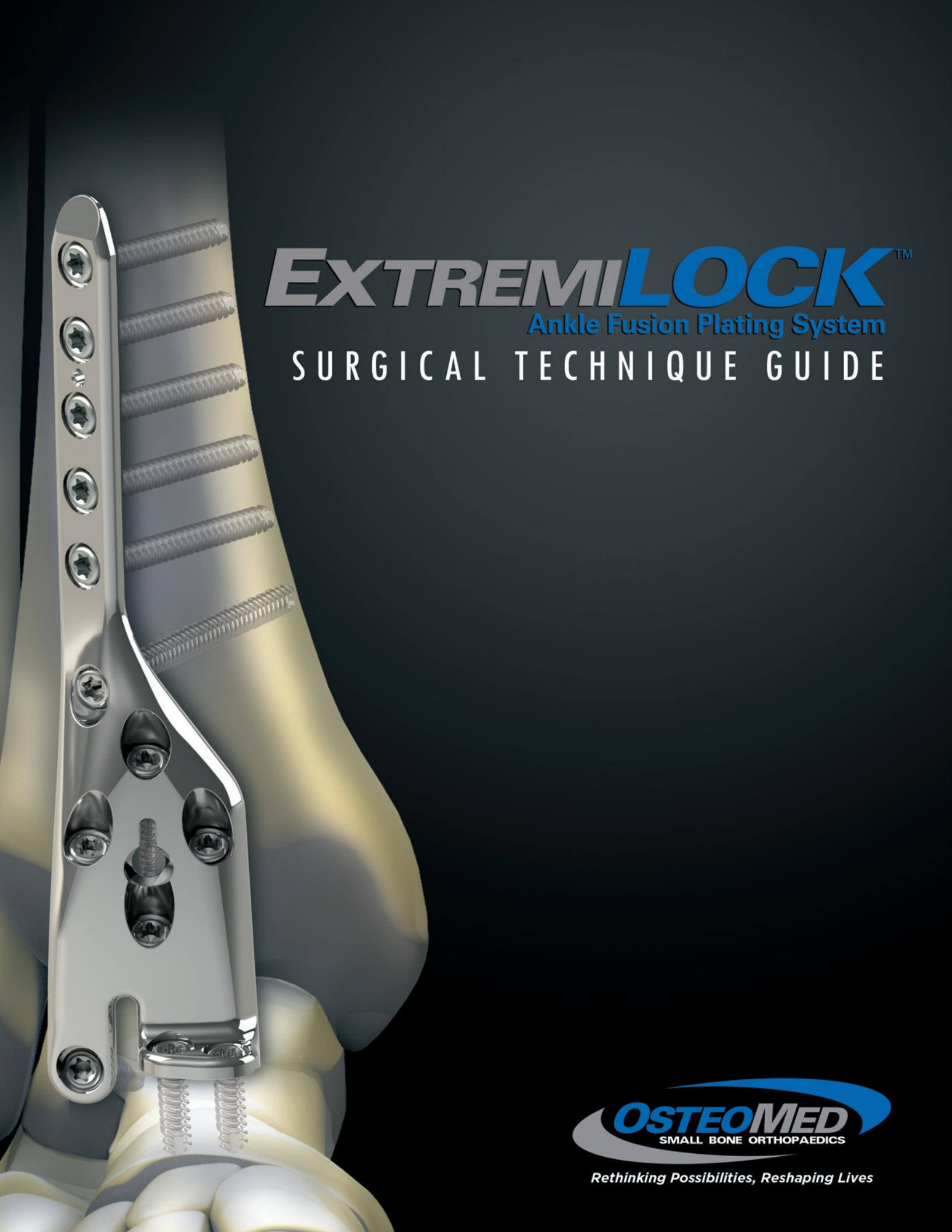

EXTREMILOCK™

Ankle Fusion Plating System

SURGICAL TECHNIQUE GUIDE

OSTEOMED
SMALL BONE ORTHOPAEDICS

Rethinking Possibilities, Reshaping Lives

ExtremiLOCK™ Ankle Fusion Plating System

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SYSTEM OVERVIEW

The ExtremiLOCK Ankle Fusion Plating System is a comprehensive implant system designed to accommodate both anterior and posterior approaches. The fusion system is a component of the ExtremiLOCK Ankle Fracture Plating System, which consists of six different types of fracture plates. Collectively, the ExtremiLOCK Fracture and Fusion Plating Systems offer:

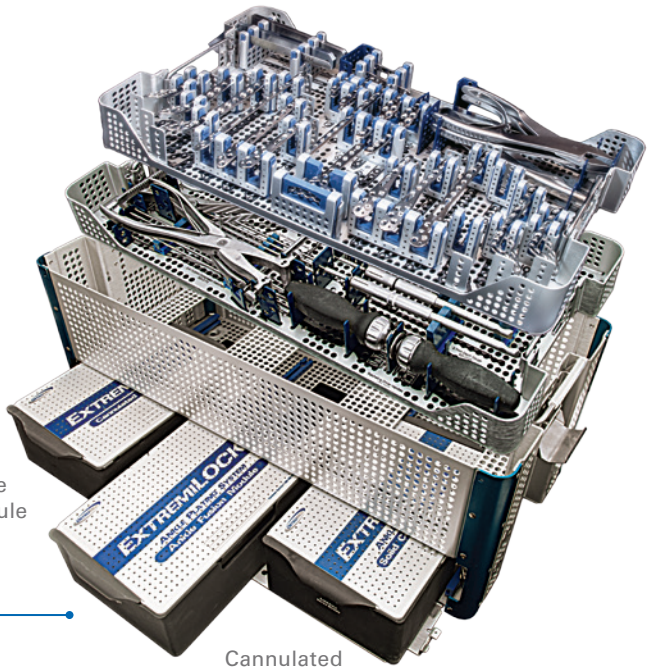
- **2** Different Fusion Plating Options
- **6** Different Types of Fracture Plating Options
- **7** Different Types of Screw Fixation Options
- Comprehensive, Color-Coded Instrumentation

INDICATIONS

The OSTEOMED ExtremiLOCK Ankle Plating System is intended for fixation of fractures, arthrodesis, osteotomies, and nonunions of the tibia and fibula. The ExtremiLOCK Ankle Plating System implants are intended for single use only.

The OSTEOMED ExtremiLOCK Ankle Plating System can be used for adult and pediatric patients.

Ankle Fusion Module



IMPLANT TRAY

The implant tray houses both anterior and posterior fusion plates as well as instruments specifically designed to complement these plates. Ancillary instruments and disposables are housed in the ExtremiLOCK Ankle Plating System.

Fusion Module Implant Tray

Anterior Fusion Plate*

336-7105
5H Anterior Fusion Plate, Left

336-7205
5H Anterior Fusion Plate, Right

Posterior Fusion Plate*

336-8003
3H Posterior Fusion Plate, Universal

Instrument

320-2790
Box Chisel

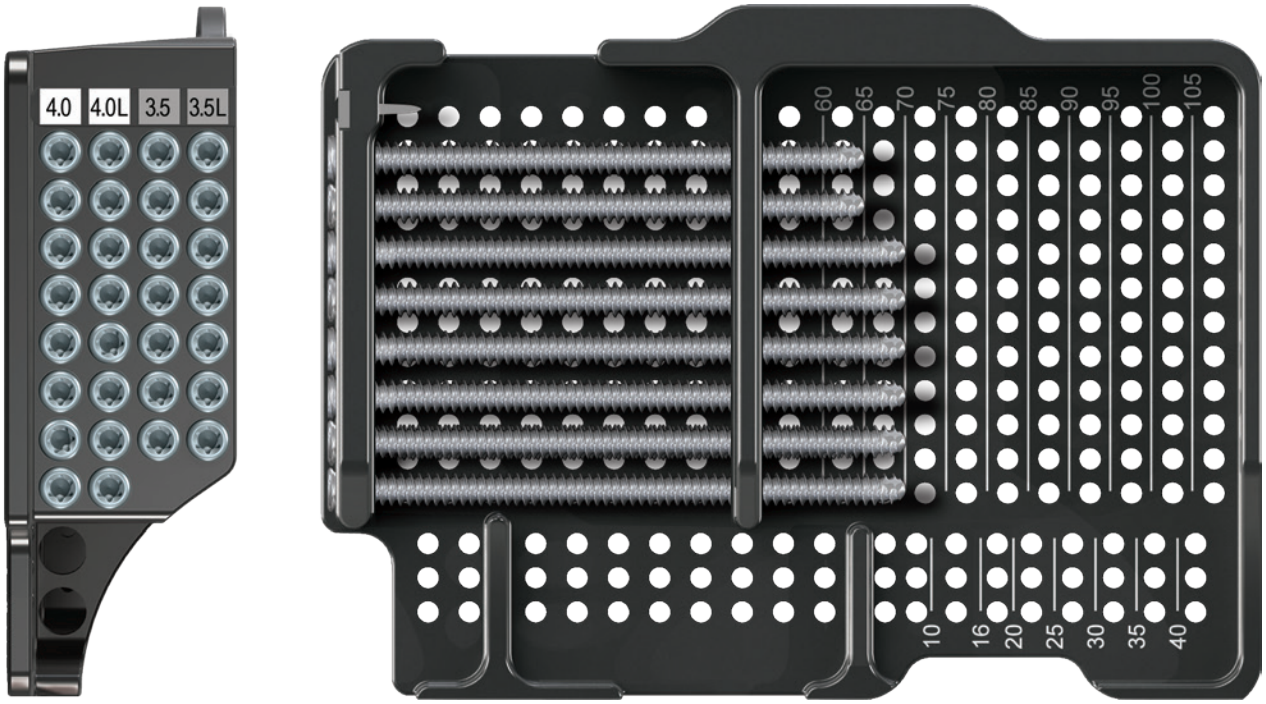
Instrument

320-2241
4.0mm Uniaxial Drill Guide

*Patent No.: US 8,529,608

SCREW INSERT

The screw insert houses screws that are 65mm in length and longer. The ExtremiLOCK Ankle Plating System's Solid Core Screw Module houses screws up to 60mm in length.



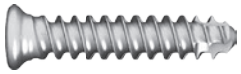
Fusion Module Screw Insert

Screws

337-35xx

3.5mm, Double-Lead, Non-Locking, 10mm-70mm

337-40xx



4.0mm, Double-Lead, Non-Locking 10mm-70mm

338-35xx

3.5mm, Double-Lead, Locking 10mm-70mm

338-40xx

4.0mm, Double-Lead, Non-Locking 10mm-70mm

339-40xx

4.0mm, Double-Lead, Non-Locking, Cannulated* 20mm-60mm

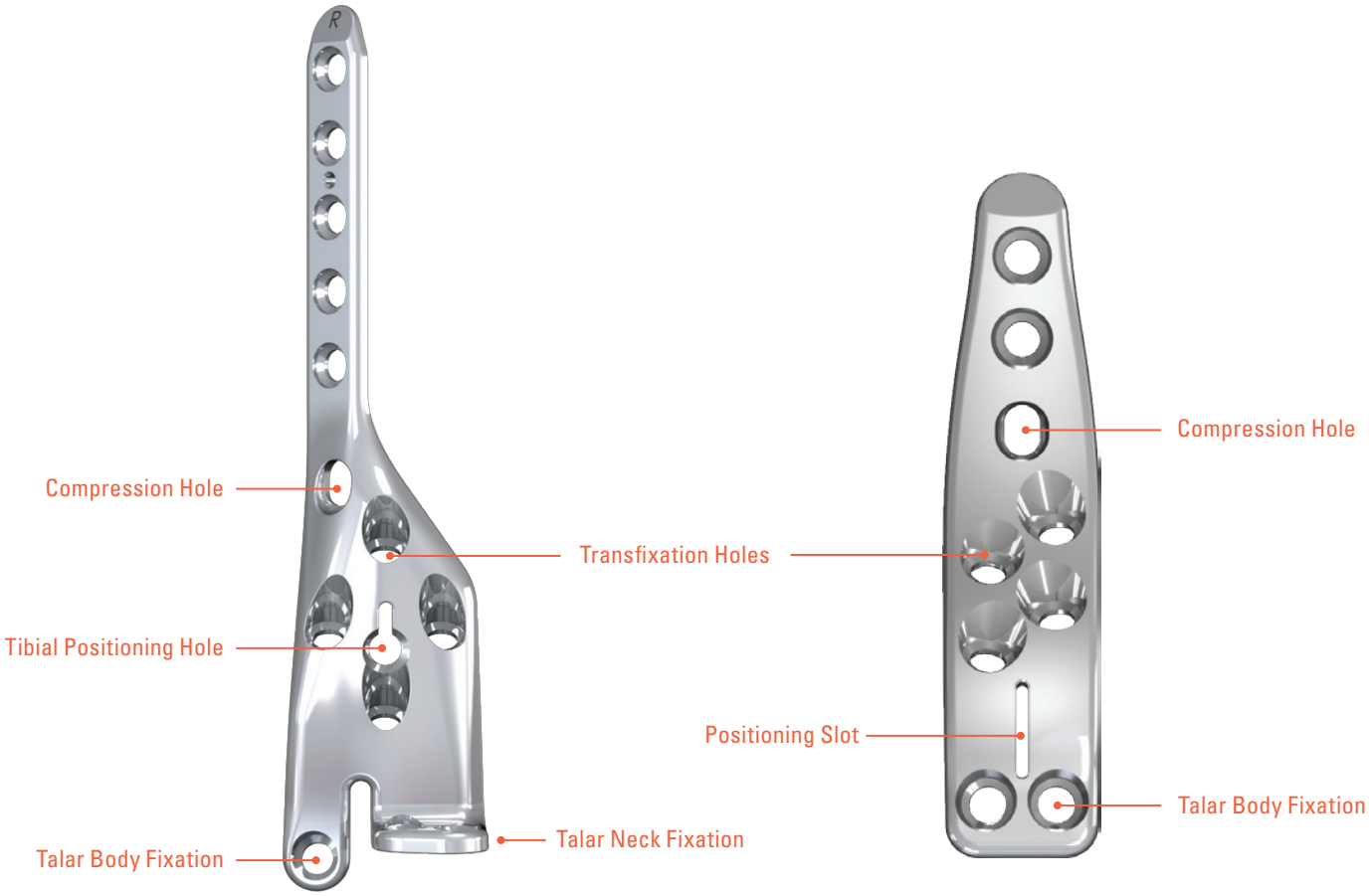
* Cannulated screws are housed in the Cannulated Screw Module.

IMPLANT SELECTION

Preoperative planning, knowledge of the surgical technique, proper implant selection and placement are important considerations when using the ExtremiLOCK Ankle Fusion Plating System. Choose implants that address the specific needs dictated by the fusion. Additional considerations include the anatomical variables of the patient.

FUSION PLATES

ExtremiLOCK fusion plating options include left and right anterior plates and a universal posterior plating option. All plates are made from surgical grade titanium and accommodate 3.5mm and 4.0mm locking and non-locking screws, as well as 4.0mm non-locking cannulated screws. Both plating options feature multiple tibiotalar fixation options, angled-locking capability, compression holes, a bulleted tip to facilitate plate insertion and an anatomic shape.

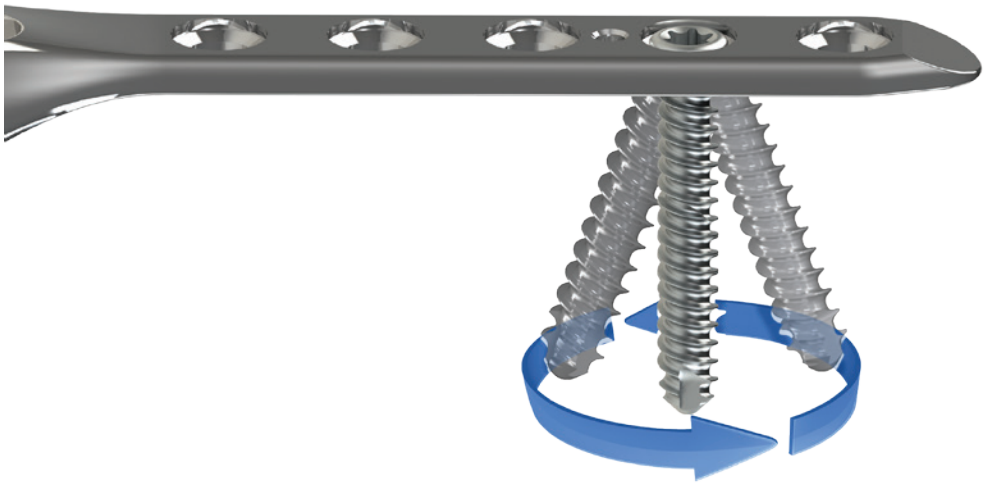


IMPLANT SELECTION

SCREWS & WASHERS

The ExtremiLOCK Ankle Plating System provides surgeons with a broad range of screw fixation options. All screws are made from titanium alloy and include: 3.5mm and 4.0mm cortical locking and non-locking screws, as well as 4.0mm cancellous non-locking, cannulated screws. Locking screws can be locked on-axis with the plate threads or up to 20 degrees of angled-locking in any direction (40 degree conical). All screws feature a universal #15 hexalobe drive mechanism, are self-tapping and have a double-lead thread pattern to promote faster screw insertion. The 4.0mm cannulated screws also incorporate a self-drilling feature to facilitate screw insertion.

Bone screw washers accommodate 3.5mm and 4.0mm non-locking screws and are intended to prevent screws from breaking through the near cortex of the bone. Bone washers are not intended to be used with the fusion plates.



40° Polyaxial Locking

3.5/4.0mm Washer

SURGICAL PROCEDURE (Anterior Ankle Fusion Plating)

INCISION

Make a standard anterior incision to gain access to the tibiotalar joint and the medial and lateral gutters. The incision should be just lateral to the palpable tibialis anterior tendon, starting in the distal third of the tibia and progressing to the navicular bone in the foot. Care should be taken to avoid injuring superficial and deep peroneal nerves. The fascia to the anterior compartment of the tibia is then incised in the interval between the tibialis anterior and the extensor hallicus longus tendons and extended through the extensor retinaculum to just beyond the talonavicular joint. Submuscular dissection is done to sweep all the contents of the anterior compartment lateral except the tibialis anterior. The tibiotalar capsule is opened and the medial and lateral gutters are exposed. The lateral talar neck and anterior lateral face of the talar body are also exposed.

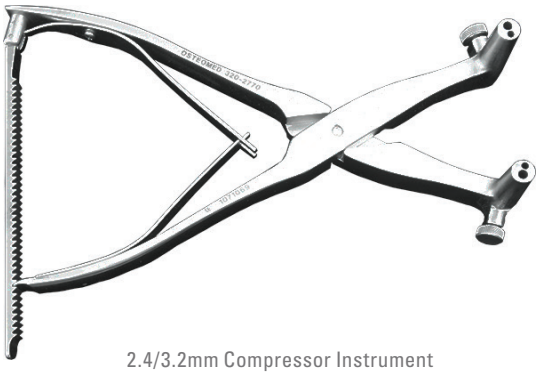
JOINT PREPARATION

JOINT PREPARATION INSTRUMENTS
2.4 / 3.2mm Compressor Instrument
2.4 / 3.2mm Distractor Instrument
2.4 x 230mm Threaded Tip Guide Pin
3.2 x 230mm Threaded Tip Guide Pin

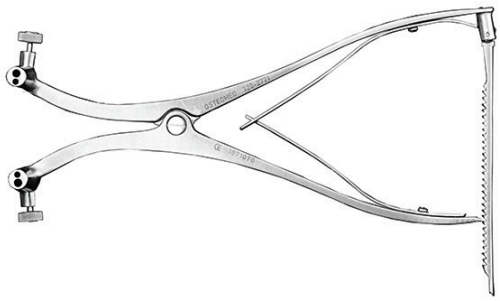
Compressors and distractors are available to assist with joint preparation. Each instrument can accept either 2.4mm or 3.2mm guide pins and feature threaded knobs to ensure a rigid interface between the instrument and the selected guide pin.

The tibiotalar joint is debrided down to subchondral bone and the bony surfaces are prepared in the normal manner. Anterior osteophytes should be removed to prevent any bony impingement when reducing the joint. Resistance to reduction due to soft tissue contracture can be improved with a percutaneous lengthening of the Achilles.

Once the joint surface is prepared and satisfactory reduction of the tibiotalar joint has been achieved, the compressor instrument can be used with threaded guide pins placed in the medial talar neck/body interval and the medial tibial metaphysis to maintain position. A second guide pin may be used to stabilize the talus in the desired position. Place a pin from the lateral tibial metaphyseal flare into the posterior lateral talus.



2.4/3.2mm Compressor Instrument



2.4/3.2mm Distractor Instrument

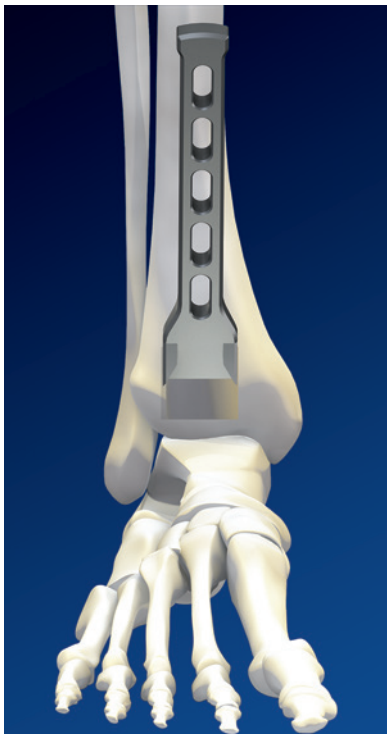
SURGICAL PROCEDURE (Anterior Ankle Fusion Plating)

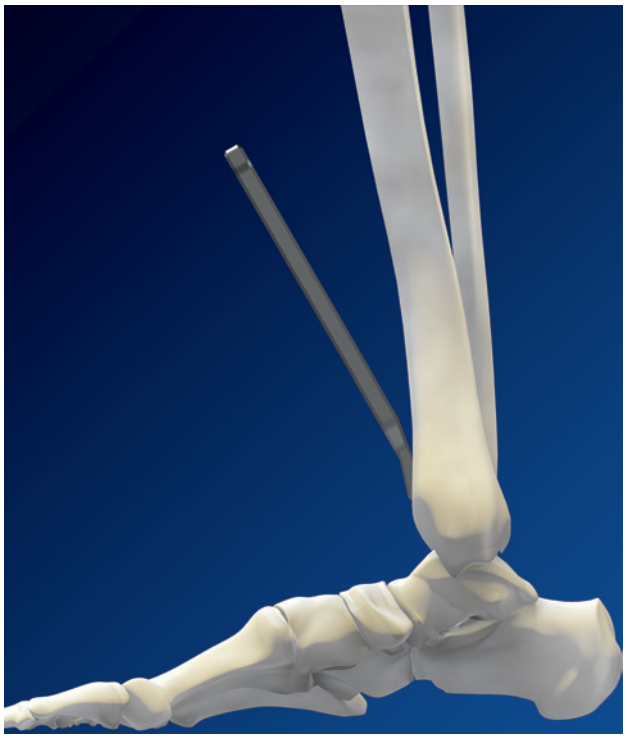
IMPLANT PLACEMENT

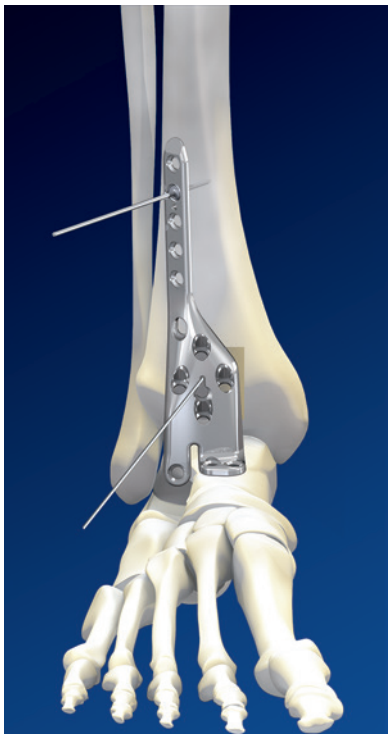
BONE/PROVISIONAL FIXATION INSTRUMENTS
1.6mm x 150mm K-Wire
1.6mm Threaded Plate Holding TAK
Box Chisel

Position the anterior fusion plate so that the lateral body tab rests just lateral to the talar neck and the proximal end of the plate rests on the lateral surface of the tibia. If the neck component of the plate does not fit flush with the talus, use a rongeur to remove bone from the dorsal surface of the talar neck. Once the alignment of the plate is satisfactory use a sterile marker to identify the medial and lateral edges of the plate on the tibia.

Use the Box Chisel to flatten the anterior aspect of the tibia and decrease implant prominence. Begin with the chisel resting on the flat anterior surface of the tibia. Line up the chisel between the two lines representing the desired placement of the plate. Remove the amount of bone needed to make the tibial metaphyseal area level with the diaphysis. The plate should now sit flush within the fusion site with good contact to both the tibia and talus. A threaded plate holding TAK can be used to provide temporary stabilization to the plate.







SURGICAL PROCEDURE (Anterior Ankle Fusion Plating)

PLATE FIXATION

3.5mm Instruments
3.5mm Drill Guide–Angled/Comp
2.5mm Pilot / 3.5mm Overdrill Guide
2.5mm Short Pilot Drill
2.5mm Long Pilot Drill
3.5mm Overdrill
3.5/4.0mm Depth Gauge
#15 Screw Driver

4.0mm Instruments
4.0mm Drill Guide–Angled/Comp
3.0mm Pilot / 4.0mm Overdrill Guide
3.0mm Short Pilot Drill
3.0mm Long Pilot Drill
4.0mm Overdrill
3.5/4.0mm Depth Gauge
#15 Screw Driver

All circular plate holes, except the tibia positioning hole, on the anterior fusion plate can accommodate 3.5mm and 4.0mm locking and non-locking screws as well as 4.0mm cannulated screws. All locking screws can be locked on-axis with the plate threads or up to 20 degrees angled-locking in any direction (40 degree conical).

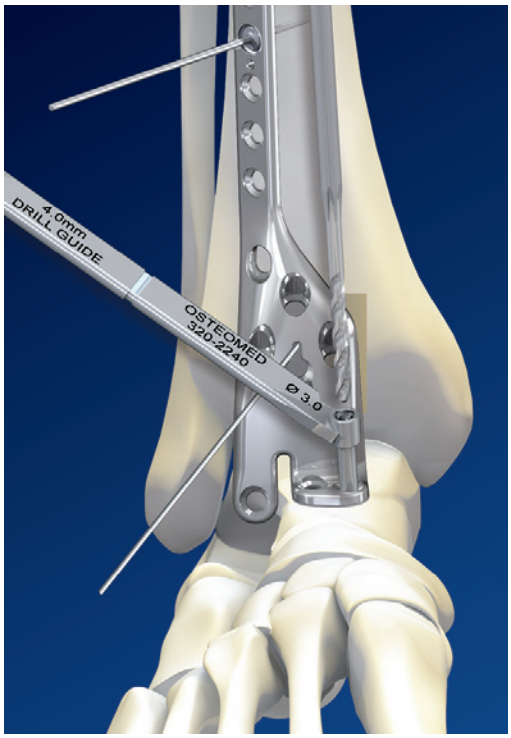
Fixation should begin with the talus. The initial screw should be a non-locking screw placed in the talar neck and angled slightly towards the talar body. Next, insert a locking screw into the adjacent talar neck screw hole. A locking screw should then be placed through the lateral talar body screw hole.

If joint compression through the plate is desired, place a non-locking screw through the compression hole of the plate. Once anterior plate compression has been achieved, one or more transfixation screws should be placed through the plate to secure the mid and posterior talar body to the tibia. Place the first screw in lag fashion with overdrilling of the tibial bone. Flouroscopy is recommended when inserting transfixation screws to get a true lateral of the talus and ensure adequate purchase in the talar body. Care should be taken to not penetrate the subtalar joint. The remaining screws can be placed per surgeon preference.

Follow the steps below for screw insertion through a plate:

1. DRILL

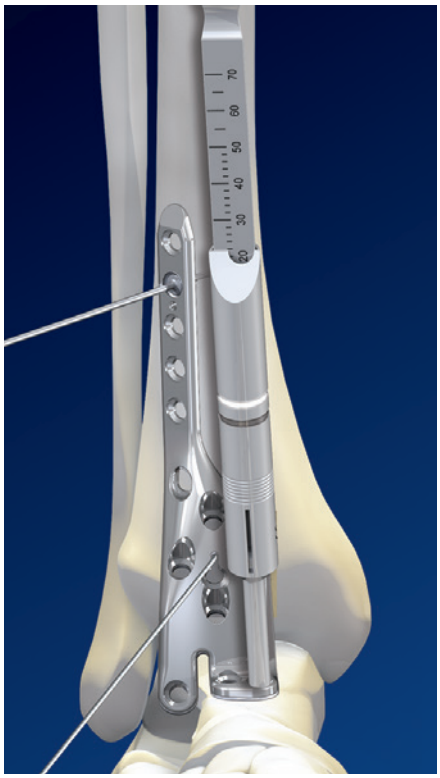
If using locking screws, select the appropriate size angled locking/compression drill guide and insert the guide into the desired plate hole. Ensure the guide is fully engaged in the corresponding plate hole. The cone will ensure the drill remains within the 40° angled locking screw range (±20° from center). If using non-locking screws, select the appropriate pilot/overdrill guide and insert the pilot drill side through the target plate hole. Continue to drill a pilot hole using the appropriately-sized pilot drill.



SURGICAL PROCEDURE (Anterior Ankle Fusion Plating)

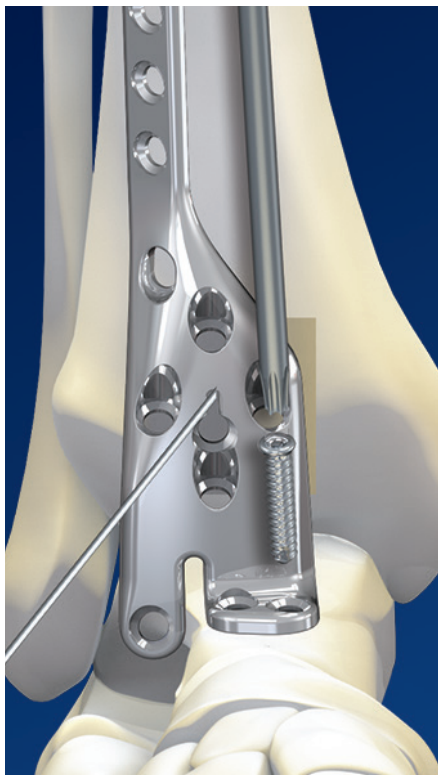
2. DETERMINE SCREW LENGTH

Select the corresponding depth gauge to determine the correct screw length.



3. SCREW INSERTION

Select the appropriate screw and insert. Screw length can be verified using the length gauge on the screw block. Final tightening should be performed using a two-finger technique to avoid over-tightening. Locking screws can be locked/unlocked up to three times in a single hole prior to final tightening. Repeat as necessary for additional screw placement.



SURGICAL PROCEDURE (Anterior Ankle Fusion Plating)

PLATE FIXATION (Compression Hole)

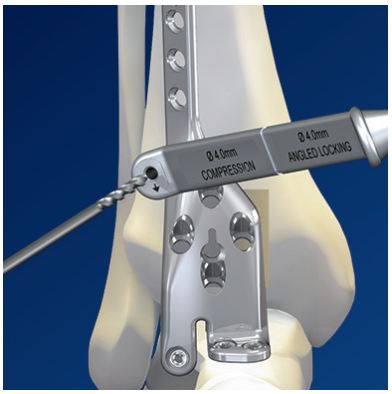
3.5mm Instruments
3.5mm Drill Guide–Angled/Comp
2.5mm Short Pilot Drill
2.5mm Long Pilot Drill
3.5/4.0mm Depth Gauge
#15 Screw Driver

4.0mm Instruments
4.0mm Drill Guide–Angled/Comp
3.0mm Short Pilot Drill
3.0mm Long Pilot Drill
3.5/4.0mm Depth Gauge
#15 Screw Driver

Compression screw holes are used for providing compression across the ankle joint and can only accommodate non-locking screws. Compression is created as the screw travels to the distal side of the compression screw hole. If compression using the compression hole is desired, it should be performed prior to placing any transfixation screws. Follow the steps below for screw insertion through a compression hole:

1. DRILL

Select the appropriate angled/compression guide and insert into the target compression hole. The arrow should point toward the fusion site to drill eccentrically. To maximize compression, ensure the drill guide is fully engaged with the target compression hole. Drill using the appropriately-sized pilot drill.

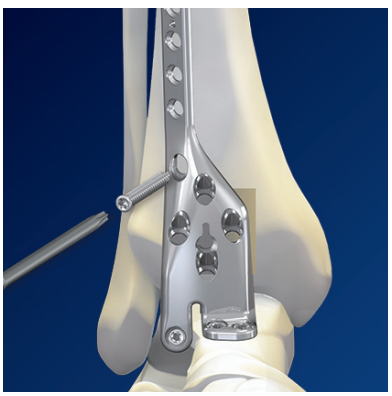


2. DETERMINE SCREW LENGTH

Select the corresponding depth gauge to determine the correct screw length.

3. SCREW INSERTION

Select the appropriate screw and insert. Screw length can be verified using the length gauge on the screw block. Final tightening should be performed using a two-finger technique to avoid over-tightening.



SURGICAL PROCEDURE (Anterior Ankle Fusion Plating)

PLATE FIXATION (Transfixation Hole)

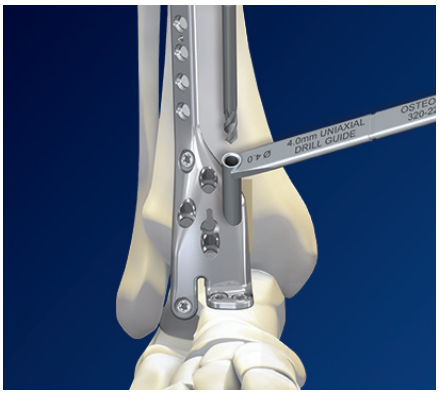
3.5mm Instruments	**4.0mm Instruments**
4.0mm Uniaxial Drill Guide	4.0mm Uniaxial Drill Guide
2.5mm Short Pilot Drill	3.0mm Short Pilot Drill
2.5mm Long Pilot Drill	3.0mm Long Pilot Drill
3.5mm Overdrill	4.0mm Overdrill
3.5/4.0mm Depth Gauge	3.5/4.0mm Depth Gauge
#15 Screw Driver	#15 Screw Driver

The ExtremiLOCK anterior fusion plates feature four transfixation screw holes that provide rigid fixation across the tibia into the talus. Each transfixation screw hole can accommodate 3.5mm and 4.0mm locking or non-locking screws. It is recommended that the first transfixation screw be placed in lag fashion to gain posterior tibiotalar compression.

The following steps describe lag screw placement through a transfixation screw hole:

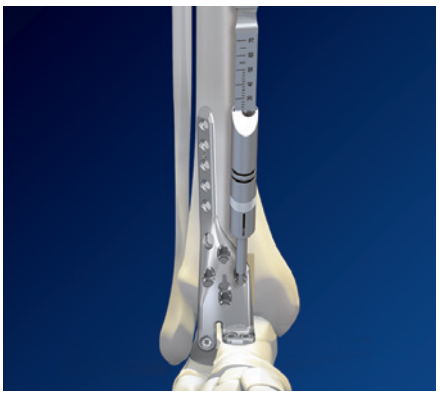
1. DRILL

Select the appropriate overdrill and drill the proximal fragment to create a gliding hole. The Uniaxial Drill Guide may be used to position the drill in the center of the corresponding screw hole. Care should be taken to ensure the joint is properly reduced prior to drilling through the distal fragment.



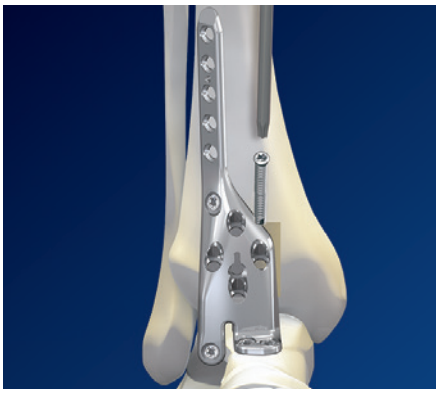
2. DETERMINE SCREW LENGTH

Select the corresponding depth gauge to determine the correct screw length.



3. SCREW INSERTION

Select the appropriate screw and insert. Final tightening should be performed using a two-finger technique to avoid over-tightening. Verify fixation with fluoroscopy.



SURGICAL PROCEDURE (Anterior Ankle Fusion Plating)

PLATE FIXATION (Tibial Positioning Hole)

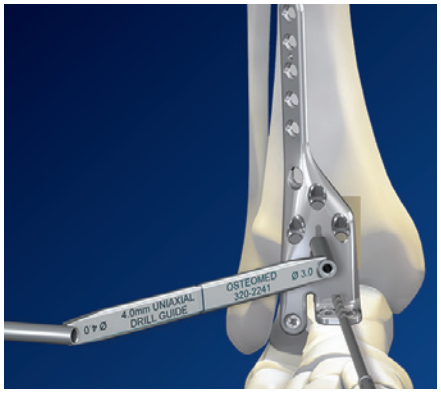
3.5mm Instruments
4.0mm Uniaxial Drill Guide
2.5mm Short Pilot Drill
2.5mm Long Pilot Drill
3.5/4.0mm Depth Gauge
#15 Screw Driver

4.0mm Instruments
4.0mm Uniaxial Drill Guide
3.0mm Short Pilot Drill
3.0mm Long Pilot Drill
3.5/4.0mm Depth Gauge
#15 Screw Driver

The ExtremiLOCK anterior fusion plates feature a tibial positioning hole that allows anterior translation of the tibia relative to the talus. The tibial positioning hole can accommodate 3.5mm and 4.0mm non-locking screws. The following steps describe screw placement through the tibial positioning hole:

1. DRILL

Select the Uniaxial Drill Guide and drill through the tibial positioning screw hole. The guide will position the screw in the center of the screw hole.



2. DETERMINE SCREW LENGTH

Select the corresponding depth gauge to determine the correct screw length.

3. SCREW INSERTION

Select the appropriate non-locking screw and insert. The screw can be used for either provisional or permanent fixation. If the screw is used for permanent fixation, care should be taken to ensure the positioning screw does not interfere with any subsequent transfixation screws.

SURGICAL PROCEDURE (Posterior Ankle Fusion Plating)

INCISION

Position the patient in the prone position with the ankle hanging off the operating table. Place the non-operative leg in a bent knee position to move the limb out of fluoroscopy view. After inflation of a high thigh tourniquet, the incision should be made directly posterior midline from the Achilles insertion to the gastrosoleus musculotendinous junction. A "Z" lengthening incision of the Achilles tendon is made to gain access to the deep compartment. After a midline incision in the deep fascia, the flexor hallicus muscle is identified and elevated off the back of the tibia and retracted medially. The posterior aspect of the tibiotalar joint is then exposed. Large posterior talar processes should be removed as well as any posterior tibial osteophytes.

JOINT PREPARATION

JOINT PREPARATION INSTRUMENTS
2.4 / 3.2mm Compressor Instrument
2.4 / 3.2mm Distractor Instrument
2.4 x 230mm Threaded Tip Guide Pin
3.2 x 230mm Threaded Tip Guide Pin

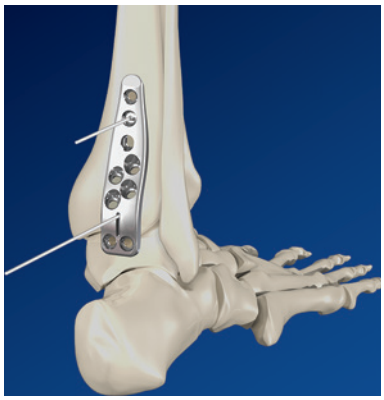
Compressors and distractors are available to assist with joint preparation. Each instrument can accept either 2.4mm or 3.2mm guide pins and feature threaded knobs to ensure a rigid interface between the instrument and the selected guide pin.

To gain access to the tibiotalar joint, the distractor instrument can be used with threaded pins placed in the talar body and tibia. If more access or better visualization is needed, the posterior malleolus, or portions of it, can be removed. The articular surfaces are cleared down to subchondral bone and the surface prepared as desired. Thin osteotomes can be used to remove any osteophytes that may be hindering the desired reduction position. Once satisfactory reduction is attained, a percutaneous threaded guide pin may be placed from the anterior portion of the medial malleolus into the talar body for provisional fixation.

IMPLANT PLACEMENT

PROVISIONAL FIXATION INSTRUMENTS
1.6mm x 150mm K-Wire
1.6mm Threaded Plate Holding TAK

The Posterior Ankle Fusion Plate is contoured to fit the average posterior lip of the tibia. It is important when selecting the position of the plate to be aware of the subtalar joint. The plate should not contact the calcaneus or interfere with subtalar motion. When the initial position is satisfactory, temporary fixation can be achieved with a threaded plate holding TAK or K-Wire in the tibial positioning slot. The tibial positioning slot will allow for minor adjustments as the talar screws are placed. In order to finalize plate position, place a guide wire down the medial talar screw hole to ensure both alignment with the talar neck and the subtalar joint is not violated.



SURGICAL PROCEDURE (Posterior Ankle Fusion Plating)

PLATE FIXATION

3.5mm Instruments	**4.0mm Instruments**
3.5mm Drill Guide–Angled/Comp	4.0mm Drill Guide–Angled/Comp
2.5mm Pilot / 3.5mm Overdrill Guide	3.0mm Pilot / 4.0mm Overdrill Guide
2.5mm Short Pilot Drill	3.0mm Short Pilot Drill
2.5mm Long Pilot Drill	3.0mm Long Pilot Drill
3.5mm Overdrill	4.0mm Overdrill
3.5/4.0mm Depth Gauge	3.5/4.0mm Depth Gauge
#15 Screw Driver	#15 Screw Driver

All circular plate holes on the posterior fusion plate can accommodate 3.5mm and 4.0mm locking and non-locking screws as well as 4.0mm cannulated screws. All locking screws can be locked on-axis with the plate threads or up to 20 degrees angled-locking in any direction (40 degree conical).

Fixation should begin with the talus. With the plate position secured with a proximal plate holding TAK and the distal end of the plate positioned to allow adequate screw purchase in the talar neck, a locking screw or cannulated screw is placed in the lateral talar hole all the way to the anterior body wall. The second talar screw is placed in the medial hole. The optimal screw length should rest well within the talar neck.

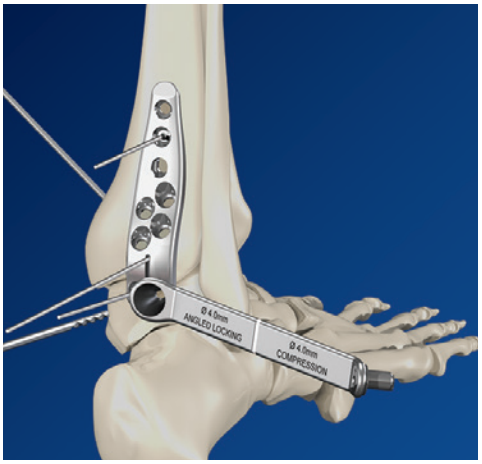
With the talus secure, and a threaded guide pin still in the medial malleolus and anterior talus, the tibial screws are then placed. If compression through the plate is desired, place a non-locking screw through the compression hole of the plate.

Transfixation screws should be placed next. Proper positioning requires the use of fluoroscopy to ensure talar body capture without violation of the subtalar joint. If desired, the first screw can be placed in a lag fashion to achieve anterior joint compression. The remaining transfixation screws can be either locking or non-locking. Care should be taken to avoid the previously placed talar screws. The remaining proximal tibial screws can be placed per surgeon preference.

Follow the steps below for screw insertion through a plate:

1. DRILL

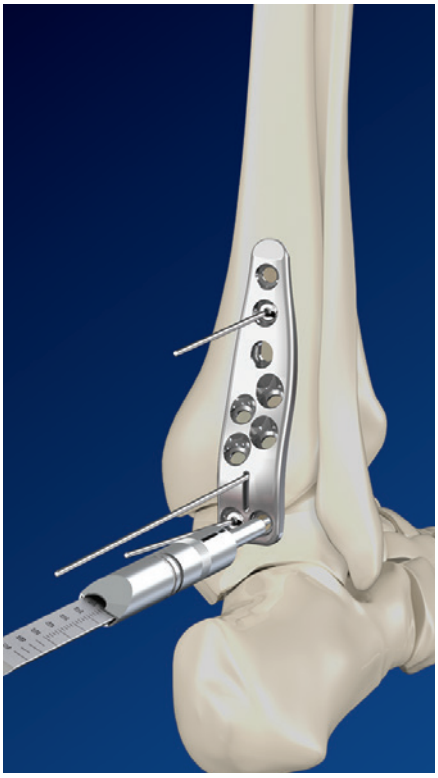
If using locking screws, select the appropriate size angled locking/compression drill guide and insert the guide into the desired plate hole. Ensure the guide is fully engaged in the corresponding plate hole. The cone will ensure the drill remains within the 40° angled locking screw range (±20° from center). If using non-locking screws, select the appropriate pilot/overdrill guide and insert the pilot drill side through the target plate hole. Continue to drill a pilot hole using the appropriately-sized pilot drill.



SURGICAL PROCEDURE (Posterior Ankle Fusion Plating)

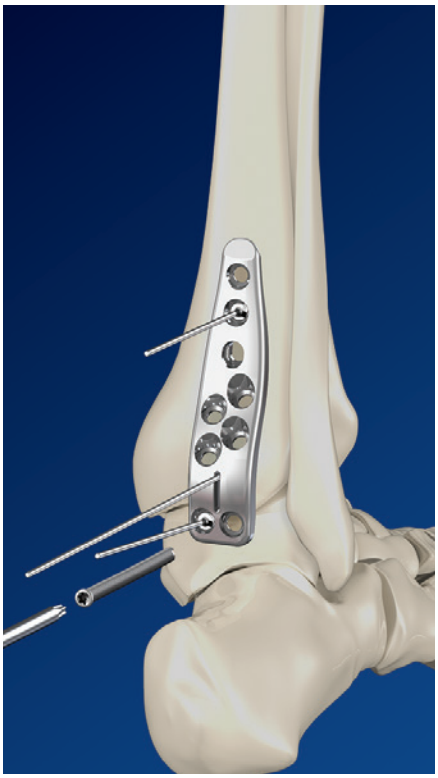
2. DETERMINE SCREW LENGTH

Select the corresponding depth gauge to determine the correct screw length.



3. SCREW INSERTION

Select the appropriate screw and insert. Screw length can be verified using the length gauge on the screw block. Final tightening should be performed using a two-finger technique to avoid over-tightening. Locking screws can be locked/unlocked up to three times in a single hole prior to final tightening. Repeat as necessary for additional screw placement.



SURGICAL PROCEDURE (Posterior Ankle Fusion Plating)

PLATE FIXATION (Compression Hole)

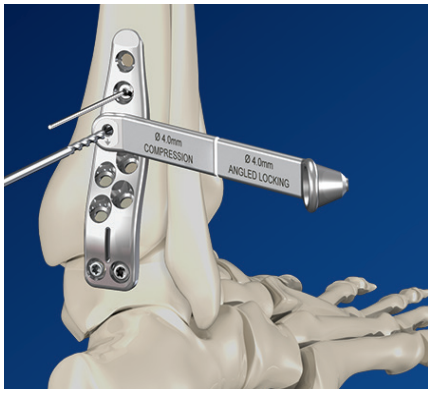
3.5mm Instruments
3.5mm Drill Guide–Angled/Comp
2.5mm Short Pilot Drill
2.5mm Long Pilot Drill
3.5/4.0mm Depth Gauge
#15 Screw Driver

4.0mm Instruments
4.0mm Drill Guide–Angled/Comp
3.0mm Short Pilot Drill
3.0mm Long Pilot Drill
3.5/4.0mm Depth Gauge
#15 Screw Driver

Compression screw holes are used for providing compression across the ankle joint and can only accommodate non-locking screws. Compression is created as the screw travels toward the distal side of the compression screw hole. Follow the steps below for screw insertion through a compression hole:

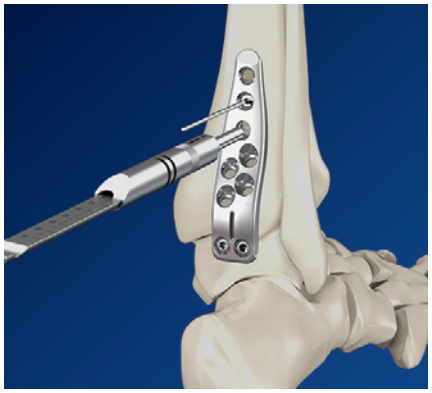
1. DRILL

Select the appropriate angled/compression guide and insert into the target compression hole. The arrow should point toward the fusion site to drill eccentrically. To maximize compression, ensure the drill guide is fully engaged with the target compression hole. Drill using the appropriately-sized pilot drill.



2. DETERMINE SCREW LENGTH

Select the corresponding depth gauge to determine the correct screw length.



3. SCREW INSERTION

Select the appropriate screw and insert. Screw length can be verified using the length gauge on the screw block. Final tightening should be performed using a two-finger technique to avoid over-tightening.

SURGICAL PROCEDURE (Posterior Ankle Fusion Plating)

PLATE FIXATION (Transfixation Hole)

3.5mm Instruments
4.0mm Uniaxial Drill Guide
2.5mm Short Pilot Drill
2.5mm Long Pilot Drill
3.5mm Overdrill
3.5/4.0mm Depth Gauge
#15 Screw Driver

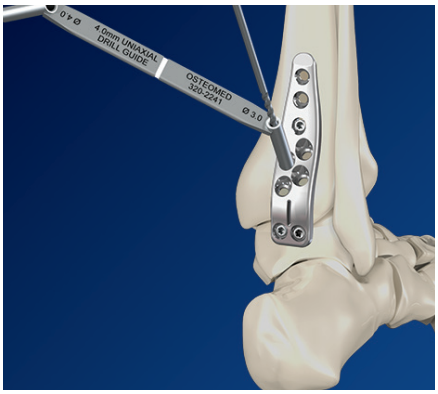
4.0mm Instruments
4.0mm Uniaxial Drill Guide
3.0mm Short Pilot Drill
3.0mm Long Pilot Drill
4.0mm Overdrill
3.5/4.0mm Depth Gauge
#15 Screw Driver

The ExtremiLOCK posterior fusion plates feature four transfixation screw holes that provide rigid fixation across the tibia into the talus. Each transfixation screw hole can accommodate 3.5mm and 4.0mm locking or non-locking screws.

The following steps describe screw placement through a transfixation screw hole:

1. DRILL

Select the Uniaxial Drill Guide and drill through the appropriate transfixation screw hole. The Uniaxial Drill Guide is intended to position the screw in the center of the corresponding screw hole.



2. DETERMINE SCREW LENGTH

Select the corresponding depth gauge to determine the correct screw length.

3. SCREW INSERTION

Select the appropriate screw and insert. Final tightening should be performed using a two-finger technique to avoid over-tightening. Verify fixation with fluoroscopy.

NOTES

NOTES

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ExtremiLOCK Ankle Plating System

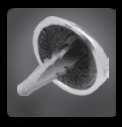

ExtremiLOCK Foot Plating System


ExtremiFix Headless Cannulated Screws


ExtremiFix Cannulated Screws


Large Cannulated Screws


ExtremiFuse

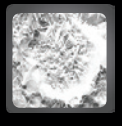

EnCompass

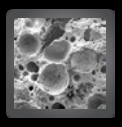

EnCompass Lessers


Hemi


ReFlexion


Talar-Fit


OsteoVation EX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