



ALIGN
ANKLE FUSION SYSTEM

Lateral Approach
Surgical Technique Guide

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

INDICATIONS FOR USE

The AlignX Ankle Fusion Plate is intended to facilitate arthrodesis of the ankle including tibiotalocalcaneal and tibiotalar joints.

This technique guide illustrates a tibiotalar fusion with a lateral approach.

Note: Incision, joint preparation, and plate reduction techniques are left to the surgeon's discretion.

Surgical Approach:

Use a standard lateral transfibular approach to expose the ankle joint.

Joint Preparation: An oblique osteotomy should be performed through the distal fibula at the level of the syndesmosis to allow for adequate visualization of the joint.

Prepare the tibiotalar joint in the standard fashion. Utilize the Parallel Compressor/Distractor to help gain exposure of the joint as required. Remove all remaining articular cartilage with a curette, osteotome, and/or rongeur.

Perforate the subchondral bone with multiple small holes ~ 2-4 mm.

With a lateral approach to ankle fusion, it may be necessary to remove the bone prominence of the lateral tibia talus and calcaneus as it may interfere with plate fit. If so, shave down prominent ridges and osteophytes along the distal metaphysis of the tibia with a rongeur, saw or with the Lateral Planer provided in the AlignX Plating System. To use the Lateral Planer, first reduce the joint to the desired position. See below for details in regard to the use of the AlignX Lateral Planer.

Joint Reduction

Reduce the tibiotalar joint to a neutral dorsi/plantarflexion and inversion/eversion position. A 2.0mm Guidewire can be placed across the joint to help maintain the reduction. The Parallel Compressor/Distractor found in the AlignX instrument set can also be used to maintain joint reduction.

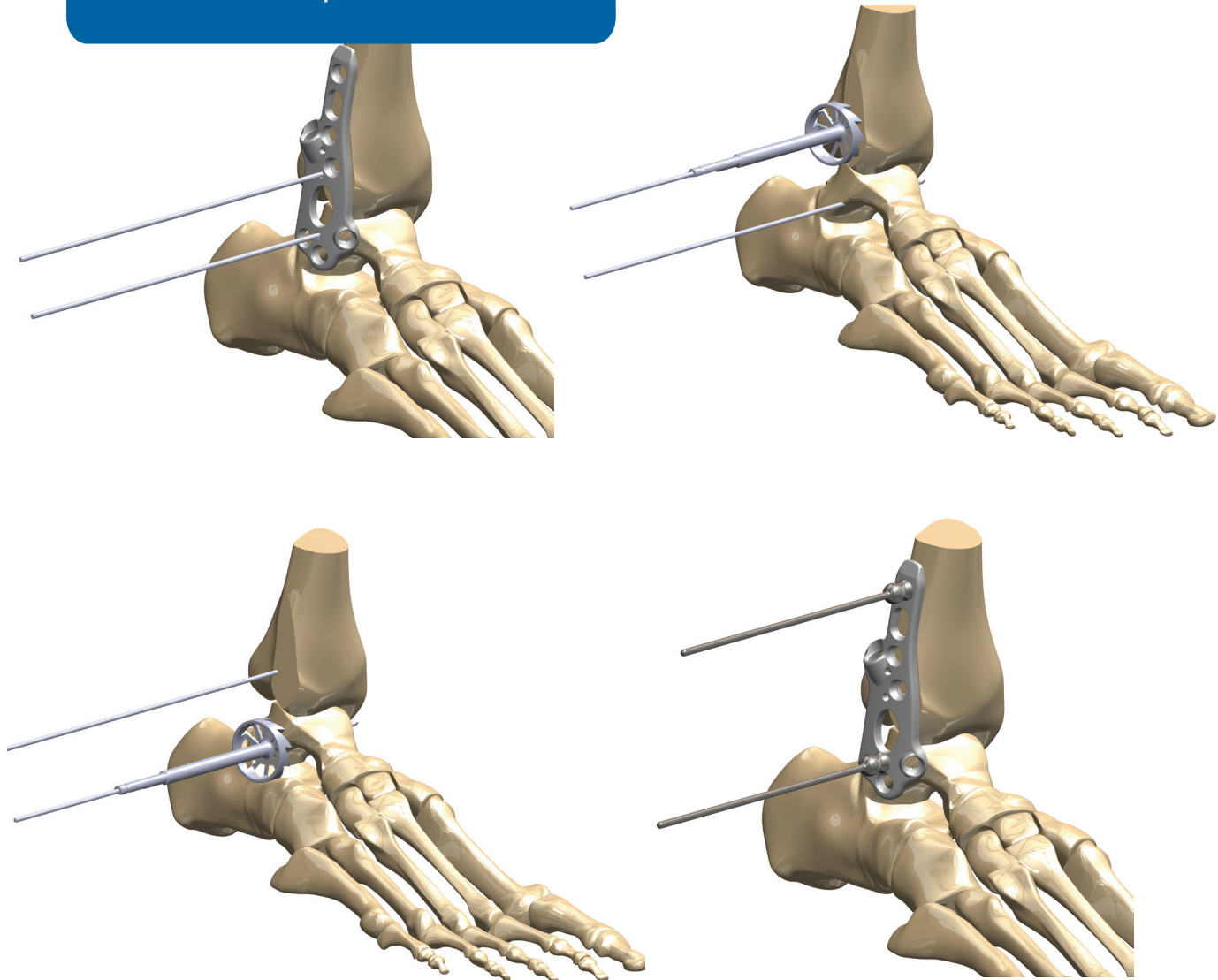
Soft tissue release/mobilization and/or bone resection may be required if an anterior extrusion of the talus is present. An Achilles tendon lengthening procedure may be required to obtain proper position.

Lateral Planer

Once the joint is reduced and provisionally fixed in the desired position, the Lateral Planer can be utilized to remove any bone prominence of the lateral tibia and talus that would interfere with plate fit.

To help determine good positioning for the Lateral Planer, provisionally pin the plate in the desired position by placing two 2.0 mm Guidewires through the guidewire holes of the plate -one in the talus, one in the tibia. Remove the plate and use Lateral Planer over the Guidewires to prepare the bone and create proper plate fit. If desired, bone shavings from the Lateral Planer may be morselized and used as graft.

Lateral Planer (Optional)



Once good fit of the plate has been achieved, remove the 2.0 mm Guidewires used for the planer and provisionally pin the lateral AlignX plate over the joint with Olive Wires (talus and tibia). The plate should be placed with lasermarked indicator in-line with joint.

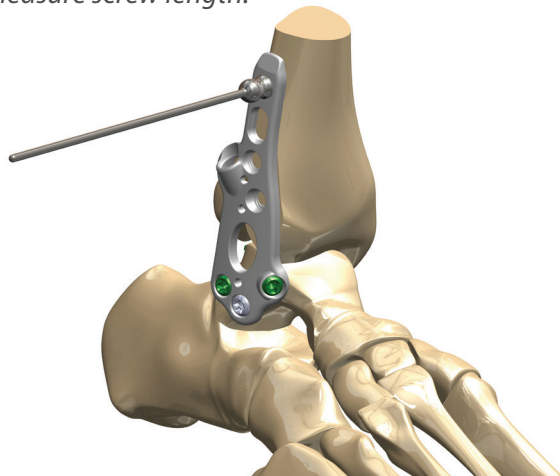
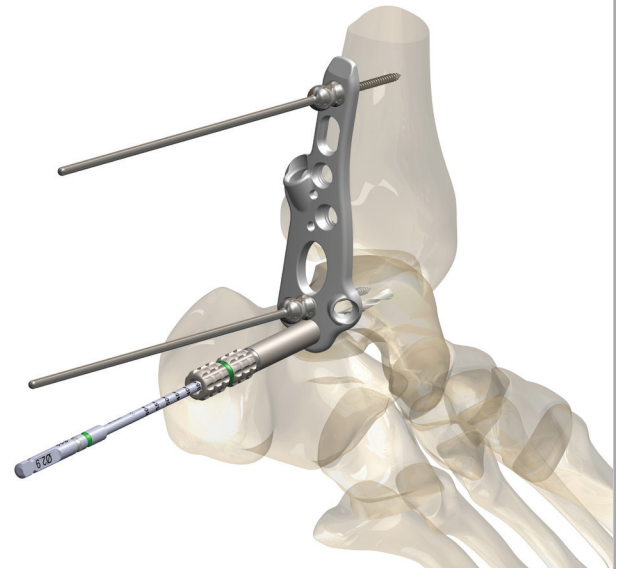
Step 1: Distal Screw Placement

Choice of screw type and size is left up to the surgeon's discretion. Regardless of the screw type chosen (locking or non-locking), it is recommended to use the Locking Drill Guides for all plate screws. This ensures both easy placement and proper trajectory of converging screws in talus. It is recommended to place a 4.0 mm Non-Locking Screw in the first hole, and Locking Screws in the second and third talar holes.

Thread the Locking Drill Guide into the plate hole, drill with the appropriately sized drill, measure and place the desired screws with the T 25 Start Driver.

Drill and measure for each subsequent screw in preferred manner.

Screw Length Measurement: All Drills in this system are calibrated to the Drill Guides and thus screw lengths can be determined directly off of the drill. Alternatively, a standard AO (hook-style) Depth Gauge is available and can be used to directly measure screw length.

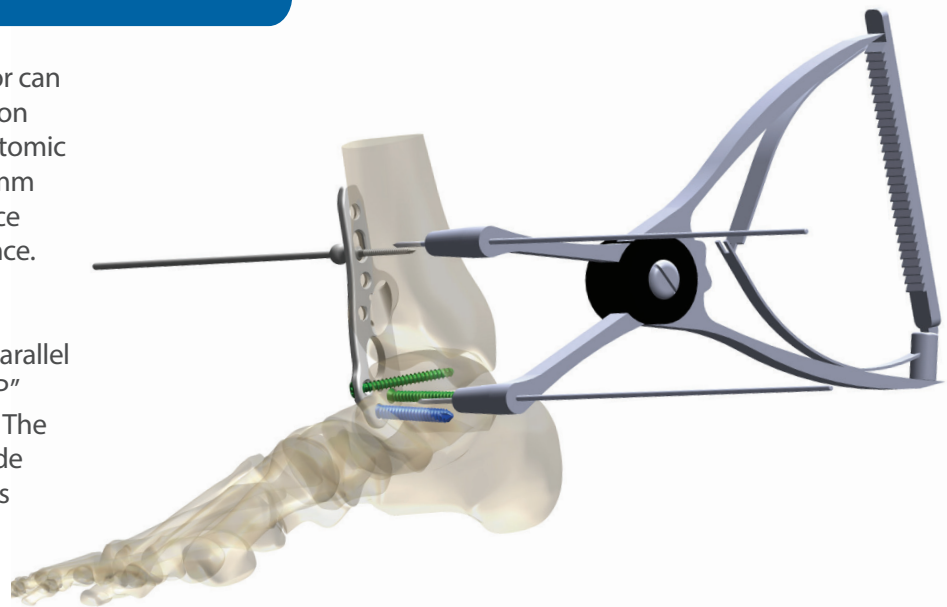


Screw	Drill Size	Drill Guide Color
4.0 mm Non-Locking	2.9mm	Gray
4.0 mm Locking	2.9mm	Green

Screw	Drill Size	Drill Guide Color
5.0 mm Non-Locking	2.9mm	Gray
5.0 mm Locking	3.5mm	Blue

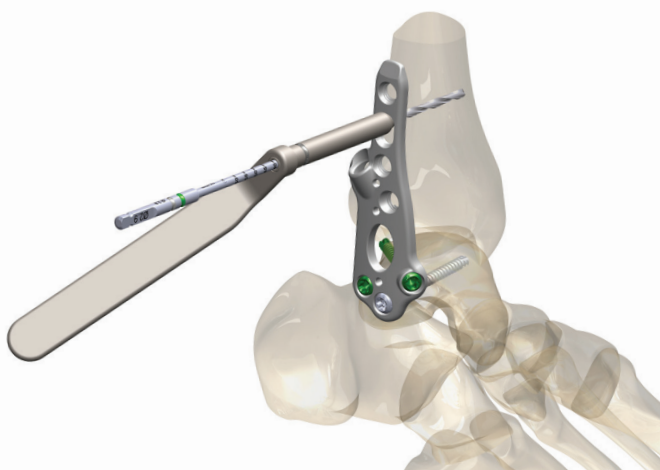
Step 2: Parallel Compression (Optional)

The Parallel Compressor/Distractor can be utilized to generate compression across the tibiotalar joint. The anatomic location for placement of the 2.0mm Guidewires utilized with this device is left up to the surgeon's preference. Place a 2.0mm Guidewire in both the talus and tibia at a maximum distance of 60mm apart. Set the Parallel Compression Device to the "COMP" setting. Squeeze the handle fully. The device is now set to compress. Slide the device over the 2.0 Guidewires and squeeze the handle to apply compression as desired.



Step 3: Axial Compression Slot (Optional)

The compression slot in the AlignX Plate can be utilized to generate axial compression by sliding the tibia distally. Place the Non-Locking Drill Guide and drill in the proximal portion of the plate's Compression Slot. Drill, measure and place a Non-Locking Screw in the most proximal portion of the slot.



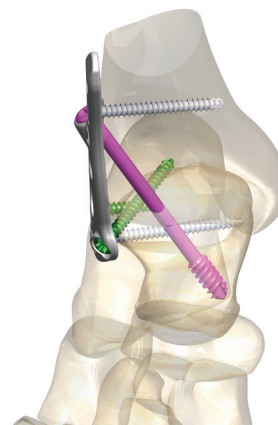
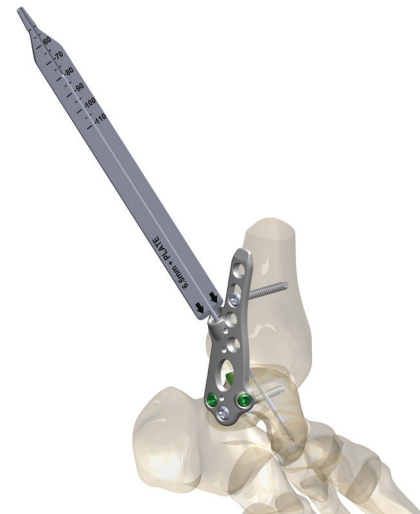
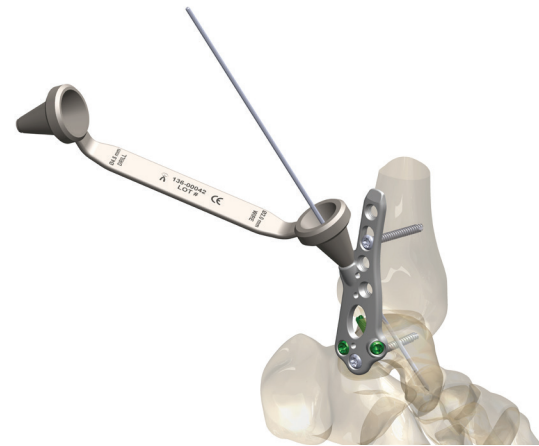
Step 4: Home Run Screw

A Home Run Screw (6.5mm Partially Threaded Screw) can be placed through the AlignX Plate to provide interfragmentary compression. The plate and Polyaxial Cone Drill Guide allows for up to 30° of angulation. The trajectory of the placement of this screw is left up to the surgeon's discretion. Place a 2.0mm Guidewire through the Polyaxial Cone Guide in the desired screw trajectory and depth. Confirm the position using an image intensifier (AP and Lateral views) to confirm the position to ensure avoidance of talar screws.

Measuring the Home Run Screw

There are two sides to the Guidewire Depth Gauge. Utilize the "6.5mm + Plate" side to measure for the Home Run Screw when used with the plate, and the "6.5mm Direct Depth" side for screws placed outside of the AlignX Plate.

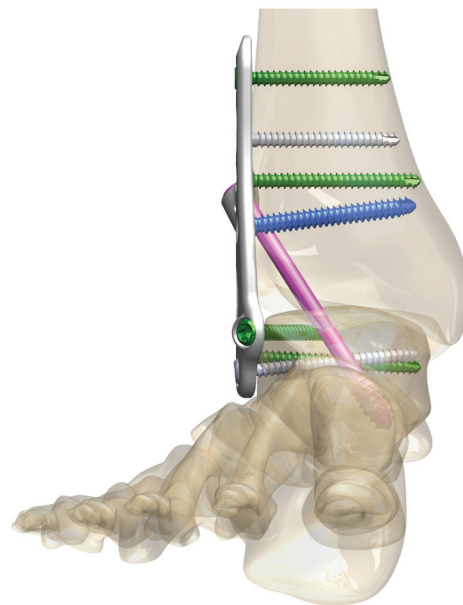
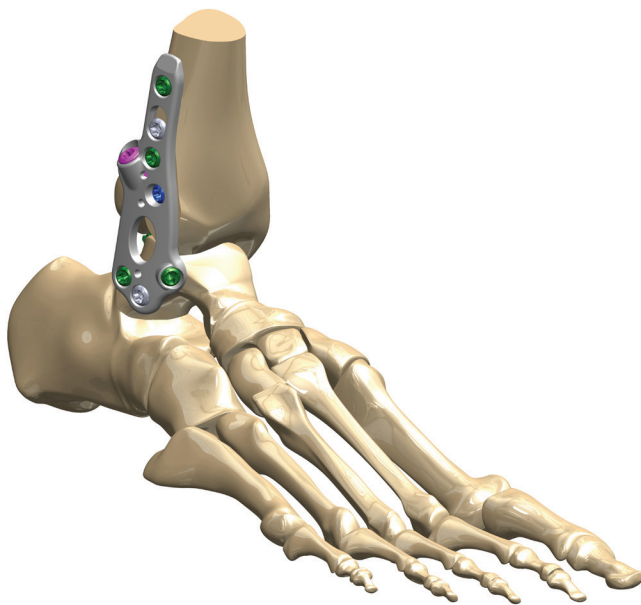
- Measure over the Guidewire for screw length.
- Drill over the Guidewire with the 4.5mm Cannulated Drill.
- Insert the appropriate length Partially Threaded 6.5mm Screw over the Guidewire.



Step 5: Screw Placement: Proximal Holes

In order to secure the plate proximally, place additional multiplanar screws in the tibia as desired working distally to proximally on the plate. In order to ensure the proper trajectory of the converging screws in tibia, it is recommended to use the Locking Drill Guide for the screws.

Size and type (locking or non-locking) is left up to the surgeon's discretion. Drill, measure and place the desired screws as previously described.






Screw	Drill Size	Drill Guide Color
4.0 mm Non-Locking	2.9mm	Gray
4.0 mm Locking	2.9mm	Green

Screw	Drill Size	Drill Guide Color
5.0 mm Non-Locking	2.9mm	Gray
5.0 mm Locking	3.5mm	Blue

Screw Length Measurement: All Drills in this system are calibrated to the Drill Guides and thus screw lengths can be determined directly off of the drill. Alternatively, a standard AO (hook-style) Depth Gauge is available and can be used to directly measure screw length.

Quick Reference:
AlignX Screw Placement Sequence



-  Locking/Non-Locking Screw Options
-  6.5mm Partially Threaded Screw
-  Non-Locking Screw Only

IMPLANT REMOVAL

Clear tissue in-growth from the screws. Insert the T25 Star Driver into the screw head and remove the screw from the plate by turning the Star Driver counter-clockwise. Remove all screws and then the plate.

Implant #	Description
Plate	
136-20011	Lateral Ankle Fusion Plate, TT, Left
136-20012	Lateral Ankle Fusion Plate, TT, Right
136-30011	Lateral Ankle Fusion Plate, TTC, Left
136-30012	Lateral Ankle Fusion Plate, TTC, Right

Implant #	Description
4.0 Non-Locking Screws (solid)	
136-40022	Non-Locking Screw - 4.0 x 22mm
136-40024	Non-Locking Screw - 4.0 x 24mm
136-40026	Non-Locking Screw - 4.0 x 26mm
136-40028	Non-Locking Screw - 4.0 x 28mm
136-40030	Non-Locking Screw - 4.0 x 30mm
136-40032	Non-Locking Screw - 4.0 x 32mm
136-40034	Non-Locking Screw - 4.0 x 34mm
136-40036	Non-Locking Screw - 4.0 x 36mm
136-40038	Non-Locking Screw - 4.0 x 38mm
136-40040	Non-Locking Screw - 4.0 x 40mm
136-40045	Non-Locking Screw - 4.0 x 45mm
136-40050	Non-Locking Screw - 4.0 x 50mm
136-40055	Non-Locking Screw - 4.0 x 55mm
136-40060	Non-Locking Screw - 4.0 x 60mm

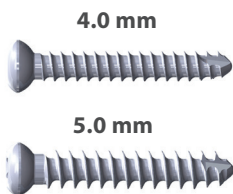
4.0 Locking Screws (solid)	
136-40122	Locking Screw - 4.0 x 22mm
136-40124	Locking Screw - 4.0 x 24mm
136-40126	Locking Screw - 4.0 x 26mm
136-40128	Locking Screw - 4.0 x 28mm
136-40130	Locking Screw - 4.0 x 30mm
136-40132	Locking Screw - 4.0 x 32mm
136-40134	Locking Screw - 4.0 x 34mm
136-40136	Locking Screw - 4.0 x 36mm
136-40138	Locking Screw - 4.0 x 38mm
136-40140	Locking Screw - 4.0 x 40mm
136-40145	Locking Screw - 4.0 x 45mm
136-40150	Locking Screw - 4.0 x 50mm
136-40155	Locking Screw - 4.0 x 55mm
136-40160	Locking Screw - 4.0 x 60mm

Implant #	Description
5.0 Non-Locking Screws (solid)	
136-50022	Non-Locking Screw - 5.0 x 22mm
136-50024	Non-Locking Screw - 5.0 x 24mm
136-50026	Non-Locking Screw - 5.0 x 26mm
136-50028	Non-Locking Screw - 5.0 x 28mm
136-50030	Non-Locking Screw - 5.0 x 30mm
136-50032	Non-Locking Screw - 5.0 x 32mm
136-50034	Non-Locking Screw - 5.0 x 34mm
136-50036	Non-Locking Screw - 5.0 x 36mm
136-50038	Non-Locking Screw - 5.0 x 38mm
136-50040	Non-Locking Screw - 5.0 x 40mm
136-50042	Non-Locking Screw - 5.0 x 42mm
136-50044	Non-Locking Screw - 5.0 x 44mm
136-50046	Non-Locking Screw - 5.0 x 46mm
136-50048	Non-Locking Screw - 5.0 x 48mm
136-50050	Non-Locking Screw - 5.0 x 50mm

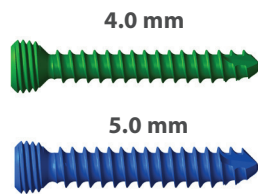
5.0 Locking Screws (solid)	
136-50122	Locking Screw - 5.0 x 22mm
136-50124	Locking Screw - 5.0 x 24mm
136-50126	Locking Screw - 5.0 x 26mm
136-50128	Locking Screw - 5.0 x 28mm
136-50130	Locking Screw - 5.0 x 30mm
136-50132	Locking Screw - 5.0 x 32mm
136-50134	Locking Screw - 5.0 x 34mm
136-50136	Locking Screw - 5.0 x 36mm
136-50138	Locking Screw - 5.0 x 38mm
136-50140	Locking Screw - 5.0 x 40mm
136-50142	Locking Screw - 5.0 x 42mm
136-50144	Locking Screw - 5.0 x 44mm
136-50146	Locking Screw - 5.0 x 46mm
136-50148	Locking Screw - 5.0 x 48mm
136-50150	Locking Screw - 5.0 x 50mm

Implant #	Description
Homerun Screws (6.5 cannulated)	
136-65150	Partially Threaded Screw - 6.5 x 50mm
136-65155	Partially Threaded Screw - 6.5 x 55mm
136-65160	Partially Threaded Screw - 6.5 x 60mm
136-65165	Partially Threaded Screw - 6.5 x 65mm
136-65170	Partially Threaded Screw - 6.5 x 70mm
136-65175	Partially Threaded Screw - 6.5 x 75mm
136-65180	Partially Threaded Screw - 6.5 x 80mm
136-65185	Partially Threaded Screw - 6.5 x 85mm
136-65190	Partially Threaded Screw - 6.5 x 90mm
136-65195	Partially Threaded Screw - 6.5 x 95mm
136-65100	Partially Threaded Screw - 6.5 x 100mm
136-65105	Partially Threaded Screw - 6.5 x 105mm
136-65110	Partially Threaded Screw - 6.5 x 110mm

Non-Locking Screws



Locking Screws



6.5 mm Partially Threaded Screw



Lateral Tibiotalar Plates

Left

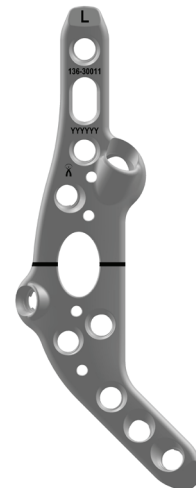


Right

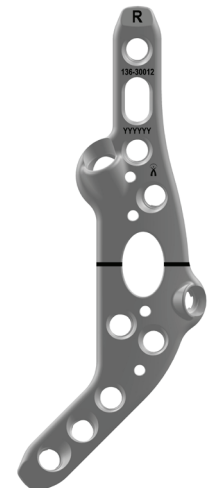


Lateral Tibiotalar Plates

Left

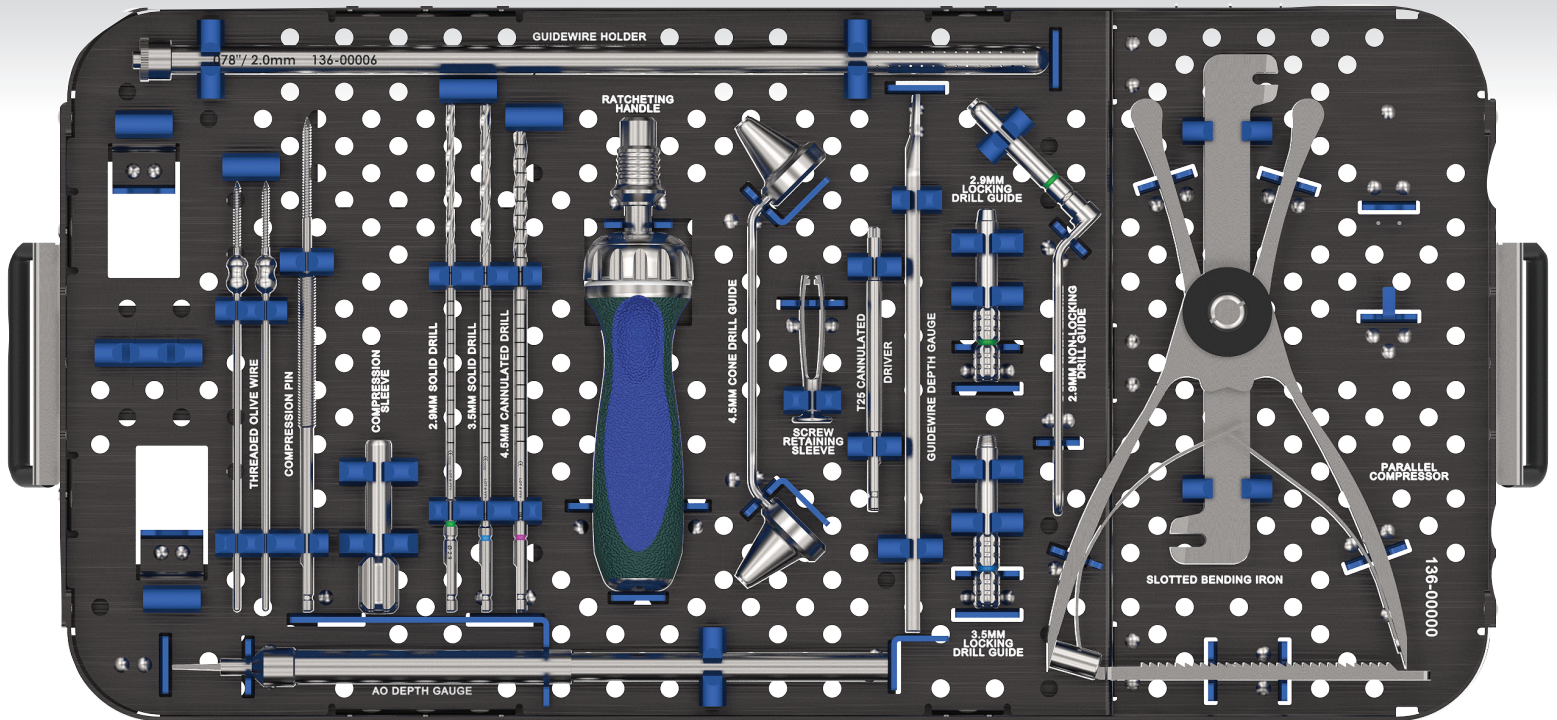


Right



NOTES:

NOTES:



Reusable Instruments

136-00000	AlignX Instrument Tray
136-00006	Guidewire Holder 2.0mm
136-00012	Screw Retaining Sleeve
136-00015	Slotted Bending Iron
136-00016	Screw Holding Forceps
136-00017	AO Depth Gauge
136-00019	Parallel Compressor/Distractor
136-00020	Compression Pin
136-00021	Compression Sleeve
136-00022	Guidewire Depth Gauge
136-00024	T25 Star Driver
136-00029	Locking Drill Guide - 2.9mm
136-00035	Locking Drill Guide - 3.5mm
136-00041	Non-Locking Drill Guide - 2.9mm
136-00042	Polyaxial Cone Drill Guide - 4.5mm
136-00129	Solid Drill - 2.9mm
136-00135	Solid Drill - 3.5mm
118-00039	Quick Connect Ratcheting Handle

Disposable Instruments

136-00005	Guidewire - 2.0mm
136-00025	Threaded Olive Wire - 2.5mm
136-00145	Cannulated Drill - 4.5mm
136-00026	AlignX Plate X-ray Template
136-00125	Threaded Olive Wire - 2.5mm, Long
136-00200	Lateral Planer