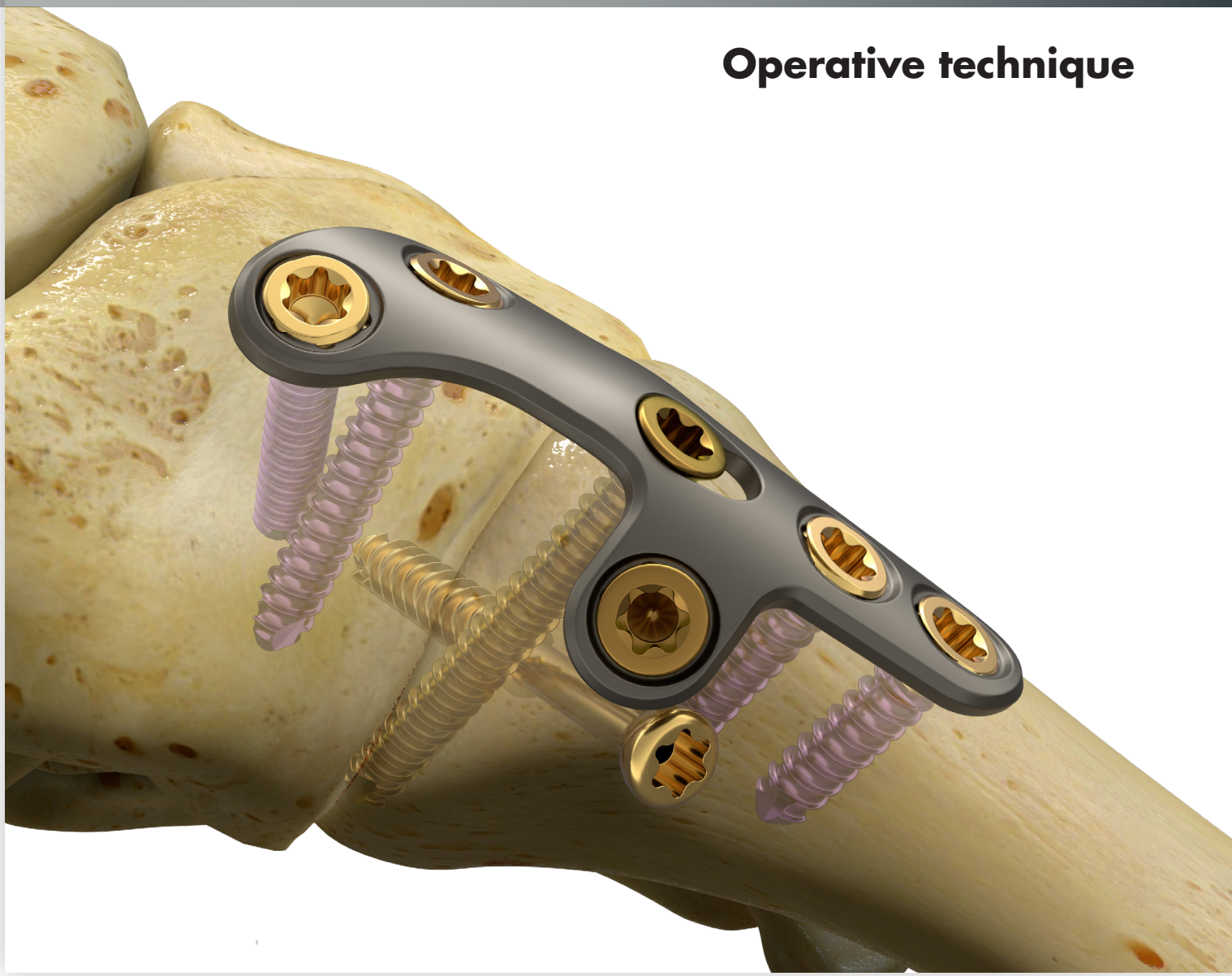
stryker

# Ortholoc™ 2 with 3Di Technology

## LapiFuse™ Triplanar Correction System

**Operative technique**



# Ortholoc 2 with 3Di Technology

LapiFuse Triplanar Correction System

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## Surgeon design team

**The Ortholoc 2 LapiFuse Triplanar Correction System was developed in conjunction with:**

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# Introduction

## Implant description

The Ortholoc 2 LapiFuse Triplanar Correction System is designed to correct hallux valgus deformity as a result of laxity and hypermobility of the first ray at the first tarsometatarsal joint. The instrumented and reproducible technique focuses on addressing the deformity through (1) joint preparation without corrective osteotomies, (2) alignment through triplanar correction, and (3) rigid, multi-cortical fixation with screws across the cuneiforms and first – second metatarsals. The surgical objective intends to correct the source of the deformity to decrease hallux valgus reoccurrence.

## Screw plates

The Ortholoc 2 LapiFuse Plates are available in 2 configurations:  Standard (5-hole) 0mm and 2mm step and trans-metatarsal (6-hole) 0mm and 2mm step. Both available in right and left. The low profile, anatomically contoured plates are designed for rigid dorso-medial fixation across the first TMT joint.

All plates have two locking holes for proximal fixation and two locking holes for distal fixation. In addition, all plates have a compression slot. The 6-hole plates have an optional second metatarsal locking hole for additional stability.  The plantar stepped plates have a smooth dorsal transition to preserve the medial cuneiform and prevent soft tissue irritation.

The Ortholoc 2 LapiFuse Plates are manufactured from titanium alloy and are Type II anodized for improved fatigue strength.* The plates are compatible with Ortholoc 3Di 2.7/3.5mm locking and non-locking screws.

## Locking and non-locking screws

Ortholoc 2 LapiFuse System includes 3.5mm locking and non-locking  screw lengths ranging from 12mm to 40mm in 2mm increments. The screws are manufactured from titanium alloy and are color anodized for surgical efficiency. The locking screws can be assembled on-axis or up to 15° off axis. The non-locking screw have a low profile head. All screws feature a cortical thread profile for improved fixation.

## Interfragmentary (cross) screws

The maxtorque self-tapping, self-drilling cannulated screws are available in a single 4mm diameter with screw lengths ranging from 35mm to 45mm in 2.5mm increments. The screws are manufactured from titanium alloy and are color anodized.

| Standard | Trans-metatarsal |
|---|---|
|  |  |
| 0mm | 0mm |
|  |  |
| 2mm | 2mm |

# Introduction (cont.)

## Instrument description

The Ortholoc 2 LapiFuse Instrumentation gives the surgeon the confidence to correct the hallux valgus deformity with maximum operational efficiency. Procedure specific instrumentation embodies several features that eliminates surgical steps, allows for intra-operative guidance, and measured correction.

## Joint preparation instruments

Shortening of the first ray and overloading the lesser metatarsals can be avoided by forgoing joint resection of the first TMT joint. Instead, the utilization of surgical tools for cartilage removal and exposure to the subchondral bone is recommended. The Ortholoc 2 LapiFuse Joint Preparation Kit (sterile) provides sharp, single use osteotome, curette, and 25mm drill with drill guide for first TMT joint preparation.

## LapiFuse clamp

Triplanar alignment, stabilization, and anatomic correction of the medial column is achieved through an instrumented clamp at the head of the metatarsal. The Ortholoc 2 LapiFuse Clamp allows for passive and active de-rotation of the hallux in the frontal plane while the ratcheting feature allows active reduction of the intermetatarsal angle in the transverse plane. The inherent off-set between the base and the hook of the clamp preserves the alignment of the first and second metatarsal in sagittal plane throughout the correction.

## LapiFuse Targeting Guide

The LapiFuse Targeting Guide utilizes fluoroscopic feedback for visualization of the interfragmentary screw placement across the arthrodesis. Fluoroscopic feedback allow for the precise targeting of the multi-cortical compression screw into the center of the intermediate cuneiform for best bone purchase.

## Indications

The Ortholoc 2 LapiFuse System is intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of bones of the feet and toes. Specific examples include: arthrodesis of the first metatarsal-cuneiform joint (lapidus fusion).

## Contraindications

The Ortholoc 2 LapiFuse Triplanar Bunion Correction System does not have product specific contraindications.

General surgical contraindications include:

- Infection
- Physiological or psychological inadequate patient
- Inadequate skin, bone, or neurovascular status
- Irreparable tendon system
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Patients with high levels of activity

# Operative technique

## Patient positioning

Place the patient in a supine position with a small bump under the ipsilateral hip to place the foot in a neutral position.

## First tarsometatarsal joint exposure

Create a dorsomedial incision over the first tarsometatarsal (TMT) joint, medial to the extensor hallux tendon (EHL). The incision should extend approximately 20mm – 25mm on either side of the TMT joint. Take care to identify and protect the overlaying neurovascular structures. Release the EHL of the first TMT joint and retract laterally.

Perform a capsulotomy of the first TMT joint. Take care to ensure complete exposure of the plantar and lateral aspects of the joint. The joint is approximately 30mm deep.

## First tarsometatarsal joint distraction and preparation

Insert a 2.5mm threaded Steinmann pin (58862515) dorsal medial into the medial cuneiform, approximately 8mm proximal to the joint. (Figure 1) Use the LapiFuse Distractor (38140002) as a guide to place a second, parallel 2.5mm threaded Steinmann pin into the base of the first metatarsal.

Distract the first TMT joint between 10mm-15mm. (Figure 2)

## Tips and tricks:

**When using distractor, place body of instrument laterally over the foot.**

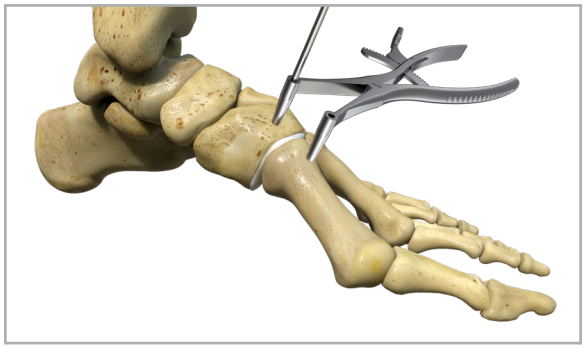


**Figure 1**

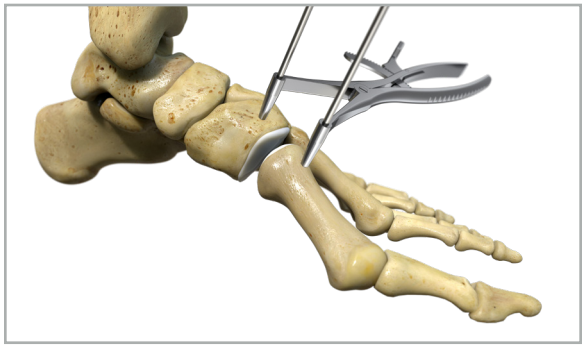
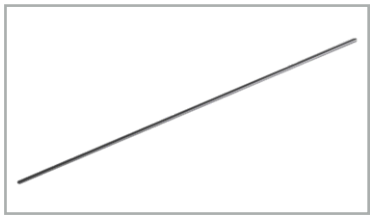


**Figure 2**



58862515
2.5mm Steinmann pins

38140002
LapiFuse Distractor

Hand prepare the joint and remove the cartilage using the joint preparation kit (9914PK01). The osteotome is intended to scrape the cartilage with limited to no removal of the subchondral bone. The straight curette may be required to reach the edges and plantar surfaces of the joint. (Figure 3) Alternatively, use the joint preparation guide.

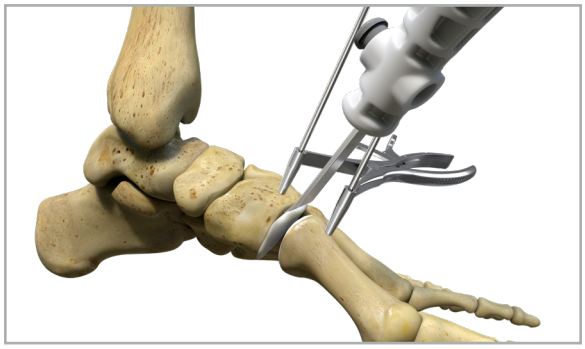
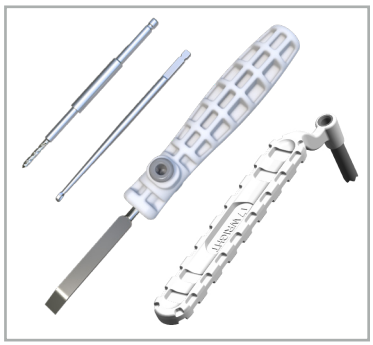


**Figure 3**

Fenestrate the proximal and distal surfaces of the subchondral bone approximately 6mm by utilizing a combination of the 2.5mm drill and drill guide from the joint preparation kit. (Figure 4) Lavage the region, reduce the joint, and protect while preparing the first metatarsophalangeal joint.

**Figure 4**



9914PK01
Joint preparation kit

58850025
2.5mm Drill

## First metatarsophalangeal and interspace exposure

Create a medial incision over the first metatarsophalangeal (MTP) joint. Start the incision proximal to the interphalangeal and complete it 15mm-25mm proximal of the metatarsal head. Minimal capsular dissection is performed.

Insert a 1.4mm Kirshner wire (CSS-040-14) true medial into the center of the metatarsal head and perpendicular to the metatarsal shaft. The location of the k-wire is approximately 6mm-8mm proximal of the MTP joint. (Figure 5)

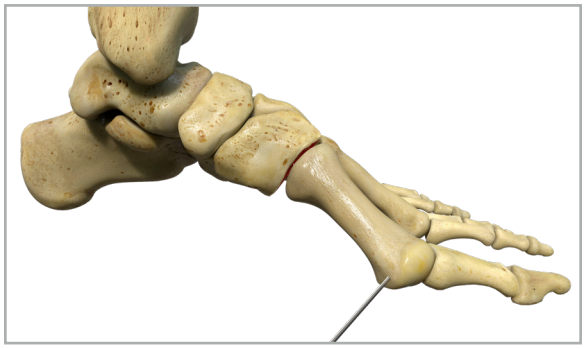


**Figure 5**

## Tips and Tricks:

- Wire should be bi-cortical while minimizing lateral protrusion.
- Keep wire parallel to sesamoids.

Perform an incision in the first interspace, between the first and second metatarsals. If required, laterally release the soft tissue and ligaments. Medially stress the toe to stretch the lateral capsule and ligaments.

If lateral ligament release is not required, make incision over second metatarsal or second interspace, instead of the first interspace.

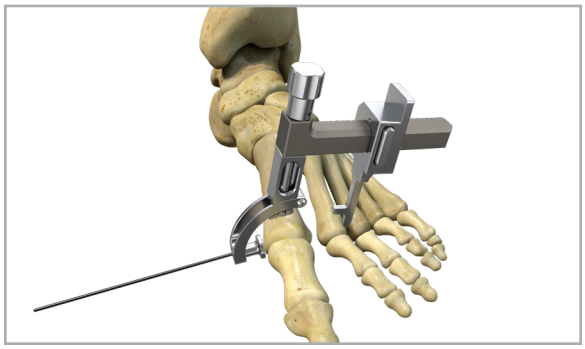


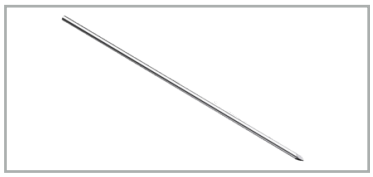
**Figure 6**

## Intermetatarsal (IM) angle reduction

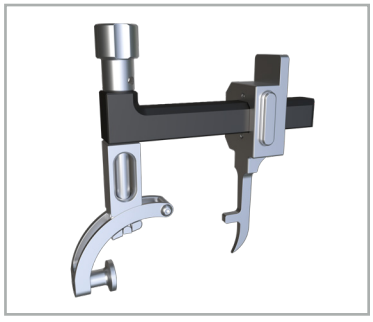
Use the LapiFuse Clamp (38140001) for multi-planar correction.

Insert the hook of the LapiFuse Clamp through the incision in the first interspace and capture the lateral head of the second metatarsal.

Insert the base of the LapiFuse Clamp on to the 1.4mm k-wire and seat flush with the head of the first metatarsal. (Figure 6)



CSS-040-14
1.4mm Kirshner wire



38140001
LapiFuse Clamp

Assemble the base and hook of the LapiFuse Clamp and reduce to the desired IM angle by compressing the ratcheting clamp. (Figure 7) Assembly of the LapiFuse Clamp should passively de-rotate the first metatarsal head. (Figure 8) If the correct position of the sesamoids is not achieved via passive de-rotation, actively de-rotate the first metatarsal to the correct position by rotating the 1.4mm k-wire in the guide.

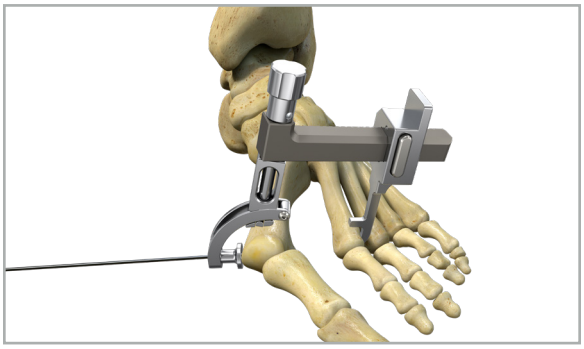


**Figure 7**

## Note 1:

**If the base and hook of the LapiFuse Clamp are not aligning, loosen the knob on the LapiFuse Clamp base to allow the ratcheting arm to swivel.**

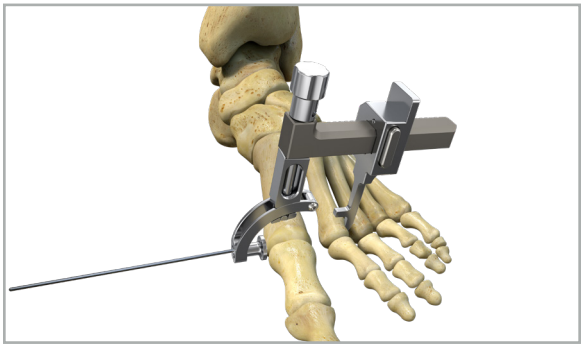


**Figure 8**

## Note 2:

**If frontal plane rotation of the first metatarsal is difficult, actively de-rotate the first metatarsal prior reducing the IM angle.**

## Interfragmentary screw placement

Use the targeting guide (38140003) to place an interfragmentary screw from the base of the first metatarsal, through the medial cuneiform, and into the body of the intermediate cuneiform. (Figure 9)

Assemble the targeting guide and insert two self-retaining 1.4mm k-wires. (58820006).

Place the drill guide at the apex of the plantar prominence on the metatarsal base at or below mid-line of first metatarsal. Under fluoroscopy, align the drill guide such that the nose of the guide is centered between the two 1.4mm k-wires. (Figure 10)

Target the trajectory of the drill guide from the plantar medial entry on the metatarsal  to the dorsal lateral proximal destination in the middle of the intermediate cuneiform. While manually ensuring axial compression across the first TMT joint, place a 1.4mm k-wire (58820006) through the targeting guide to temporarily secure the joints. Additional k-wires can be used for stabilization outside the targeting guide.

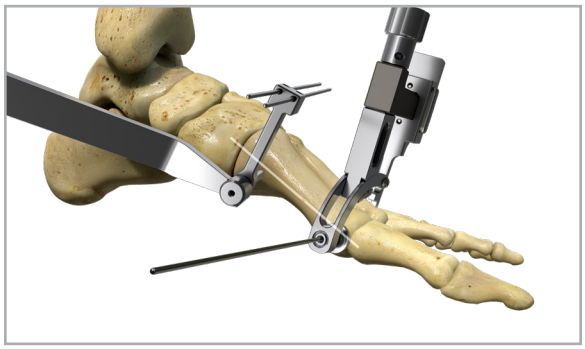


**Figure 9**

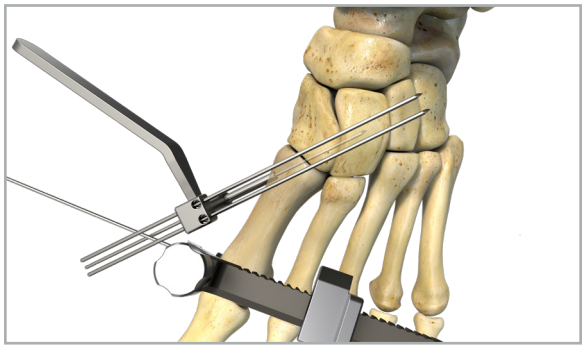
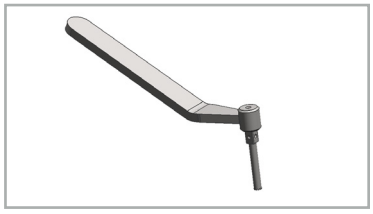
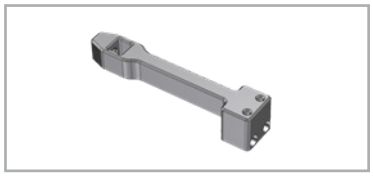


**Figure 10**



38140003
Targeting guide



38140003
Targeting guide:
alignment tower

Remove the targeting guide from the k-wire and replace with the lag screw depth gauge (38140004) to determine the length of the interfragmentary screw.

Use the 2.7mm drill (CSS-071-27) and drill guide (CSS-071-277) to prepare a pilot hole across the joints. If required, use the counter-sink (MSD-070-40) to seat the head of the screw flush with the bone. (Figure 11)

By hand, assemble the interfragmentary screw (MSD-010-40-xxxx) across the first TMT joint and into the intermediate cuneiform, utilizing the cannulated T15 driver (MSD-056-40) and ratcheting driver (58881T15). Optionally, use the dome washer (3814006) with the interfragmentary screw for improved stress distribution across the bone. (Figure 12)

## Note:

**Dome washer laser etch should be facing the bone.**

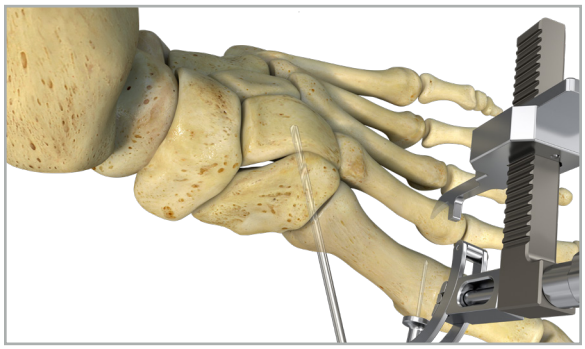


**Figure 11**

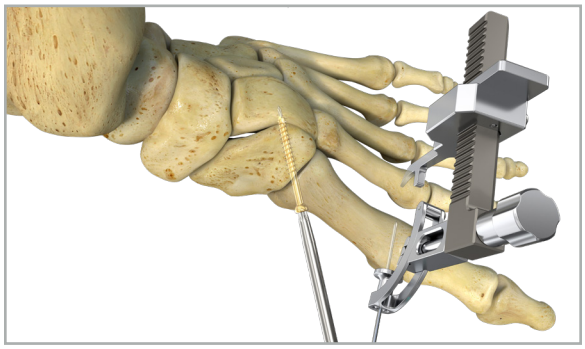
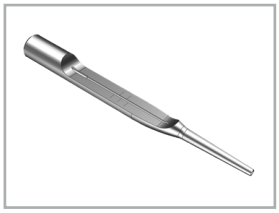


**Figure 12**

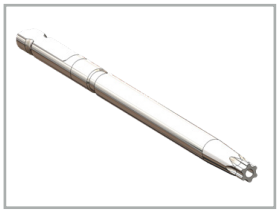


38140004
Depth gauge

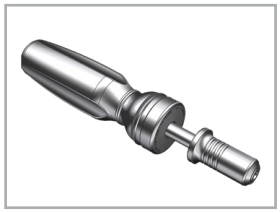
CSS-071-27
2.7mm Drill

CSS-071-277
Drill guide

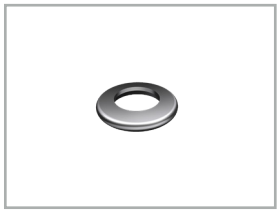
MSD-010-40-xxxx
Interfragmentary screw



MSD-056-40
Hexstar driver



58881T15
Ratcheting driver



3814006
Dome washer

MSD-070-40
Countersink

Remove the targeting guide from the k-wire and replace with the lag screw depth gauge (38140004) to determine the length of the interfragmentary screw.

Use the 2.7mm drill (CSS-071-27) and drill guide (CSS-071-277) to prepare a pilot hole across the joints. If required, use the counter-sink (MSD-070-40) to seat the head of the screw flush with the bone.

By hand, assemble the interfragmentary screw (MSD-010-40-xxxx) across the first TMT joint and into the intermediate cuneiform utilizing the cannulated T15 driver (MSD-056-40) and ratcheting driver (58881T15). Optionally, use the dome washer (3814006) with the interfragmentary screw for improved stress distribution across the bone. (Figure 13)

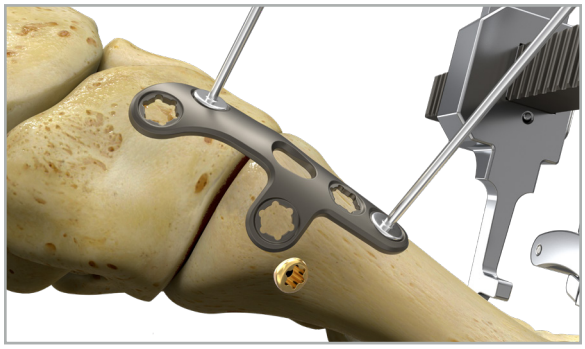


**Figure 13**

## Note:

**Threaded bending iron (5887003) is available to contour the plate to the bone. Thread the bending iron into the plate completely prior to bending. Do not bend the plates without the bending iron.**

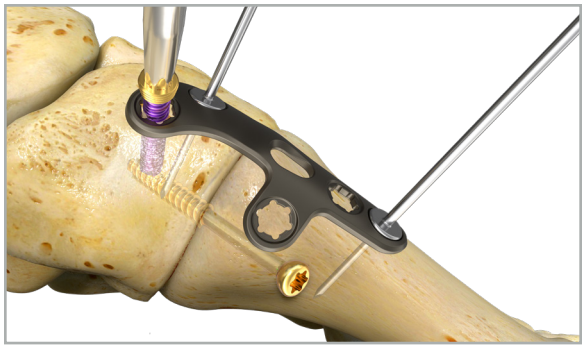


**Figure 14**

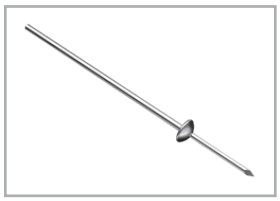
## Caution:

**Plate bending should only occur in one direction. Reverse or repeated bending will weaken the plate or cause it to break.**

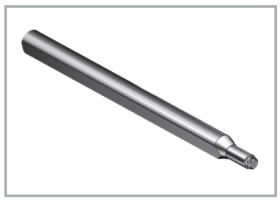
Proximally fix the plate to the bone with locking (588035xx) and/or non-locking (588133xx) screws using a T15 driver (58861T15), after preparing the pilot hole using either the on-axis (58872560) or conical (58872028) drill guide and the 2.5mm drill (58850025). (Figure 14) The on-axis drill guide must completely thread onto the plate, whereas the conical drill must mate with the hexalobular feature in the locking hole. Use the plate screw depth gauge (5362000160) to determine the appropriate screw length.

## Caution:

**Locking screws can be unlocked, redirected, and relocked in various orientations a maximum of only 3 times.**

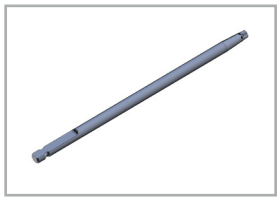


58820006
Fixation pin

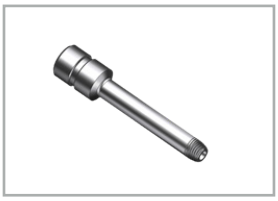


5887003
Threaded bending iron

588035xx
Locking screw



58861T15
t15 driver



58872560
2.8mm threaded
drill guide

58872028
2.0/2.8 poly axial
drill guide

588133xx
Non-locking screw

58850025
2.5mm drill

If additional compression across the TMT joint is required, utilize the compression slot. Drill a 2.5mm hole at the furthest distal point on the compression slot, measure the screw length, and drive a non-locking screw into the bone until fully seated into the plate. (Figure 15)

## Note:

**Compression across the joint is created as the screw travels proximally down the compression slot.**

## Caution:

**Bi-cortical fixation is required for the screw in the compression slot.**

Distally fix the plate to the bone with locking and/or non-locking screws in a similar manner as described above for proximal fixation.

## Note:

**Retightening the 4mm interfragmenting screw after implentation of the non-locking screw through the compression slot may be required.**

## First – second metatarsal fixation

If additional stability in the forefoot is required, the surgeon has the option for transverse fixation across the first – second metatarsal. (Figure 16) If using the 6-hole plate, transverse fixation can be achieve by manually placing either a locking or non-locking screw through the out-of-plane locking hole.

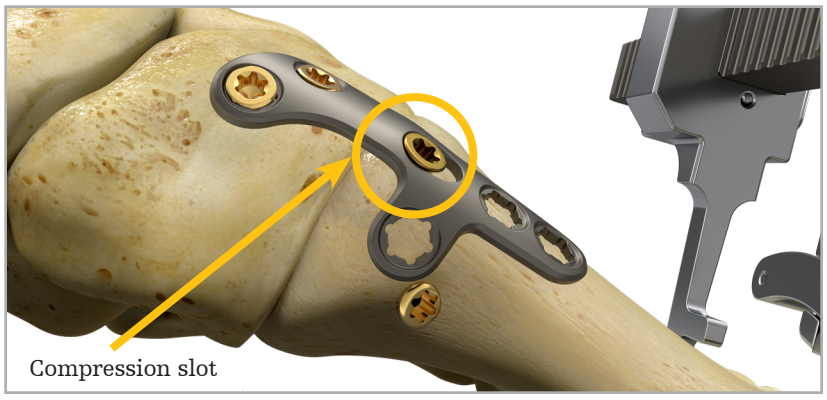



**Figure 15**

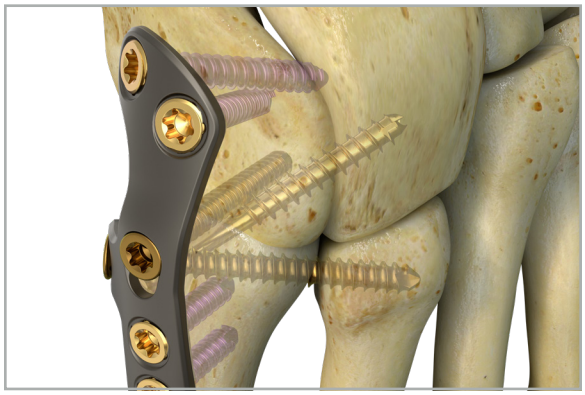
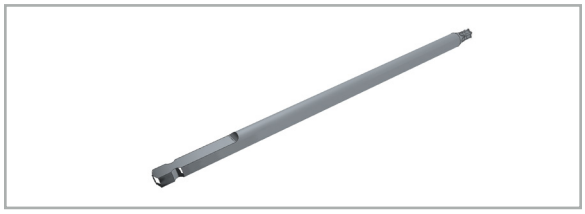


**Figure 16**

## Explant information

Removal of the plate may be performed by first extracting the plate screws using the Star 15 straight drivers (58861T15), not included in the kit, and then removing the plate from the bone.

If the removal of the implant due to revision or failure of the device, the surgeon should contact the manufacturer to receive instructions for returning the explanted device to the manufacturer for investigation.



58861T15
Star 15 straight drivers

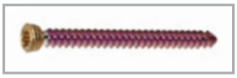
## Postoperative management

Postoperative care is the responsibility of the medical professional.

# Ordering information


## Plates

| Part number | Description |
|---|---|
| 3814000L | Standard lapidus plate left |
| 3814000R | Standard lapidus plate right |
| 3814100L | Trans-metatarsal lapidus plate left |
| 3814100R | Trans- metatarsal lapidus plate right |
| 3814002L | Standard lapidus 2mm plate left |
| 3814002R | Standard lapidus 2mm plate right |
| 3814102L | Trans-metatarsal lapidus 2mm plate left |
| 3814102R | Trans-metatarsal lapidus 2mm plate right |



## Locking screws

| Part number | Description |
|---|---|
| 58803512 | 3.5mm x 12mm |
| 58803514 | 3.5mm x 14mm |
| 58803516 | 3.5mm x 16mm |
| 58803518 | 3.5mm x 18mm |
| 58803520 | 3.5mm x 20mm |
| 58803522 | 3.5mm x 22mm |
| 58803524 | 3.5mm x 24mm |
| 58803526 | 3.5mm x 26mm |
| 58803528 | 3.5mm x 28mm |
| 58803530 | 3.5mm x 30mm |
| 58803532 | 3.5mm x 32mm |
| 58803534 | 3.5mm x 34mm |
| 58803536 | 3.5mm x 36mm |
| 58803538 | 3.5mm x 38mm |
| 58803540 | 3.5mm x 40mm |

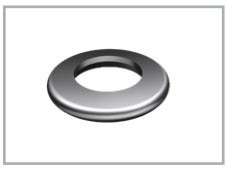
## Non-locking screws

| Part number | Description |
|---|---|
| 58813512 | 3.5mm x 12mm |
| 58813514 | 3.5mm x 14mm |
| 58813516 | 3.5mm x 16mm |
| 58813518 | 3.5mm x 18mm |
| 58813520 | 3.5mm x 20mm |
| 58813522 | 3.5mm x 22mm |
| 58813524 | 3.5mm x 24mm |
| 58813526 | 3.5mm x 26mm |
| 58813528 | 3.5mm x 28mm |
| 58813530 | 3.5mm x 30mm |
| 58813532 | 3.5mm x 32mm |
| 58813534 | 3.5mm x 34mm |
| 58813536 | 3.5mm x 36mm |
| 58813538 | 3.5mm x 38mm |
| 58813540 | 3.5mm x 40mm |

## Lag screws

| Part number | Description |
|---|---|
| MSD-010-40-035L | MSD-010-40-035L |
| MSD-010-40-375L | MSD-010-40-375L |
| MSD-010-40-040L | MSD-010-40-040L |
| MSD-010-40-425L | MSD-010-40-425L |
| MSD-010-40-045L | MSD-010-40-045L |

# Ordering information (cont.)



## Washer

| Part number | Description |
|---|---|
| 3814006 | Dome washer |

## Instruments

| Part number | Description |
|---|---|
| 38140001 | LapiFuse Clamp |
| 38140002 | LapiFuse Distractor |
| 38140003 | LapiFuse Targeting Guide |
| 58870003 | Threaded bending iron |
| 58871010 | Ratcheting driver handle |
| 38140004 | Lag screw depth gauge |
| 5362000160 | Plate Screw depth gauge |
| 58820006 | Temporary fixation pin 1.1mm |
| 58862515 | Threaded k-wire 2.5mm |
| 58850025 | Drill bit 2.5mm |
| 58872560 | Threaded drill guide 2.8mm |
| 58872028 | 2.0/2.8 Poly axial drill guide |
| 58881T15 | Star 15 self-retaining driver |
| CSS-040-14 | Guide wire 1.4mm |
| CSS-071-27 | Straight drill guide 2.7mm |
| CSS-072-27 | Drill Bit 2.7mm |
| MSD-070-40 | Countersink 4mm |
| MSD-056-40 | Hexstar driver 4mm |

## Joint prep instruments

| Part number | Description |
|---|---|
| 9914pk01 | Lapifuse Joint Preparation Instruments |
| 9914pk02 | Lapifuse Joint Preparation Guide |

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## Foot & Ankle

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**AP-012394D, 02-Dec-2020**



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