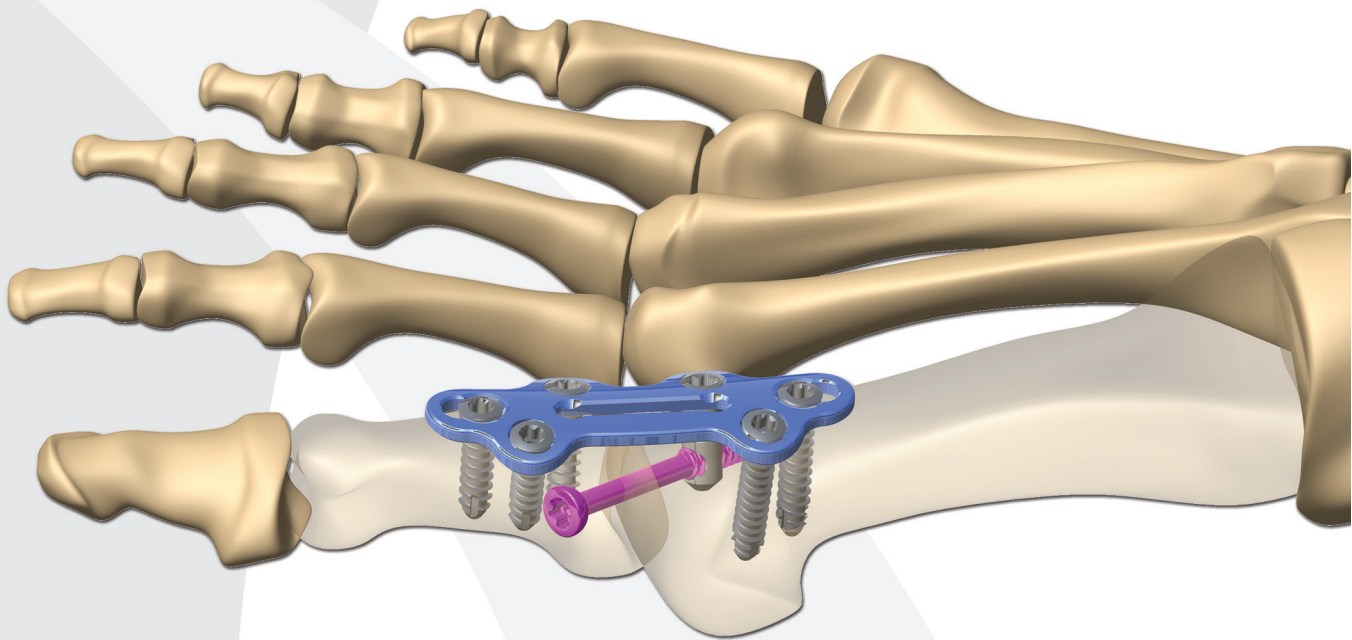


OMNI

PLATING SYSTEM

MTP Fusion Surgical Technique



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

INDICATIONS FOR USE

The Omni Foot Plating System is intended for use in internal fixation, reconstruction, or arthrodesis of the 1st Metatarsalphalangeal joint.

The Omni MTP Plating system was designed to provide the foot and ankle surgeon multiple surgical options for the arthrodesis of the 1st Metatarsalphalangeal joint.

Joint Exposure

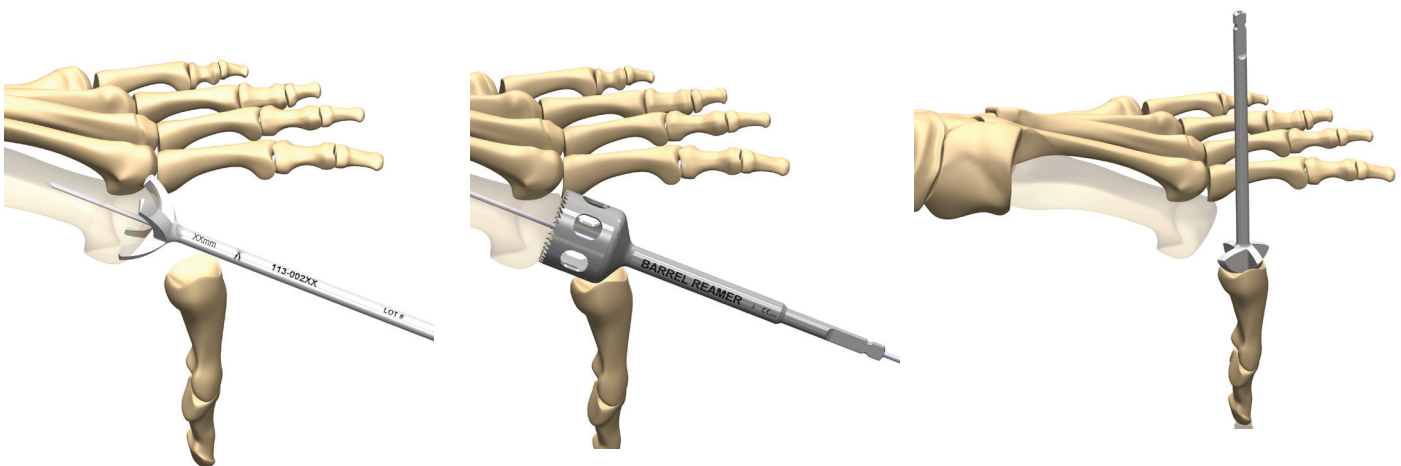
Exposure the MTP joint by creating a dorsal longitudinal incision beginning just proximal to the interphalangeal joint, extending over the extensor hallucis longus tendon medially, and ending 2 – 3 cm proximal to the joint. Incise and release the joint capsule, exposing the base of the proximal phalanx and metatarsal head.

Joint Preparation

Insert 1.4 mm Guidewire in the central aspect of the metatarsal. Using a power saw, resect the bone and shape the metatarsal head to prepare for rasping. Elevate the metatarsal head and plantarflex the proximal phalanx. When utilizing the Cup and Cone Rasps, start spinning the rasp prior to engaging the bone. Place the Cup Rasp over the Guidewire and gently rasp the metatarsal head using a “peck-drilling” technique until bleeding subchondral bone becomes visible on the joint surface. See the instrument listing at the back of this guide for Rasp size options. To remove excess bone from the rim of the metatarsal, place the Barrel reamer over the 1.4mm Guidewire and advance it over the head of the metatarsal. Remove the Guidewire from the rasp.

Insert a 1.4 mm Guidewire in the central aspect of the proximal phalanx. Place the Cone Rasp over the Guidewire and gently rasp the articular surface until healthy, bleeding bone is present. The rasp sizes should be consistent for both the metatarsal and phalanx to create congruent surfaces.

Once adequately prepared, align the joint in the desired position for fusion and provisionally pin with a 1.4mm Guidewire to maintain reduction.



PlantarFiX™ Compression Post/Screw Placement Option

STEP 1 - Plate Placement & Proximal Fixation

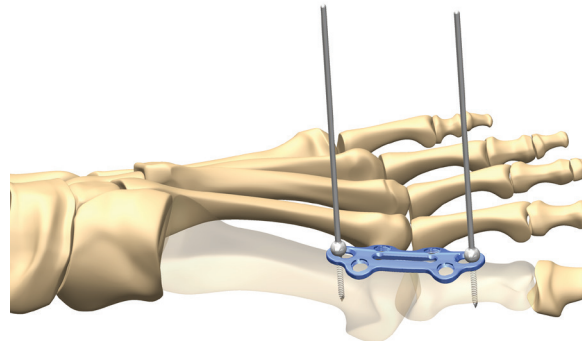
Provisionally pin the plate using Olive Wires. The olive wires can be placed in the slots at either end of the plate or along the central slot.

Prior to placing the PlantarFiX™ Post in hole #3, place a Non-Locking Screw in the compression slot of the plate (#1), and a Locking Screw into hole #2.

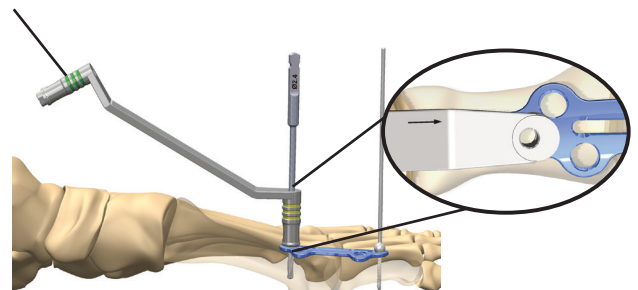
Only non-locking screws can be used in the compression slot of the plate (#1). To generate compression, the Compression Drill Guide should be oriented with the handle away from the plate. To place non-compression screw in slot the guide should be oriented with the handle over the plate.

Each screw type and size has a dedicated Drill and Drill Guide – see images and chart. Drill for the screws with the appropriate size solid drill through the dedicated Drill Guide.

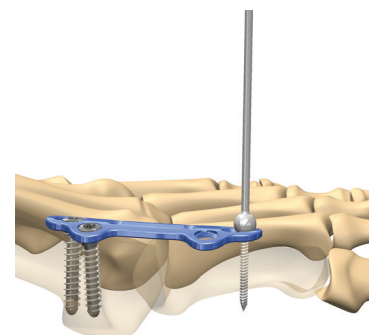
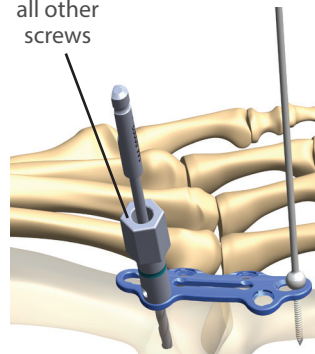
Measure screw length with the AO-style Depth Gauge. Place the selected screw with the T10 Driver.



Compression Slot
Drill Guide



Drill sleeve
all other
screws



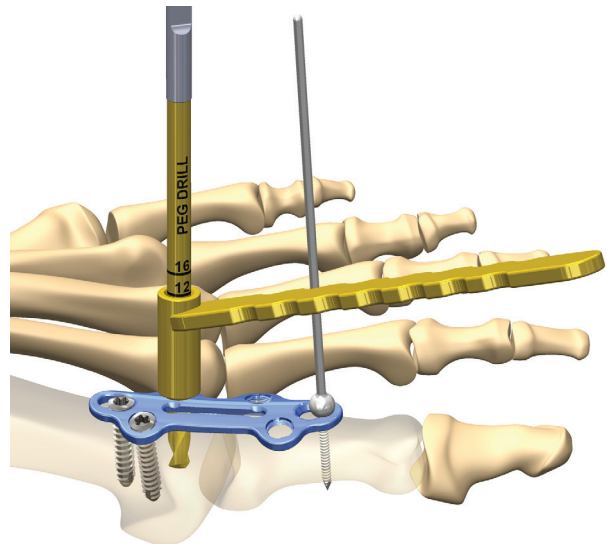
Screw Size	Solid Drill Size	Drill Guide & Drill Colors
2.8 mm	2.4 mm	Yellow
3.5 mm	2.7 mm	Green

STEP 2 - PlantarFiX™ Compression Post

Note: All instrumentation for the PlantarFiX™ Compression Post are colored gold.

Place the Post Drill Guide in the desired hole of the Omni MTP Plate. Drill with the Post Drill to the desired depth. Measure the length of the PlantarFiX™ Compression Post off of the calibration on the Post Drill/Post Drill Guide. The PlantarFiX™ Compression Posts are available in 12 and 16mm lengths.

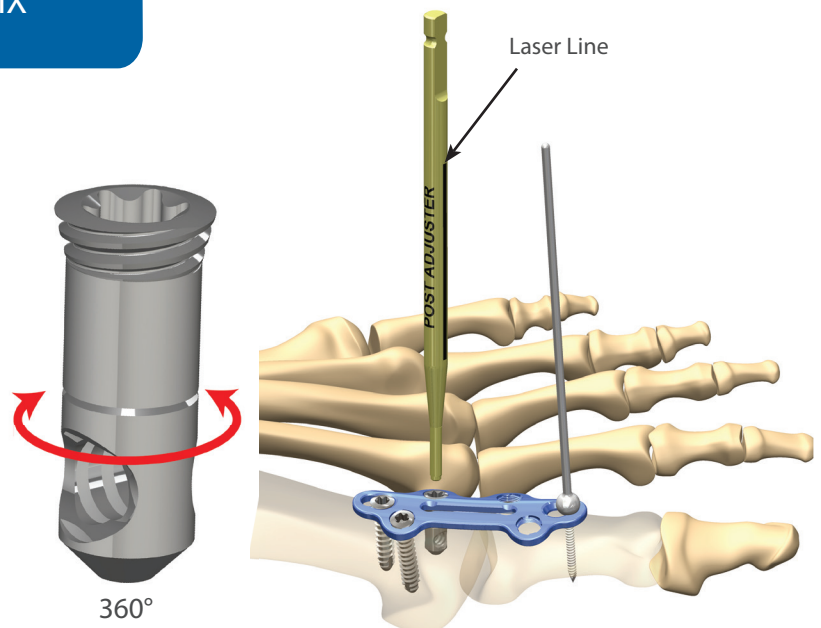
Insert and lock the PlantarFiX™ Compression Post into the plate with the T15 Driver. The proximal end of the Post locks into the plate in the same manner as the locking screws.



STEP 3 - Targeting the PlantarFiX™ Compression Post

The plantar hole of the Post rotates 360° to allow for flexible screw placement.

Place the Post Adjuster into the head of the Post utilizing the black laser line on the Adjuster to orient the distal hole of Post towards the desired trajectory for the 3.5mm Cannulated Compression Screw.

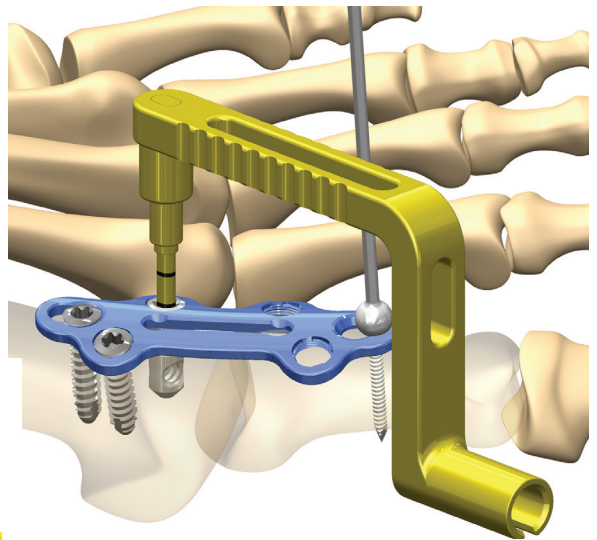
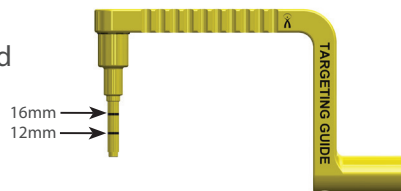


STEP 3 - Targeting the PlantarFiX™ Compression Post (continued)

The Targeting Guide is keyed with the PlantarFiX™ Post. This couples the distal hole of the Post with the Targeting Guide ensuring accurate targeting and placement of the 3.5mm Compression Screw. Place the Targeting Guide into the Post. Ensure that one of the laser marks on the Targeting Guide is in-line with the top of the Post, confirming the proper seating position.

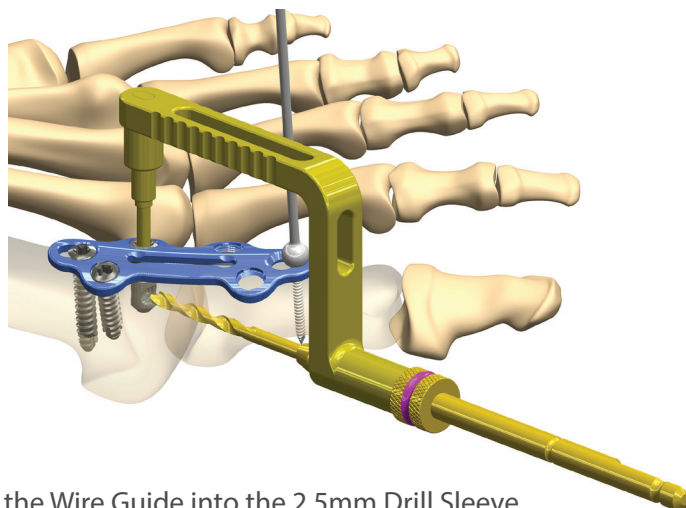
16mm Post= top line
12mm Post= bottom line

Rotate the Guide to the desired position for the Compression Screw placement.



Step 4 - Compression Screw Placement

This drilling step creates the desired trajectory for the 3.5mm Compression Screw ensuring accurate targeting. Place the 2.5mm Drill Sleeve (magenta color) into the Targeting Guide. Drill with the 2.5mm Solid Drill, advancing the 2.5mm Solid Drill until the depth stop on the drill reaches the barrel.



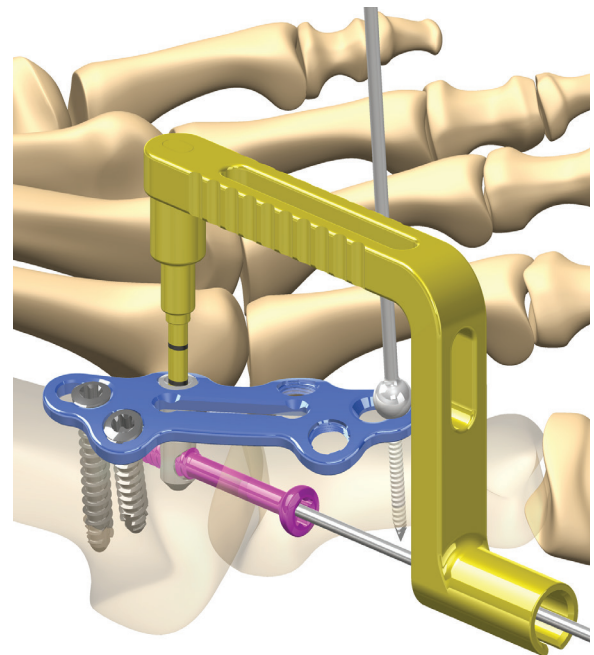
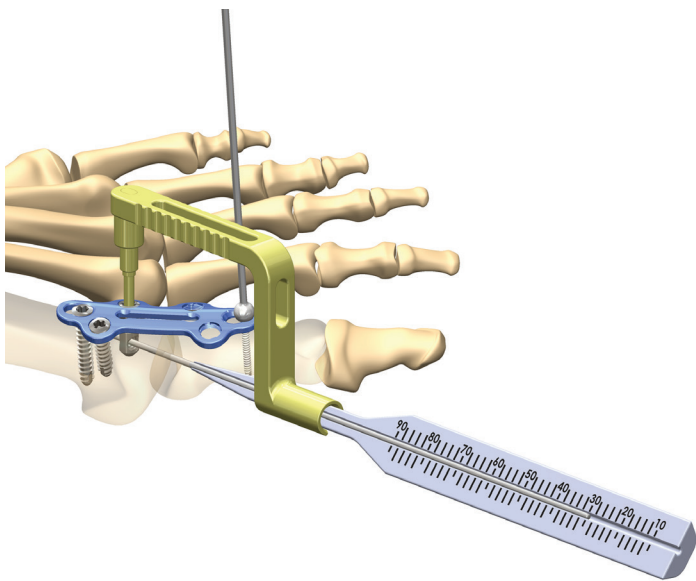
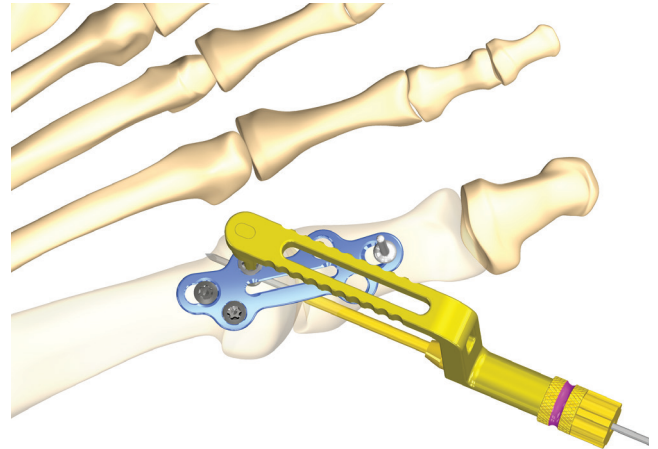
Remove the 2.5mm Drill and insert the Wire Guide into the 2.5mm Drill Sleeve.

Step 4 -Compression Screw Placement (continued)

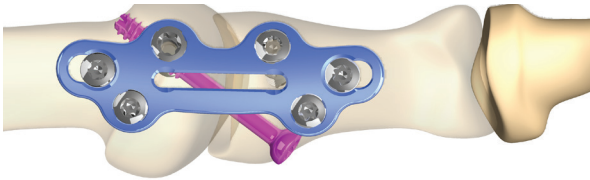
Place the Wire Guide into the 2.5 mm Drill Sleeve. Advance a 1.4 mm Guidewire through the PlantarFiX™ Compression Post approximately 5mm past the Post. Confirm Guidewire positioning and placement with fluoroscopy.

Remove the Drill Sleeve and Wire Guide. Advance the Cannulated Depth Gauge over the Guidewire and through the Targeting Guide down to bone to measure for the length of the 3.5mm Compression Screw. Insert the Compression Screw over the Guidewire (T15 Driver) until compression is achieved.

NOTE: A cannulated Headed Screw Countersink is provided in the system. Countersinking is left up to the surgeon's discretion.



Step 5. Distal Fixation



Insert the distal 2.8mm or 3.5mm Screws as desired. Each of these sized screws has a unique Drill and Drill Guide - see chart. Drill with the appropriate size solid drill. Measure screw lengths with the AO-style Depth Gauge. Place the selected solid screw with the T10 Driver. Unicortical or bicortical screw placement is left up to the surgeon's discretion.

Screw Size	Solid Drill Size	Drill Guide & Drill Colors
2.8 mm	2.4 mm	Yellow
3.5 mm	2.7 mm	Green

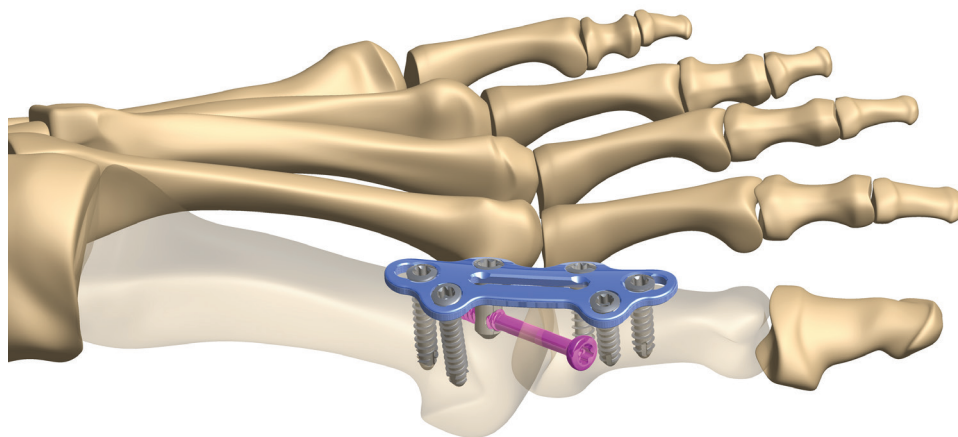
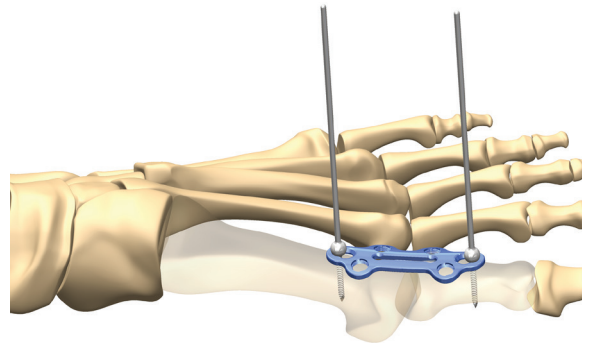


Plate with Interfragmentary Screw Outside of Plate

STEP 1 - Plate Placement and Provisional Pinning

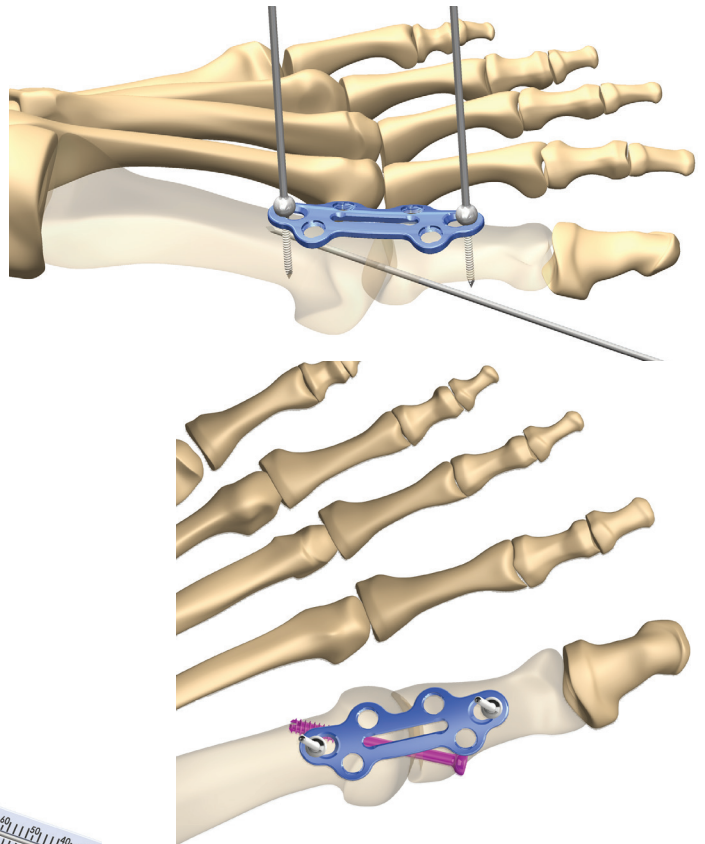
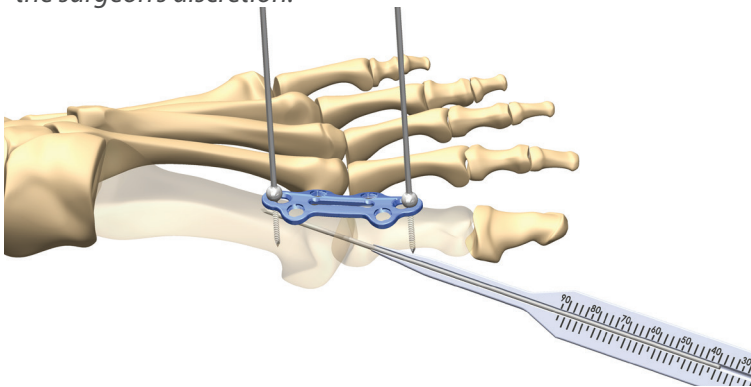
Provisionally pin the plate using Olive Wires. The Olive Wires can be placed in the slots at either end of the plate or along the central slot.



STEP 2 -Compression Screw

Insert a 1.4 mm Guidewire across the joint in an oblique fashion. Verify the placement of this Compression Screw Guidewire with fluoroscopy. Measure the length of the screw utilizing the Cannulated Depth Gauge, then drill using the 2.5 Cannulated Drill. Utilize the T15 Driver to advance the 3.5mm Compression Screw to the desired depth.

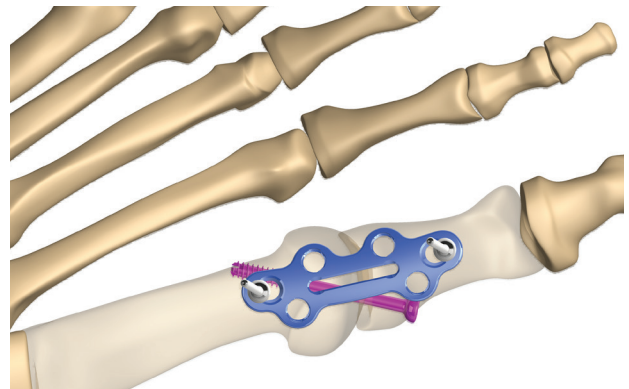
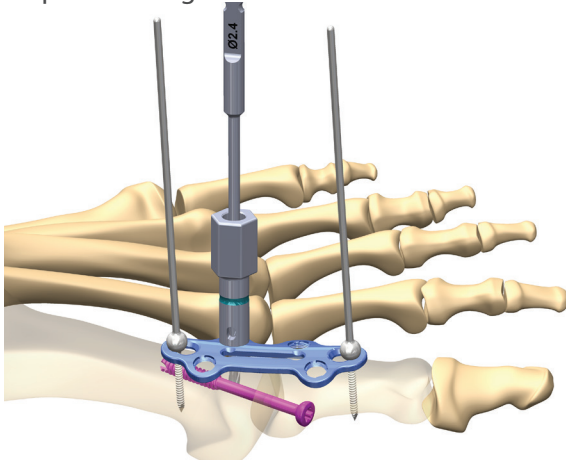
Note: A cannulated Headed Screw Countersink is provided in the system. Countersinking is left up to the surgeon's discretion.



STEP 3 - Proximal Fixation

Place the Non-Locking and/or Locking Solid Screws into the proximal portion of the plate first. Each solid screw size option (2.8mm and 3.5mm) has a unique Drill and Drill Guide - see chart. Drill with the appropriate size solid drill. Measure screw lengths with the AO-style Depth Gauge. Place the selected solid screw with the T10 Driver. Unicortical or bicortical screw placement is left up to the surgeon's discretion.

Screw Size	Solid Drill Size	Drill Guide & Drill Colors
2.8 mm	2.4 mm	Yellow
3.5 mm	2.7 mm	Green

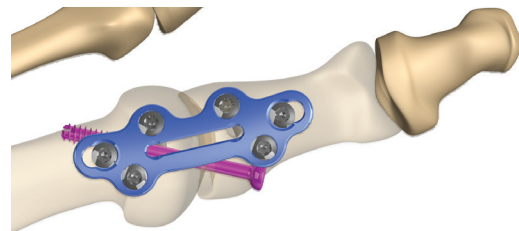
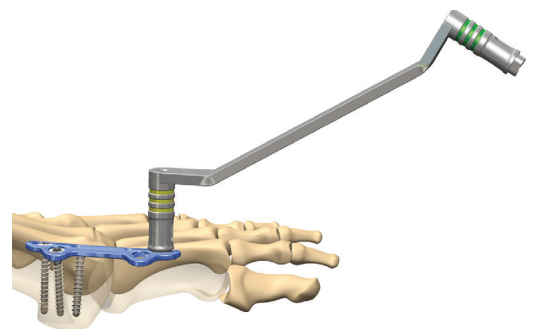


STEP 4 - Distal Fixation

The compression slots can be used to generate additional compression. To utilize the compression slot, remove the Olive Wire, and drill with the appropriate size solid drill in the most distal aspect of the slot with the compression Drill Guide. Measure for the length of the screw with the AO Style Depth Gauge. Place the selected Non-Locking Screw with the T10 Driver.

Insert all other screws as described in Step 3

Screw Size	Solid Drill Size	Drill Guide & Drill Colors
2.8 mm	2.4 mm	Yellow
3.5 mm	2.7 mm	Green

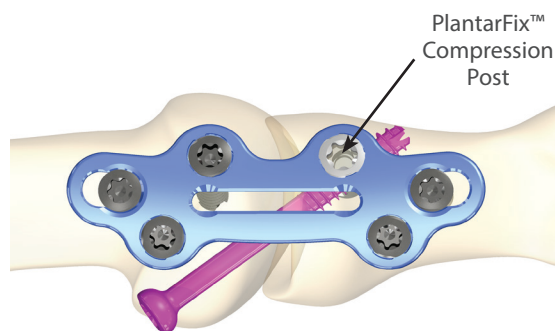


Additional Omni MTP Fixation Options

PlantarFiX™ Post in Phalanx

PlantarFiX Post Modularity

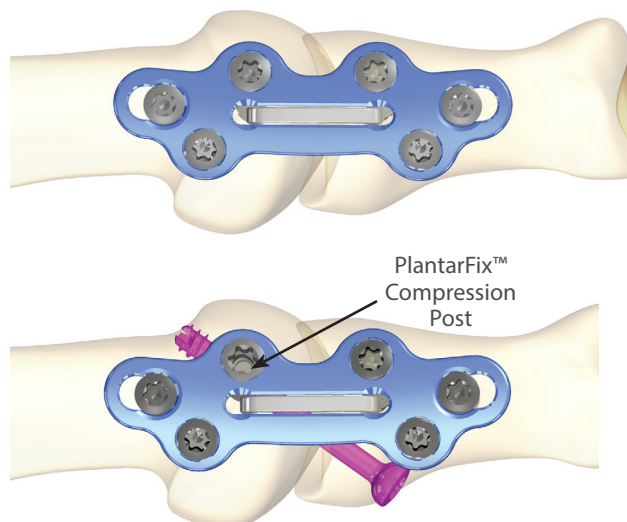
The PlantarFiX Post can be utilized in any of the locking holes of the plate.



Superelastic Nitinol Compression Staple

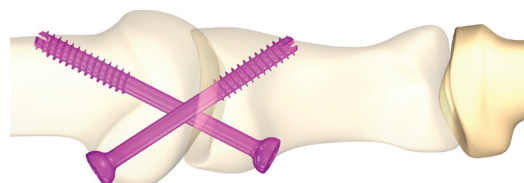
The Omni MTP Plate was designed to provide clearance for up to a 15mm Express Staple. This Superelastic staple can provide additional compression.

The system does allow for the placement of a staple in combination with the PlantarFiX™ Post.



Crossing Screws

The 3.5mm Compression Screws are cannulated and can be used as crossing screws. Place the 1.4mm Guidewire in the desired locations for the screws. Measure the Guidewires with the Cannulated Depth Gauge. Pre-drill with the 2.5mm Cannulated Drill. Insert the 3.5mm Compression Screws with the T-15 Driver.



Implants

MTP Plates

Reference #	Description
144-10011	MTP Fusion Plate, Slim, Left
144-10012	MTP Fusion Plate, Slim, Right
144-10031	MTP Fusion Plate, Universal, Short
144-10032	MTP Fusion Plate, Universal, Long

2.8mm Solid Screws

Reference #	Description
144-28010	Solid Non-Locking Screw - 2.8 x 10mm
144-28012	Solid Non-Locking Screw - 2.8 x 12mm
144-28014	Solid Non-Locking Screw - 2.8 x 14mm
144-28016	Solid Non-Locking Screw - 2.8 x 16mm
144-28018	Solid Non-Locking Screw - 2.8 x 18mm
144-28020	Solid Non-Locking Screw - 2.8 x 20mm
144-28022	Solid Non-Locking Screw - 2.8 x 22mm
144-28110	Solid Locking Screw - 2.8 x 10mm
144-28112	Solid Locking Screw - 2.8 x 12mm
144-28114	Solid Locking Screw - 2.8 x 14mm
144-28116	Solid Locking Screw - 2.8 x 16mm
144-28118	Solid Locking Screw - 2.8 x 18mm
144-28120	Solid Locking Screw - 2.8 x 20mm
144-28122	Solid Locking Screw - 2.8 x 22mm

3.5mm Solid Screws

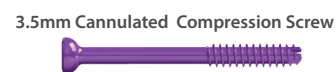
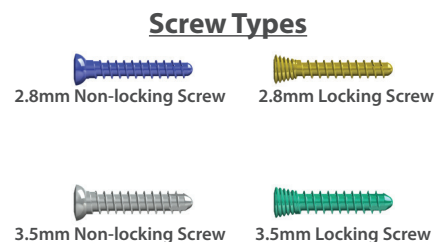
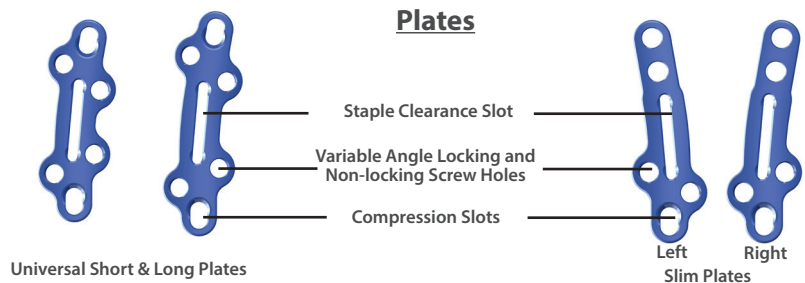
Reference #	Description
144-35010	Solid Non-Locking Screw - 3.5 x 10mm
144-35012	Solid Non-Locking Screw - 3.5 x 12mm
144-35014	Solid Non-Locking Screw - 3.5 x 14mm
144-35016	Solid Non-Locking Screw - 3.5 x 16mm
144-35018	Solid Non-Locking Screw - 3.5 x 18mm
144-35020	Solid Non-Locking Screw - 3.5 x 20mm
144-35022	Solid Non-Locking Screw - 3.5 x 22mm
144-35110	Solid Locking Screw - 3.5 x 10mm
144-35112	Solid Locking Screw - 3.5 x 12mm
144-35114	Solid Locking Screw - 3.5 x 14mm
144-35116	Solid Locking Screw - 3.5 x 16mm
144-35118	Solid Locking Screw - 3.5 x 18mm
144-35120	Solid Locking Screw - 3.5 x 20mm
144-35122	Solid Locking Screw - 3.5 x 22mm

3.5mm Cannulated Compression Screws

Reference #	Description
144-35224	Cannulated Compression Screw - 3.5 x 24mm
144-35226	Cannulated Compression Screw - 3.5 x 26mm
144-35228	Cannulated Compression Screw - 3.5 x 28mm
144-35230	Cannulated Compression Screw - 3.5 x 30mm
144-35232	Cannulated Compression Screw - 3.5 x 32mm
144-35234	Cannulated Compression Screw - 3.5 x 34mm
144-35236	Cannulated Compression Screw - 3.5 x 36mm
144-35238	Cannulated Compression Screw - 3.5 x 38mm
144-35240	Cannulated Compression Screw - 3.5 x 40mm

PlantarFix™ Compression Post

Reference #	Description
144-42112	PlantarFix™ Compression Post - 12 mm
144-42116	PlantarFix™ Compression Post - 16 mm



Post



Instrumentation

Disposable Instruments

Reference #	Description
144-00011	Olive Wire 1.6 mm, Threaded
144-00012	Headed Screw Countersink
144-00014	1.4 mm Guidewire
144-00016	Barrel Reamer
144-00025	2.5 mm Cannulated Drill
144-00003	Drill Bit for 2.8 Screw
144-00004	Drill Bit for 3.5 Screw
144-00017	2.5 mm Solid Drill with Stop
144-00018	Post/Peg Drill, 4.2mm (Gold)
113-00114	14 mm Cone Rasp
113-00116	16 mm Cone Rasp
113-00118	18 mm Cone Rasp
113-00120	20 mm Cone Rasp
113-00214	14 mm Cup Rasp
113-00216	16 mm Cup Rasp
113-00218	18 mm Cup Rasp
113-00220	20 mm Cup Rasp

Other Instruments

Reference #	Description
144-00000	OMNI MTP Fusion Tray
144-00001	OMNI MTP Fusion Implant Caddy
144-00002	Grasping Forceps
127-00006	AO Handle
144-00006	Depth Gauge for 2.8 and 3.5 screws
144-00007	Compression Drill Guide for 2.8 and 3.5 screws
144-00008	Drill Sleeve for 2.8 Screw
144-00009	Drill Sleeve for 3.5 Screw
144-00010	T10 Driver, Solid
144-00013	Depth Gauge for Cannulated Screw
144-00015	T15 Driver, Cannulated
144-00019	Wire Guide
144-00020	Targeting Guide
144-00021	Post/Peg Adjuster (Gold)
144-00022	2.5 mm Drill Sleeve
144-00023	Post/Peg Drill Guide (Gold)
144-00026	Guidewire Holder

Removal Instructions

- Clear tissue in-growth from the screws
- Insert the T10 Driver into the screw head and remove the screw from the plate by turning the Driver counter-clockwise
- Remove all screws and then the plate
- If the Plantar Compression Post and 3.5mm Compression Screw is present, remove the 3.5mm Cannulated Compression Screw and then the subsequent PlantarFiX Compression Post from the plate with the T15 Cannulated Driver prior to removing the screws in the plate

