

Ortholoc™ 3Di

Foot Reconstruction System Sterile Offering

Operative technique



Powered by the **PULSE Intelligent Delivery Platform**

Ortholoc 3Di

Foot Reconstruction System Sterile Offering

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Important:

- The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.
- Removal or revision of the device may be required sometime in the future.
- Cleaning and sterilization information is provided in the applicable instructions for use.
- Non-sterile devices, including implants and instruments, must be cleaned and sterilized prior to use, in accordance with validated methods.
- Devices that are able to be disassembled should be disassembled prior to point-of-use processing. Additionally, devices with movable components that do not facilitate disassembly should be manually articulated during the point-of-use processing step in order to evacuate additional soils.
- Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.
- Consult Instructions for Use (<https://ifu.stryker.com>) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.
- The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.

An implant whose packaging is open or damaged or whose expiration date has passed must not be used. Every precaution must be taken to ensure sterility when opening the packaging of the implant and during implantation.

Table of contents

Introduction	3
Ortholoc 3Di Hallux System	4
Intended Use	4
Device Description	5
Preoperative Planning	6
MTP Fusion Technique	10
Lapidus Fusion Technique	13
Ortholoc 2 Crosscheck	17
Intended Use	17
Ortholoc 2 Crosscheck Module	18
Preoperative Planning	19
MTP Fusion Technique	22
Lapidus Fusion Technique	26
Explant Information	29
Postoperative Management	29
Ordering Information	30

Introduction

The Ortholoc 3Di Foot Reconstruction System is a multi-indication foot reconstruction solution providing indication specific implants and instruments designed to address the unique demands of the forefoot and midfoot. Each Ortholoc 3Di Polyaxial Locking Technology allows the surgeon the options of 2.7mm or 3.5mm locking screws capable of locking at up to 15° off axis to the plate.

System Features

- Universal plate hole accepts 2.7mm and 3.5mm locking and non-locking screws
- Four indications and anatomic specific plate designs
- Ortholoc 3Di Polyaxial locking capability
- Compression holes in selected plates
- Anatomic and indication specific implants

Intended Use

Indications*

The Ortholoc 3Di Hallux 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:

- First metatarsal osteotomies for hallux valgus correction including:
 - Opening base wedge osteotomy
 - Closing base wedge osteotomy
 - Crescentic osteotomy
 - Proximal Chevron osteotomy
 - Distal Chevron osteotomy (Austin)
- First metatarsal fracture fixation
- Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion)
- Arthrodesis of the first metatarsophalangeal joint (MTP) including:
 - Primary MTP Fusion due to hallux rigidus and/or hallux valgus
 - Revision MTP Fusion
 - Revision of failed first MTP Arthroplasty implant

Contraindications

No product specific contraindications.

*The techniques contained represent the Pulse sterile offering of the Ortholoc 3Di Hallux system. For interest in other techniques/devices in the Ortholoc 3Di Hallux system not shown, please contact your sales rep for more information on ordering.

Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.

Device Description

3Di Hallux Module – Ortholoc 3Di Hallux Sterile Offering

The Hallux module of the Ortholoc 3Di System focuses on implant solutions related to indications and procedures of the first ray. The implants included in this model are designed to provide highly anatomic and versatile plating options for first MTP fusions and Lapidus procedures.



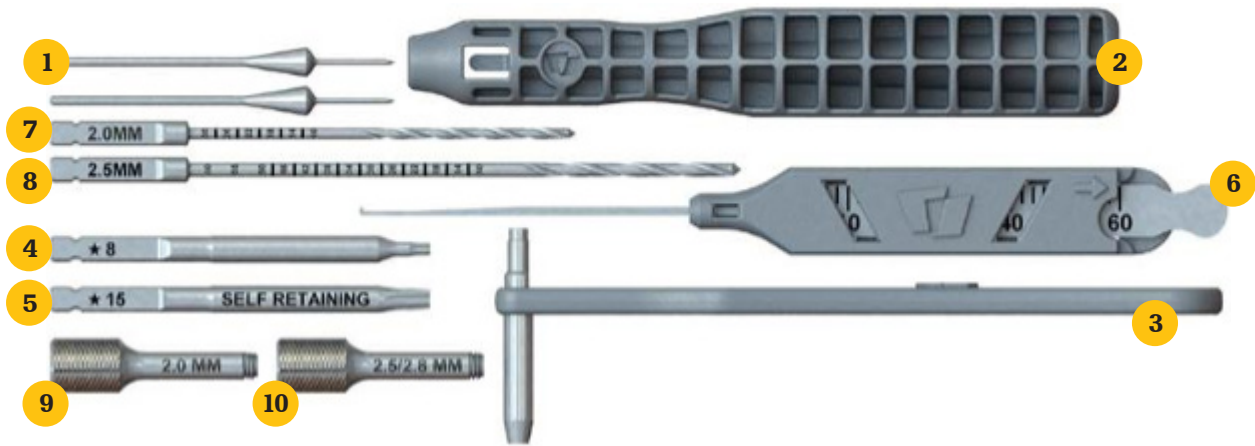
MTP Fusion Plate



Lapidus Fusion Plate

The Ortholoc 3Di Foot Reconstruction System is available in a sterile, ready-for-surgery offering that includes individually packed implants and instrument packs that includes drills, drivers, and handles needed for surgery with individually packaged MTP reamers.

Instrument Pack Contents (58A91000)



1. 1.1mm Temporary Fixation Pins (2x)
2. AO Handle
3. Drill Guide
4. T8 Driver
5. T15 Driver
6. Bi-cortical Depth Gauge
7. 2.0mm Drill
8. 2.5mm Drill
9. 2.0mm Locking Drill Guide
10. 2.5mm Locking Drill Guide

Preoperative Planning

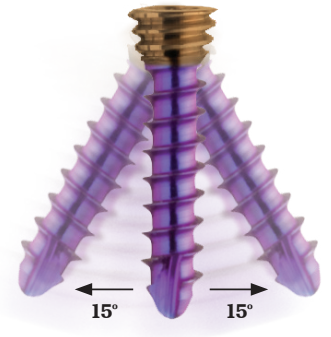
Implant Selection

Plates

Like any lower extremity procedure, preoperative planning is vital to the overall outcome of joint fusion and osteotomy fixation. Careful consideration must be given to implant selection. Choose an implant that addresses the specific needs dictated by the indication, patient anatomy, and overall surgical goals.

Screws

The Ortholoc 3Di Locking hole has been designed to accept the 2.7mm and 3.5mm Ortholoc 3Di locking and non-locking screws. Choose the most appropriate screw diameter and type based on anatomy, bone quality, and surgical goals.



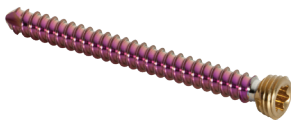
2.7mm Locking Screw

- On-axis polyaxial locking capability
- Cortical bone thread
- 2.0mm pre-drill
- 10 – 30mm lengths



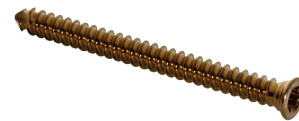
2.7mm Non-Locking Screw

- Low-profile head sits flush with plate
- Cortical bone thread
- 2.0mm pre-drill
- 10 – 30mm lengths



3.5mm Locking Screw

- On-axis polyaxial locking capability
- Cortical bone thread
- 2.5mm pre-drill
- 10 – 60mm lengths



3.5mm Non-Locking Screw

- Low-profile head sits flush with plate
- Cortical bone thread
- 2.5mm pre-drill
- 10 – 60mm lengths

Preoperative Planning (cont.)

Screw Fixation

When using a locking screw on-axis with the plate, thread the appropriate locking drill guide into the 3Di locking hole and use the corresponding drill (Table 1) through the guide to the appropriate depth.



2.0mm drill guide for 2.7mm
Locking and Non Locking screws



2.5/2.8mm drill guide for 3.5mm
Locking and Non Locking screws

All 3Di locking holes and locking screws have polyaxial locking capabilities. To engage a locking screw off-axis to the plate threads, use the drill corresponding to the selected screw to drill to the appropriate depth ensuring that the drill trajectory stays within 15° from center axis.

IMPORTANT NOTE: For a misdirected screw, the Ortholoc 3Di locking screws can be disengaged from a locking hole, redirected, and locked again up to three times.

Determining Screw Length

Screw length can be determined with the drill and drill guides. Use the appropriate drill to penetrate through the near cortex and continue until the far cortex is reached. Stop drilling just as the far cortex of the bone is penetrated and note where the screw length reference on the drill meets the drill guide. (Figure 4) Alternatively, a depth gauge is included in the sterile instrument pack.



Preoperative Planning (cont.)

Compression Slots

Compression across a fracture site can be achieved using the oblong compressions slots in selected plates. (Figure 1)

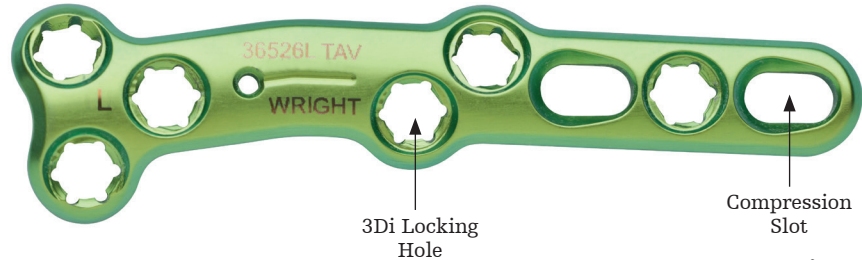


Figure 1

Fixate the side of the plate opposite to the compression slot using the appropriate locking or non-locking screw. Using the appropriate pre-drill, drill a hole at the furthest point in the compressions slot away from the fusion site, (Figure 2) and drive the appropriate non-locking screw until fully seated in the plate. (Figure 3) Compression across the fusion site is created as the screw travels to the center of the compressions slot. Additional fixation is recommended after compression is achieved.

IMPORTANT NOTE: Bicortical fixation is required for proper use of the compressions slot feature.

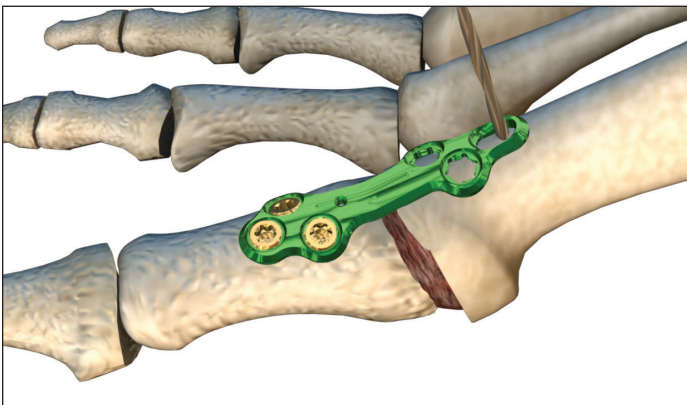


Figure 2

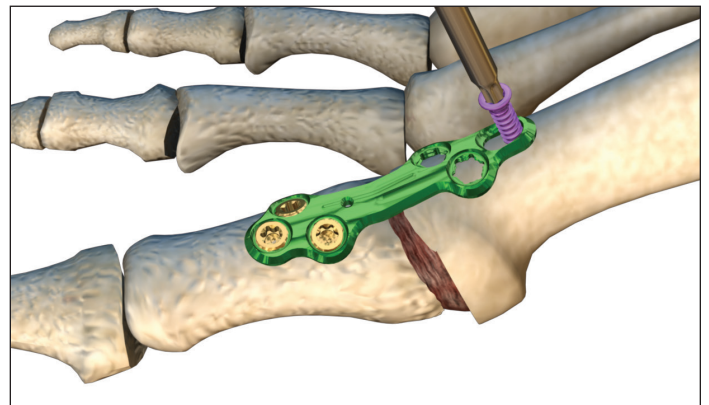


Figure 3

Plate Contouring

The Ortholoc 3Di Foot Reconstruction Plates have been designed to match the anatomic contours of the forefoot and midfoot. In most cases, intraoperative plate contouring will not be necessary. In cases of bone deformity or abnormalities some contouring may be required.

IMPORTANT NOTE: Care should be taken to avoid over-bending or bending in a back-and-forth motion to prevent stress risers.

Operative technique

MTP Fusion Technique

Surgical Approach

A dorsal longitudinal or dorso-medial incision is the recommended surgical approach, as it provides the best exposure for plating of the MTP joint. In patients where healing of the skin flap may be problematic, a medial approach may be considered.

Start the incision just proximal to the interphalangeal joint and extend it over the dorsum of the MTP joint, medial to the Extensor Hallucis Longus (EHL) tendon. End the incision on the medial aspect of the metatarsal, 2-3cm proximal to the joint.

Incise and release the joint capsule collateral ligaments to expose the base of the proximal phalanx and the metatarsal head.



Component of 58A9CCXT, 58A9LAPT, 58A9MTPL, 58A9MTPR, 58A9REVT

Metatarsal Preparation

Displace the phalanx plantarly, exposing the metatarsal head. Use the MTP Reamer Trial to determine the appropriate size of cup and cone reamer to prepare the metatarsal head and phalanx.

Using a powered drill, place a 1.6mm K-Wire through the center of the metatarsal head into the diaphysis of the metatarsal. Place the MTP Reamer Trial over the K-Wire and press the concave sizers against the metatarsal head to determine the best fit. Select the appropriate size (16mm, 18mm, 20mm, 22mm) for joint preparation.

Place the cone-shaped metatarsal head reamer over the K-Wire and ream using a “peck-drilling” technique until bleeding subchondral bone becomes visible on the joint surface. (Figure 4) Use of the power driver at a low RPM and occasional irrigation is recommended to prevent thermal necrosis.

Phalangeal Preparation

Reaming of the phalanx is performed in a similar fashion to the metatarsal head. To properly expose the articular surface of phalanx, plantarflex the toe and turn into valgus to avoid interference with the metatarsal head. A curved McGlamry or Hohman retractor (not provided) is usually helpful for exposure and in protecting the metatarsal head during reaming. The 1.6mm K-Wire is again placed in the center of the articular cartilage and directed through the diaphysis.

Proceed cautiously, taking care not to remove too much bone or damage the metatarsal head. (Figure 5)

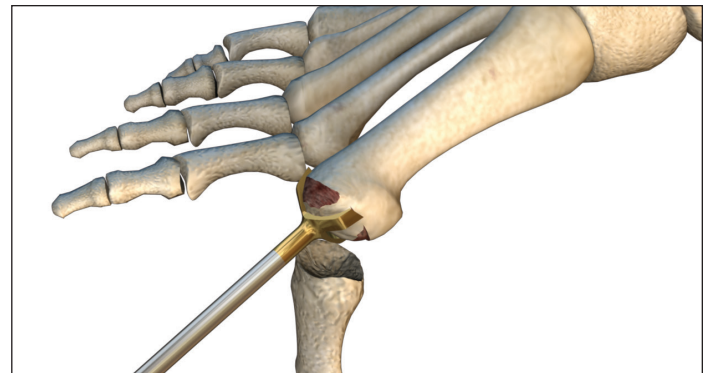


Figure 4

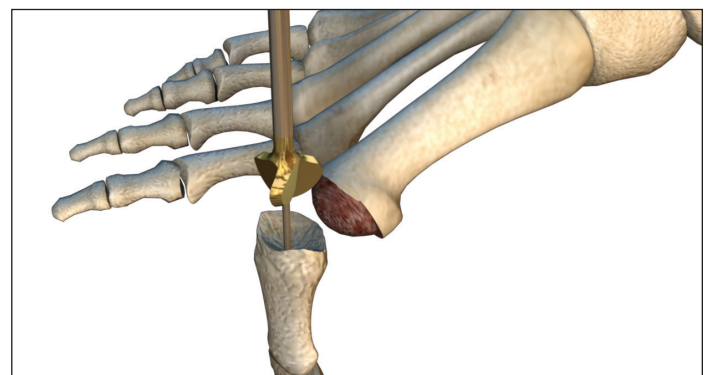


Figure 5

MTP Reamer 16mm	58A92016
MTP Reamer 18mm	58A92018
MTP Reamer 20mm	58A92020
MTP Reamer 22mm	58A92022

Plate Selection

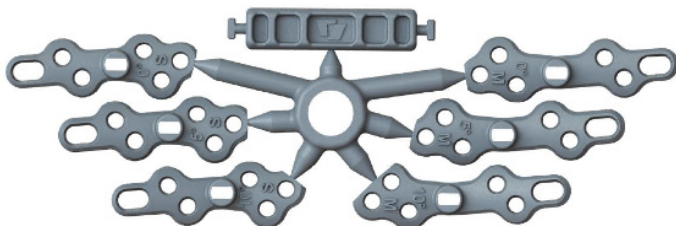
Surgical Approach

The Ortholoc 3Di Foot Reconstruction System provides multiple MTP Arthrodesis plating options and styles. (Table 2) All implants are left/right specific, feature 10° of valgus correction, and multiple dorsiflexion options. Additionally, all plates feature internal compression slots. Plate selection should be based on surgical goals, patient anatomy, activity level, and shoe wear preferences.

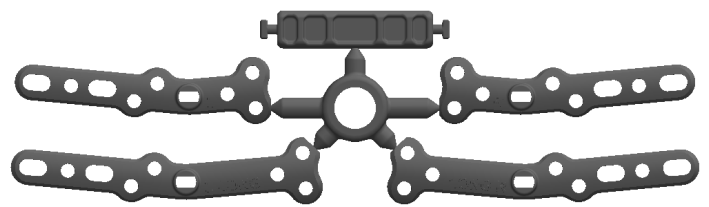
Table 2: MTP Plating Options

		Length	Dorsiflexion Options	Valgus
Primary	Small	42mm	0°, 5°, 10°	10°
	Medium			
	Revision	60mm	0°	10°
	Revision Long	73mm	0°	10°

A series of plate trials are available to assist in selecting the correct implant and fit. Each plate trial can be removed from the plate trial assembly and locked into the trial handle to trial the plate position and fit intra-operatively.



MTP Plate Trials
(58A9MTPL, 58A9MTPR)



MTP Revision Plate Trials
(58A9REVT)

Using the provided temporary fixation pins, provisionally fixate the plate to the bone proximally and distally to the joint. (Figure 6) Temporary fixation pins can be placed in the temporary fixation holes (if provided) and/or any 3Di locking screw hole.

With the plate provisionally fixed to the bone, dorsiflexion, valgus angle and plate position can now be assessed. Generally, 5° to 10° of dorsiflexion is desired for fusion. Fluoroscopy should also be utilized to evaluate valgus angle and proper plate placement. Use a flat object to simulate standing posture and determine appropriate dorsiflexion.

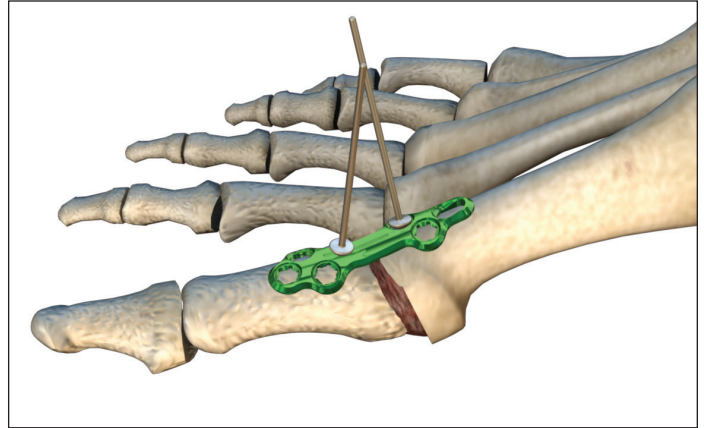


Figure 6

Screw Fixation

Using the techniques described in the screw fixation section of this guide, place locking and/or non-locking screws through all 3Di locking plate holes. (Figures 7 and 8) It is recommended that distal fixation is achieved before proximal holes are filled and always prior to using the proximal compression slots (see compression slots guide section). 2.7mm screws are recommended for fixation of the MTP plate, however 3.5mm locking screws may be used in cases of larger anatomy.

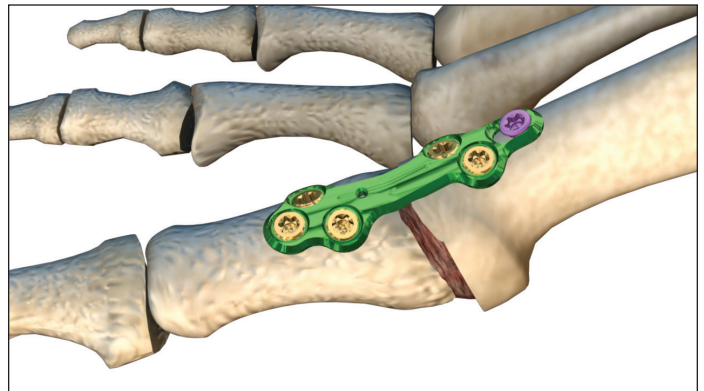


Figure 7

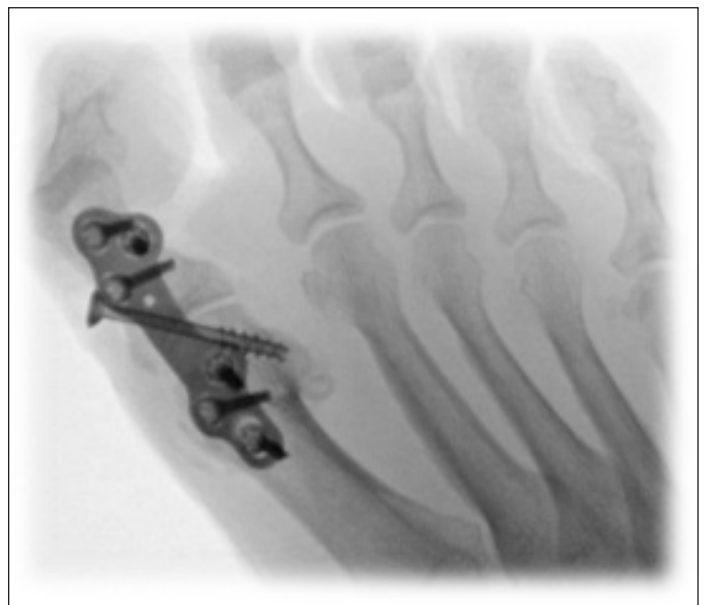


Figure 8

Lapidus Fusion Technique

Surgical Approach

Plan a dorsomedial approach to the proximal 1st TMT, just medial to the EHL tendon. The approach should extend 2-3cm on either side of the TMT. (Figure 9) Create the skin incision taking care to identify and protect any overlying neurovascular structures. Deepen the incision through the fascial layers to the dorsal capsule of the TMT. Using blunt dissection, release the EHL off the TMT and retract the tendon laterally. Confirm the location of the 1st TMT joint either directly or using fluoroscopy.



Figure 9

Perform a capsulotomy at the superior aspect of the 1st TMT to expose the entire joint. Care should be taken to ensure complete exposure of the plantar and lateral aspects of this joint, which is quite deep. Hand prepare the joint and remove the cartilage using the Joint Preparation Kit (9914PK01). The osteotome is tended 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. Alternatively, use the Joint Preparation Guide (9914PK02).

Joint Preparation

A distraction device should be used to gain exposure to the first TMT joint. Take care in planning pin placement to avoid interference with the planned plate position. (Figure 9)

With the joint distracted, take down the cartilage of the 1st TMT per standard procedure. Remove the cartilage thoroughly until dense subchondral bone is completely exposed on both sides of the joint.

Lapidus Approach (cont.)

Interfragmentary Screw Placement

Correction of the first intermetatarsal angle is addressed per standard technique. If first ray shortening is experienced the metatarsal may be translated plantarly or plantarflexed to compensate. Once the metatarsal has been placed appropriately and IM angle addressed, drive a 1.4mm K-Wire distal-plantar to proximal-dorsal as a means of temporary fixation. (Figure 10) Verify correction fluoroscopically.

The use of a 4.0mm or 4.5mm cannulated screw is suggested to augment plate fixation and prevent plantar gapping. Using the driven K-Wire as a guide, place the screw across the fusion site per standard technique. (Figure 11) Additional compressions may be achieved through the compression slot features on all Lapidus plates.



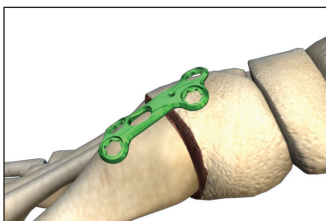
Figure 10



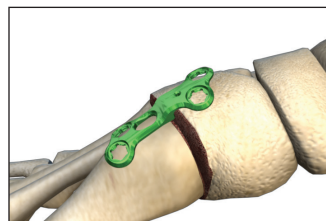
Figure 11

Plate Selection

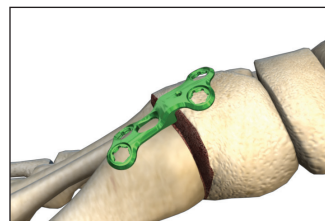
The Ortholoc 3Di Lapidus plate has been designed with progressive plantar steps to counteract first ray shortening. Plantar steps have been designed with a smooth dorsal transition to prevent soft tissue irritation. Select the plate that corresponds with the corrected joint, and that meets the specific needs associated with the patient's anatomy and surgical goals.



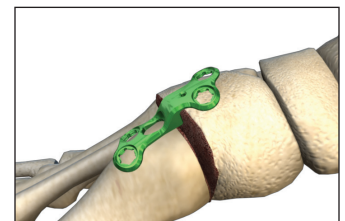
0mm Step
(Flat Plate)



2mm Step



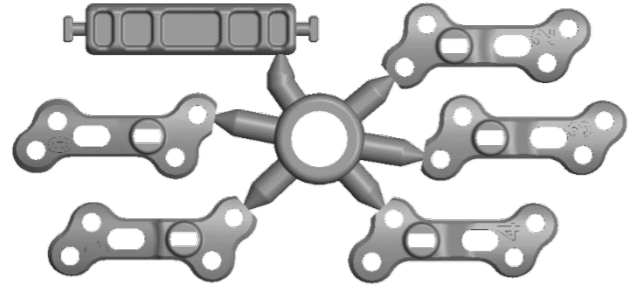
3mm Step



4mm Step

Lapidus Approach (cont.)

A series of plate trials are available to assist in selecting the correct implant and fit. Each plate trial can be removed from the plate trial assembly and locked into the trial handle to trial the plate position and fit intra-operatively.



Lapidus Trials
(58A9LAPT)

Provisional Plate Placement

The Ortholoc 3Di Lapidus Plate should be placed dorso-medial over the first TMT joint. Ensure that the compression slot is distal to the joint, and that the slot completely clears the joint space. Provisional fixation is achieved by placing the temporary fixation pins proximal and distal to the joint in the temporary fixation holes or any plate screw hole. (Figure 12)

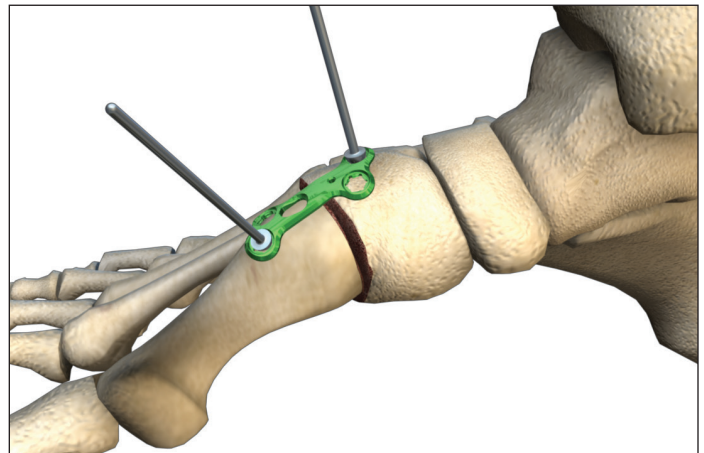


Figure 12

Screw Fixation

Using the techniques previously described, place locking and/or non-locking screws through all plate holes. (Figures 13 and 14) It is recommended that proximal fixation is achieved before distal holes are filled and always prior to using the distal compression slot (see compression slot guide section). 3.5mm screws are generally recommended for fixation of the lapidus plate. Once final screw placement is complete, all screws used on axis should sit flush with the plate.

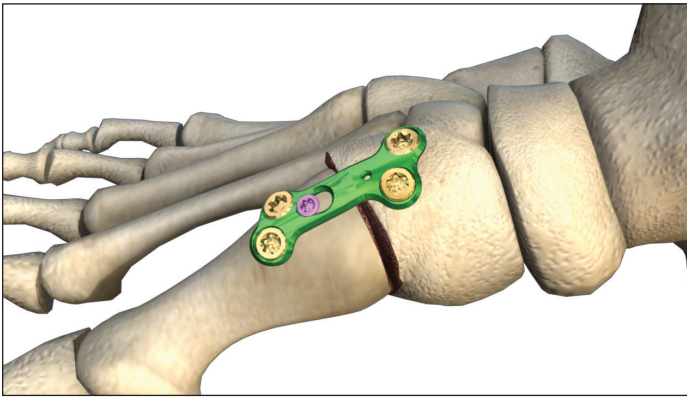


Figure 13

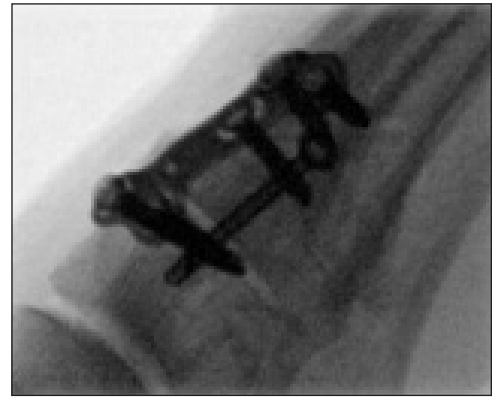


Figure 14

Intended Use

Indications*

The Ortholoc 3Di Foot Reconstruction System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet.

Specific examples include:

- Mid / Hindfoot Fusions
- LisFranc Arthrodesis and/or Stabilization
- 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
- Intercuneiform Fusions
- Navicular-Cuneiform (NC) Fusion
- Tal-Navicular (TN) Fusion
- Calcaneo-Cuboid (CC) Fusion
- Medial Column Fusion

First metatarsal osteotomies for hallux valgus correction including:

- Opening base wedge osteotomy
- Closing base wedge osteotomy
- Crescentic osteotomy
- Proximal Chevron osteotomy
- Distal Chevron osteotomy (Austin)

First metatarsal fracture fixation

Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion)

Arthrodesis of the first metatarsophalangeal joint (MTP) including:

- Primary MTP Fusion due to hallux rigidus and/or hallux valgus
- Revision MTP Fusion
- Revision of failed first MTP Arthroplasty implant

Flatfoot Osteotomies

- Lateral Column Lengthening (Evans Osteotomy)
- Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)

Contraindications

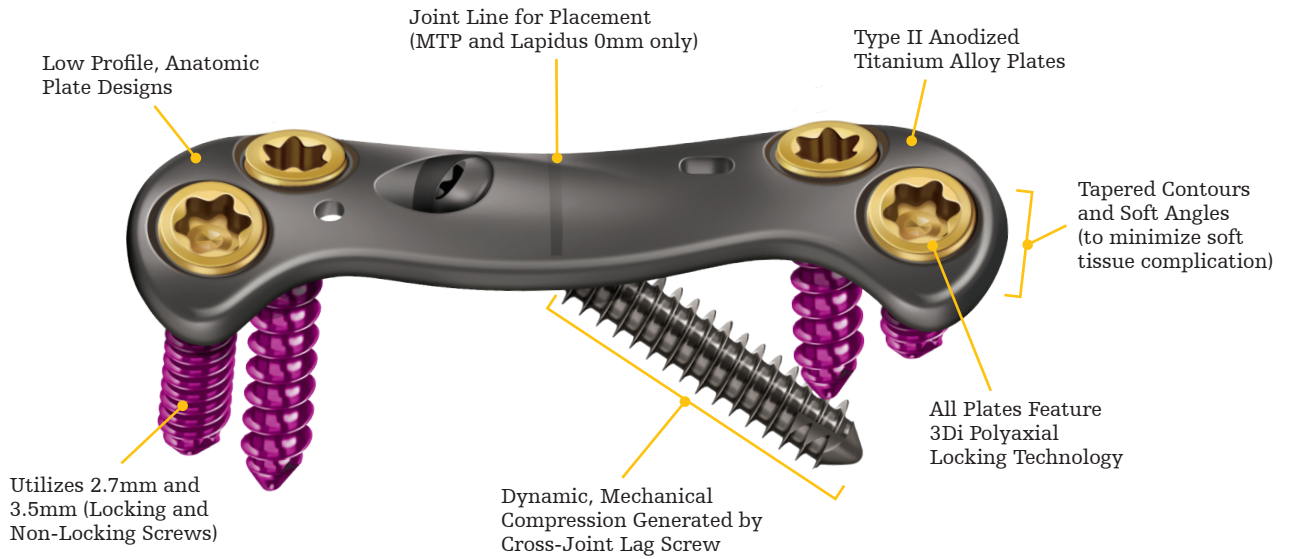
No product specific contraindications.

*The techniques contained represent the Pulse sterile offering of the Ortholoc 3Di Crosscheck Reconstruction system. For interest in other techniques/devices in the Ortholoc 3Di Crosscheck system not shown, please contact your sales rep for more information on ordering.

Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.

Ortholoc 2 Crosscheck Module

The Ortholoc 3DI Crosscheck module is a multi-functional plating system which utilizes 2.7mm and 3.5mm non-locking and polyaxial locking screws as well as a 3.5mm system specific cross screw that interfaces with the plate. The system includes anatomic, Type II anodized titanium alloy plates specifically indicated for MTP and Lapidus fusions, in addition to utility plates for reconstruction of small bones in the foot and toes.



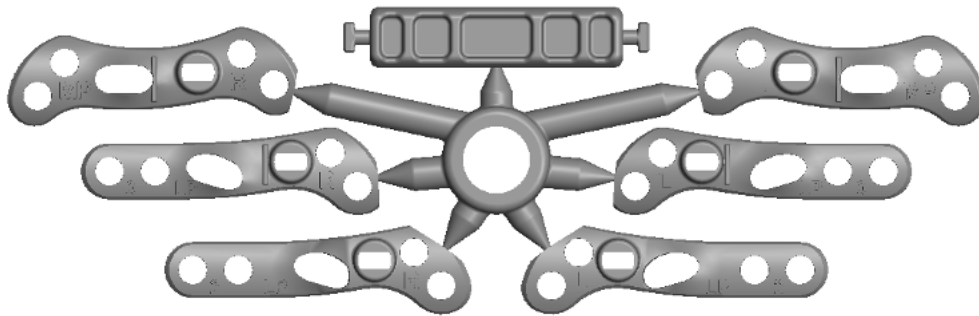
Preoperative Planning

Implant Selection

Plates

Like any lower extremity procedure, preoperative planning is vital to the overall outcome of joint fusion and osteotomy fixation. Careful consideration must be given to implant selection. Choose an implant that addresses the specific needs dictated by the indication, patient anatomy, and overall surgical goals.

A series of plate trials are available to assist in selecting the correct implant and fit. Each plate trial can be removed from the plate trial assembly and locked into the trial handle to trial the plate position and fit intra-operatively.

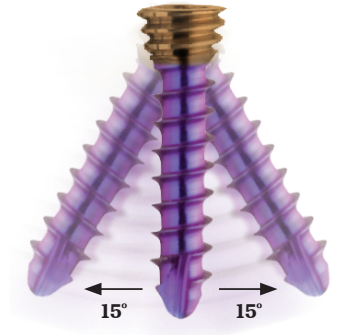


Crosscheck Trials
(58A9CCXT)

Preoperative Planning (cont.)

Screws

The Ortholoc 3Di Locking hole has been designed to accept the 2.7mm and 3.5mm Ortholoc 3Di locking and non-locking screws. Choose the most appropriate screw diameter and type based on anatomy, bone quality, and surgical goals.



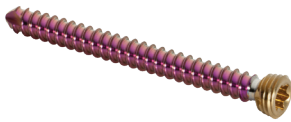
2.7mm Locking Screw

- On-axis polyaxial locking capability
- Cortical bone thread
- 2.0mm pre-drill
- 10 – 30mm lengths



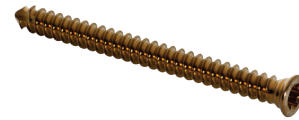
2.7mm Non-Locking Screw

- Low-profile head sits flush with plate
- Cortical bone thread
- 2.0mm pre-drill
- 10 – 30mm lengths



3.5mm Locking Screw

- On-axis polyaxial locking capability
- Cortical bone thread
- 2.5mm pre-drill
- 10 – 60mm lengths



3.5mm Non-Locking Screw

- Low-profile head sits flush with plate
- Cortical bone thread
- 2.5mm pre-drill
- 10 – 60mm lengths



3.5mm Cross Screw*

- Cortical bone thread
- 2.5mm pre-drill
- 18 – 40mm lengths
- Head profile fits within plate

*For use only with Ortholoc 2 Crosscheck

Preoperative Planning (cont.)

Screw Fixation

When using a locking screw on-axis with the plate, thread the appropriate locking drill guide into the 3Di locking hole and use the corresponding drill through the guide to the appropriate depth.



2.0mm drill guide for 2.7mm
Locking and Non Locking screws



2.5/2.8mm drill guide for 3.5mm
Locking and Non Locking screws

All 3Di locking holes and locking screws have polyaxial locking capabilities. To engage a locking screw off-axis to the plate threads, use the drill corresponding to the selected screw to drill to the appropriate depth ensuring that the drill trajectory stays within 15° from center axis.

IMPORTANT NOTE: For a misdirected screw, the Ortholoc 3Di locking screws can be disengaged from a locking hole, redirected, and locked again up to three times.

Determining Screw Length

Screw length can be determined with the drill and drill guides. Use the appropriate drill to penetrate through the near cortex and continue until the far cortex is reached. Stop drilling just as the far cortex of the bone is penetrated and note where the screw length reference on the drill meets the drill guide. (Figure 15) Alternatively, a depth gauge is included in the sterile instrument pack.



Figure 15

Operative technique

MTP Fusion Technique

Surgical Approach

A dorsal longitudinal or dorso-medial incision is the recommended surgical approach, as it provides the best exposure for plating of the MTP joint. In patients where healing of the skin flap may be problematic, a medial approach may be considered.

Start the incision just proximal to the interphalangeal joint and extend it over the dorsum of the MTP joint, medial to the Extensor Hallucis Longus (EHL) tendon. End the incision on the medial aspect of the metatarsal, 2-3 cm proximal to the joint.

Incise and release the joint capsule collateral ligaments to expose the base of the proximal phalanx and the metatarsal head.

Step 1: Metatarsal Preparation

Displace the phalanx plantarly, exposing the metatarsal head. Use the MTP Reamer Trial to determine the appropriate size of cup and cone reamer to prepare the metatarsal head and phalanx.

Using a powered drill, place a 1.6mm K-Wire through the center of the metatarsal head into the diaphysis of the metatarsal. Place the MTP Reamer Trial over the K-Wire and press the concave sizes against the metatarsal head to determine the best fit. Select the appropriate size (16mm, 18mm, 20mm, 22mm) for joint preparation.

Place the cone-shaped reamer trial against the metatarsal head and select the appropriate size (16mm, 18mm, 20mm, or 22mm) for joint preparation. Place the cone-shaped metatarsal head reamer over the K-Wire and ream using a “peck-drilling” technique until bleeding subchondral bone becomes visible on the joint surface. (Figure 17) Use of the power driver at a low RPM and occasional irrigation is recommended to prevent thermal necrosis.



Figure 16



Component of 58A9CCXT, 58A9LAPT, 58A9MTPL, 58A9MTPR, 58A9REVT

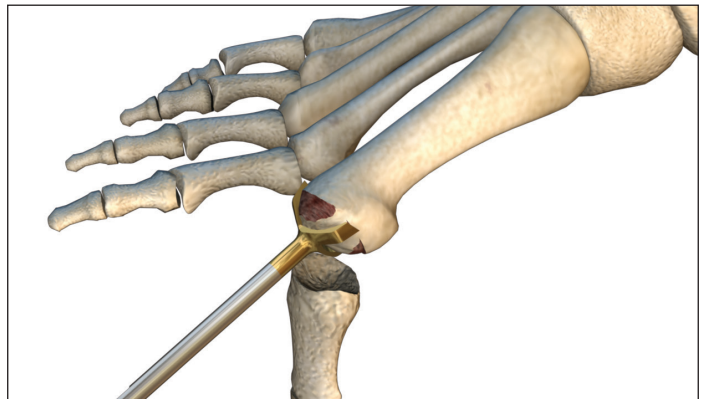


Figure 17

MTP Reamer 16mm	58A92016
MTP Reamer 18mm	58A92018
MTP Reamer 20mm	58A92020
MTP Reamer 22mm	58A92022

Step 2: Phalangeal Preparation

Reaming of the phalanx is performed in a similar fashion to the metatarsal head. To properly expose the articular surface of phalanx, plantarflex the toe and turn into valgus to avoid interference with the metatarsal head. A curved McGlamry or Hohman retractor (not provided) is usually helpful for exposure and in protecting the metatarsal head during reaming. The 1.6mm K-Wire is again placed in the center of the articular cartilage and directed through the diaphysis.

Proceed cautiously, taking care not to remove too much bone or damage the metatarsal head.

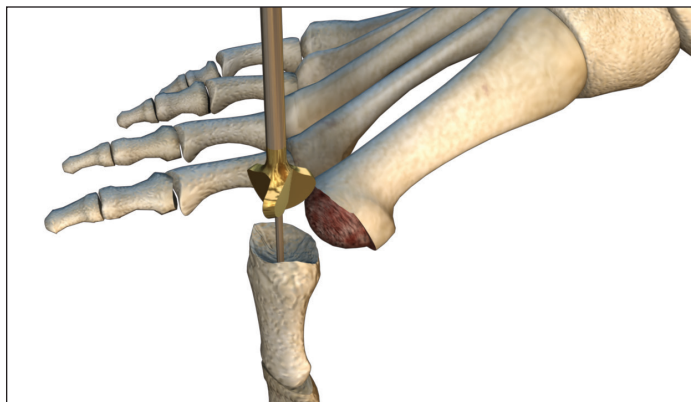


Figure 18

Step 3: Plate Placement

Ensure that the cross screw hole is distal to the point, that the hole completely clears the joint space, and that the laser mark line of the plat is approximately at the joint line. Utilize the 1.1mm temporary fixation pins in the distal pin hole and the proximal pint slot. Ensure that the 1.1mm temporary fixation pin is the most proximal it can be within the slotted hold as shown.

MTP Reamer 16mm	58A92016
MTP Reamer 18mm	58A92018
MTP Reamer 20mm	58A92020
MTP Reamer 22mm	58A92022

Step 4: Screw Placement

Once the temporary pins are placed, screws should be inserted in the sequence shown. Place a 2.7mm or 3.5mm non-locking screw or polyaxial locking screws through both distal 3Di plate holes first, using the T15 driver located in the plating instrument pack.

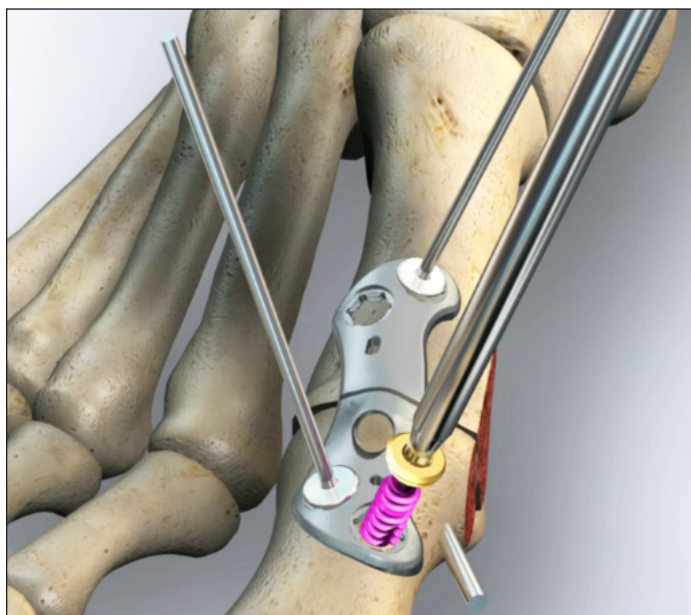


Figure 21

Note: T15 driver is used to place 2.7/3.5 locking and non-locking screws.

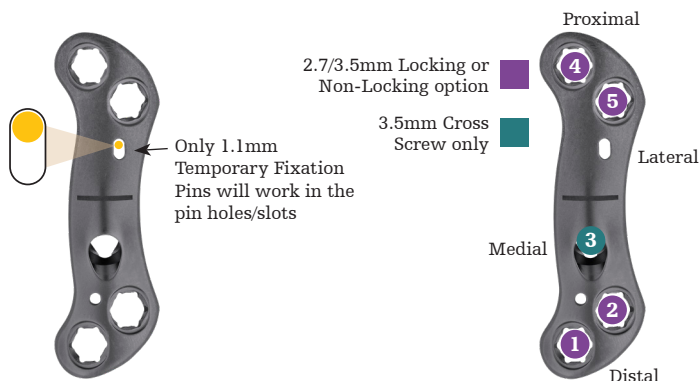


Figure 19
1.1mm Temporary Fixation Pin Location

Figure 20
Screw Size and Sequence



Driver Star 15 Straight
58861T15

Step 5: Cross Screw Preparation

Once the distal screws are in place, remove the distal fixation pin. Use the 2.5mm cross screw drill guide and the 2.5mm drill to prepare the cross screw hole. Using the drill guide, aim the drill to the portion just proximal of the sesamoids to achieve the optimal cross screw position shown.

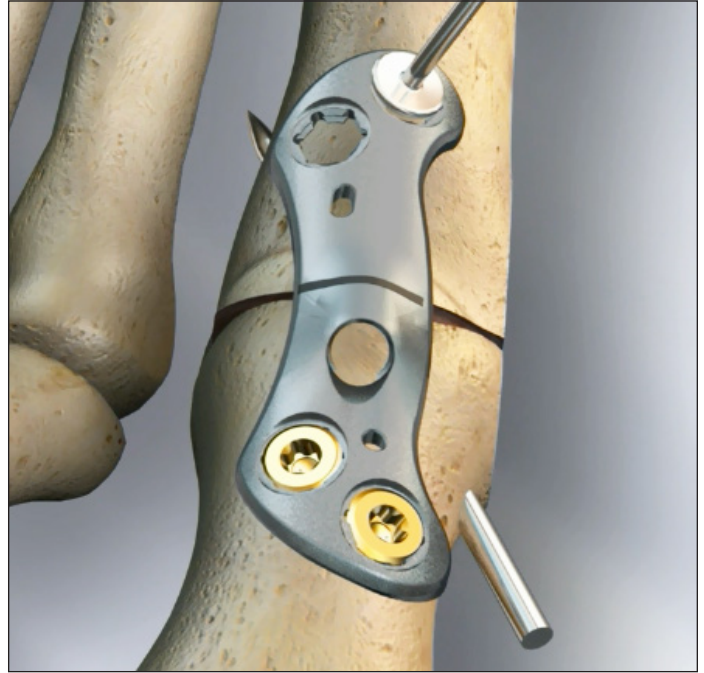


Figure 22

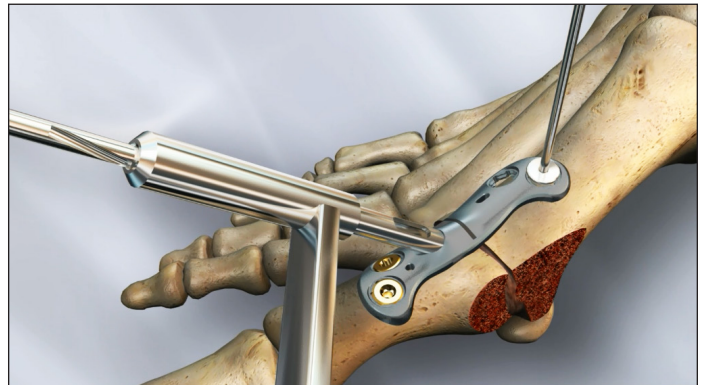


Figure 23

Step 6: Determining Ideal Cross Screw

To determine the length, use the Ortholoc 2.5mm drill and the 2.5mm drill guide provided in 58A91000. Using the drill through the guide, penetrate through the near cortex and continue until the far cortex is reached. Stop drilling just as the far cortex of the bone is penetrated and note where the screw length reference on the drill meets the drill guide.

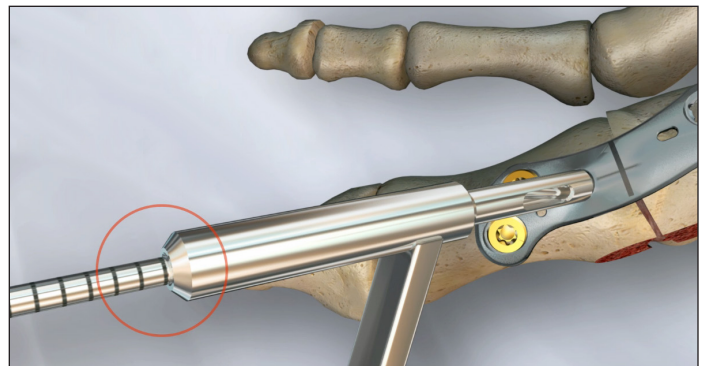


Figure 24

Step 7: Cross Screw Placement

The 3.5mm cross screw should be advanced in a clockwise motion using the T8 driver. Angle the screw to cross the joint and hit the plantar aspect of the metatarsal just proximal to the sesamoids. Once the joint is compressed, the remaining proximal screws are inserted.

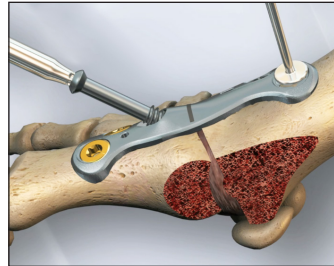


Figure 25



Figure 26

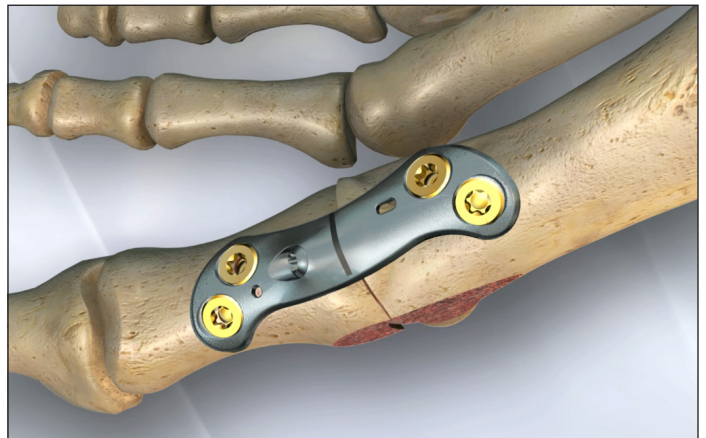


Figure 27

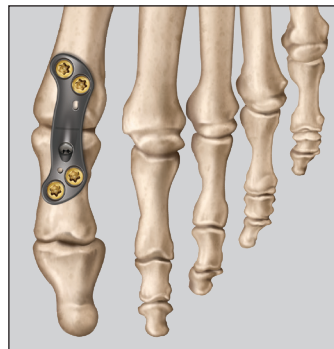


Figure 28



Figure 29

Lapidus Fusion Technique

Surgical Approach

Plan a dorsomedial approach to the proximal 1st TMT, just medial to the EHL tendon. The approach should extend 2-3cm on either side of the TMT. Create the skin incision, taking care to identify and protect any overlying neurovascular structures. Deepen the incision through the fascial layers to the dorsal capsule of the TMT. Using blunt dissection, release the EHL off the TMT and retract the tendon laterally. Confirm the location of the 1st TMT joint either directly or using fluoroscopy.



Figure 30

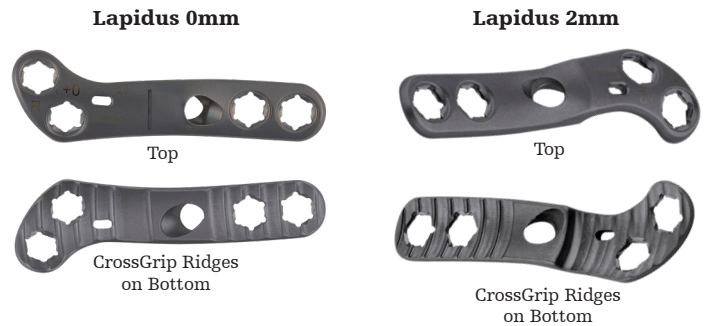
Perform a capsulectomy at the superior aspect of the 1st TMT to expose the entire joint. Care should be taken to ensure complete exposure of the plantar and lateral aspects of this joint, which is quite deep.

Step 1: TMT Joint Preparation

A distraction device should be used to gain exposure to the first TMT joint. Take care in planning pin placement to avoid interference with the planned plate position. 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. Alternatively, use the Joint Preparation Guide (9914PK02).

Step 2: Plate Selection

The Ortholoc 2 Crosscheck Lapidus plates have been designed with plantar steps to counteract first ray shortening. Plantar steps have a smooth dorsal transition to prevent soft tissue irritation. Select the plate that corresponds with the corrected joint, which also meets the specific needs associated with the patient's anatomy and surgical goals.



Step 3: Plate Placement

The Ortholoc 2 Crosscheck Lapidus Plate should be placed dorsal over the first TMT joint. Ensure that the cross screw hole is distal to the joint, that the hole completely clears the joint space, and that the laser mark line of the plate is approximately at the joint line. Provisional fixation is achieved by placing the temporary fixation pins proximal and distal to the joint in the temporary fixation holes or any plate screw hole.



Figure 31

Step 4: Screw Placement

Once the temporary pins are placed, screws should be inserted in the sequence shown. Place 2.7mm or 3.5mm non-locking or polyaxial locking screws through both distal 3Di plate holes first, using the T15 driver.

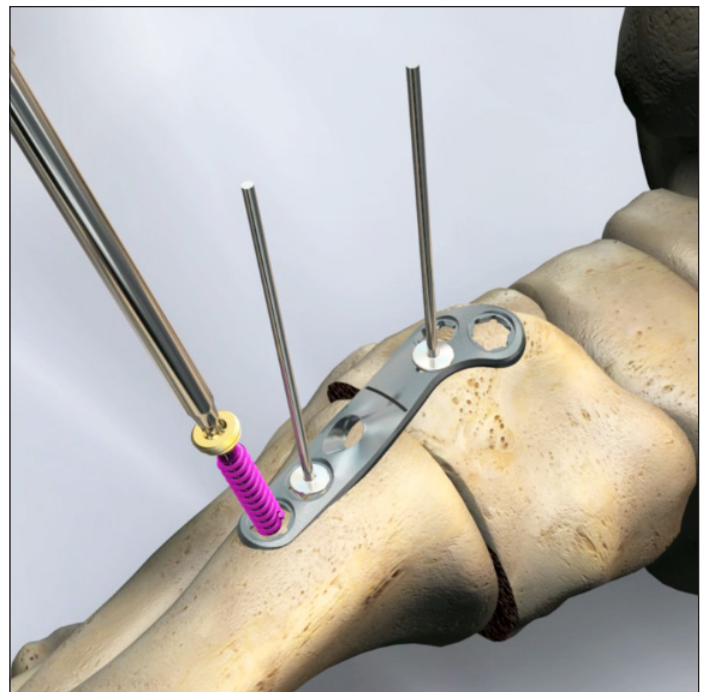


Figure 32

Step 5: Cross Screw Preparation

Once the distal screws are in place, use the 2.5mm cross screw drill guide and the 2.5mm drill to prepare the cross screw hole. Using the drill guide, aim the drill to the medical/plantar 1/3 of the cuneiform near the first metatarsal-cuneiform joint to achieve the optimum cross screw position.



Figure 33

Step 6: Determining Ideal Cross Screw

To determine the length needed for the 3.5mm cross screw, use the Ortholoc 2.5mm drill and the 2.5mm drill guide. Using the drill through the guide, penetrate through the near cortex and continue until the far cortex is reached. Stop drilling just as the far cortex of the bone is penetrated and note where the screw length reference on the drill meets the drill guide.

NOTE: T8 driver is used to place 3.5mm non-locking cross screw.

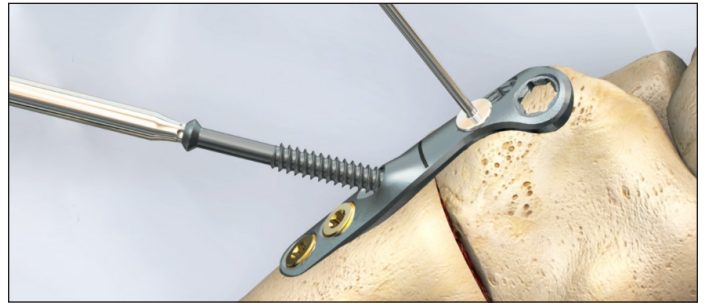


Figure 34

Step 7: Cross Screw Placement

Use the T8 driver to place the 3.5mm cross screw in the cross screw hole. The angle of the screw should hit the plantar/medial aspect of the medial cuneiform. After the cross screw is placed, place the remaining 2.7mm and/or 3.5mm non-locking or polyaxial locking screws in the proximal 3Di holes.

NOTE: Remove the proximal fixation pin prior to seating cross screw.

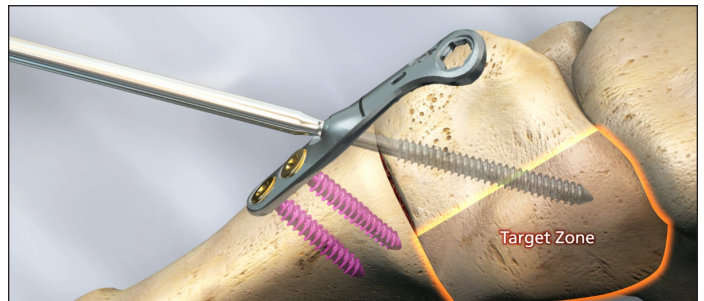
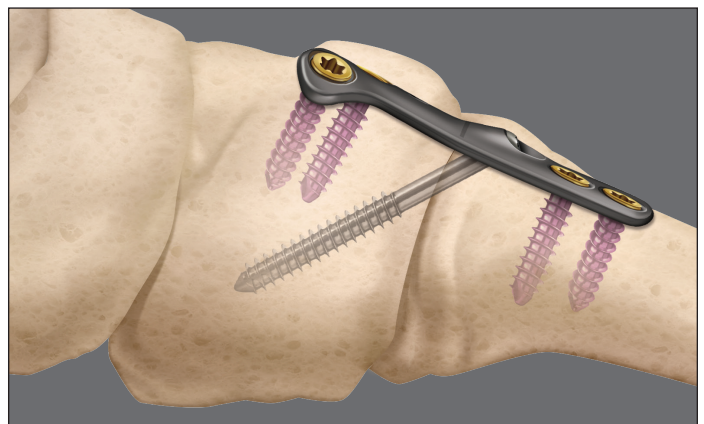


Figure 35



Explant Information

Removal of the plate may be performed by first extracting the plate screws using the STAR 15 Straight Driver (58861T15) and then removing the plate from the bone.

If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

Postoperative Management

Postoperative care is the responsibility of the medical professional.

Ordering Information

Reamers

Part No.	Description
58A9T200	MTP Cone Reamer Trial
58A92016	MTP Reamer Pack – 16mm
58A92018	MTP Reamer Pack – 18mm
58A92020	MTP Reamer Pack – 20mm
58A92022	MTP Reamer Pack – 22mm

Plates

Part No.	Description
58A110LT	MTP Fusion Small 0DG LT
58A110RT	MTP Fusion Small 0DG RT
58A111LT	MTP Fusion Small 10DG LT
58A111RT	MTP Fusion Small 10DG RT
58A115LT	MTP Fusion Small 5DG LT
58A115RT	MTP Fusion Small 5DG RT
58A220LT	MTP Fusion Medium 0DG LT
58A220RT	MTP Fusion Medium 0DG RT
58A221LT	MTP Fusion Medium 10DG LT
58A221RT	MTP Fusion Medium 10DG RT
58A225LT	MTP Fusion Medium 5DG LT
58A225RT	MTP Fusion Medium 5DG RT
58A338LT	MTP Fusion Revision RT
58A338RT	MTP Fusion Revision Large RT
58A439LT	MTP Fusion Revision LT
58A439RT	MTP Fusion Revision Large LT
58A10000	Lapidus Plate 0mm
58A10001	Lapidus Plate 1mm
58A10002	Lapidus Plate 2mm
58A10003	Lapidus Plate 3mm
58A10004	Lapidus Plate 4mm
58A0MPX1L	3Di Crosscheck MTP Left
58A0MPX1R	3Di Crosscheck MTP Right
58A0LPX0L	3Di Crosscheck LAP 0mm Left
58A0LPX0R	3Di Crosscheck LAP 0mm Right
58A0LPX2L	3Di Crosscheck LAP 2mm Step Right
58A0LPX2R	3Di Crosscheck LAP 2mm Step Left

Instruments

Part No.	Description
58A91000	Ortholoc Plating Inst Pack
58990016	K-Wire 1.6mm x 150mm Pack
58A93001	2.8 Drill Pack
58A93002	Locking Drill Guide Pack
9914PK01	Joint Preparation Kit
9914PK02	Joint Preparation Guide

Trials

Part No.	Description
58A9MTPR	MTP S/M Right Trials
58A9MTPL	MTP S/M Left Trials
58A9REVT	MTP Revision Trials
58A9LAPT	Lapidus Plate Trials
58A9CCXT	Crosscheck Plate Trials

Crosscheck Screws

Part No.	Description
58A0X3518	3Di Crosscheck Lag Screw 3.5 x 18mm
58A0X3520	3Di Crosscheck Lag Screw 3.5 x 20mm
58A0X3522	3Di Crosscheck Lag Screw 3.5 x 22mm
58A0X3524	3Di Crosscheck Lag Screw 3.5 x 24mm
58A0X3526	3Di Crosscheck Lag Screw 3.5 x 26mm
58A0X3528	3Di Crosscheck Lag Screw 3.5 x 28mm
58A0X3530	3Di Crosscheck Lag Screw 3.5 x 30mm
58A0X3532	3Di Crosscheck Lag Screw 3.5 x 32mm
58A0X3534	3Di Crosscheck Lag Screw 3.5 x 34mm
58A0X3536	3Di Crosscheck Lag Screw 3.5 x 36mm
58A0X3538	3Di Crosscheck Lag Screw 3.5 x 38mm
58A0X3540	3Di Crosscheck Lag Screw 3.5 x 40mm

Screws

Part No.	Description
58A02710	Locking LG HD Screw 2.7 x 10mm
58A02712	Locking LG HD Screw 2.7 x 12mm
58A02714	Locking LG HD Screw 2.7 x 14mm
58A02716	Locking LG HD Screw 2.7 x 16mm
58A02718	Locking LG HD Screw 2.7 x 18mm
58A02720	Locking LG HD Screw 2.7 x 20mm
58A02722	Locking LG HD Screw 2.7 x 22mm
58A02724	Locking LG HD Screw 2.7 x 24mm
58A02726	Locking LG HD Screw 2.7 x 26mm
58A02728	Locking LG HD Screw 2.7 x 28mm
58A02730	Locking LG HD Screw 2.7 x 30mm
58A03510	Locking Screw 3.5 x 10mm
58A03512	Locking Screw 3.5 x 12mm
58A03514	Locking Screw 3.5 x 14mm
58A03516	Locking Screw 3.5 x 16mm
58A03518	Locking Screw 3.5 x 18mm
58A03520	Locking Screw 3.5 x 20mm
58A03522	Locking Screw 3.5 x 22mm
58A03524	Locking Screw 3.5 x 24mm
58A03526	Locking Screw 3.5 x 26mm
58A03528	Locking Screw 3.5 x 28mm
58A03530	Locking Screw 3.5 x 30mm
58A03532	Locking Screw 3.5 x 32mm
58A03534	Locking Screw 3.5 x 34mm
58A03536	Locking Screw 3.5 x 36mm
58A03538	Locking Screw 3.5 x 38mm
58A03540	Locking Screw 3.5 x 40mm
58A03542	Locking Screw 3.5 x 42mm
58A03544	Locking Screw 3.5 x 44mm
58A03546	Locking Screw 3.5 x 46mm
58A03548	Locking Screw 3.5 x 48mm
58A03550	Locking Screw 3.5 x 50mm
58A03555	Locking Screw 3.5 x 55mm
58A03560	Locking Screw 3.5 x 60mm

Screws

Part No.	Description
58A12710	Low Profile Cort Screw 2.7 x 10mm
58A12712	Low Profile Cort Screw 2.7 x 12mm
58A12714	Low Profile Cort Screw 2.7 x 14mm
58A12716	Low Profile Cort Screw 2.7 x 16mm
58A12718	Low Profile Cort Screw 2.7 x 18mm
58A12720	Low Profile Cort Screw 2.7 x 20mm
58A12722	Low Profile Cort Screw 2.7 x 22mm
58A12724	Low Profile Cort Screw 2.7 x 24mm
58A12726	Low Profile Cort Screw 2.7 x 26mm
58A12728	Low Profile Cort Screw 2.7 x 28mm
58A12730	Low Profile Cort Screw 2.7 x 30mm
58A13510	Low Profile Cort Screw 3.5 x 10mm
58A13512	Low Profile Cort Screw 3.5 x 12mm
58A13514	Low Profile Cort Screw 3.5 x 14mm
58A13516	Low Profile Cort Screw 3.5 x 16mm
58A13518	Low Profile Cort Screw 3.5 x 18mm
58A13520	Low Profile Cort Screw 3.5 x 20mm
58A13522	Low Profile Cort Screw 3.5 x 22mm
58A13524	Low Profile Cort Screw 3.5 x 24mm
58A13526	Low Profile Cort Screw 3.5 x 26mm
58A13528	Low Profile Cort Screw 3.5 x 28mm
58A13530	Low Profile Cort Screw 3.5 x 30mm
58A13532	Low Profile Cort Screw 3.5 x 32mm
58A13534	Low Profile Cort Screw 3.5 x 34mm
58A13536	Low Profile Cort Screw 3.5 x 36mm
58A13538	Low Profile Cort Screw 3.5 x 38mm
58A13540	Low Profile Cort Screw 3.5 x 40mm
58A13542	Low Profile Cort Screw 3.5 x 42mm
58A13544	Low Profile Cort Screw 3.5 x 44mm
58A13546	Low Profile Cort Screw 3.5 x 46mm
58A13548	Low Profile Cort Screw 3.5 x 48mm
58A13550	Low Profile Cort Screw 3.5 x 50mm
58A13555	Low Profile Cort Screw 3.5 x 55mm
58A13560	Low Profile Cort Screw 3.5 x 60mm

Foot & Ankle

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

The instructions for use, operative techniques, cleaning instructions, patient information leaflets and other associated labeling may be requested online at ifu.stryker.com or stryker.com. If saving the instructions for use, operative techniques, cleaning instructions from the above mentioned websites, please make sure you always have the most up to date version prior to use.

Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks or service marks: Ortholoc and Stryker. All other trademarks are trademarks of their respective owners or holders.

AP-016056A, 06-2022

Copyright © 2022 Stryker



Manufacturer:
Wright Medical
Technology
1023 Cherry Road
Memphis, TN 38117
800 238 7117
901 867 9971
www.wright.com