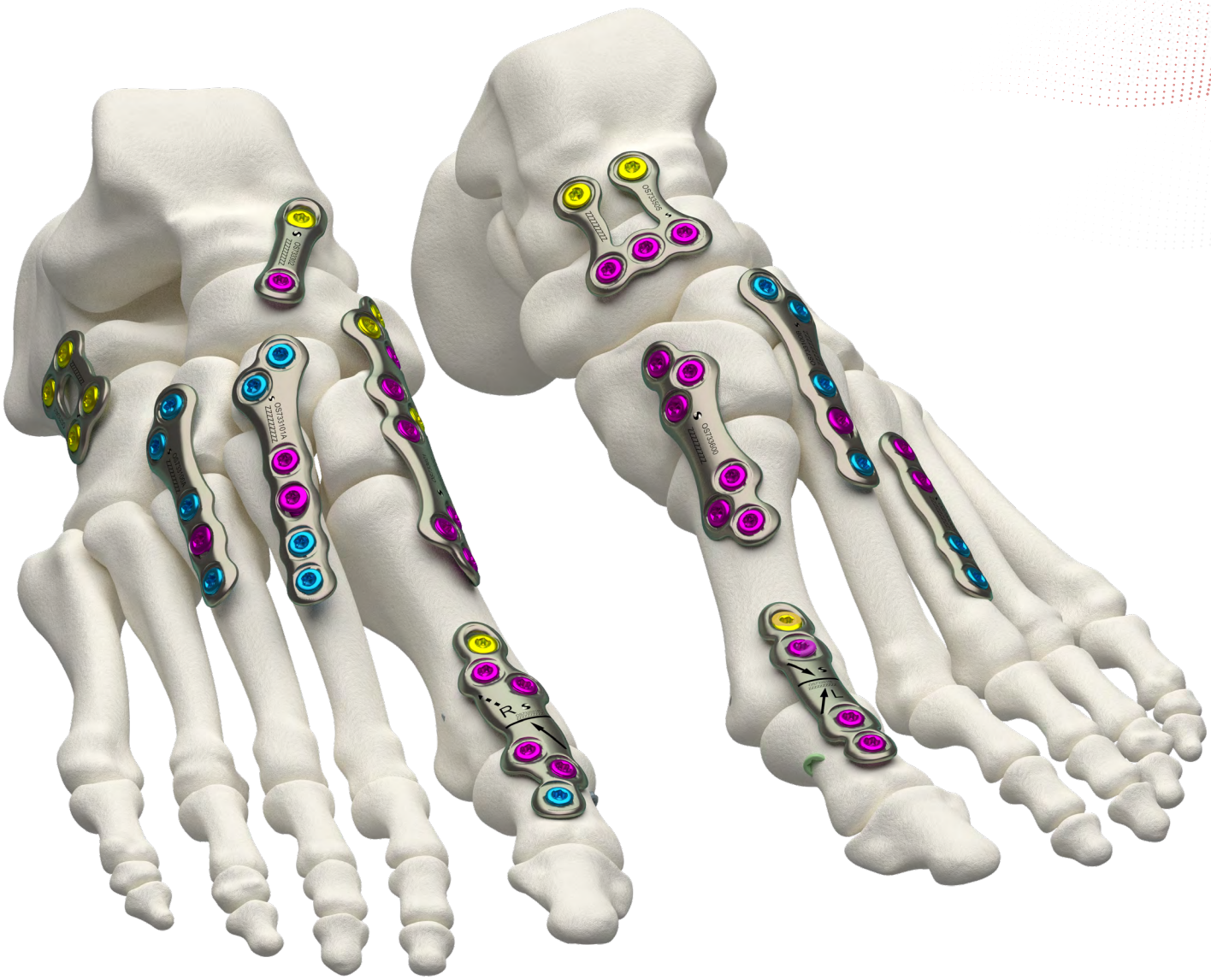


VOLITION® Plating System.
MTPJ and Utility Plates Surgical Technique

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

OrthoSolutions Group

Advancing Foot & Ankle Care

CONTENTS

3. Plate Guide Instructions

4. Tips for Using Guides

Volition®
PLATING SYSTEM

This surgical technique guide is intended as a reference for trained orthopaedic surgeons. It does not replace the full Instructions for Use (IFU), which contains material/allergen/biocompatibility information, indications, contraindications, warnings and precautions, sterilisation/processing instructions, an MRI safety statement and other information critical to safe and effective device usage.

Surgeons should consult the IFU before use. The IFU for the Volition® Plating System is available electronically at www.orthosol.com/eIFU or in paper form upon request by contacting regulatory@orthosol.com.

1. Volition® Plating System Overview

1.1 Plating Options

Volition® Foot Plates are inclusive of both Volition® MTPJ Plates and Volition® Utility Plates. MTPJ Plates include In-Line, Long In-Line, Narrow, XS (not shown in diagram below), Standard & Revision for both left and right rays. A plethora of plate options are available within the Utility Plate Caddy.

MTPJ Plates

1.2 Plating Guides

The Volition® MTPJ Plate range work in conjunction with specific plate guides. This enables placement of a desired lag screw to increase construct stability. In-Line plates allow proximal-to-distal and/or distal-to-proximal trajectory; Standard and Revision plates allow distal-to-proximal trajectory only.

1.3 V-Lock® Technology

V-Lock® Technology provides secure, polyaxial screw locking with up to 30 degrees of conical freedom, giving surgeons the flexibility to optimise screw trajectory. The system allows controlled polyaxial screw placement before locking and offers a simplified technique while maintaining the benefits of a locking construct.

1.4 VOLITION® Screw Fixation

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

The 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 utilise a self-retaining T10 Screwdriver bit (OS721010-NS).

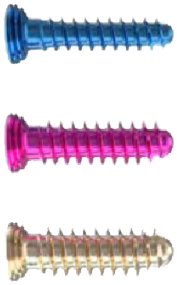
1.5 Drill Guides & Measurement

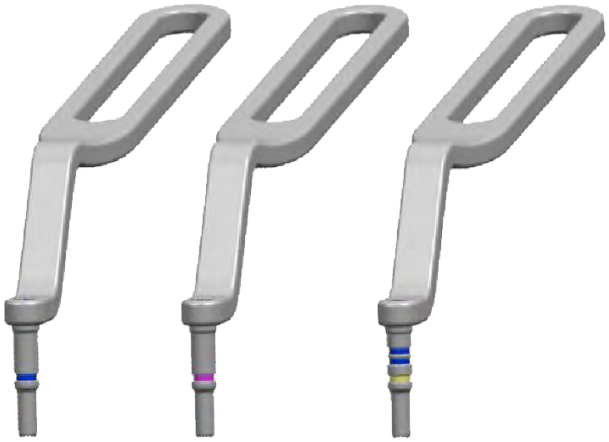
Drill guide devices correlate specifically to the diameter of the screw which is intended to be used, and hence the appropriately sized drill bit.

Fixed-Angle Drill Guides (Towers)

Variable-Angle Drill Guides (Cones)

Color Scheme:
Blue: Ø2.7mm
Magenta: Ø3.5mm
Gold: Ø4.0mm





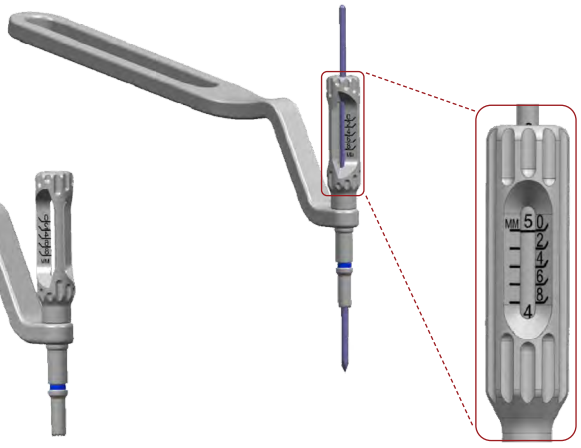
Hand-Held Drill Guides for NL Screws

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

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 50mm depth)

Depth Gauge Extension

Extension Attached to Hand-held Guide



Length Measurement off Extension

2. Surgical Guidance

2.1 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 Fenestrator Ø1.8mm (OS722118-S) is supplied and can be used to create channels at the prepared 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 (OS722216-S or OS722116-S) may be inserted in any screw hole within the desired plate.

Warning: *Any k-wires & olive wires (OS722216-S or OS722116-S) are not intended to be left in-situ as permanent implants.*

When loading the olive wires into a wire collet, please note that the proximal end of the olive wires (OS722216-S or OS722116-S) are Ø2.0mm in diameter.

2.2 Screw & Washer Fixation (Outside of Plate)

The Volition® Plating System non-locking plate screws may be used to stabilise fractures, fusions, and osteotomies without being inserted into a plate. Compatible washers are also provided for optional use (OS710000-S). Alternatively, partially threaded 3.5mm headed or headless cannulated screws are provided within the set for use, if desired.

The Volition® Plating System non-locking 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 colour 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 Ø2.7mm drill bit and drill guides are dual purpose: for use with Ø4.0mm screws (pilot hole) and for Ø2.7mm screws (lag).

If the pilot hole depth was not measured during drilling, use the UltOS/Volition depth gauge (OS328001-NS) 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 minimise screw head prominence when used without a plate or washer. If desired, attach the relevant AO countersink to either AO handle.

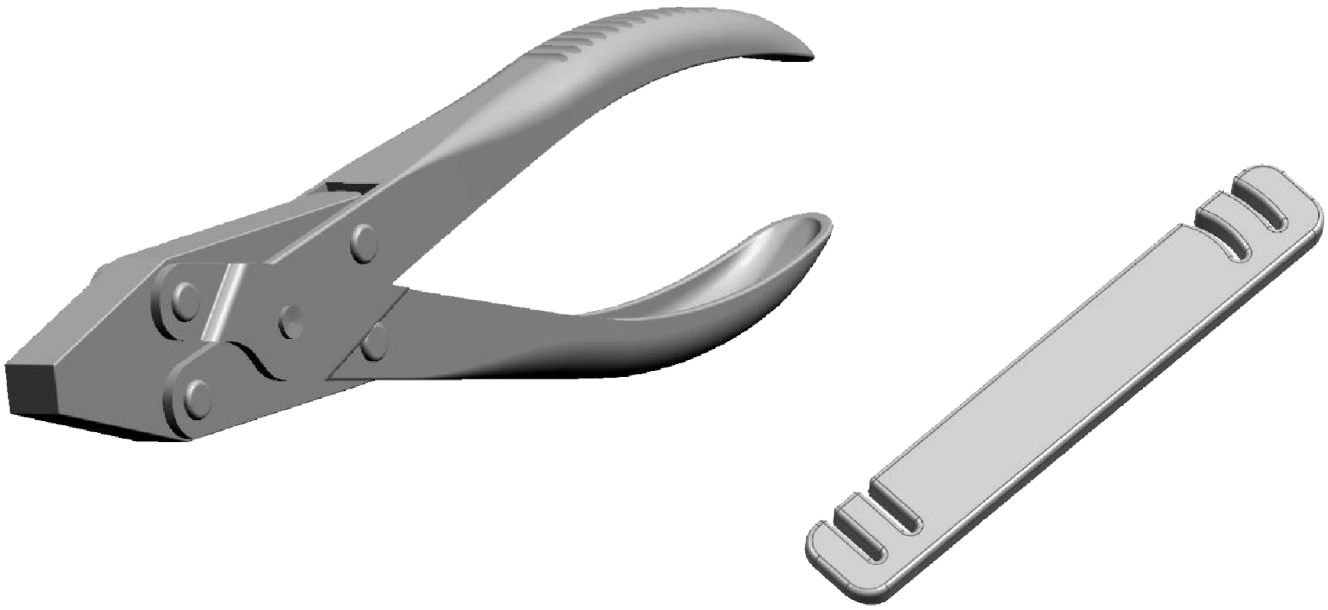
Precaution: Do not use the countersink with powered instruments.

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

2.3 Plate Fixation

Choose the desired 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, as 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 designated Ortho Solutions® instruments are to be used in accordance with the specified protocols (UltOS 3.5mm Parallel Plate Bending Pliers, OS328008-NS or the Plate Bending Iron, OS721004-NS).

Use two or more olive wires (OS722216-S or OS722116-S), to temporarily affix the plate to the bone before screw insertion. Olive wires (OS722216-S or OS722116-S) may be inserted through any of the screw holes within the plate.

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

Drill pilot holes for the screws using appropriately sized drill bits and drill guides as previously mentioned. If an '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. If an 'on-axis' screw trajectory is desired, use the appropriately sized tower drill guides by threading them into the plate hole; each screw size has a corresponding drill guide. 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 was not measured during drilling, use the UltOS/Volition depth gauge (OS328001-NS) 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 bit with powered instruments.

Implant as many screws as necessary to stabilise the bone fragments. Additional screws may be implanted outside the plate as described earlier.

2.4 Creating Compression

If compression is desired across the fracture, fusion or osteotomy site, there are three options:

1) Utilisation of the compression slot within a plate (if applicable as not all plates contain a compression slot).

2) Utilisation of the handheld Compression Distraction Device.

3) Utilisation of a lag screw outside of the plate.

2.5 Utilisation of the Compression Slot within the Plate

In order to create compression from the compression slot within the plate, temporarily affix the plate to bone using the provided olive wires (OS722216-S or OS722116-S), as described in section 2.3 ‘Plate Fixation’. In this instance, do not place the olive wires, (OS722216-S or OS722116-S) into the compression slot.

The first screw should be inserted into the plate on the opposite side of the fracture, fusion or osteotomy where in relation to the compression slot.

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, insert the desired non-locking screw and corresponding diameter into the prepared drill hole. Do not fully seat the seat the non-locking screw; insert as far as the head and neck of the screw remain above the plate.

Remove all olive wires (OS722216-S or OS722116-S) 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 slot until adequate compression is achieved or until the screw head is flush to the top surface of the plate.

2.6 Utilisation of the handheld Compression Distraction Device (OS900091-NS)

In order to create compression from the handheld Compression Distraction Device (OS900091-NS), temporarily affix the plate to bone using the provided olive wires (OS722216-S or OS722116-S). In this instance, do not place an olive wire into the compression slot of the plate.

The handheld Compression Distraction Device (OS900091-NS) can be used after placing a screw in the compression slot or prior to any screw insertion via placement of the device outside of the plate.

Precaution: Do not use the handheld Compression Distraction Device (OS900091-NS) after a lag screw has been implanted as this could potentially loosen the fixation of the implanted lag screw.

If the handheld Compression Distraction Device (OS900091-NS) is preferred to be utilised, 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 Compression Distraction Device (OS900091-NS) over the olive wire (OS722216-S or OS722116-S) that is used to stabilise 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 Compression Distraction Device (OS900091-NS) span the fracture, fusion or osteotomy site).

Place the other eyelet of the handheld Compression Distraction Device (OS900091-NS) on the side with the compression slot of the plate over bone.

Insert a Ø2.0mm k-wire (OS292220-S) through the remaining eyelet and squeeze the handheld Compression Distraction Device (OS900091-NS) until adequate compression is achieved.

Return to the inserted non-locking screw and continue to advance the screw within the compression slot until adequate compression is achieved or until the screw head is flush to the top surface of the plate.

Insert locking screws into any remaining screw holes on the side of the plate with the compression slot in order to maintain the compression achieved. Remove all k-wires and olive wires (OS722216-S or OS722116-S) at this point as well as the handheld Compression Distraction Device (OS900091-NS).

2.7 Utilisation of a Lag Screw Outside of the Plate Construct

In order to create compression via utilisation of a lag screw outside of the plate, temporarily affix the plate to bone using the provided olive wires as described in section 2.3 **'Plate Fixation'**. 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 utilised with or without the aid of the Compression Distractor Device (OS900091-NS).

The lag screw technique can be utilised as described in section 2.2 **'Screw and Washer Fixation (outside of Plate)'**. Alternatively, 3.5mm headed or headless partially threaded Cannulated Screws may be used which can be found within the set. If the latter is desired, please refer to the 'Using In-Line and MTPJ Plate Guides' instructions below.

3. Plate Guide Instructions

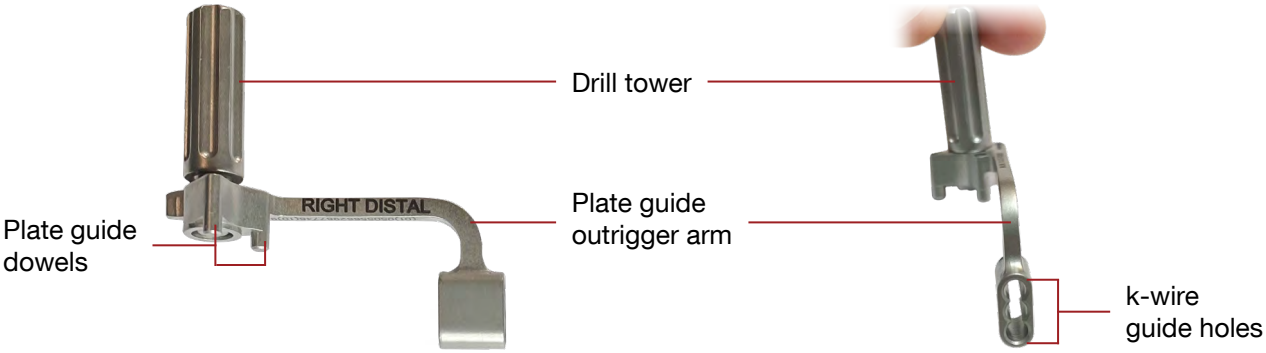
3.1 Plate Guide for In-Line MTPJ Plates

2 plate guides for the Inline plates to allow lag screw trajectory - proximal to distal and/or distal to proximal:

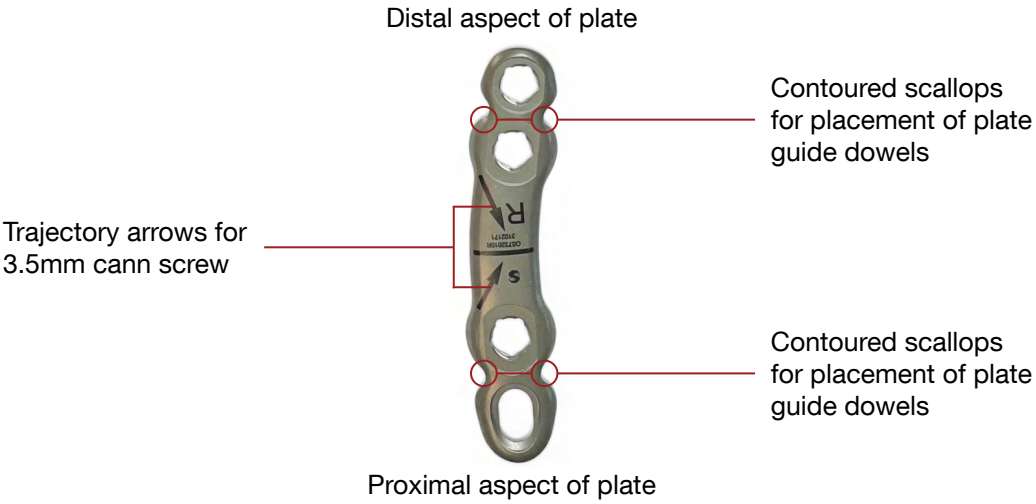
1 plate guide - Right distal/Left proximal (Alpha)

1 plate guide - Right proximal/Left distal (Beta)

3.2 Components of the Plate Guide for In-Line MTPJ Plates



In-Line MTPJ Plate



3.3 In-Line MTPJ Plate - Plate Guide attachment

- Ascertain screw trajectory
  (distal to proximal or proximal to distal)

- Choose correct plate guide
  (R distal/L proximal or R proximal/L distal)

- Place plate guide dowels into contoured scallops on plate

- Fix by threading drill tower into plate screw hole

NOTE: the arrow on the plate guide should sit directly over the arrow etched on the plate

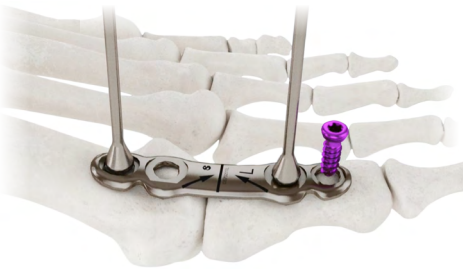
3.3 In-Line MTPJ Plate - Plate Guide attachment

Ensure temporary fixation of the joint has been undertaken prior to plate placement

Place plate onto desired position

Initially fix using Olive wires

Using an appropriate drill guide and drill, perform drilling the most distal screw hole of the plate

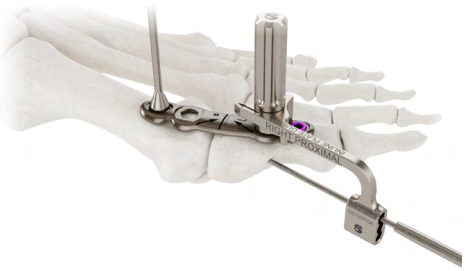


The screw should be advanced to a position where the head is flush with the plate

Remove the most distal olive wire

Insert appropriate In-Line MTPJ Plate Guide onto the available distal plate screw hole

Insert k-wire guide into top slot of the distal Plate Guide if a dual cross screw construct is desirable



NB: If a single crossing-screw construct is desirable, optimal location of the Guide Insert is into the middle slot of the Plate Guide

Insert 1.4mm x 150mm k-wire through the k-wire guide and advance into the phalanx. Keep advancing k-wire until the lateral cortex of the metatarsal is reached

Remove the k-wire guide from the Plate Guide and unscrew the Plate Guide from the plate

Measurement of the required screw length is established using the cannulated depth gauge

Use 2.6mm cannulated drill prior to advancing the screw. Ensure the screw head is flush, taking care not to fracture the cortex

3.3 In-Line MTPJ Plate - Plate Guide attachment

Remove the most proximal olive wire

Using an appropriate drill guide and drill, perform drilling the most proximal screw hole of the plate

The screw should be advanced to a position where the head is flush with the plate

Insert appropriate In-Line MTPJ Plate Guide onto the available proximal plate screw hole

Insert k-wire guide into bottom slot of the proximal Plate Guide if a dual cross screw construct is desirable

NB: If a single crossing-screw construct is desirable, optimal location of the Guide Insert is into the middle slot of the Plate Guide

Insert 1.4mm x 150mm k-wire through the k-wire guide and advance into the metatarsal bone. Keep advancing k-wire until the lateral cortex of the phalanx is reached

Remove the k-wire guide from the Plate Guide and unscrew the Plate Guide from the plate

Measurement of the required screw length is established using the cannulated depth gauge

Use the 2.6mm cannulated drill prior to advancing the screw. Ensure the screw head is flush, taking care not to fracture the cortex

Using an appropriate drill guide and drill, perform drilling the remaining screw holes of the plate

The screws should be advanced to a position where the head is flush with the plate

3.4 MTPJ Plate Guide for MTPJ Extra Short (XS) Plate, to allow Lag Screw Trajectory Distal to Proximal

3.5 Components of the MTPJ Plate Guide for MTPJ XS Plate

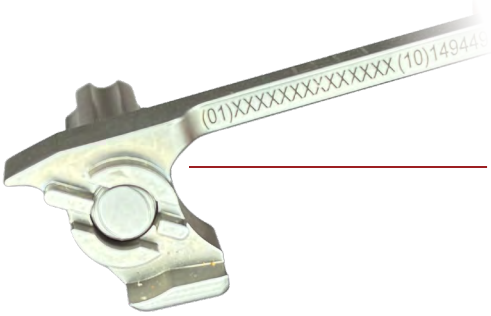


Fig 1. Jig to plate mating mechanism

Fig 2.
Drill tower

K-wire guide holes

Distal Aspect of plate

Fig 3.

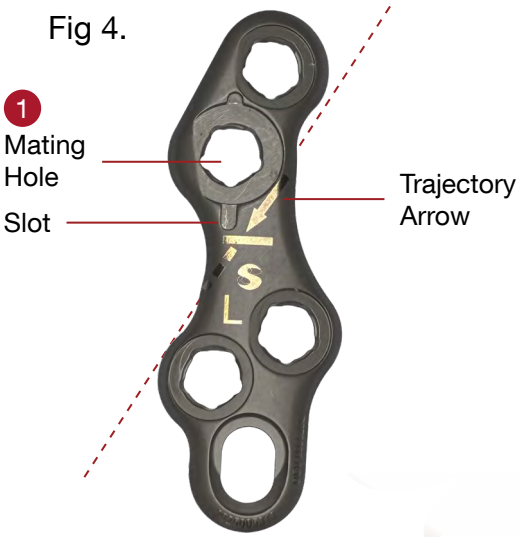
Mating Hole

Jig Slot

Proximal Aspect of plate

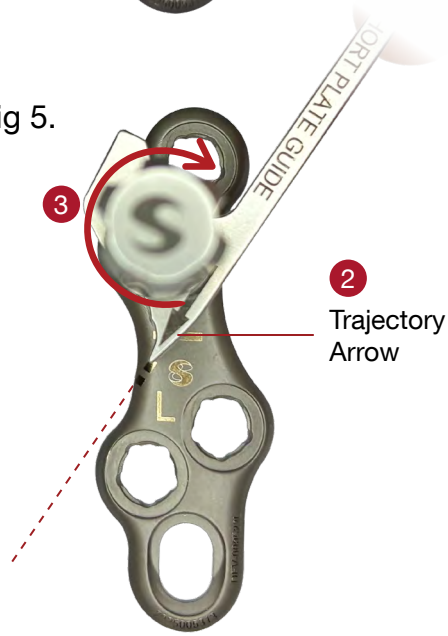
3.6 MTPJ XS Plate - Plate Guide Attachment

Fig 4.



1. Identify the correct screw hole for the MTPJ guide attachment (the ‘Mating Hole’). This is the hole closest to the etched arrow. (Fig. 4)

Fig 5.



2. Place the guide onto the plate, aligning the trajectory arrow on the top of the MTPJ plate guide with the arrow on the plate. Ensure the guide has inserted into the plate slot, preventing rotation

3. Rotate the top of the drill guide clockwise until the drill guide base is held flush and secure against the flat surface of the plate (Fig. 5)

Fig 6.
Underside of XS MTPJ Plate with Plate guide in situ

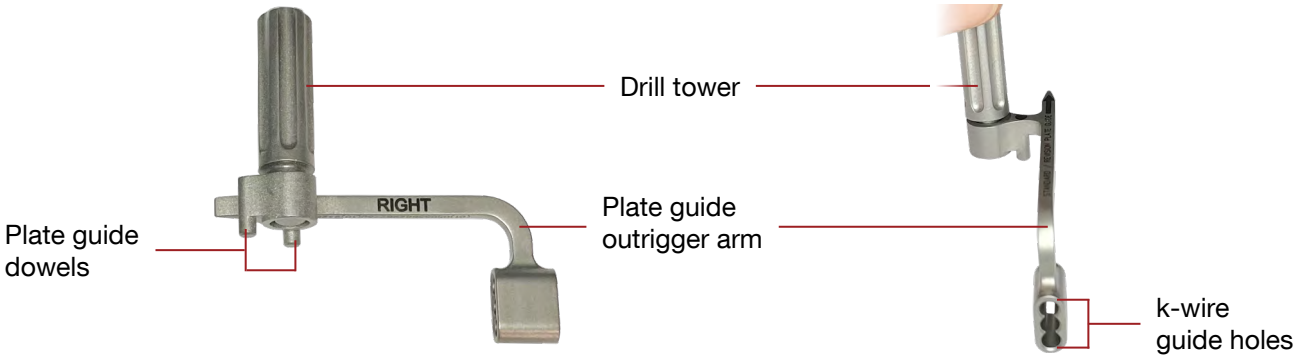
3.7 MTPJ Plate Guide for MTPJ Standard and Revision Plates

MTPJ Plate Guides for MTPJ Standard and Revision plates, to allow lag screw trajectory distal to proximal:

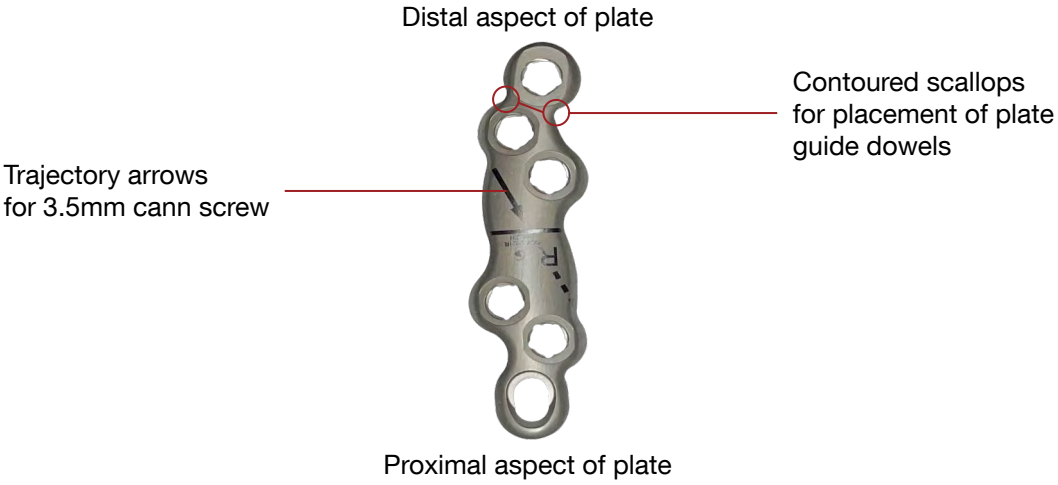
1 Plate Guide - Right

1 Plate Guide - Left

3.8 Components of the MTPJ Plate Guide for MTPJ Standard and Revision Plates



MTPJ Standard Plate



3.9 MTPJ Standard and Revision Plate - Plate Guide Attachment

- Place plate guide dowels into contoured scallops on plate

- Fix by threading drill tower into most distal plate screw hole

NOTE: the arrow on the Plate Guide should sit in line with the arrow etched on the plate

3.9 MTPJ Standard and Revision Plate - Plate Guide Attachment

Ensure temporary fixation of the joint has been undertaken prior to plate placement

Place plate onto desired position

Initially fix the plate using Olive wires

Using an appropriate drill guide and drill, perform drilling the most medial screw hole on the distal portion of the plate

The screw should be advanced to a position where the head is flush with the plate

Remove the most distal olive wire

Insert appropriate MTP Plate Guide onto the most distal screw hole of the plate

Insert k-wire guide into Plate Guide. 3 options of position are available in accordance to maximise bone purchase

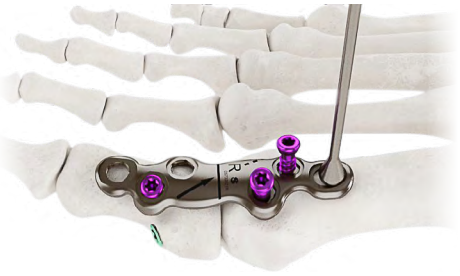
Insert 1.4mm x 150mm k-wire through the k-wire guide and advance into the phalanx. Keep advancing k-wire until the lateral cortex of the metatarsal is reached

Remove the k-wire guide from the Plate Guide and unscrew the Plate Guide from the plate

Measurement of the required screw length is established using the cannulated depth gauge

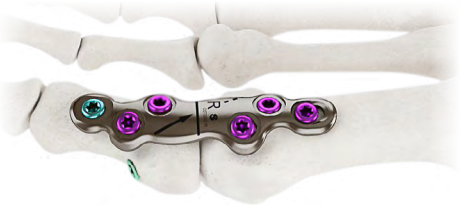
Use the 2.6mm cannulated drill prior to advancing the screw. Ensure the screw head is flush, taking care not to fracture the cortex

Using an appropriate drill guide and drill, perform drilling the remaining screw holes of the plate



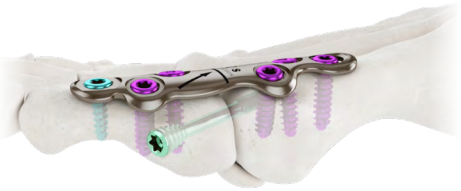
The locking screws should be advanced to a position where the head is flush with the plate

3.9 MTPJ Standard and Revision Plate - Plate Guide Attachment



Remove the most proximal olive wire

Perform drilling according to the selected preferred screw size in the most proximal dynamic standard screw position. After determining length with the depth gauge, insert the appropriate non-locking screw



4. Tips for Using Guides

4.1 Using A single Plate Guide with In-Line MTPJ Plates

“In-Line MTPJ Plate Guides” are to only be used in conjunction with “In-Line MTPJ Plates”

They can be used to help guide/aim a 3.5mm cross-screw from distal to proximal and/or proximal to distal

Optimal cross-screw orientation will be from distal to proximal in terms of bone purchase

Use the **Alpha/L Proximal/ R Distal** In-Line Plate Guide in conjunction with a **Right** In-Line/In-Line Long MTPJ Plate to guide/aim a cross-screw from **distal to proximal**

Conversely, use the **Beta/R Proximal/L Distal** In-Line Plate Guide in conjunction with a **Left** In-Line/In-Line Long MTPJ Plate to guide/aim a cross-screw from **distal to proximal**

These guides are to be affixed to the hole of the plate just distal to the laser-etched midline and the dowels/pins will thus be located distal to the hole of application

From a dorsal viewpoint, ensure that the laser etched arrow on the guide matches the orientation of the laser etched arrow on the plate

When creating a single crossing-screw construct, optimal location of the Guide Insert is into the **middle slot of the Plate Guide**

Locking and non-locking plate screws must be inserted ‘on axis’ when using the Plate Guides for In-Line MTPJ plates

4.2 Using Dual Guides with In-Line MTPJ Plates

Utilise the process previously for application of the initial guide to aim a cross-screw from distal to proximal, then continue with the following application:

Use the **Beta** In-Line MTPJ Plate Guide in conjunction with a **Right** In-Line/In-Line Long MTPJ Plate if a cross-screw from **proximal to distal** orientation is also desired

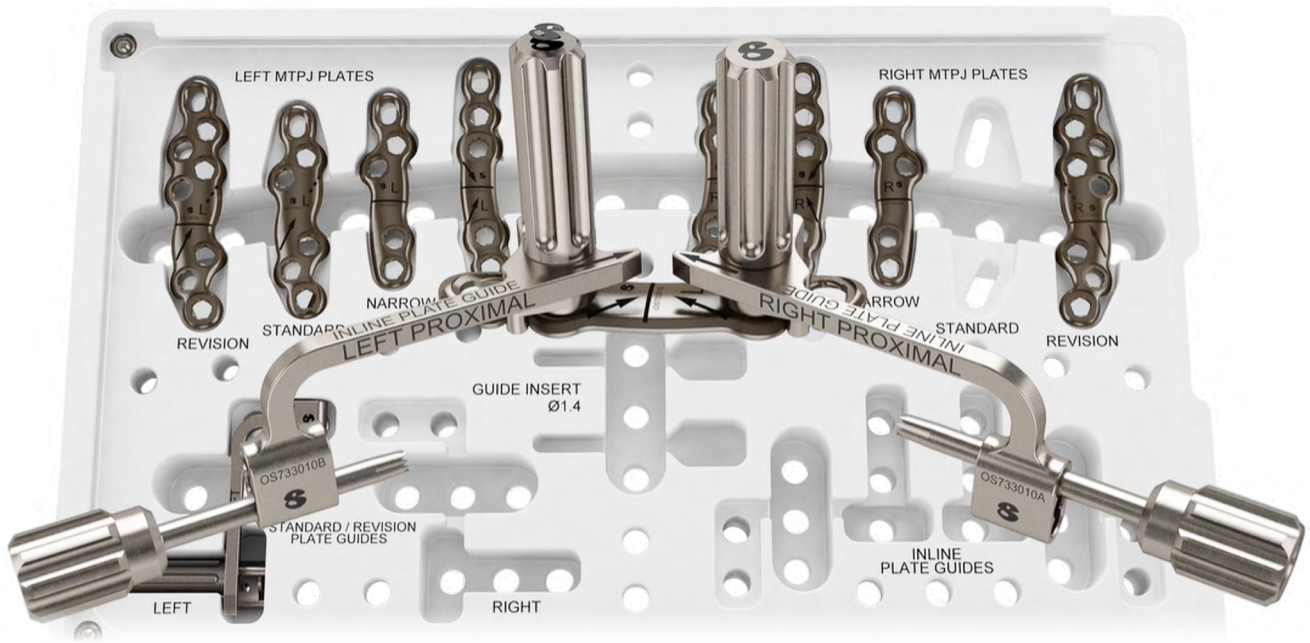
Use the **Alpha** In-Line MTPJ Plate Guide in conjunction with a **Left** In-Line/In-Line Long MTPJ Plate if a cross-screw from **proximal to distal** orientation is also desired

These guides are to be affixed to the hole of the plate just proximal to the laser-etched midline and the dowels/pins will thus be located proximal to the hole of application

From a dorsal viewpoint, ensure that the laser etched arrow on the guides matches the orientation of the laser etched arrows on the plate

When creating a dual crossing-screw construct, the Guide Insert must be placed into opposites within the slot of the Plate Guide; if the first Guide Insert is placed through the **top slot** of the **distal** Plate Guide, then the second Guide Insert needs to be placed through the **bottom slot** of the **proximal** Plate Guide or visa-versa

Locking and non-locking plate screws must be inserted ‘on axis’ when using the Plate Guides for In-Line MTPJ plates



4.3 Using Guides with the XS MTPJ Plates

“MTPJ Extra Short Plate Guides” are to only be used in conjunction with “XS MTPJ Plates”

They can be used to help guide/aim a 3.5mm cross-screw from distal to proximal

Use the Right MTPJ Extra Short Plate Guide in conjunction with a Right XS MTPJ Plate Use the Left MTPJ Extra Short Plate Guide in conjunction with a Left XS MTPJ Plate

Locking and non-locking plate screws must be inserted ‘on axis’ when using the MTPJ Extra Short Plate Guides for the XS MTPJ Plate

4.4 Using Guides with the Standard or Revision MTPJ Plates

“Standard/Revision Plate Guides” are to only be used in conjunction with “Standard/Revision Plates”

They can be used to help guide/aim a 3.5mm cross-screw from distal to proximal

Use the Right Standard/Revision Plate Guide in conjunction with a Right Standard or Revision MTPJ Plate

Use the Left Standard/Revision Plate Guide in conjunction with a Left Standard or Revision MTPJ Plate

Locking and non-locking plate screws must be inserted ‘on axis’ when using the Standard/ Revision Plate Guides for the Standard or Revision MTPJ Plates

These guides are to be affixed to the most distal hole

From a dorsal viewpoint, ensure that the laser etched arrow on the guide matches the orientation of the laser etch arrow on the plate

The dowels/pins will thus be located proximal to the hole

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*1. CE/ UKCA marking and the Notified/ Approved Body number is applied per part number and appears on the device packaging, or the device if applicable

UK CA 0086 *1

Rx only

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

Consult instructions for use

CE 2797 *1

Surgeon must be fully trained in the surgical technique