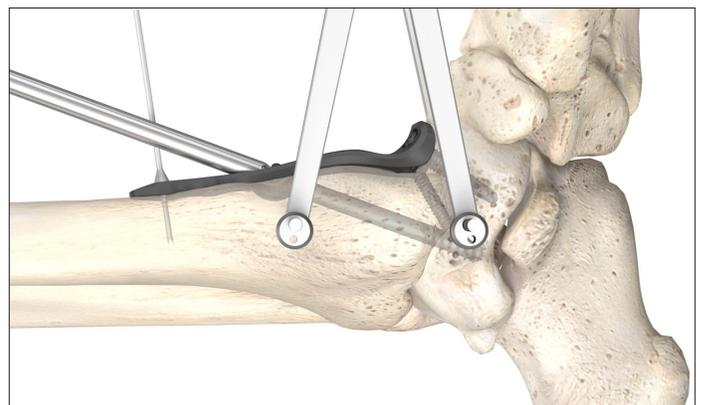


Figure 6.1b CP

Step 7

Tibial fixation

7.1 Screw selection

Choose the desired screw for the three remaining screw holes (Figure 7.1) from the available system options:

Non-Locking

3.5 / 4.0 mm Cortex

4.0 mm Cancellous (Partial or Full Thread)

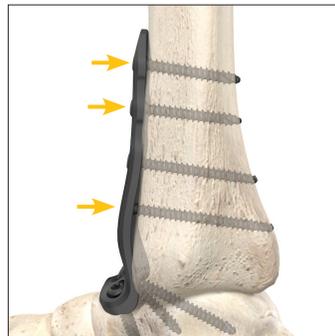
Locking (Fixed Angle)

4.0 mm

NOTICE

Always insert all non-locking screws in a bone before you use locking screws.

Standard plate



CP plate

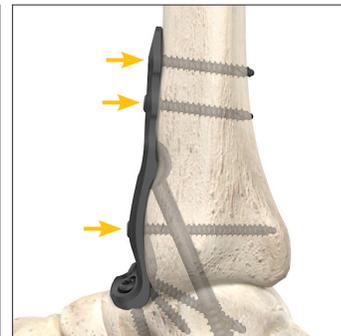


Figure 7.1

7.2 Drill

Screw or place the desired drill guide into each of the threaded tibial screw holes for each screw preparation. An optional K-wire (390192) may be inserted first to confirm trajectory. The polyaxial drill sleeve (705824) can be inserted in any of the universal holes. It allows predrilling with the Ø2.5mm drill in a 10° cone for a Ø3.5mm or 4mm cortex screw. Drill through the far cortex or preferred depth using the appropriate drill bit. (Figure 7.2a; Figure 7.2b)

CAUTION

Always use the locking drill sleeve when drilling for locking screws.

CAUTION

Always use the appropriate drill guide when predrilling for a screw: Drill Sleeve 3.1mm Locking (705004) for locking screws or for straight insertion of a bone screw; Drill Sleeve Polyaxial Ø2.5mm (705824) or Drill Guide Ø2.5mm Non-Locking (705022) for bone screws; Drill Guide for Compression, Ø2.5mm (705817).

WARNING

When using the drill and/or tap, be sure to stop once through the far cortex to avoid damaging soft tissue structures.

Non-locking screws



Locking screws



Figure 7.2a

Non-locking screws



Figure 7.2b

7.3 Tap

Tapping is optional as the screws are self-tapping. Tap, if desired, using the appropriate tap. (Figure 7.3)

- Non-locking screw taps
- Cancellous 4.0mm (705805)
 - Cortex 4.0mm (705829)
 - Cortex 3.5mm (702804)

- Locking screw tap
- Locking 4.0mm (702772)

⚠ CAUTION

It is advisable to tap hard (dense) cortical bone before inserting screw.

⚠ WARNING

When using the drill and/or tap, be sure to stop once through the far cortex to avoid damaging soft tissue structures.

7.4 Measure

The appropriate screw length can be measured off the drill or with the depth gauge (705012). (Figure 7.4a; Figure 7.4b)

Appropriate screw length selection is important for the stability of the fixation. Measurements follow the principle of “what you read is what you get.” This means that the measured value in millimeters on the depth gauge (705012) or the drill bit is the exact value of the screw selected.

⚠ CAUTION

In case a self-tapping screw is intended to be positioned bi-cortically, make sure the tip is slightly sticking out on the far cortex (1-3mm) in order to allow for good cortical purchase.

⚠ CAUTION

Always measure the screw length before insertion and ensure correct screw length and position with fluoroscopy.

⚠ CAUTION

Fluoroscopy is required to ensure correct length and position.

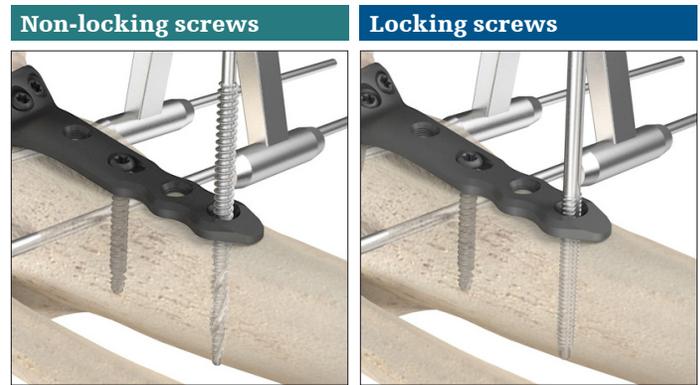


Figure 7.3

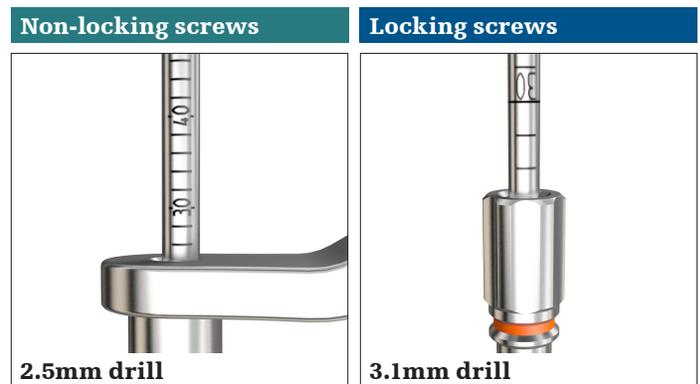


Figure 7.4a



Figure 7.4b

7.5 Screw insertion

Insert tibial screws with the handle (703920), handle insert (703922) and screwdriver bit T15 (705015). Repeat for each non-locking tibial screw, and then for all locking screws. If using a locking screw, perform final tightening with the handle (703920), handle insert (703922), torque limiter, 2.5Nm (702760) and screwdriver bit T15 (705015). (Figure 7.5a)

▲ CAUTION

Always start inserting the screw manually to ensure proper alignment in the plate thread and core hole. It is recommended to start inserting the screw using “the three finger technique” on the handle. Avoid any angulations or excessive force on the screwdriver, as this could cross-thread the screw.

▲ CAUTION

If inserting locking screws under power, make sure to use a low speed drill setting to avoid damage to the screw/plate interface and bone necrosis.

▲ CAUTION

Do not over-tighten as this might cause stripping of the threads in the bone and affect the construct stability.

▲ CAUTION

Always perform final tightening of the locking screws by hand using the 2.5Nm torque limiter (702760). This prevents overtightening of locking screws and also ensures that these screws are properly tightened with a torque of 2.5Nm. The device will click when the torque reaches 2.5Nm. This procedure is repeated for all locking screws.

▲ CAUTION

Use low speed only and do not apply axial pressure if power screw insertion is selected. Stop power insertion approximately 1cm before engaging the screw head in the plate.

▲ CAUTION

The ratchet mechanism on the compressor and distractor has sharp edges, take care to avoid catching any gloves while releasing the ratchet mechanism.

Remove all instrumentation. Confirm final implant position with fluoroscopy.



Figure 7.5a



Figure 7.5b

Standard plate



CP plate



Figure 7.5c

Post-operative management

For a minimum of six weeks, the patient should be placed in a non-weight bearing cast. The patient should keep "toes above the nose" as much as possible while limiting all physical activities. Following a six week checkup post-operation with radiographic confirmation of fusion, patient may gradually weight bear per the surgeon's discretion.

Implant removal

Select the appropriate screwdriver and back out the screw by turning the screwdriver counter-clockwise. Use the handle (703920), handle insert (703922) and screwdriver bit T15 (705015) for the 3.5/4.0mm cortex or cancellous screws. Use the delta handle, modified trinkle (2351-0140) and the solid or cannulated screwdriver T30 (705813/705812) for the 6.5mm cannulated screws.

Remove the plate once all screws have been removed.



AxSOS 3 Titanium compatibility chart

The chart shows the compatibility of SPS Small and Basic Fragment Titanium screws with AxSOS 3 Titanium plates and vice-versa.

			Screws																														
			AxSOS 3 Ti 4.0mm				AxSOS 3 Ti 5.0mm						AxSOS 3 Ti 6.5mm	SPS 3.5mm		SPS 4.5mm		SPS 2.7mm															
			661014/-095	666114/-170	661410/-520	607310/-400	607410/-500	661612/-640	661004	661114/-195	661714/-850	608230/-350	608020/-150	608445/-550	661922/-975	661308/-320	661005	991088S	661002S	666435/-515	666675/-740	603010/-090	604010/-060	604210/-260	601014/-150	602030/-150	602245/-400	602420/-550	605008/-060				
			4.0mm locking Ti screw	4.0 mm cortex Ti screw	3.5mm cortex Ti screw	4.0mm cancellous Ti screw - full thread	4.0mm cancellous Ti screw - partial thread	3.5mm cortex shaft Ti screw	4.0mm blind screw	5.0mm locking screw	4.5mm cortex Ti screw	6.0mm cancellous Ti screw - TL-16	6.0mm cancellous Ti screw - full thread	6.0mm cancellous Ti screw - TL-32	4.5mm cortex shaft Ti screw	5.0mm periprosthetic locking screw	5.0mm blind screw	5.0mm variable angle extension arm	5.0mm cable plug	6.5 mm cannulated screw - 16mm thread	6.5 mm cannulated screw - 32mm thread	SPS 3.5mm Ti cortical screw	SPS 4.0mm Ti cancellous full	SPS 4.0mm Ti cancellous partial	SPS 4.5mm Ti cortical screw	SPS 6.5mm Ti cancellous 16.0mm	SPS 6.5mm Ti cancellous 32.0mm	SPS 6.5mm Ti cancellous full thread	SPS 2.7mm Ti cortical screw				
Plates	AxSOS 3 Ankle Fusion	630101/-102	Anterior TT Plate	X	X	X	X	X	X											X	X												
		630103/-104	Anterior TT CP Plate	X	X	X	X	X	X												X	X											
		630111/-112	Antero-Lateral TT Plate	X	X	X	X	X	X												X	X											
		630113 /-114	Antero-Lateral TT CP Plate	X	X	X	X	X	X												X	X											
	AxSOS 3 Ti 4mm	627302/-352	Proximal lateral tibia plate	X	X	X	X	X	X	X															X	X	X						
		627404/-452	Distal medial tibia plate	X	X	X	X	X	X	X															X	X	X						
		627454/-500	Distal anterolateral tibia plate	X	X	X	X	X	X	X															X	X	X						X
		627704/-752	Proximal medial tibia plate	X	X	X	X	X	X	X															X	X	X						
		627203/-250	Proximal lateral humerus plate	X	X	X	X	X	X	X															X	X	X						
		627502/-520	4mm compression plate	X	X	X	X	X	X	X															X	X	X						
	AxSOS 3 Ti 5mm	627604/-650	Distal lateral femur plate							X	X	X	X	X	X	X	X	X	X								X						
		627532/-552	5mm compression plate narrow							X	X	X	X	X	X	X	X	X	X								X						
		627566/-582	5mm compression plate broad							X	X	X	X	X	X	X	X	X	X								X						
	SPS Small Fragment	621423/-436	T-plate		X	X	X	X																X	X	X							
		621463/-468	Oblique T-plate		X	X	X	X																X	X	X							
		621443/-450	Cloverleaf plate		X	X	X	X																X	X	X							
621122/-134		One third tubular plate		X	X	X	X																X	X	X								
SPS Basic Fragment	620413/-413	T-plate																								X	X	X	X				
	620454/-458	T-buttress plate																								X	X	X	X				
	620704/-706	L-buttress plate, left																								X	X	X	X				
	620754/-758	L-buttress plate, right																								X	X	X	X				

Foot & Ankle

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AXSOS-ST-66_Rev-1, 05-2021

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