



ALIGN

ANKLE FUSION SYSTEM
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 Anterior Ankle Fusion Plate is intended to facilitate arthrodesis of the ankle including tibiotalocalcaneal and tibiotalar joints.

Plate Selection and Preparation

The AlignX Ankle Fusion System's Plates are right and left specific and are offered in standard (dual tab) and slim (single tab) configurations. The standard plate incorporates a lateral tab design that enhances construct stability and can assist in the distribution of compressive forces when combined with the Home Run Screw. Pre-operative assessment and templating is recommended to assess the most appropriate plate selection for each patient.

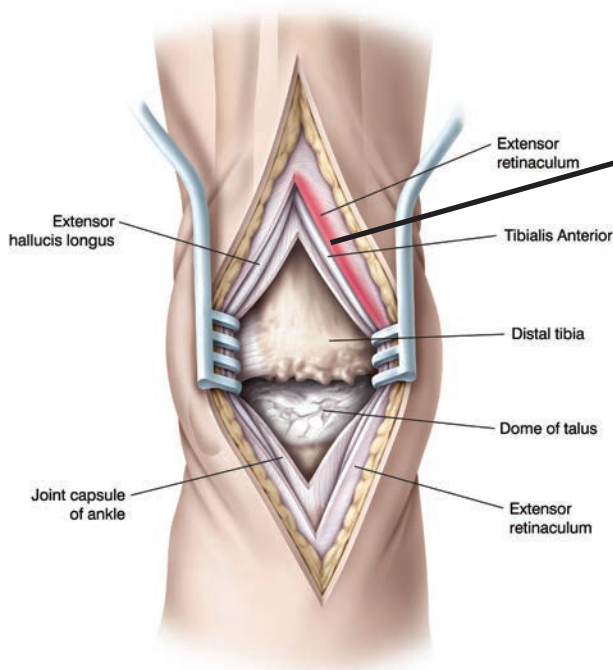
Incision, Joint Preparation and Plate Reduction Guidelines

Incision

Make an incision approximately 3 cm lateral to the tibial ridge and lateral to tibialis anterior tendon. Extend it distally to a point approximately 1 cm medial to the lateral edge of the talonavicular joint, roughly in line with the second ray. The extensor retinaculum should be mobilized off the tibial ridge, while preserving the integrity of the tibialis anterior tendon sheath where possible, in order to facilitate closure of the extensor retinaculum over the plate and the contents of the anterior compartment at the completion of the procedure.

Dissection is carried down to the deep fascia keeping the incision in the interval between the tibialis anterior and the extensor hallucis longus (caution should be taken to avoid the neurovascular bundle).

Dissection is taken directly down to the tibia and developed distally to the talar neck. Elevate the soft tissue off the distal tibia to expose medial and lateral gutters.



NOTE: The extensor retinaculum should be mobilized off the tibial ridge medially to allow for closure of soft tissue over the plate. The dorsomedial and lateral aspects of the talus should be exposed.

Joint Preparation

The tibiotalar joint should be prepared for arthrodesis in the standard fashion. Utilize the Parallel Compressor/Distractor to help gain exposure of the joint as required. All remaining articular cartilage should be removed with a curette, osteotome, and/or rongeur. The subchondral bone should be perforated with multiple small holes or a burr to a recommended depth of 2-4 mm.

Joint Reduction

The tibiotalar joint should be reduced to neutral dorsi/plantarflexion and inversion/eversion. A 2.0mm Guidewire can be placed across the joint to help maintain the 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.

Anterior osteophytes should be removed as required to allow proper positioning of the tibiotalar joint and placement of the plate.

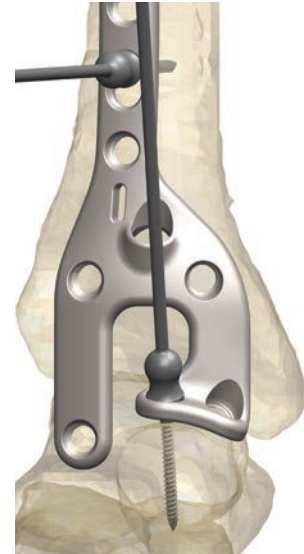
Note: *Incision, joint preparation, and plate reduction techniques are left to the surgeon's discretion*

STEP 1 - Plate Placement

Place the AlignX Anterior Fusion Plate so that the lateral tab rests lateral to the talar neck and the proximal end of the plate rests on the anterolateral aspect of the tibia.

Provisionally pin the plate with an Olive Wire in the most dorsal hole on the medial tab. Subsequently add a second Olive Wire in the tibia in the axial compression slot.

Note: If the neck component of the plate does not fit flush on the talus, remove osteophytes from the dorsal and lateral surface of the talar neck.



STEP 2 - Screw Placement - 1st Medial Tab Hole

In order to ensure the proper trajectory of the converging screws in the medial tab, it is recommended to use the Locking Drill Guide for both of the medial tab screws. Choice of screw type is left up to the surgeon's discretion. It is recommended to place a Non-Locking 4.0mm Screw in the first hole, and a 4.0mm Locking Screw in the second.

Place the 2.9mm Non-Locking Drill Guide into the most medial hole on the medial tab. For tibiotalar arthrodesis, it is recommended that the medial tab screws be drilled in unicortical fashion to avoid violation of the medial facet of the subtalar joint. Measure and drill for screw length. Insert the appropriate 4.0mm Screw.

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

Note: Drills are calibrated to Drill Guides and thus screw lengths can be determined directly off of the drill. Alternatively, a standard hook-style Depth Gauge is available and can be used to directly measure screw length. Drill and measure for each subsequent screw in preferred manner.

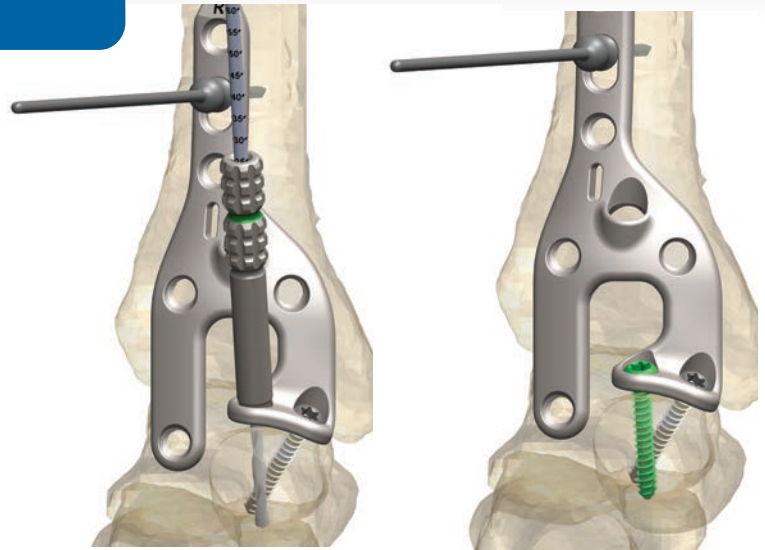


STEP 3 - Screw Placement - 2nd Medial Tab Hole

Place the 2.9mm Locking Drill Guide into the most dorsal hole of the medial tab.

Drill and measure for screw length. Insert the appropriate 4.0mm Locking Screw.

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



Optional Step: Plate Reduction

It is recommended to reduce the Plate to the tibia prior to the placement of the lateral tab and tibial screws.

Proximal Tibia

The Compression Pin/Compression Sleeve device can be utilized to reduce the plate to the tibia. Place the Compression Pin in the most proximal hole of the plate. Advance the Compression Sleeve over the Compression Pin. Turn the compression sleeve clockwise to reduce the plate.

Distal Tibia

An Olive Wire can be utilized to help reduce the plate to the distal tibia. Place an Olive Wire in either of the plates most distal tibial holes ("shoulder holes") to reduce the plate to bone if this part of the plate is elevated off of the tibia.

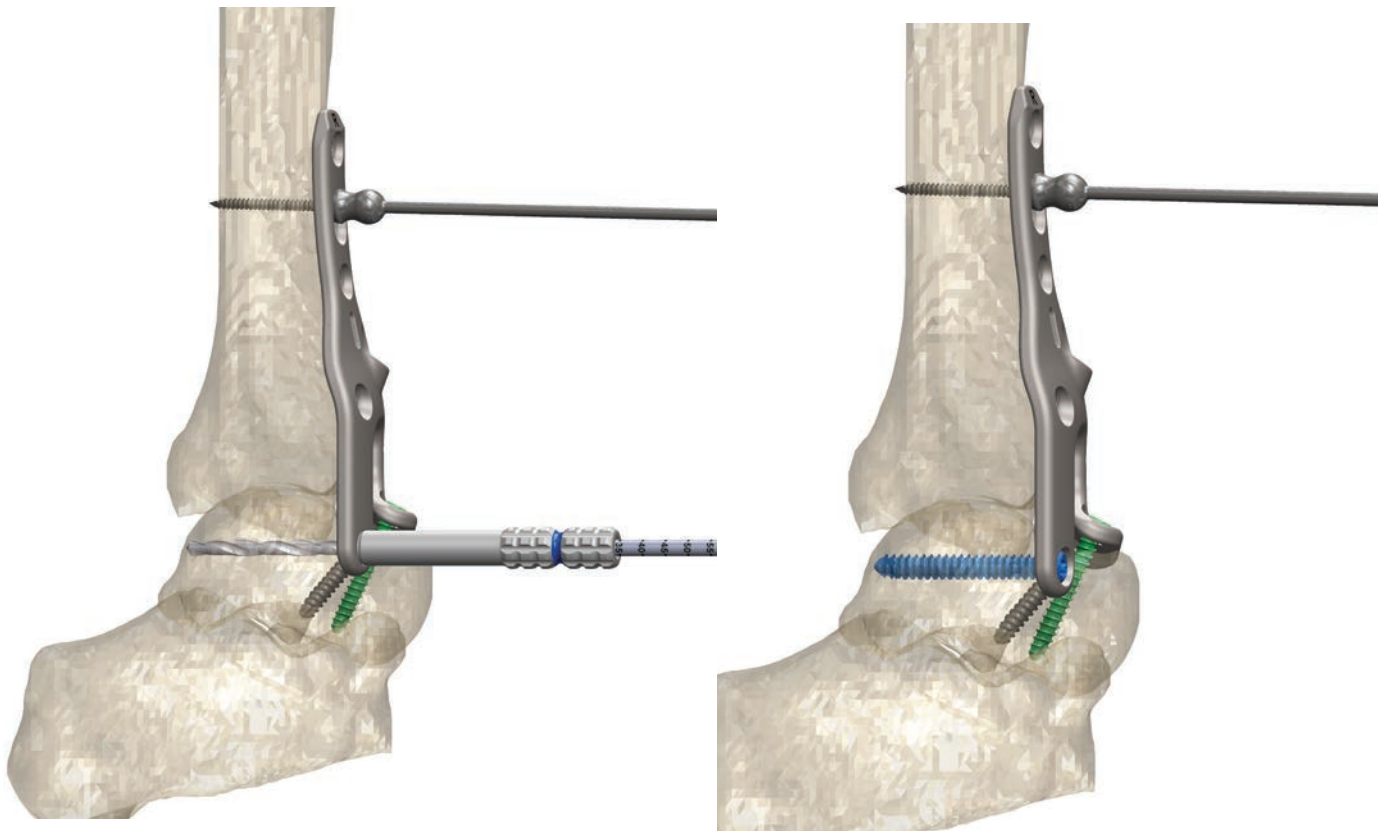


STEP 4 - Screw Placement - Lateral Tab Hole: Standard Plate

Care should be taken to assess proper alignment of the plate with relation to the tibia prior to placing the lateral tab screw.

Place the 3.5mm Locking Drill Guide into the lateral tab hole. Drill and measure for screw length. Insert the appropriate length 5.0mm screw.

Note: A 5.0mm Non-Locking Screw can be used to reduce the lateral tab down to bone. Utilize the 2.9mm Drill Guide & 2.9mm Drill to prepare for this non-locking screw.

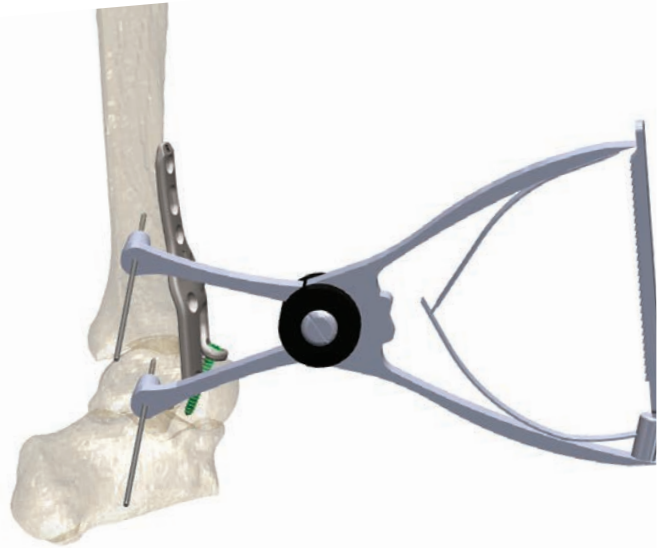


Screw	Drill Size	Drill Guide Color
5.0 mm Non-Locking	2.9mm	Gray
5.0 mm Locking	3.5mm	Blue

STEP 5 - Parallel Compression

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. Lateral placement (illustrated in this guide) can be helpful to assist in the reduction and maintenance of correction of a varus deformity. Medial placement can be helpful to assist in the reduction and maintenance of correction of a valgus deformity.

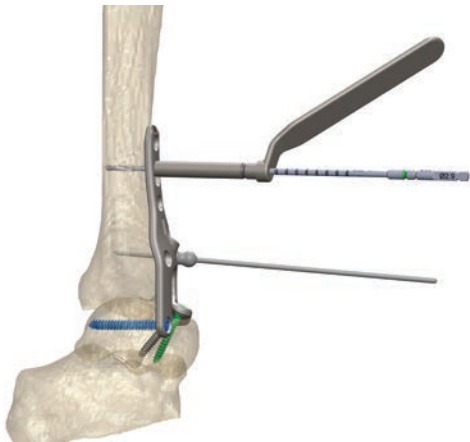
Place a 2.0mm Guidewire in both the talus (anterior to the fibula) and tibia at a maximum distance of 60mm apart. Set the Parallel Compression Device to the "COMP" setting. Squeeze the handle fully. The device is now set to compress. Slide the device over the 2.0 Guidewires and squeeze the handle to apply compression as desired.



Optional- Axial Compression Slot

The compression slot in the AlignX Plate can be utilized to generate additional axial compression by sliding the tibia distally.

Remove the Olive Wire. 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 6 - Home Run Screw Placement

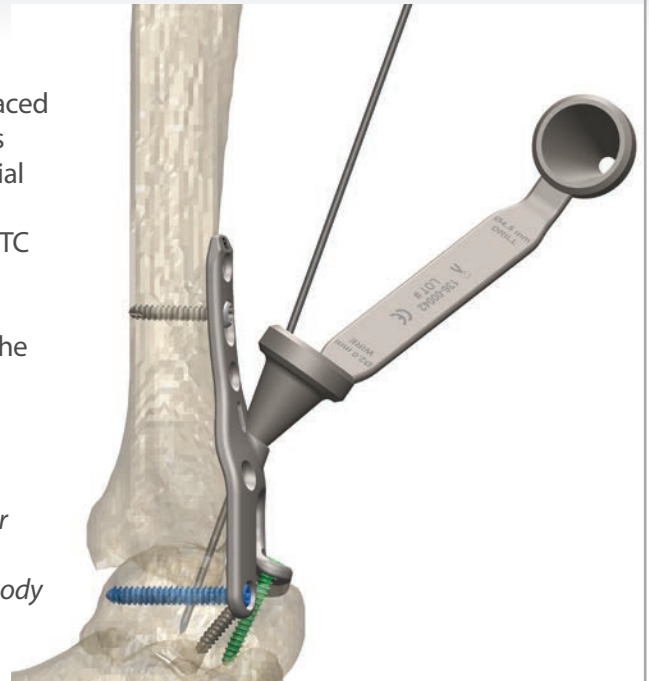
A Home Run Screw (6.5mm Partially Threaded Screw) can be placed through the AlignX Plate. The trajectory of the placement of this screw is left up to the surgeon's discretion. The plate and Polyaxial Cone Drill Guide allows for up to 30° of angulation which allows for screw placement across the tibiotalar or subtalar joint for a TTC Fusion.

Place a 2.0mm Guidewire through the Polyaxial Cone Guide in the desired screw trajectory and depth.

Note: Home Run Screw Guidewire placement recommendations:

Tibiotalar Fusion: Place the guidewire in the center most portion of the posterior talar body and advance it ~8mm from the posterior cortex of the talus.

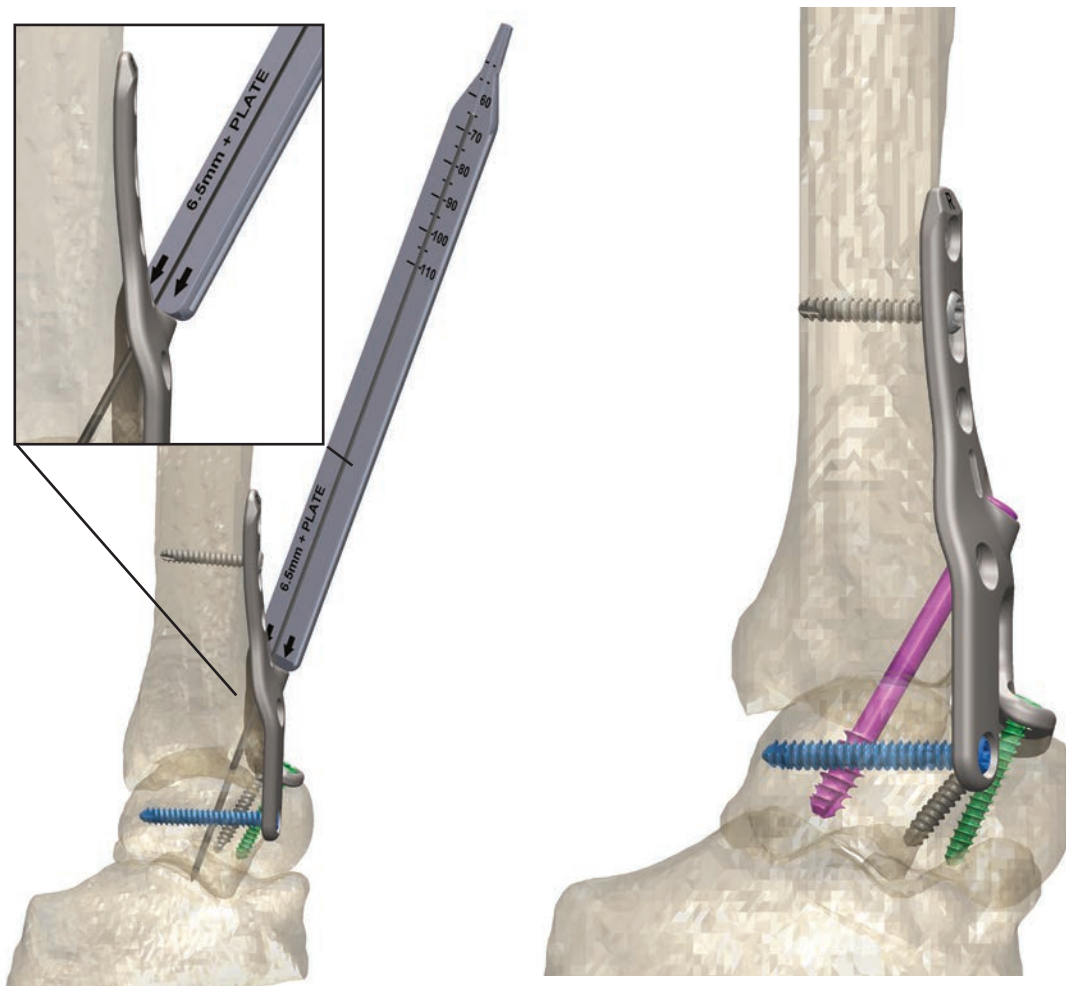
Tibiototalcalcaneal Fusion: Place the guidewire in the calcaneal body just lateral to the medial wall.



STEP 6 - Home Run Screw Placement (continued)

There are two sides to the Guidewire Depth Gauge. Utilize the "6.5mm + Plate" side to measure for the Home Run Screw. Utilize 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 7 - Screw Placement:
Proximal Holes**

Insert remaining proximal screws as desired.

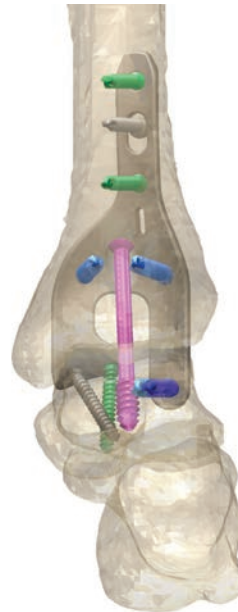
Anterior



Lateral



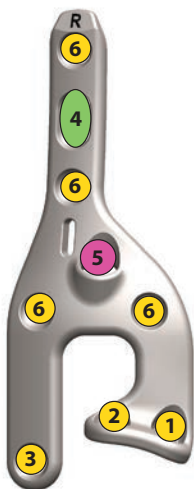
Posterior



TTC



**Quick Reference:
AlignX Screw Placement Sequence**



Locking/Non-Locking Screw Options



6.5mm Partially Threaded Screw



Non-Locking Screw Only

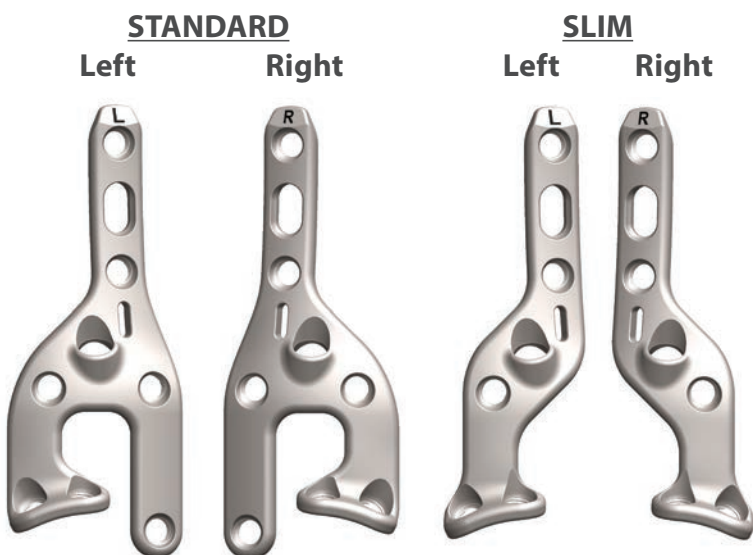
IMPLANT REMOVAL

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.

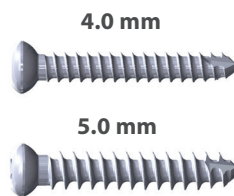
Implant #	Description
Plate	
136-10011	Anterior Ankle Fusion Plate, Slim, Left
136-10012	Anterior Ankle Fusion Plate, Slim, Right
136-10031	Anterior Ankle Fusion Plate, Standard, Left
136-10032	Anterior Ankle Fusion Plate, Standard, Right

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
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

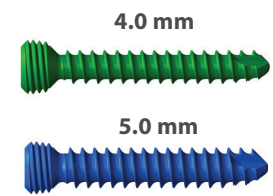
Implant #	Description
5.0 Non-Locking Screws (solid)	
136-50030	Non-Locking Screw - 5.0 x 30mm
136-50032	Non-Locking Screw - 5.0 x 32mm
136-50034	Non-Locking Screw - 5.0 x 34mm
136-50036	Non-Locking Screw - 5.0 x 36mm
136-50038	Non-Locking Screw - 5.0 x 38mm
136-50040	Non-Locking Screw - 5.0 x 40mm
136-50042	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)	
136-50130	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
Home Run Screws (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

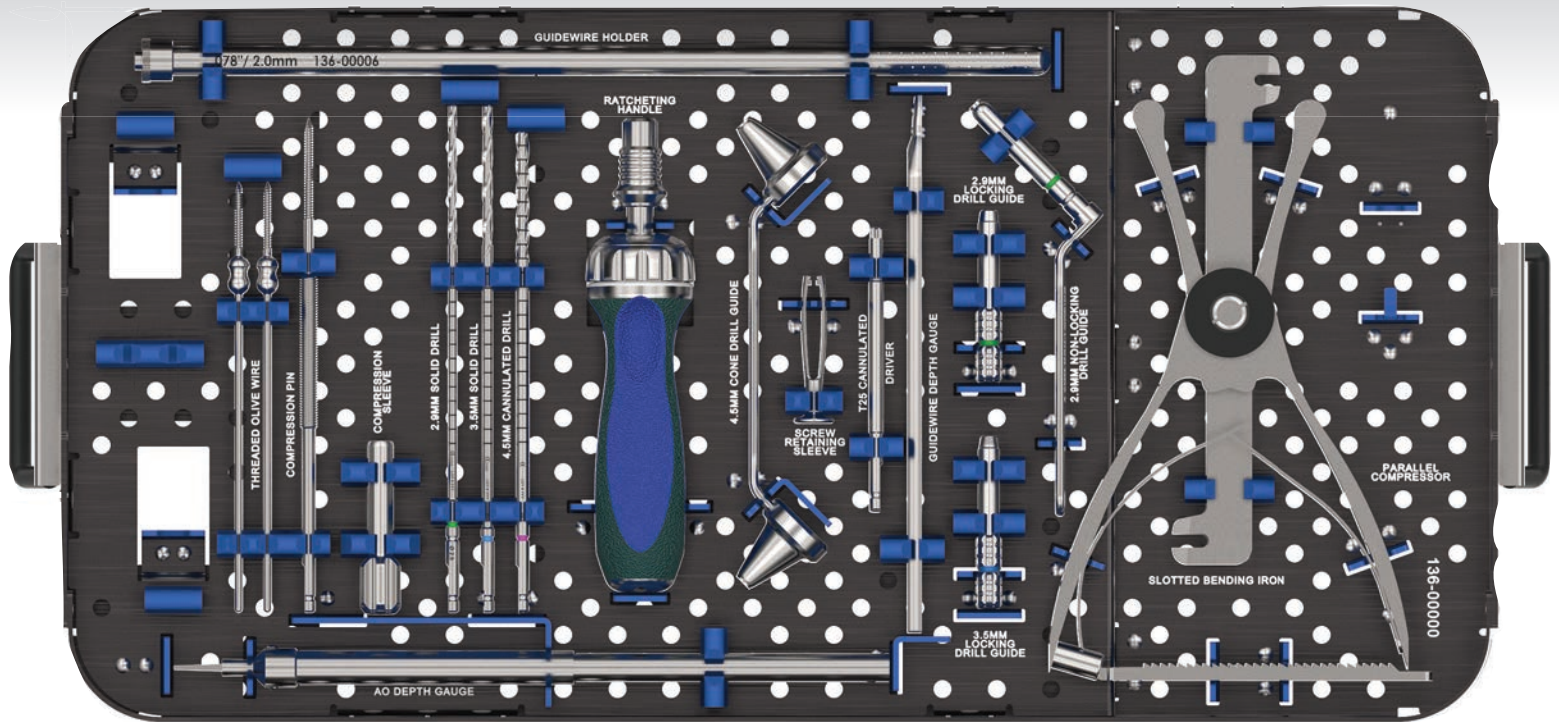


Locking Screws



6.5 mm Partially Threaded Screw





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