

ORTHOLOC[®] 3Di

Foot Reconstruction System: Flatfoot Module

SURGICAL TECHNIQUE



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Flatfoot Module

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Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. 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 Wright Medical Technology, Inc.

Please contact your local Wright representative for product availability.

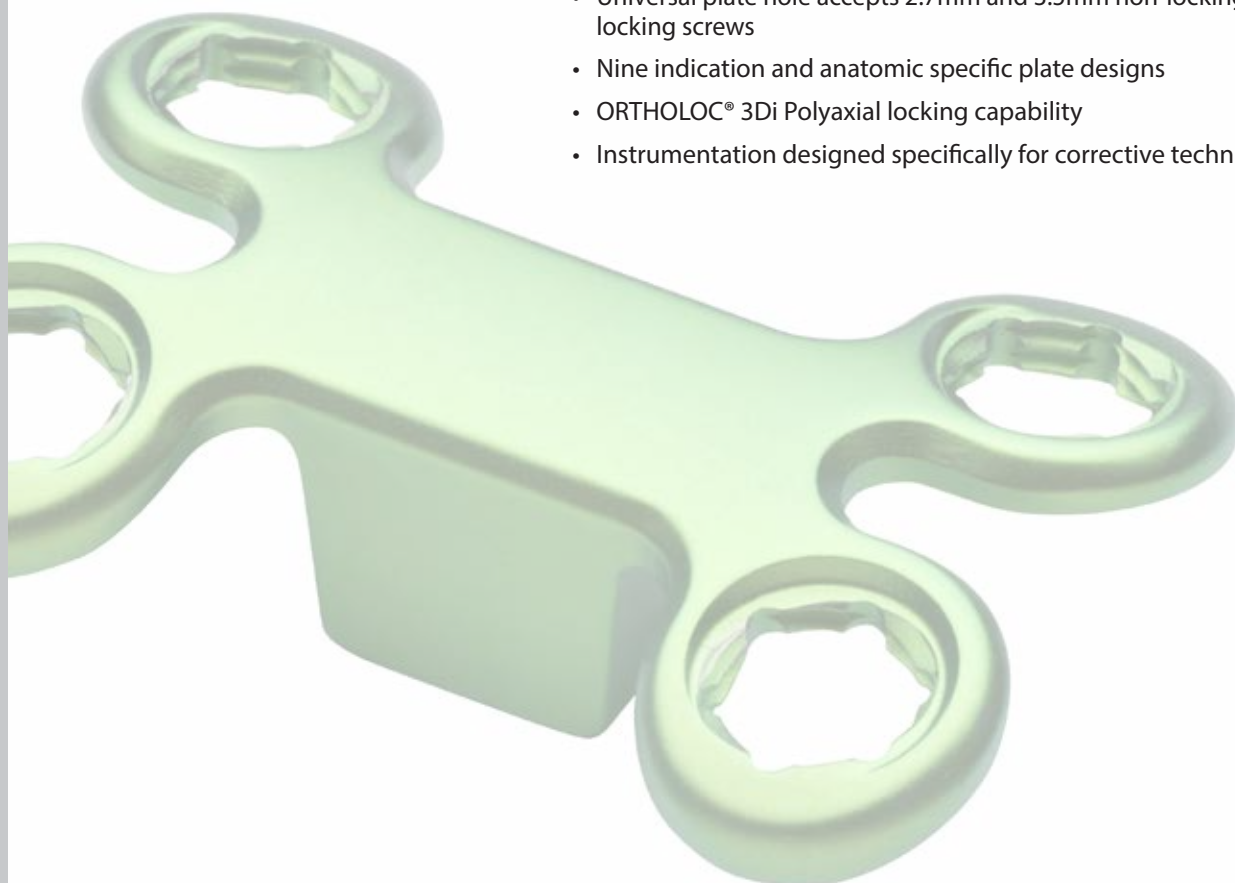
Introduction



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, midfoot and hindfoot. Each ORTHOLOC® 3Di implant has been designed with a focus on strength, versatility, and low-profile anatomic contours. Additionally, the employment of the ORTHOLOC® 3Di Polyaxial Locking Technology allows the surgeon the option 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 non-locking and polyaxial locking screws
- Nine indication and anatomic specific plate designs
- ORTHOLOC® 3Di Polyaxial locking capability
- Instrumentation designed specifically for corrective techniques



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:

Flatfoot Osteotomies:

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

Midfoot / Hindfoot Fusions:

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

Product Specific Contraindications

No device specific contraindications

General Surgical Contraindications

- Active Infection
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Insufficient bone quantity or quality of bone to permit stabilization
- Suspected or documented metal allergy or intolerance

Flatfoot Module

The Flatfoot module of the ORTHOLOC® 3Di System focuses on implant solutions related to joint arthrodesis, stabilizations, and osteotomies. The implants included in this module are designed to provide highly anatomic and versatile plating options for an array of fusions and osteotomies.

Plate Selection



Evans Osteotomy Plate



Cotton Osteotomy Plate

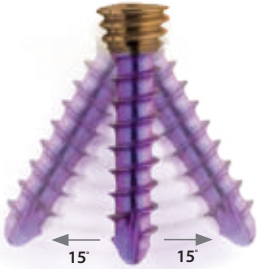


Medial Displacement
Calcaneal Osteotomy
(MDCO) Plate

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 non-locking and polyaxial locking screws. Choose the most appropriate screw diameter and type based on anatomy, bone quality, and surgical goals.



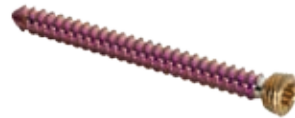
2.7mm Locking Screw

- On-axis and 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 and polyaxial locking capability
- Cortical bone thread
- 2.8mm 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

General System Procedures

Color Coding

The ORTHOLOC® 3Di Core Set features an instrument and implant color coding system designed to increase O.R. efficiency and speed. After choosing the appropriate screw for a given application, select the drill and drill guide with the corresponding color coded markings. | **FIGURE 1**



| **FIGURE 1**



2.0mm Locking Drill Guide	58872030
2.8mm Locking Drill Guide	58872560

| FIGURE 2

Screw Fixation

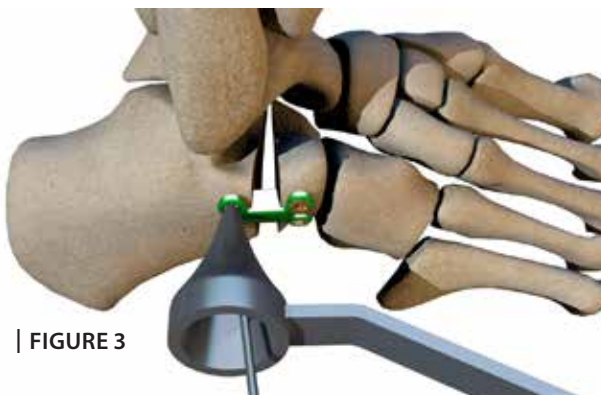
When using a locking screw on-axis with the plate, thread the appropriate locking drill guide into the 3Di locking hole and use the corresponding drill (Table 1) through the guide to the appropriate depth. | FIGURE 2

All 3Di locking holes and locking screws have polyaxial locking capabilities. To engage a locking screw off-axis to the plate threads, place the polyaxial drill guide into the desired locking hole. | FIGURE 3 Ensure the guide mates properly with the 3Di locking feature, and remains firmly engaged with the plate at 90° to the hole trajectory. Use the drill corresponding to the selected screw type to drill to the appropriate depth ensuring that the drill trajectory stays within the 30 degree guide cone (up to 15° from center axis).

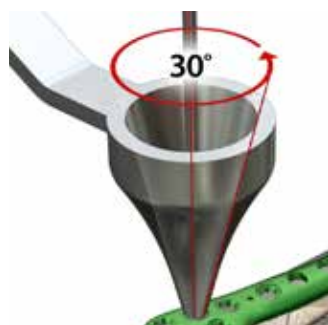
Table 1. Screw/Drill Reference Guide

Screw	Drill	Part Number
2.7mm Locking	2.0mm	58880020
2.7mm Non-Locking	2.0mm	58880020
3.5mm Locking	2.8mm	58850028
3.5mm Non-Locking	2.5mm	58850025

IMPORTANT NOTE: As a bailout for a misdirected screw, the ORTHOLOC® 3Di locking screws can be disengaged from a locking hole, redirected, and locked again up to three times.



| FIGURE 3



Polyaxial Drill Guide
58872028

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 As an alternative, a traditional screw depth gauge has also been provided in the system.



| FIGURE 4

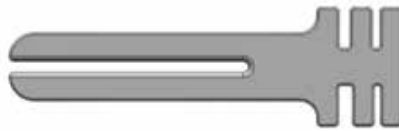
NOTE: To ensure bicortical fixation, add 2mm to the lag screw length.

Plate Contouring

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

Use the plate bending irons provided in the system to slightly modify plate contours as needed. | **FIGURE 5** Multiple slot widths are available to accommodate all plate types and thicknesses. Alternatively, threaded *in situ* plate benders are also provided in the system | **FIGURE 6** for contouring plates while on the bone. Thread the bender into any 3Di locking hole, ensuring full engagement to the plate threads. Lever the bender down, contouring the plate flush to the bone.

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



Slotted Plate Bender 58872031

| **FIGURE 5**

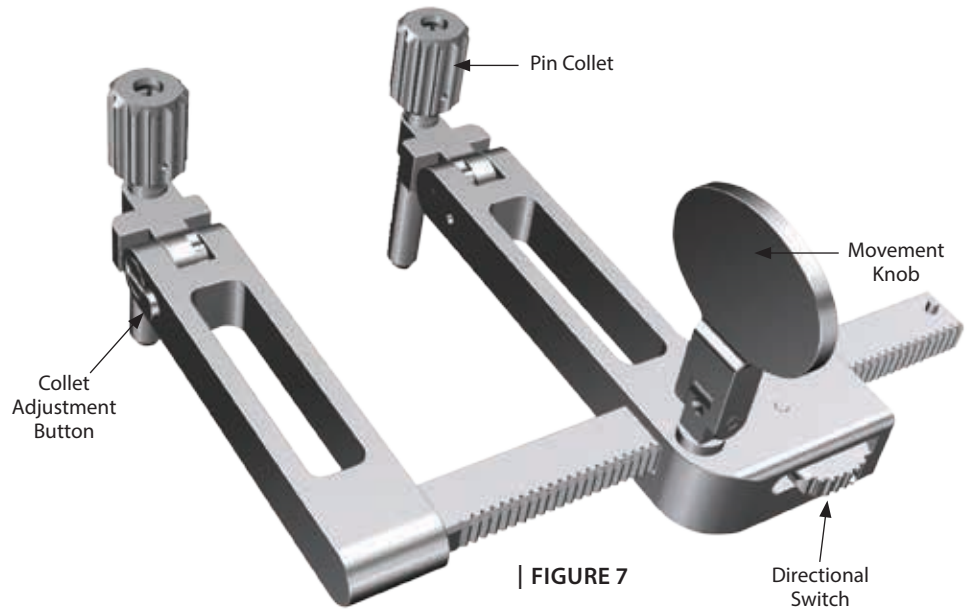


In Situ Plate Bender 58870003

| **FIGURE 6**

X-Track Distraction/Compression Device

The X-Track Distraction/Compression device has been designed specifically for foot and ankle indications, and can be used for a variety of procedures in the midfoot and hindfoot. Both distraction and compression can be achieved with the device by switching the directional switch adjacent to the movement knob. Additionally, the device can be adjusted to maximize site exposure and avoid interference with other instrumentation. | **FIGURE 7**



Insert the 2.5mm Steinmann Pin (P/N 58862515) provided in the system into the bone on one side of the appropriate joint or osteotomy and slide the pin collet over the pin. Place the second pin using the remaining X-Track pin collet as a guide for pin placement. Lock the pins in place by turning the knobs clockwise on the pin collets. Once locked, the pins can be trimmed to decrease interference in the workspace. For distraction, adjust the directional switch so that the arrow is pointed away from the joint (opposite for compression). Finally, the movement knob is rotated, moving the pin collets away from one another and creating distraction across the joint or osteotomy.

If needed, the core body of the device can be adjusted by pushing the collet adjustment button and relocked at 0°, 45°, or 90° positions.



X-Track Device
5882000X

Medial Displacement Calcaneal Osteotomy

Surgical Approach

The Medial Displacement Calcaneal Osteotomy (MDCO) incision is started laterally at the superior aspect of the posterior calcaneal tuberosity, just anterior to the insertion point of the Achilles tendon and posterior to the peroneal tendons. Extend the incision distally at a 45 degree angle relative to the plantar surface of the foot. Care should be taken to identify and retract the sural nerve anteriorly. Once the nerve is retracted, the incision can be taken down to bone and the periosteum carefully incised and reflected from the lateral calcaneal wall.

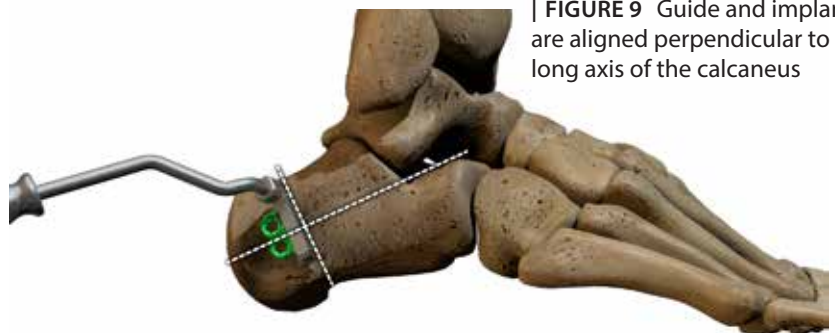
Osteotomy

The MDCO plate and accompanying instrumentation has been designed to facilitate an accurate and controlled osteotomy. The following steps are recommended as a means to possibly improve the efficiency of the procedure; however a traditional freehand cut of this osteotomy can be used.

Assemble the Cutting Guide/Inserter to the MDCO Plate prior to introducing the implant into the surgical site. | **FIGURE 8** Place the assembly on the bone ensuring that the anterior shelf of the plate is located at the desired osteotomy location and is aligned so the shelf of the implant is perpendicular to the longitudinal axis of the calcaneus. | **FIGURE 9** Provisional fixation of the plate is achieved using a temporary fixation pin in one of the posterior plate holes. Plate position is verified fluoroscopically.



| **FIGURE 8** Cutting Guide/Inserter (58190017) is threaded into shelf portion of implant using T15 Driver.

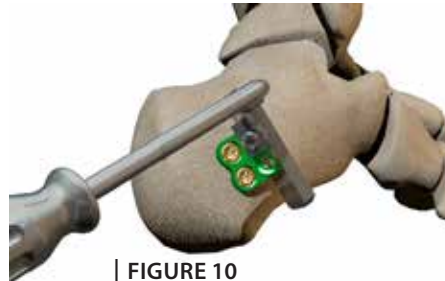


| **FIGURE 9** Guide and implant are aligned perpendicular to the long axis of the calcaneus

Fixation

Lock the appropriate 3Di locking drill guide into the posterior locking screw hole adjacent to the temporary fixation pin and insert the appropriate 3Di locking screw into the hole according to the procedure previously described. Remove the adjacent temporary fixation pin and insert the second posterior locking screw. | **FIGURE 10**

With the implant and cutting guide secured to the bone, use the cutting guide to control the angle and placement of the bone cut. | **FIGURE 11** Use caution while penetrating the medial cortex. The osteotomy should be finished using an osteotome to avoid damaging the neurovascular bundle medially. Finally, verify that the posterior tuberosity is completely released from the body of the calcaneus, and remove the cutting guide from the implant.

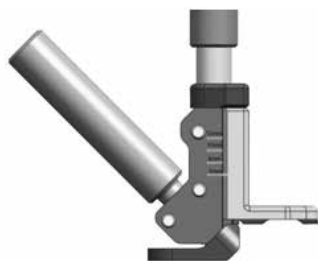


| **FIGURE 10**



| **FIGURE 11**

Verify the Displacement Instrument is set to 6mm of displacement (6mm is the minimum amount of correction the MDCO Plate will allow), | **FIGURE 12** and assemble the device to the implant according to the instructions below. | **FIGURE 13**



Displacement Instrument
58190016

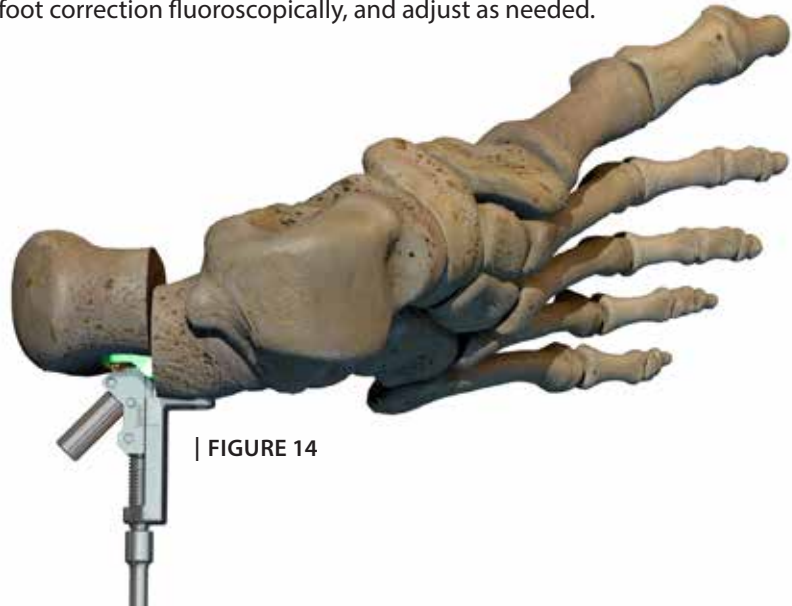


| **FIGURE 12** Ensure Instrument is set to 6mm



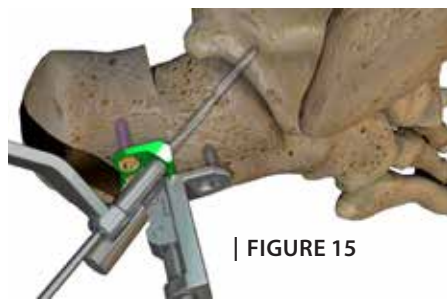
| **FIGURE 13**
1. Mate the MDCO Plate (A) to the end of the instrument.
2. Lock the implant to the instrument by threading the drill guide (B) into the implant.

With the displacement instrument assembled, provisionally fixate the instrument/plate construct to the anterior bone fragment by driving a 2.7mm non-locking screw through the anterior fixation slot and manually shift the posterior fragment medially. | **FIGURE 14** Based on the amount of correction desired, adjust the displacement instrument by turning the handle in a clockwise motion; one complete turn shifts the posterior tuberosity medially an additional 1mm. Verify hindfoot correction fluoroscopically, and adjust as needed.

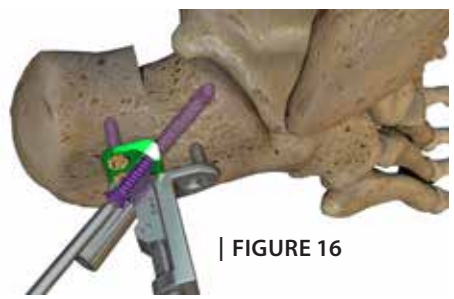


| **FIGURE 14**

Using the 2.5mm drill bit, freehand drill through the exposed anterior screw hole, aiming the drill bit in the direction of the sustentaculum. | **FIGURE 15** Measure the hole for screw length and drive the appropriate 3.5mm non-locking screw until adequate compression across the osteotomy is achieved and the screw is seated flush with the plate. | **FIGURE 16**



| **FIGURE 15**



| **FIGURE 16**

Finally, use the appropriate drill through the captured displacement instrument drill guide, remove the instrument from the plate, and drive the remaining locking or non-locking screw until seated with the plate.

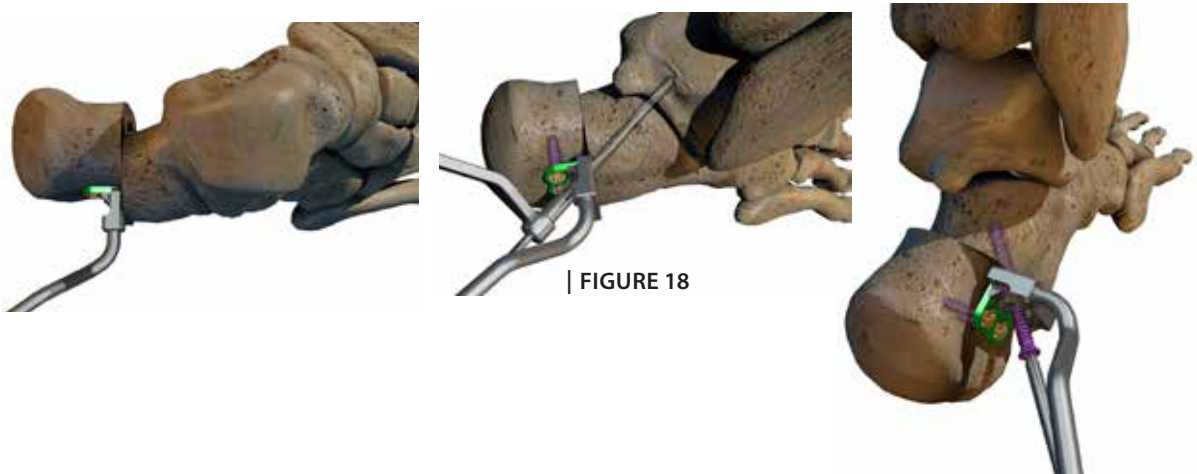
NOTE: If measuring for screw length from the displacement instrument drill guide, 10mm must be added to the measurement.

If desired, the overhanging lateral edge can be beveled using a bone tamp or osteotome to reduce soft tissue irritation. Verify correction and fixation clinically and fluoroscopically, and close the wound using standard techniques. | **FIGURE 17**



Option 2

Alternatively, the posterior calcaneal fragment may be shifted by using the Cutting Guide/Inserter. After the optimal amount of correction has been achieved, maintain the fragment's position and repeat the previously outlined steps to achieve fixation. | **FIGURE 18**



Evans Osteotomy

Incision and Osteotomy

Make a longitudinal incision along the calcaneocuboid joint and 1 cm below the tip of the fibula. Take care to avoid the sural nerve and peroneal tendons.

| **FIGURE 19**



| **FIGURE 19**

Using a blunt retractor, continue dissection and exposure with the release of dorsal and plantar soft tissue from the planned osteotomy site. Take care to avoid violating the calcaneocuboid joint in order to preserve the ligamentous attachments and to prevent hypermobility.

Perform the osteotomy 1 cm to 1.5 cm proximal to the calcaneocuboid joint, and finish medially using an osteotome.

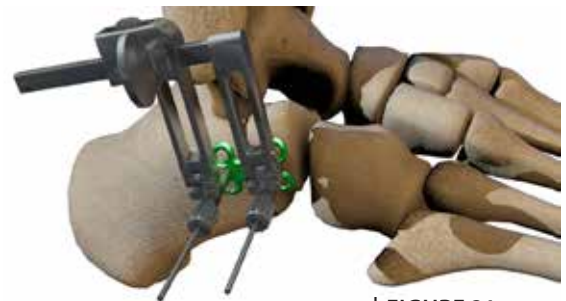
Place a 2.5 mm Steinmann pin at the center-point of the bone, between the calcaneocuboid joint and the created bone osteotomy. Slide one of the X-Track pin collets over the Steinmann pin and position the free collet on the proximal side of the osteotomy. Place the proximal Steinmann pin through the proximal collet and into the bone ensuring there is approximately 2 cm of space between the osteotomy and the pin. Slide the X-Track pin collets down the pins until bone is contacted, and lock both collets to the Steinmann pins.

The osteotomy is now opened using the X-Track Distraction/Compression Device per the techniques previously described (See X-Track Distraction/Compression Device), and alignment is evaluated clinically and fluoroscopically.

| **FIGURE 20 and 21**



| **FIGURE 20**



| **FIGURE 21**

Plate Selection

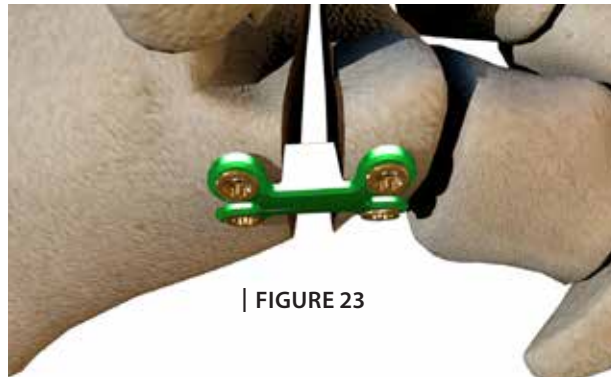
Plate selection is based on the amount of osteotomy distraction. Choose the plate with the wedge size that matches closest to the amount of osteotomy distraction required. | **FIGURE 22**



Plate Placement and Fixation

Temporary fixation can be achieved by placing a temporary fixation pin in any 3Di locking hole. Once proper plate placement has been achieved, fill 3Di screw holes using the appropriate locking/non-locking screws. | **FIGURE 23**

NOTE: 3.5mm locking or non-locking screws are recommended for fixation of the Evans osteotomy.



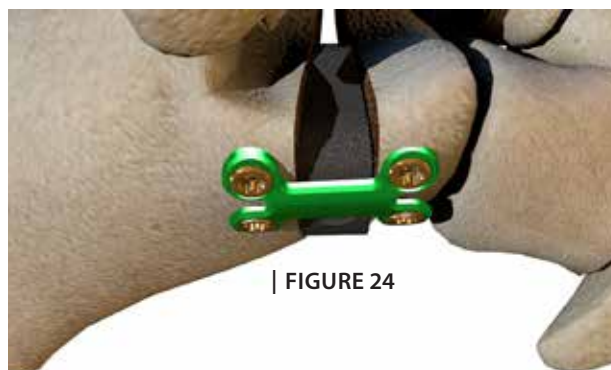
0mm Wedge / Neutral Plate

Alternative Wedge

As an alternative to the wedge plate, the 0mm or Neutral Evans plate can be used in conjunction with the BIOFOAM® Evans Wedge System. Please see these respective surgical techniques for a detailed description of the implantation procedures. | **FIGURE 24**



BIOFOAM® Evans Wedge



Cotton Osteotomy

Incision and Osteotomy

A dorsal incision is made directly over the medial cuneiform. The extensor hallucis longus is identified and retracted medially, and dissection is carried out down to bone.

Fluoroscopy should be used to identify the center of the medial cuneiform, the desired location of the osteotomy. The osteotomy is performed with a micro-sagittal saw and finished using a small straight osteotome.

Plate Selection

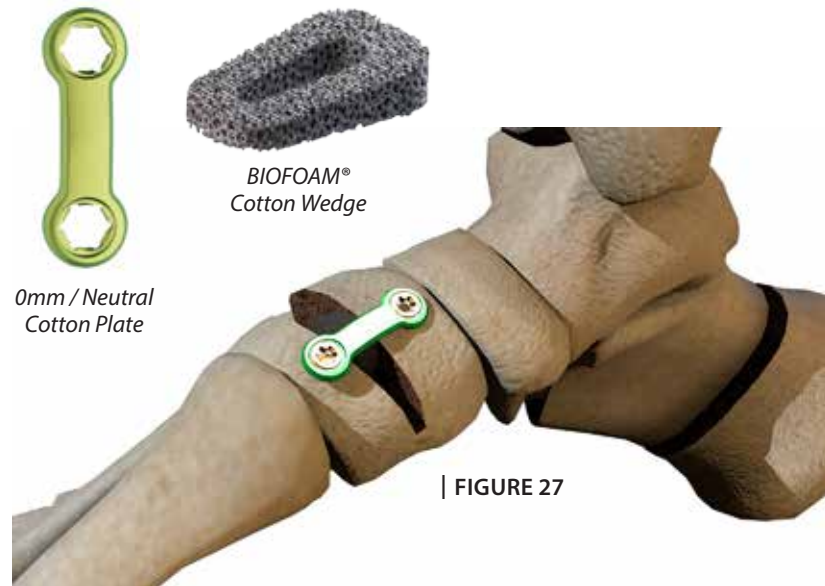
Using the X-Track Distraction Device, the osteotomy is opened until the metatarsal head is plantarflexed to a desired position. The osteotomy gap is now measured and the corresponding implant is selected for fixation. | **FIGURE 25**



Fixation of the ORTHOLOC® 3Di Cotton plates is carried out using the techniques previously described. | **FIGURE 26**



Alternatively, an implant such as the BIOFOAM® Cotton Wedge may be used in conjunction with the two hole neutral plate. Please see the BIOFOAM® Cotton Wedge surgical technique for a detailed description of the device and implantation procedures. | **FIGURE 27**



Explant Information

Removal of the ORTHOLOC® 3Di Foot Reconstruction Plates may be performed by first extracting the plate screws using the STAR 15 driver (P/N 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



Evans Opening Wedge Plate

P/N	Description
58130000	EVANS OPENING WEDGE PLATE, 0MM
58130006	EVANS OPENING WEDGE PLATE, 6MM
58130008	EVANS OPENING WEDGE PLATE, 8MM
58130010	EVANS OPENING WEDGE PLATE 10MM



Cotton Wedge Plate

P/N	Description
58140000	COTTON WEDGE PLATE, 0MM
58140045	COTTON WEDGE PLATE, 4.5MM
58140055	COTTON WEDGE PLATE, 5.5MM
58140065	COTTON WEDGE PLATE, 6.5MM



MDCO Plate

P/N	Description
58190006	MDCO PLATE

2.7mm Non-Locking Screws

P/N	Description
58812710	NON-LOCKING SCREW 2.7 X 10MM
58812712	NON-LOCKING SCREW 2.7 X 12MM
58812714	NON-LOCKING SCREW 2.7 X 14MM
58812716	NON-LOCKING SCREW 2.7 X 16MM
58812718	NON-LOCKING SCREW 2.7 X 18MM
58812720	NON-LOCKING SCREW 2.7 X 20MM
58812722	NON-LOCKING SCREW 2.7 X 22MM
58812724	NON-LOCKING SCREW 2.7 X 24MM
58812726	NON-LOCKING SCREW 2.7 X 26MM
58812728	NON-LOCKING SCREW 2.7 X 28MM
58812730	NON-LOCKING SCREW 2.7 X 30MM

3.5mm Non-Locking Screws

P/N	Description
58813510	NON-LOCKING SCREW 3.5 X 10MM
58813512	NON-LOCKING SCREW 3.5 X 12MM
58813514	NON-LOCKING SCREW 3.5 X 14MM
58813516	NON-LOCKING SCREW 3.5 X 16MM
58813518	NON-LOCKING SCREW 3.5 X 18MM
58813520	NON-LOCKING SCREW 3.5 X 20MM
58813522	NON-LOCKING SCREW 3.5 X 22MM
58813524	NON-LOCKING SCREW 3.5 X 24MM
58813526	NON-LOCKING SCREW 3.5 X 26MM
58813528	NON-LOCKING SCREW 3.5 X 28MM
58813530	NON-LOCKING SCREW 3.5 X 30MM
58813532	NON-LOCKING SCREW 3.5 X 32MM
58813534	NON-LOCKING SCREW 3.5 X 34MM
58813536	NON-LOCKING SCREW 3.5 X 36MM
58813538	NON-LOCKING SCREW 3.5 X 38MM
58813540	NON-LOCKING SCREW 3.5 X 40MM
58813542	NON-LOCKING SCREW 3.5 X 42MM
58813544	NON-LOCKING SCREW 3.5 X 44MM
58813546	NON-LOCKING SCREW 3.5 X 46MM
58813548	NON-LOCKING SCREW 3.5 X 48MM
58813550	NON-LOCKING SCREW 3.5 X 50MM
58813555	NON-LOCKING SCREW 3.5 X 55MM
58813560	NON-LOCKING SCREW 3.5 X 60MM

2.7mm Locking Screws

P/N	Description
58802710	LOCKING SCREW 2.7 X 10MM
58802712	LOCKING SCREW 2.7 X 12MM
58802714	LOCKING SCREW 2.7 X 14MM
58802716	LOCKING SCREW 2.7 X 16MM
58802718	LOCKING SCREW 2.7 X 18MM
58802720	LOCKING SCREW 2.7 X 20MM
58802722	LOCKING SCREW 2.7 X 22MM
58802724	LOCKING SCREW 2.7 X 24MM
58802726	LOCKING SCREW 2.7 X 26MM
58802728	LOCKING SCREW 2.7 X 28MM
58802730	LOCKING SCREW 2.7 X 30MM

3.5mm Locking Screws

P/N	Description
58803510	LOCKING SCREW 3.5 X 10MM
58803512	LOCKING SCREW 3.5 X 12MM
58803514	LOCKING SCREW 3.5 X 14MM
58803516	LOCKING SCREW 3.5 X 16MM
58803518	LOCKING SCREW 3.5 X 18MM
58803520	LOCKING SCREW 3.5 X 20MM
58803522	LOCKING SCREW 3.5 X 22MM
58803524	LOCKING SCREW 3.5 X 24MM
58803526	LOCKING SCREW 3.5 X 26MM
58803528	LOCKING SCREW 3.5 X 28MM
58803530	LOCKING SCREW 3.5 X 30MM
58803532	LOCKING SCREW 3.5 X 32MM
58803534	LOCKING SCREW 3.5 X 34MM
58803536	LOCKING SCREW 3.5 X 36MM
58803538	LOCKING SCREW 3.5 X 38MM
58803540	LOCKING SCREW 3.5 X 40MM
58803542	LOCKING SCREW 3.5 X 42MM
58803544	LOCKING SCREW 3.5 X 44MM
58803546	LOCKING SCREW 3.5 X 46MM
58803548	LOCKING SCREW 3.5 X 48MM
58803550	LOCKING SCREW 3.5 X 50MM
58803555	LOCKING SCREW 3.5 X 55MM
58803560	LOCKING SCREW 3.5 X 60MM



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