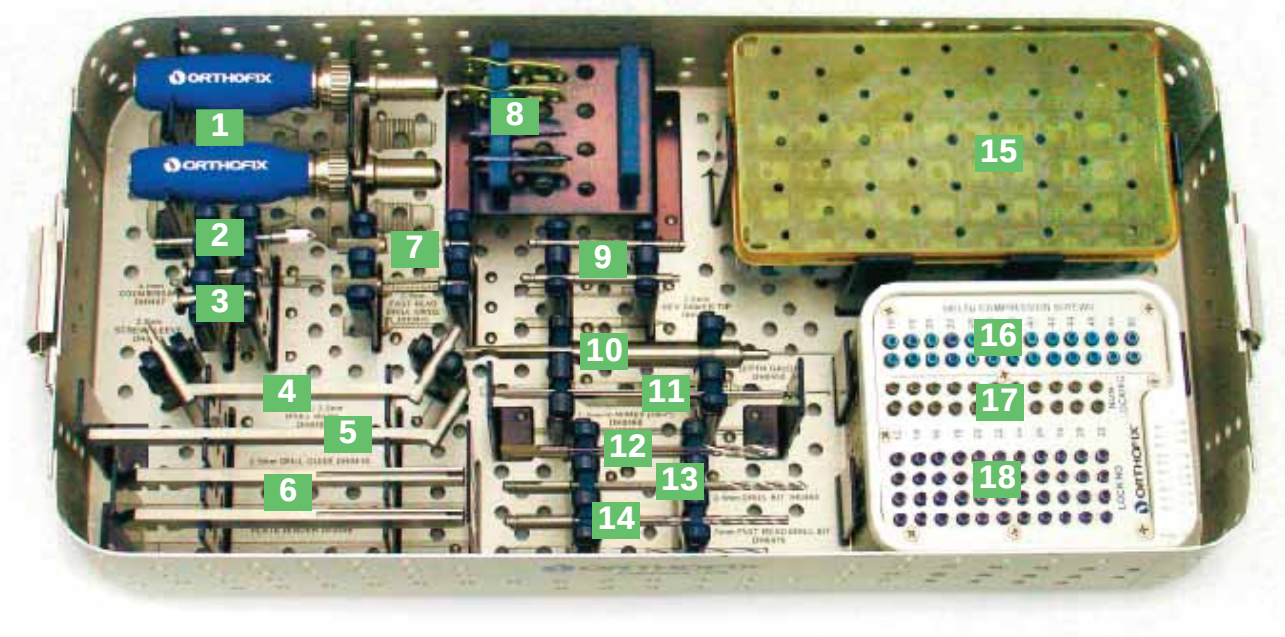
ContoursLPS
LAPIDUS PLATING SYSTEM

Hallux Valgus Deformity

OPERATIVE TECHNIQUE

ORTHOFIX®

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see Instructions for Use for the complete list of indications, warnings, precautions, and other important medical information.



INSTRUMENT TRAY

#	Description	Catalog #
1	Ratchet Handle	DH0455
2	3.5mm Countersink	DH0467
3	3.5mm Screw Sleeve	DH0452
4	2.5mm/3.5mm Drill Guide for Compression Screws	DH0469
5	2.5mm Drill Guide for Delta Hole	DH0416
6	Plate Benders	DH0466
7	Fast Drill Guides	DH0475
	Left Plate	(L) LPL0200
8	Right Plate	(R) LPR0300
9	2.5mm Hex Drivers	DH0459
10	Depth Gauge	DH0450
11	K-Wires, 1.4mm (.054)	DH0460
12	3.5mm Drills	DH0468
13	2.5mm Cannulated Drill Bits	DH0477
14	2.5mm Quick Read Drill Bits	DH0476
15	Spare Caddy	
16	3.5mm Delta Compression Screws	PSC35DXX
17	3.5mm Non-Locking Screws	PSC35NXX
18	3.5mm Locking Screws	PSC35L45XX

PLATES

Catalog #	Description	QTY
LPL0200	Lapidus Plate - Left	2
LPR0300	Lapidus Plate - Right	2

LOCKING SCREWS

Catalog #	Description	QTY
PSC35L4512	3.5mm x 12mm Locking Screw	4
PSC35L4514	3.5mm x 14mm Locking Screw	4
PSC35L4516	3.5mm x 16mm Locking Screw	4
PSC35L4518	3.5mm x 18mm Locking Screw	4
PSC35L4520	3.5mm x 20mm Locking Screw	4
PSC35L4522	3.5mm x 22mm Locking Screw	4
PSC35L4524	3.5mm x 24mm Locking Screw	4
PSC35L4526	3.5mm x 26mm Locking Screw	4
PSC35L4528	3.5mm x 28mm Locking Screw	4
PSC35L4530	3.5mm x 30mm Locking Screw	4
PSC35L4532	3.5mm x 32mm Locking Screw	4

NON-LOCKING SCREWS

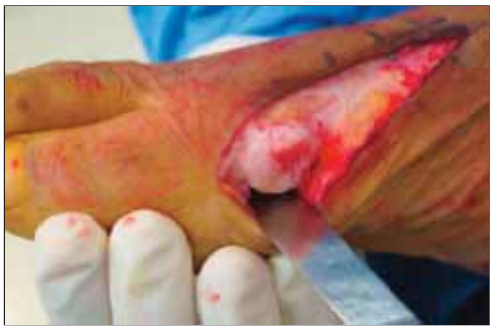
Catalog #	Description	QTY
PSC35N12	3.5mm x 12mm Non-Locking Screw	2
PSC35N14	3.5mm x 14mm Non-Locking Screw	2
PSC35N16	3.5mm x 16mm Non-Locking Screw	2
PSC35N18	3.5mm x 18mm Non-Locking Screw	2
PSC35N20	3.5mm x 20mm Non-Locking Screw	2
PSC35N22	3.5mm x 22mm Non-Locking Screw	2
PSC35N24	3.5mm x 24mm Non-Locking Screw	2
PSC35N26	3.5mm x 26mm Non-Locking Screw	2
PSC35N28	3.5mm x 28mm Non-Locking Screw	2
PSC35N30	3.5mm x 30mm Non-Locking Screw	2
PSC35N32	3.5mm x 32mm Non-Locking Screw	2

DELTA/COMPRESSION SCREWS

Catalog #	Description	QTY
PSC35D16	3.5mm x 16mm Delta/Compression Screw	2
PSC35D18	3.5mm x 18mm Delta/Compression Screw	2
PSC35D20	3.5mm x 20mm Delta/Compression Screw	2
PSC35D22	3.5mm x 22mm Delta/Compression Screw	2
PSC35D25	3.5mm x 25mm Delta/Compression Screw	2
PSC35D30	3.5mm x 30mm Delta/Compression Screw	2
PSC35D35	3.5mm x 35mm Delta/Compression Screw	2
PSC35D40	3.5mm x 40mm Delta/Compression Screw	2
PSC35D42	3.5mm x 42mm Delta/Compression Screw	2
PSC35D44	3.5mm x 44mm Delta/Compression Screw	2
PSC35D46	3.5mm x 46mm Delta/Compression Screw	2
PSC35D48	3.5mm x 48mm Delta/Compression Screw	2
PSC35D50	3.5mm x 50mm Delta/Compression Screw	2

INSTRUMENTS

Catalog #	Description	QTY
DH0416	2.5mm Drill Guide	1
DH0476	2.5mm Quick read drill bit, Lapidus System	2
DH0460	1.4mm K-wire	10
DH0455	Ratchet Handle AO	2
DH0475	Fast drill guide, Lapidus System	2
DH0459	2.5mm Hex Driver Tip	2
DH0452	Screw Sleeve for 2.5mm Hex Driver Tip	2
DH0469	2.5mm/3.5mm Drill Guide	1
DH0468	3.5mm Drill	2
DH0477	2.5mm Cannulated drill bit, Lapidus System	2
DH0467	3.5mm Countersink	1
DH0466	Small Plate Bender	2
DH0450	Depth Gauge, 50mm	1

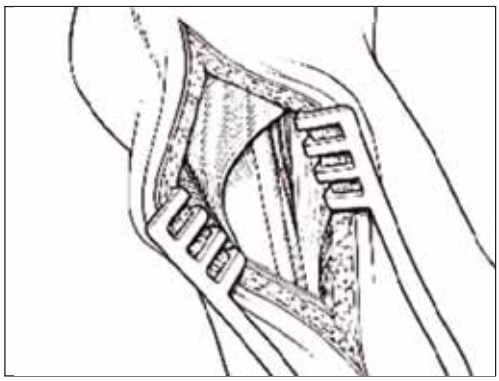


1. INCISION & DISSECTION

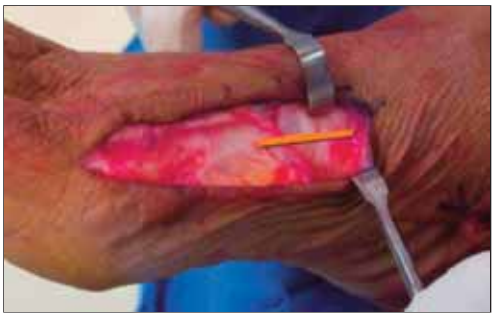
1. A curvilinear skin incision is recommended.

2. The incision is placed dorsal medially over the first ray – medial to the extensor hallucis longus, extending ~2 cm proximal to the 1st tarsal-metatarsal (TMT) and distally ~ 3cm.

TIP: The proximal portion of the skin incision can be angulated medially to avoid the medial dorsal cutaneous nerve.



3. When concomitant Modified McBride Procedure is performed, the incision should be carried distally to the 1st metatarsal-phalangeal joint (MTPJ). Resection of the medial eminence and adductor release is performed or should be performed in a manner that is comfortable for the surgeon.

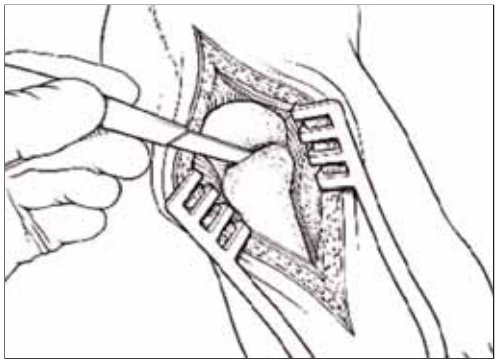


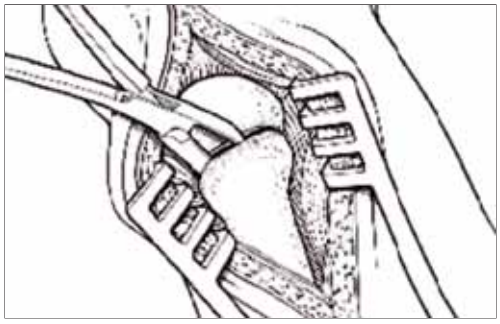
2. TMT CAPSULOTOMY

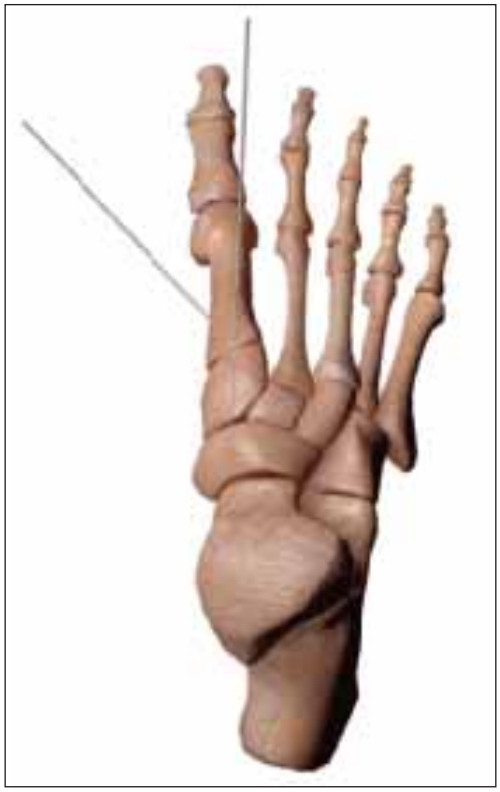
1. A linear longitudinal capsulotomy is recommended.

2. The capsulotomy allowing for access to the joint should be placed medial and slightly inferior, allows for access to the joint.

TIP: Keeping the capsulotomy more medial allows for easier re-approximation during closure. The joint should be exposed dorsally and medially.







3. JOINT PREPARATION (REMOVE CARTILAGE)

1. All cartilage is removed from the opposing surfaces of the 1st tarsal-metatarsal (TMT) using appropriate instrumentation. The cartilage may be removed via "curettage resection" or "saw resection" as deemed appropriate by the surgeon.

TIP: A smooth Lamina spreader allows deep access to denude all cartilage of the TMT. The plantar capsule of the TMT will often need to be transected as this structure limits access to the plantar joint.

2. The subchondral plate should be perforated to achieve bleeding bone at the interface of the fusion. Several methods exist and selection will be determined by the surgeon. These include drilling, burring, scaling, and picking.

4. POSITIONING & TEMPORARY FIXATION OF THE FIRST RAY

1. The position of the first metatarsal is balanced in all three planes:

- **A.** Transverse plane: the first metatarsal should be positioned as close to parallel to the second metatarsal as possible.
- **B.** Coronal plane: Position is neutral.
- **C.** Sagittal plane: the first metatarsal should be positioned so that there is a return of weight-bearing presence on the ball of the foot.

TIP: Because the procedure involves joint resection, there is anatomic shortening of the first ray segment. To compensate, the first metatarsal should be either inferiorly translated on the medial cuneiform, or plantarflexed. This should be performed in most cases, and the amount is at the discretion of the surgeon.

2. Once the first ray position is acceptable, temporary fixation is performed with K-wires.

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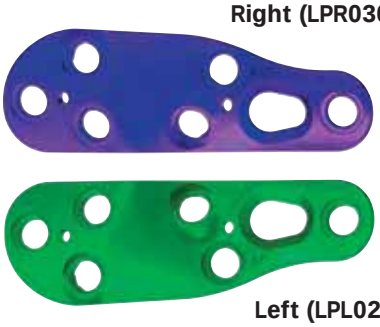
3. The first K-wire is used to stabilize the first metatarsal to the medial cuneiform.

TIP: The K-wire should be placed dorsal lateral on the first metatarsal to avoid the interference with the Contours Lapidus Plate.

4. The second K-wire is used to stabilize the first metatarsal to the intermediate cuneiform. This K-wire should be be placed inferiorly on the metatarsal shaft at the metaphyseal level.

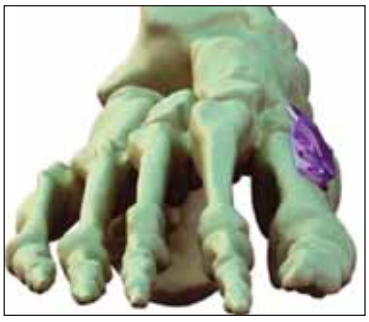
TIP: The intermetatarsal angle should be manually firmly reduced while the temporary fixation is placed to maintain the position.

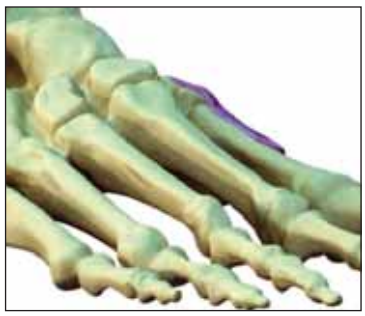
5. Check the reduced position of the metatarsal on fluoroscopy.



Right (LPR0300)

Left (LPL0200)





5. PLATE SELECTION, POSITIONING & PROVISIONAL FIXATION

1. Select the proper sided plate: Right (Vector Purple) or Left (Seafoam Green).

2. Place the plate on the medial surface of the medial cuneiform and first metatarsal.

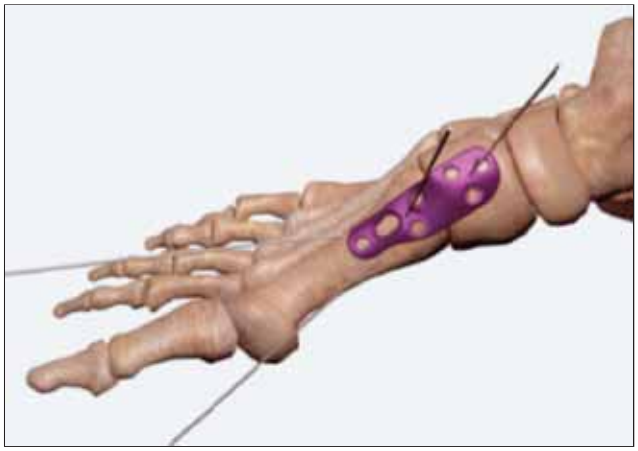
TIP: Align the notched recess on the plate with the anatomic prominence of the medial cuneiform. Then angle the distal aspect of the plate. The notch on the plate will facilitate placement and improper fit indicates the fusion is poorly placed or the plate is not aligned properly.

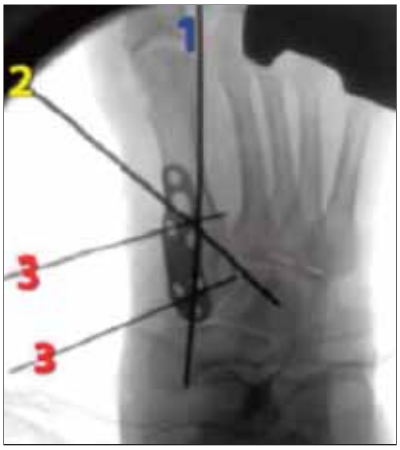
3. Verify position with fluoroscopy.

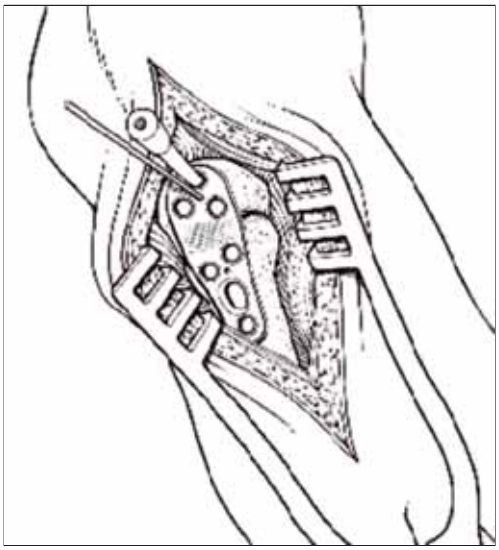
4. The plate is held in place with two K-wires (DH0460).

NOTE: Bending of the Contours Lapidus Plate

- **A.** The Plate is designed and contoured to be as close to the normal anatomy as possible, so bending of the plate is not typically necessary, but this is at the surgeon's discretion.
- **B.** If bending is deemed necessary by the surgeon, then it should be performed with Plate Benders (DH0466).
- **C.** Bending over screw holes should be avoided because they may become distorted, inhibiting the locking capability of that particular hole.
- **D.** Insert the Non-locking screws (PSC35NXX) if any bending of a screw hole occurs.





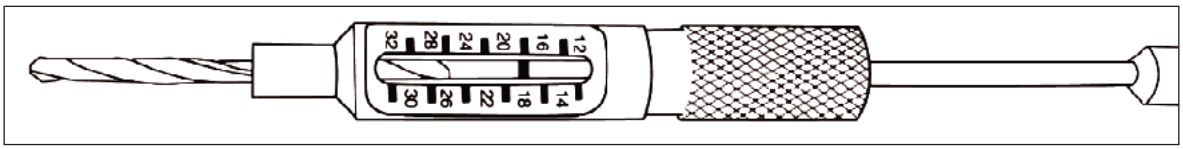


6A. DEFINITIVE FIXATION FOR THE CONTOURS LPS

1. Step 1 – Proximal Fixation Point

A. Fixation should be placed into the proximal aspect of the plate first. Drill and insert a 3.5mm Locking (PSC35L45XX) or Non-Locking (PSC35NXX) screw into (only) one of the three (3) proximal holes.

TIP: 1) Inserting more than one screw at this point can cause displacement when compression takes place due to not allowing for rotation of the plate. This rotation is necessary until compression occurs.
2) Non-Locking screw (PSC35NXX) will draw the plate closer to the bone,and this can be changed out for a locking screw after additional fixation is placed. If the contact of the plate with the bone is good, then a locking screw can be used instead.

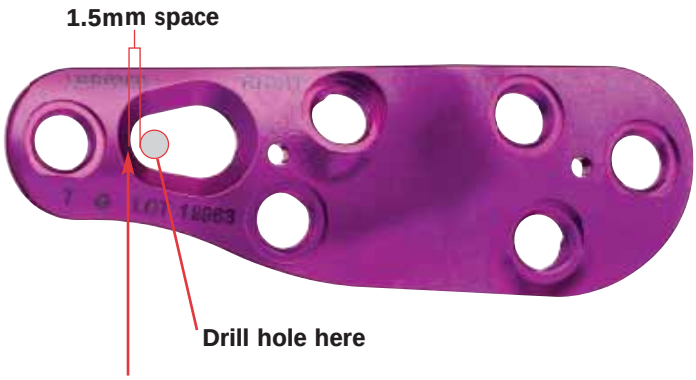


2. Step 2 – Delta Hole

A. The Delta Hole is used when compression is needed as determined by the surgeon.

B. Remove the K-wire that stabilized the first metatarsal to the intercuneiform. It can act as a distracting force, causing displacement of the correct position during application of the Delta/Compression Screw (PSC35DXX)

C. The Delta Hole offers 2mm of compression. The 3.5mm Delta/Compression screws (PSC35DXX) are REQUIRED for compression of the Delta Hole.

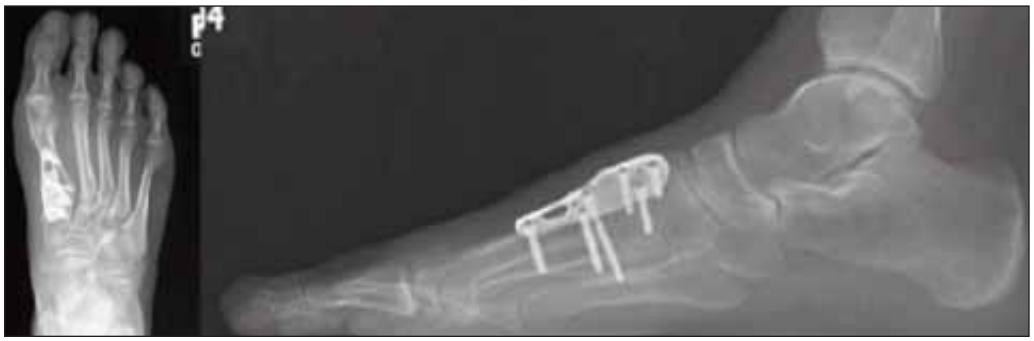


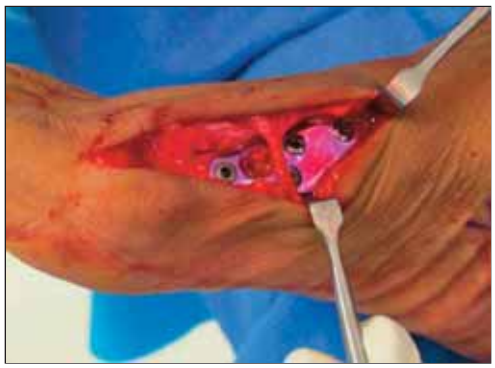
PROPERLY DRILLING THE DELTA HOLE

• Do not eccentrically drill the Delta Hole (i.e., drilling directly up against the plate). The design of this hole configuration provides compression.
• Using the 2.5mm Drill Guide (DH0416) ensures the drill is precisely placed within the Delta Hole by placing the instrument directly up against (i.e. flush) the distal end of the respective hole.

CAUTION: Improper drilling of Delta Hole may prevent the screw from engaging the plate properly and stripping of this hole.

• Consider using a Delta/Compression screw (PSC35DXX) 2-4 mm longer than measured. This ensures the distal screw threads engage the distal cortex as the screw is recessed into the Delta Hole.
• The Delta/Compression screw can be removed after all screws are inserted into place.





3. Step 3 – Remaining Screw Placement
Locking (PSC35L45XX)or Non-Locking (PSC35NXX) screws may be used.

- **A.** Proceed to drill, measure, and insert screws into the remaining holes.
- **B.** There is no particular sequence in which the remaining screws need to be placed.

TIP: Avoid placing screws that are too long into the proximal holes (medial cuneiform) as this may irritate the intercuneiform articulation. Confirm appropriate screw length using fluoroscopy.

7. AUGMENTING FUSION WITH STRESS RELIEVING BONE GRAFT

1. Prominent bone at the medial cuneiform can be debrided with a rongeur and placed along the fusion site as bone graft at the surgeon's discretion. This procedure may enhance union by increasing the active bone formation surface area.

2. Non-locally derived bone can also be used here at the discretion of the surgeon.

CLOSURE

1. Deep capsule closure is performed at the TMT level for soft tissue coverage over the plate.

DESCRIPTION:
The Contours Lapidus Plating System consists of plates, screws and instrumentation. The anatomically contoured titanium plates are low-profile and designed specifically for 1st metatarsal and cuneiform allowing compression across the joint achieved through a delta-shaped hole and compression screws. Contours Lapidus System screws are titanium, low-profile and self-tapping, and include locking, non-locking, and bone compression screws in a variety of lengths. Instrumentation includes a threaded drill guide, drill bits, depth gauge, screw sleeve, ratcheting AO wrench, and plate bender.

INDICATIONS FOR USE:
The Contours Lapidus Plating System is intended for revision procedures and joint fusion in the small bones of the foot.

WARNINGS:
- Bone plates, bone screws, drill bits and K-Wires are SINGLE USE ONLY. Reuse could result in injury or require reoperation due to breakage or infection. DO NOT attempt to resterilize implants that come in contact with body fluids.
- The Contours Lapidus Plating System has not been evaluated for safety and compatibility in the MR environment. The Contours Lapidus Plating System has not been tested for heating or migration in the MR environment.
- All instruments should be used for their intended purpose only.
- The Contours Lapidus plate should be used in skeletally mature patients only.

PRECAUTIONS:
- The Contours Lapidus Plating System is intended for use with the Lapidus Surgical Procedure.
- It is essential that proper operative technique be followed for implantation. Refer to Operative Technique Guide.
- It is recommended that the Contours Lapidus plate and associated screws be implanted prior to implantation of any additional hardware.
- Patient selection is important to achieving a successful outcome. The following factors and/or conditions may impact overall success: appropriateness of implant size, patient's occupation and/or activity level, ability to understand and follow postoperative instructions, potential for material sensitivity, adequate bone stock and soft tissue coverage, poor quality bone or metabolic bone disorders such as severe osteopenia, osteomyelitis, poorly controlled diabetes mellitus, neurovascular status, overall general health, etc.
- Examine all components carefully PRIOR to use. If you believe any component to be faulty, damaged or suspect, **DO NOT USE**.
- The Steri-Tray is for sterilization of Contours Lapidus Plating System components **ONLY**.

POTENTIAL COMPLICATIONS AND ADVERSE EFFECTS:
- Intrinsic risks associated with anesthesia and surgery
- Infection and/or painful, swollen or inflamed implant site
- Failure to achieve the desired correction
- Breaking of the plate or loosening, bending, or breaking of the bone screws
- Re-operation may be necessary to replace or remove the plate and/or screws
- Complications associated with metal sensitivity including allergic reaction to the implantmaterial
- Migration of particle wear debris that could possibly result in a bodily response
- Embolism
- Untoward histological responses that could involve macrophages and/or fibroblasts
- Bone resorption or over production

Instructions for Use (IFU):
See actual package insert for instructions for use.

Sterilization:
Refer to the Instructions for Use (IFU) for sterilization information.

Manufactured by:
ORTHOFIX Srl
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Telephone +39 045 6719000, Fax +39 045 6719380

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

Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the "instructions for Use" supplied with the product for full information on indications for use, contraindications, warnings, precautions, adverse reactions information and sterilization.

www.orthofix.com

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