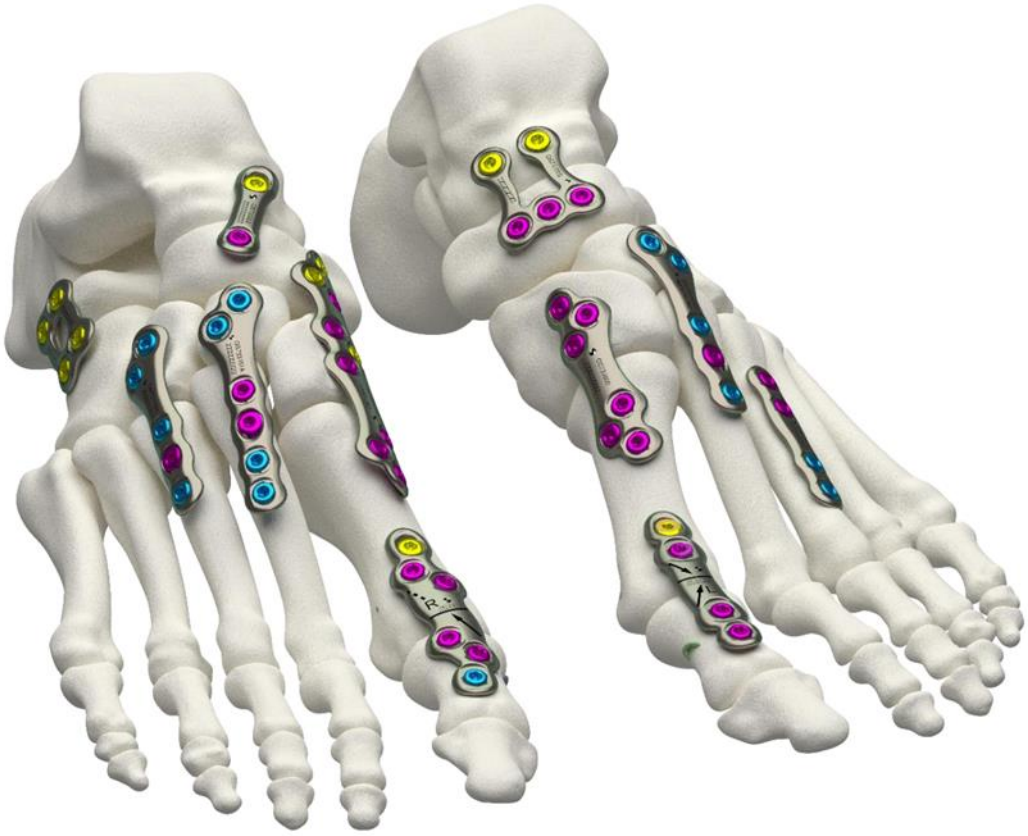
VOLITION™ PLATING SYSTEM

Foot Plates

Surgical Technique



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

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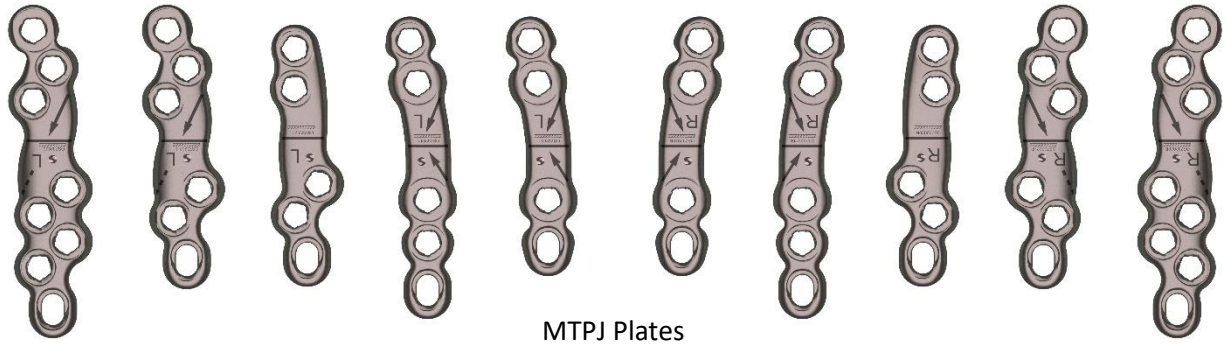
PLATING SYSTEM

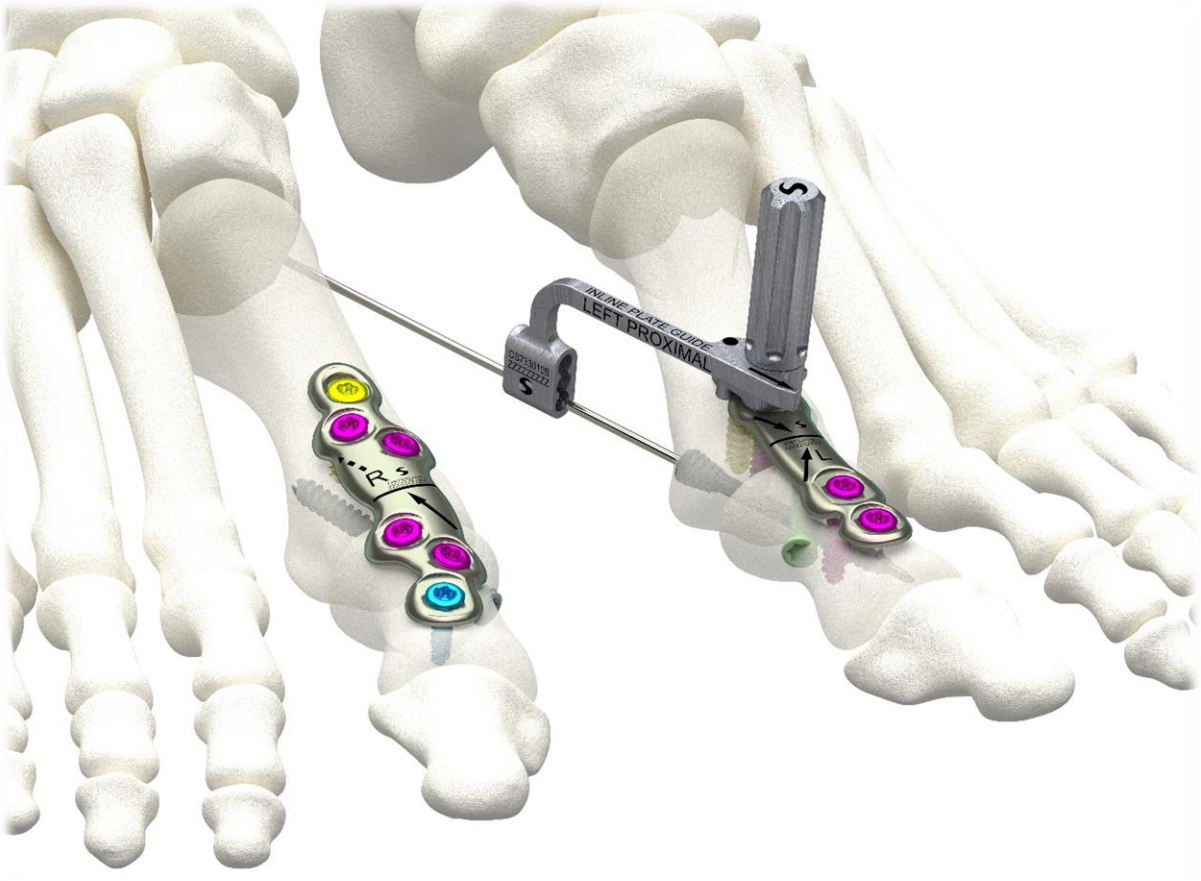
System Overview

Volition™ Foot Plates are inclusive of both Volition™ MTPJ Plates and Volition™ Utility Plates. MTPJ Plates include In-Line, Long In-Line, Narrow, Standard & Revision for both left and right rays. A plethora of plate options are available within the Utility Plate Caddy.



MTPJ Plates

MTPJ Plates work in conjunction with custom guides that enable placement of lag screw fixation to optimize compression or stabilization of the construct. These guides allow the surgeon to either shoot the lag screw from proximal to distal or distal to proximal. Further, with the In-Line MTPJ Plates, the surgeon can utilize the guides to shoot lag screws in both orientations and not run into each other.



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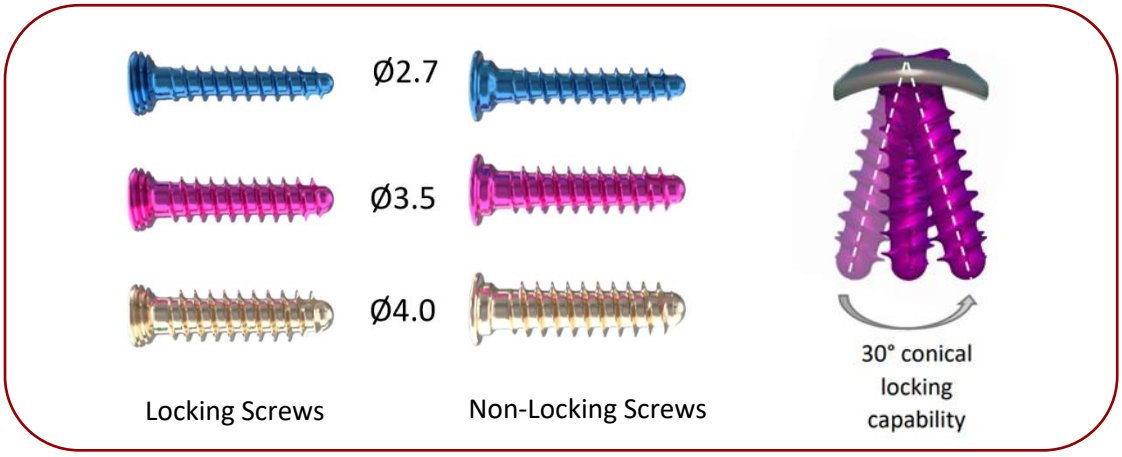
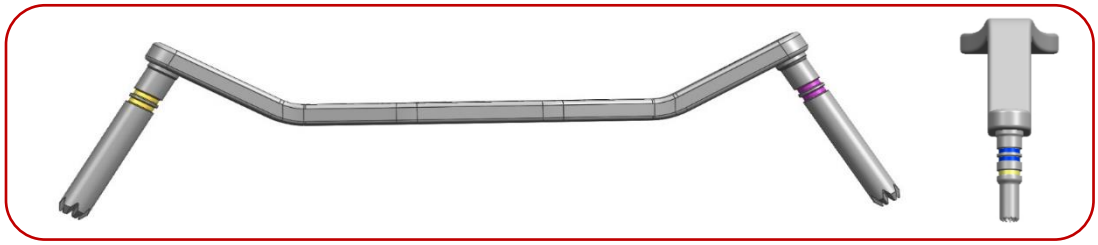
Volition™ Plating System non-locking screws are compatible with washers and any screw hole in the plates.

Volition™ Plating System locking screws are not compatible with any oblong hole; compression slot. Locking screws are also not compatible with washers.

All plate screws may be inserted through the screw holes in a ±15° conical range of trajectories. All plate screws utilize the same size driver. Each driver has a non-working AO-quick connect and a standard sized torx working end.



Pilot hole drill bits & drill guides include a single-stripe colored band denoting the color of their intended screw. Lag drill bits & drill guides are differentiated with a double-stripe colored band.



Note 1: Drill guide devices correlate specifically to the diameter of the screw which is intended to be used, and hence the appropriately sized drill bit.

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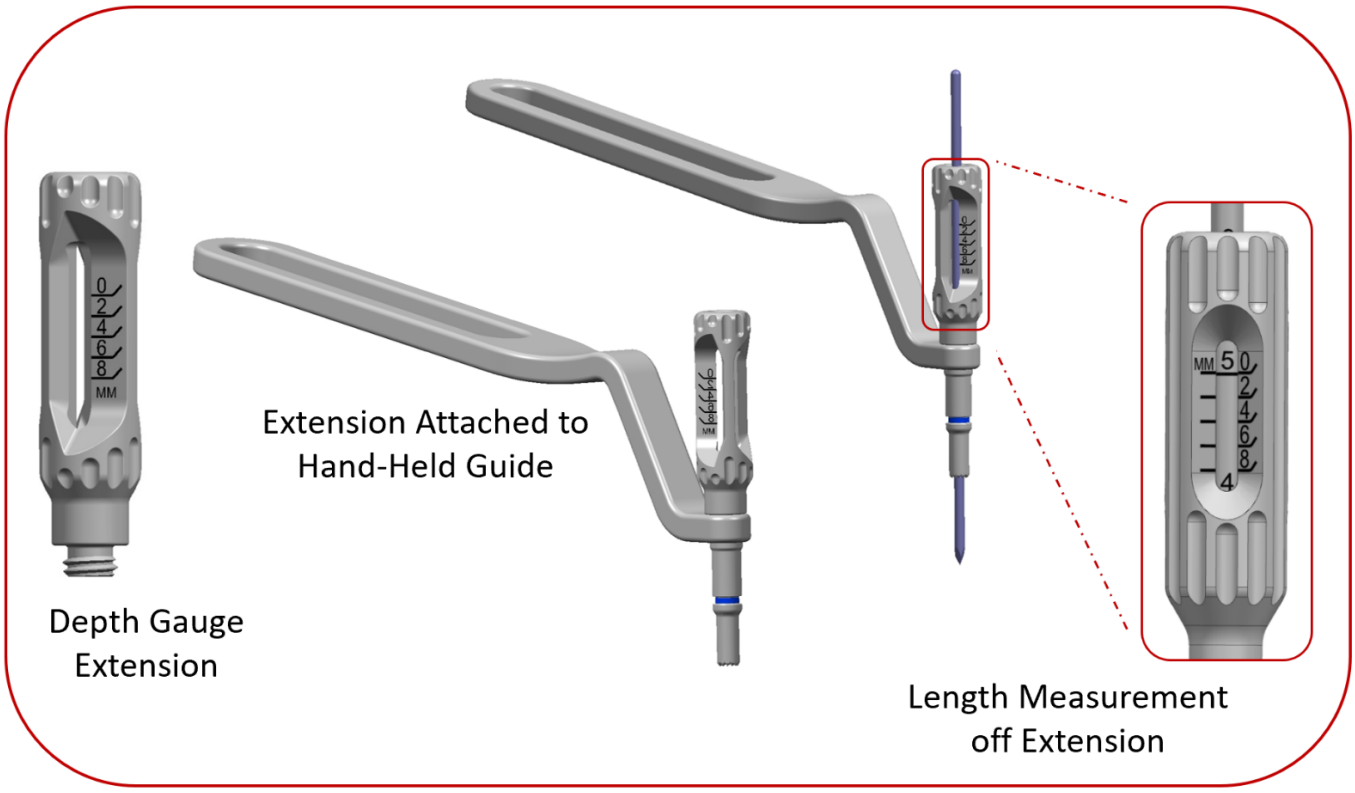
Note 2: Depth gauge extensions are compatible with all 3 diameters of pilot hole drill bits and therefore do not have any colored bands. They are not compatible with lag drill guides.

Note 3: A depth gauge extension may be optionally threaded into the top of the handheld pilot hole drill guide to determine the depth during drilling. The first digit is read from the drill bit and the second digit is read from the drill guide (e.g. "5" on the drill bit and "0" on the guide yields a 50 mm depth)



Site Preparation & Temporary Fixation

Use standard approaches and techniques to expose the anatomy. If a fracture is being fixed, clean and reduce the fracture as per standard fracture care and protocols. If a fusion or osteotomy is being performed, standard joint or osteotomy site preparation should be created with standard protocols. If desired, a fluted Fenestrator is supplied and can be used to create channels at the fusion site to help induce primary contact healing. Additionally, cup and cone reamers can be requested to use for joint preparation of the first MTPJ to create fresh, bleeding subchondral bone.

Use an appropriately sized powered k-wire driver to advance k-wires to temporarily hold the reduced bone fragments in place, if desired.

Olive wires may be inserted in any screw hole. Alternatively, k-wires may also be used to temporarily affix the plate to the bone through specific k-wire holes or wire slots within the plates. K-wire holes in the plate accept Ø1.6mm diameter wires and smaller; they are not compatible with Ø2.0mm k-wires or olive wires.

Warning: The k-wires & olive wires are not intended to be left as permanent implants.

Note 4: When loading the olive wires into a wire collet, please note that the proximal end of the olive wires is Ø2.0mm.

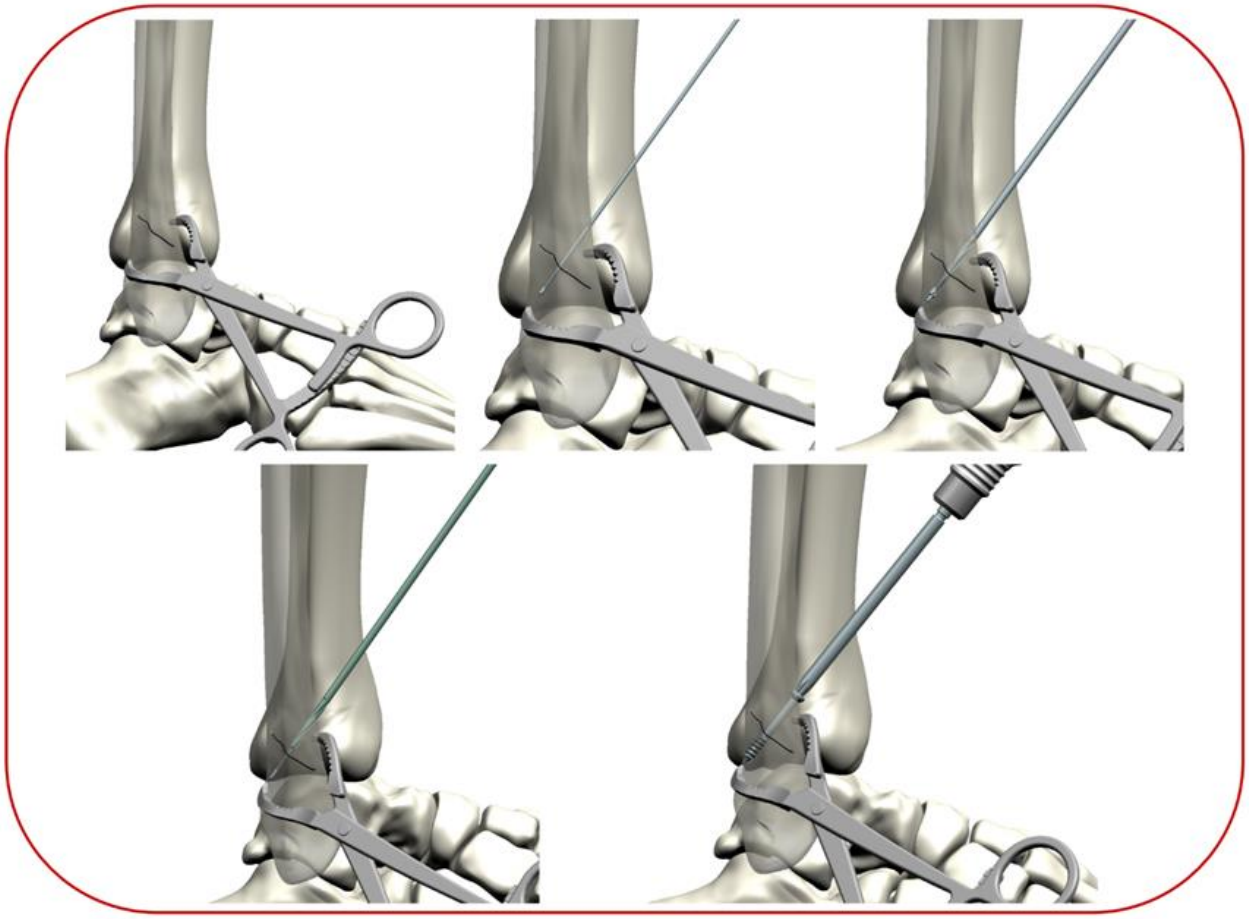
Warning: Do not use Ø2.0mm k-wires through the plates.

Screw and Washer Fixation (Without Plate)

Volition™ non-locking, solid plate screws may be used to stabilize fractures, fusions, and osteotomies without a plate. Compatible washers are also provided for optional use. Alternatively, partially threaded S26 cannulated screws are provided within the set for use if desired.

The Volition™ plate screws are fully threaded so, when used without a plate, lag-drill techniques should be used to apply compression between two bone fragments.

Drill pilot holes and lag (glide) holes for the screw using appropriately sized drill bits and handheld drill guides per the drill bit size compatibility table below. Drill bits feature an AO connector to attach to powered drills with AO couplers and lag guides indicated with double epoxy color bands.



Precaution: When intending to use a washer, do not exceed the ±15° conical compatible trajectories.

Precaution: Do not attempt to read depth measurements from the top of the drill guides. Use depth measurement instruments only as instructed in this technique.

Drill bit size compatibility

Screw Dia. (mm)	Pilot Drill Bit Dia. (mm)	Lag Drill Bit Dia. (mm)
Ø2.7	Ø1.9	Ø2.7[1]
Ø3.5	Ø2.4	Ø3.5
Ø4.0	Ø2.7[1]	Ø4.0

[1] The Ø2.7 mm drill bit and drill guides are dual purpose: for use with Ø4.0 mm screws (pilot hole) and for Ø2.7 mm screws (lag).

If the pilot hole depth wasn't measured during drilling, use the standard depth probe to measure the drilled depth by placing the narrow end of the outer housing directly against the near cortex and sliding the probe to hook on the far cortex.

Countersinks are provided to optionally ream the near cortex to minimize screw head prominence when used without a plate or washer. If desired, attach the AO countersink to either AO handle.

Precaution: Do not use the countersink with powered instruments.

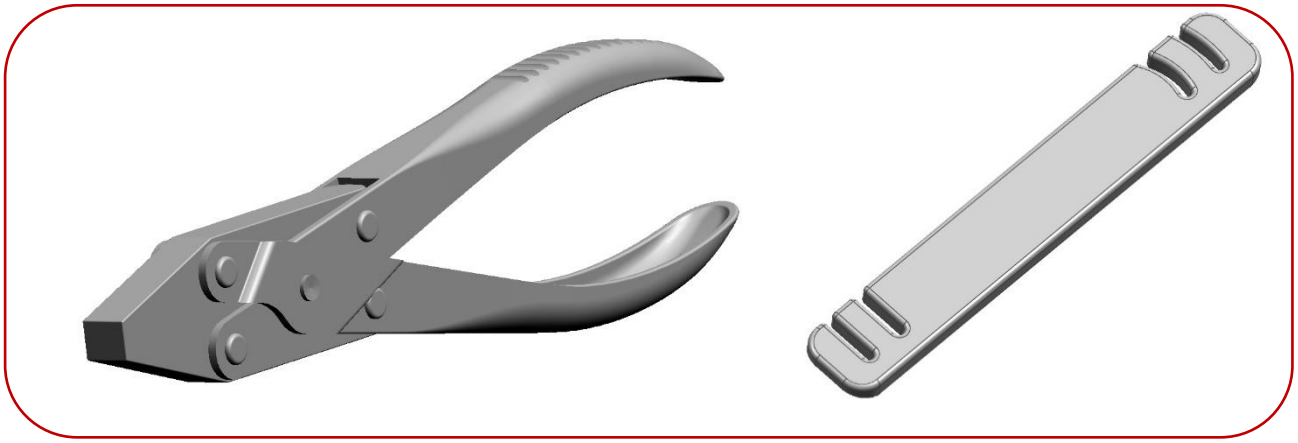
Attach the AO screwdriver bit to either AO handle to insert the screw.

Precaution: Do not use the screwdriver bits with powered instruments.

Plate Fixation

Choose the plate to implant and fit the plate to the bone, if needed, to capture the bone fragments.

Two styles of plate bending instruments are provided to optionally contour the plates to fit the bone. Plate bending pliers feature flat jaws to grip various positions on the plates. Plate bending irons feature various flat and curved slots to fit the plates in multiple positions.



Precaution: Contouring or bending implants should be avoided, where possible, because it may reduce the device's fatigue strength. If contouring is necessary, avoid sharp bends, reverse bends, or bending the device at a screw hole. When contouring implants, only Ortho Solutions instruments are to be used in accordance with the specified protocols.

Use two or more olive wires, or Ø1.6 mm k-wires, to temporarily affix the plate to the bone before screw insertion. Olive wires may be inserted through any of the plate's screw holes. Alternatively, Ø1.6 mm k-wires may be inserted through any of the plate's k-wire holes or wire slots.

Drill pilot holes for the screws using appropriately sized drill bits and drill guides as previously mentioned. If off-axis screw trajectory is desired, use the appropriately sized conical drill guides by threading them into the plate hole; each screw size has a corresponding drill guide – tower guides for on-axis drilling or conical guides for off-axis drilling. Alternatively, simple hand-held guides may be used to drill for non-locking screws.

Precaution: Do not exceed the ±15° conical range of compatible trajectories in any screw hole.
Note: The drilled depth may also be measured via the aforementioned technique from the depth gauge extender, by using the fixed angle drill guide or via a standard depth gauge.

If the pilot hole depth wasn't measured during drilling, use the standard depth probe to measure the drilled depth by placing the narrow end of the outer housing directly against the near cortex/plate hole and sliding the probe to hook on the far cortex.

Attach the AO screwdriver bit to either AO handle to insert the screw.

Precaution: Do not use the screwdriver bits with powered instruments.

Implant as many screws as necessary to stabilize the bone fragments. Additional screws may be implanted outside the plate as per **Screw and Washer Fixation (Without Plate)** above.

Creating Compression

If compression is desired across the fracture, fusion or osteotomy site, there are three options: 1) utilization of the compression ramp within a plate (if applicable as not all plates contain a compression ramp), 2) utilization of the custom compression/distraction handle or 3) utilization of a lag screw outside of the plate.

In order to create compression from the compression ramp within the plate, temporarily affix the plate to bone using either the provided olive wires or Ø1.6mm k-wires as described per **Plate Fixation** above. In this instance, do not place an olive wire into the compression slot.

A first screw should be inserted into the plate on the opposite side of the fracture, fusion or osteotomy where in relation to the compression ramp as described per **Plate Fixation** above.

Then using a handheld drill guide corresponding to the screw diameter of choice, place the tip of the guide as far from the fracture, fusion or osteotomy as possible and drill with the drill bit which corresponds to the screw diameter of choice.

Once drilled, fill the drill hole with the Non-locking screw and corresponding diameter in relation to drill hole prepared. Do not fully seat the seat screw; insert screw only until head and neck of the screw remain above the plate.

Remove all olive wires and or k-wires at this point that have been used in conjunction with temporary fixation of the plate to the bone(s).

Continue to advance the screw within the compression ramp until adequate compression is achieved or until the screw head is flush to the top surface of the plate.

In order to create compression from the Handheld Compressor/Distractor Device, temporarily affix the plate to bone using either the provided olive wires or Ø1.6mm k-wires as described per **Plate Fixation** above. In this instance, do not place an olive wire into the compression slot.

The Handheld Compressor/Distractor Device can be used after placing a screw in the compression ramp or prior to any screw insertion via placement of the device outside of the plate.

Precaution: Do not use the Handheld Compressor/Distractor Device after a lag screw has been implanted as this will loosen the fixation of said lag screw.

If the Handheld Compressor/Distractor Device is preferred to be utilized, insert a non-locking screw as described above but do not fully seat the screw in the compression slot.

Slide one eyelet of the Handheld Compressor/Distractor Device over the k-wire or olive wire that is used to stabilize the plate to the bone on the opposite side of the fracture, fusion or osteotomy as the other eyelet (such that the eyelets of the Handheld Compressor/Distractor Device span the fracture, fusion or osteotomy site).

Locate the other eyelet of the Handheld Compressor/Distractor Device on the side with the compression ramp of the plate over bone.

Insert a k-wire through the remaining eyelet and squeeze the Handheld Compressor/Distractor Device until adequate compression is achieved.

Finish torquing the non-locking screw in the compression ramp until it is fully seated into the plate.

Place a locking screw into any remaining screw hole on the side of the plate with the compression ramp in order to maintain the compression achieved. Remove all k-wires and olive wires at this point as well as the Handheld Compressor/Distractor Device.

In order to create compression via utilization of a lag screw outside of the plate, temporarily affix the plate to bone using either the provided olive wires or Ø1.6mm k-wires as described per **Plate Fixation** above. In this instance, do not place an olive wire into the compression slot.

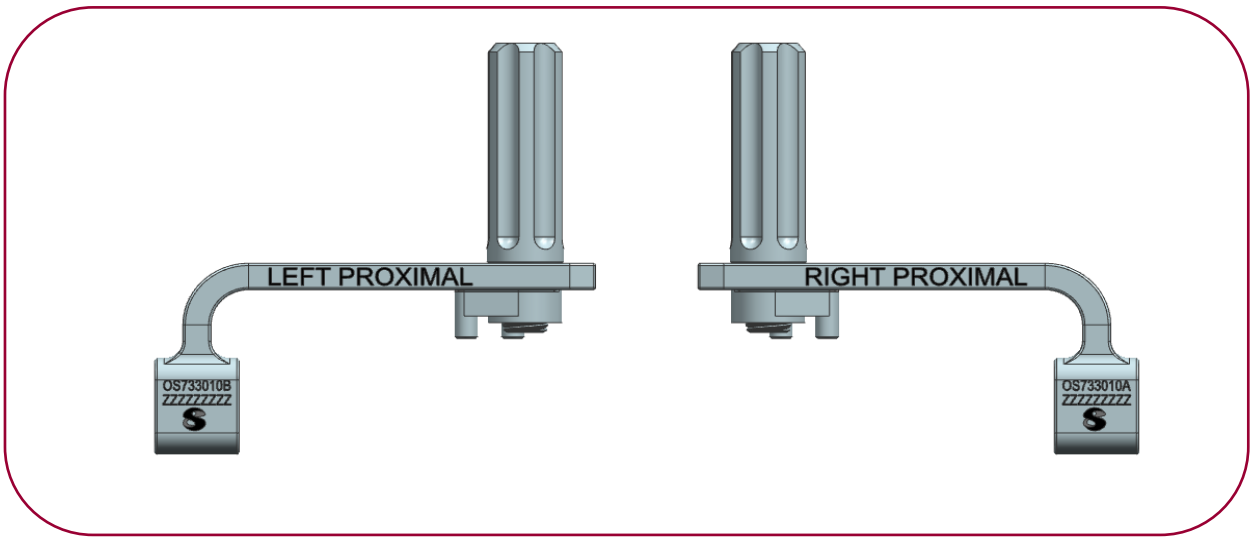
If lag screw technique is preferred, a lag screw can be placed across the fracture, fusion or osteotomy site prior to plate implantation or prior to the plate being permanently affixed to the bone. A lag screw can be utilized with or without the aid of the Compressor/Distractor Device.

The lag screw technique can be utilized as described per **Screw and Washer Fixation Without a Plate** above. Alternatively, S26 Cannulated Screws may be used which can be found within the set. If the latter is desired, please refer to that separate technique.

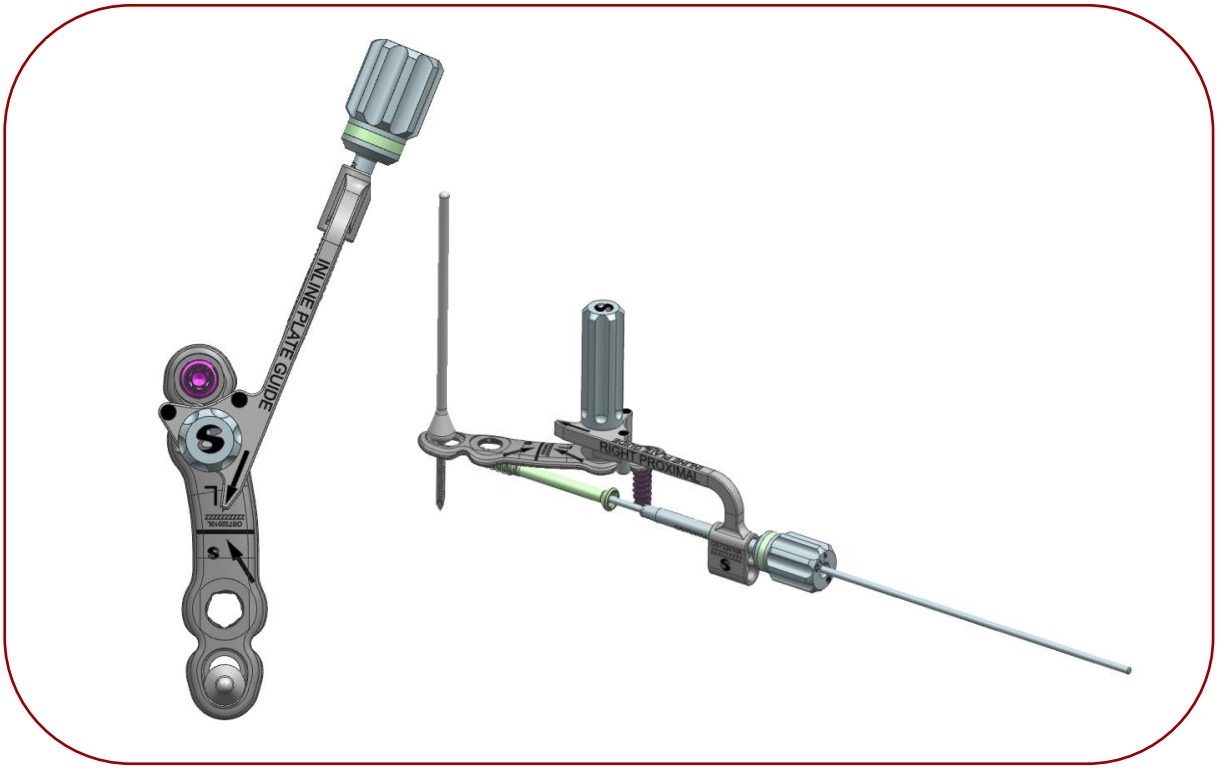
Using In-Line MTPJ and MTPJ Plate Guides

If an In-Line MTPJ Plate is to be implanted, custom lag guides can be utilized to aid in insertion and placement of the lag screw across the joint. Further, the guides can either aid in placement of a single lag screw, from either proximal to distal or distal to proximal, or both. These guides are pictured below.

The Right Proximal In-Line Guide should be utilized when targeting a lag screw in conjunction with either a Right In-Line Plate when placing a screw from proximal to distal OR in conjunction with a Left In-Line Plate when placing a screw from distal to proximal. The contrary is also applicable: a Left Proximal In-Line Guide should be utilized when targeting a lag screw with a Left In-Line Plate when placing a screw from proximal to distal OR in conjunction with a Right In-Line Plate when placing a screw from distal to proximal.



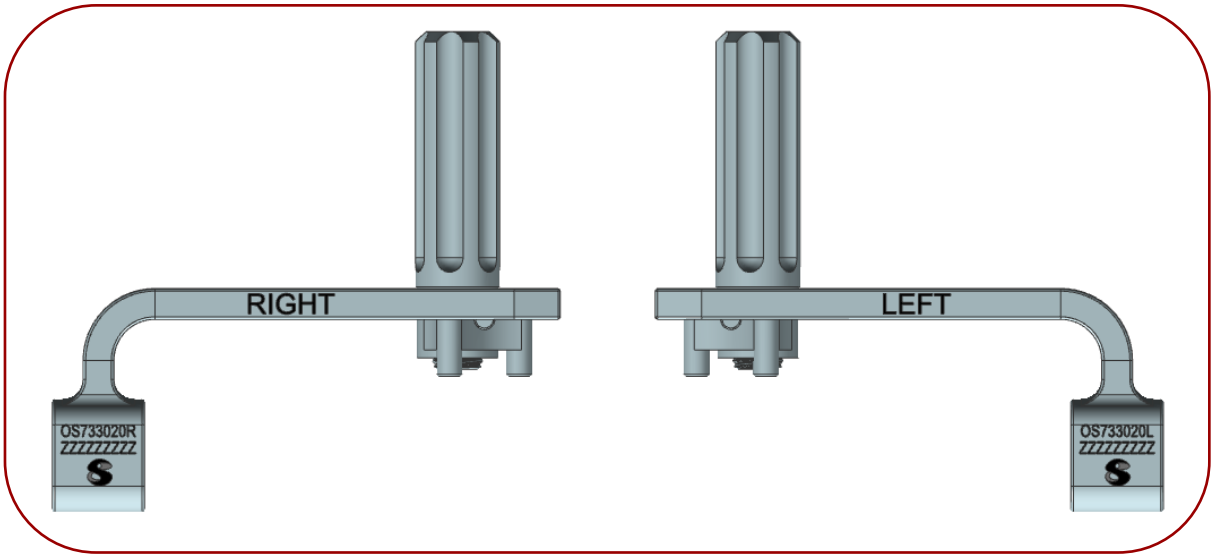
Once the appropriate guide is affixed to the plate in the correct orientation, shoot a Ø1.6mm k-wire through the desired eyelet on the targeting guide. Ensure that a screw has already been placed into the plate distal to the joint and that an olive wire has been placed into the proximal aspect of the compression slot.



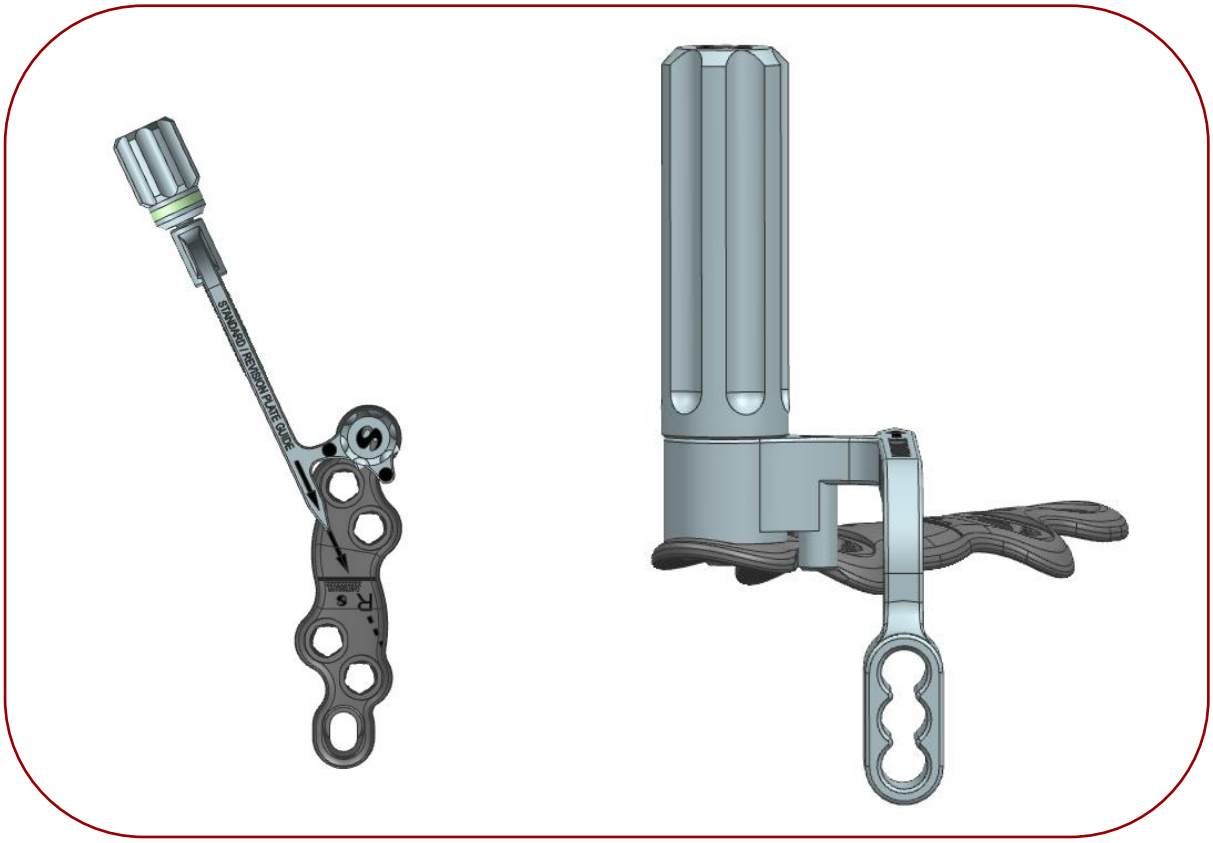
Note 5: ensure that the locking set tower is tightened to the plate prior to inserting the guide wire sleeve into the guide.

Note 6: there is a guide arrow located on the guide arm of the drill guide that indicates the approximate orientation of the lag screw relative to the plate.

If a Narrow, Standard or Revision MTPJ Plate is to be implanted, custom lag guides can be utilized to aid in insertion and placement of the lag screw across the joint. These guides can either be utilized for lag screw placement from either proximal to distal OR distal to proximal, but not both with these plates.



For use in conjunction with the MTPJ Narrow, Standard or Revision Plates, the Right Guide is to be utilized in conjunction with the Right Plate whether the preferred lag screw placement is distal to proximal or proximal to distal. The same is true for the Left side.



Surgery Completion

Remove any temporary fixation wires, instruments, or other non-implantable components from the patient prior to the completion of surgery.

Check implant positioning in multiple planes using fluoroscopy.

Close the surgical incision using the desired technique.