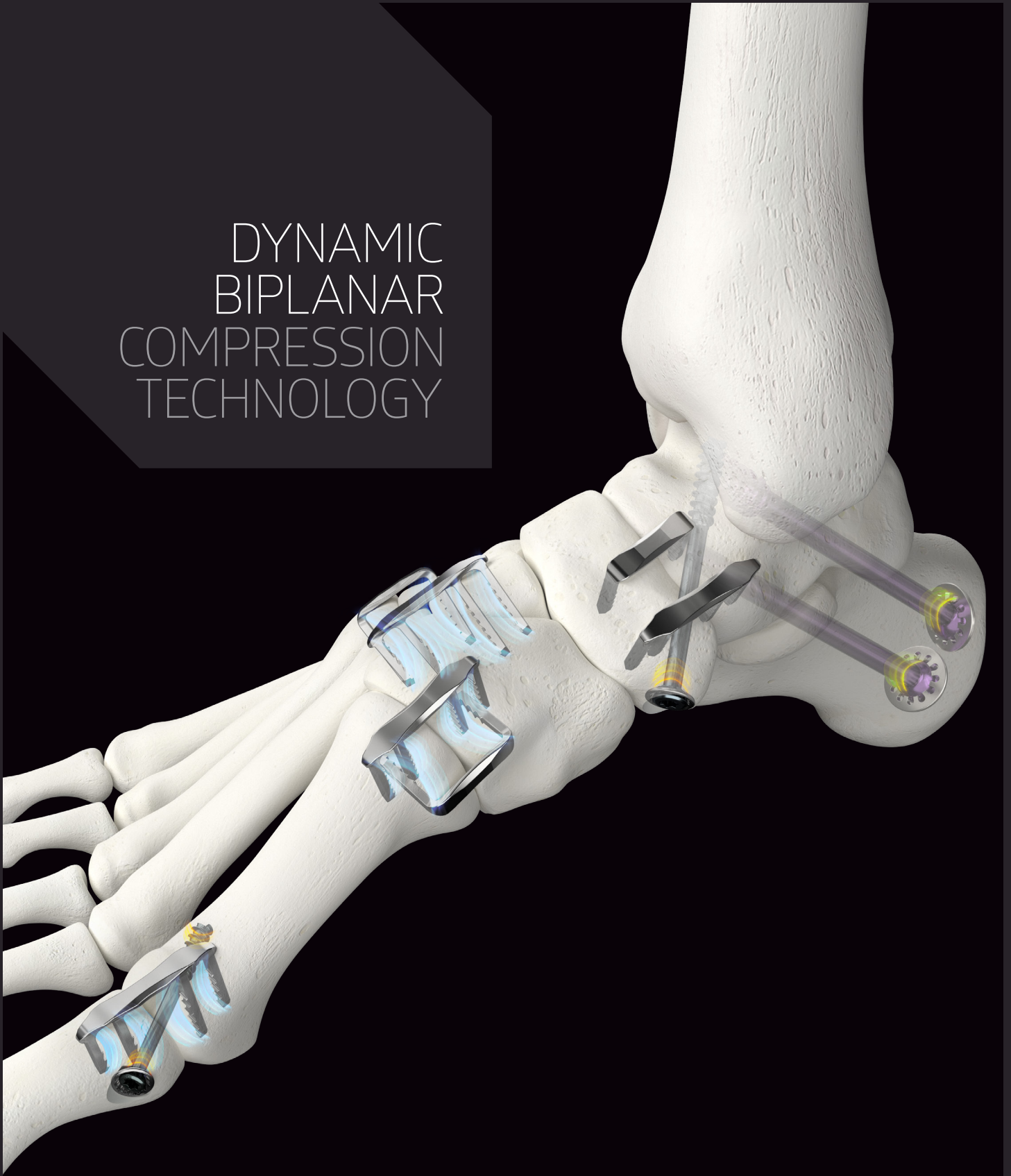




UNITE[®]
FOOT & ANKLE

REFLEX[®] Foot Recon Nitinol Implant System
System overview & surgical technique.

DYNAMIC
BIPLANAR
COMPRESSION
TECHNOLOGY



Discover compression without compromise

While nitinol staples have steadily risen in popularity, static plates and screws are widely used in conjunction with staples to provide added fixation and stability. A key disadvantage of such hybrid constructs is the inherent neutralization of compression caused by the addition of static devices such as locking plates and cannulated screws.

Common constructs incorporating Nitinol



Staple with static screw



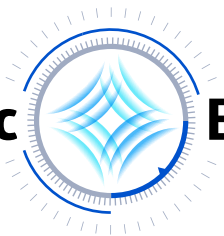
Plate with staple



Nitinol plate with static screw

REFLEX®

Dynamic

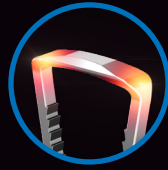


Biplanar Compression

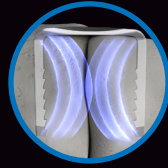
Technology

Fortunately, technology is evolving, leading the way to new possibilities for internal fixation. REFLEX® represents a major step forward for nitinol by harnessing superelastic and shape memory properties and applying them to novel implants.

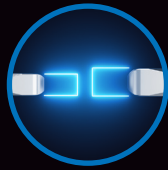
Staple features



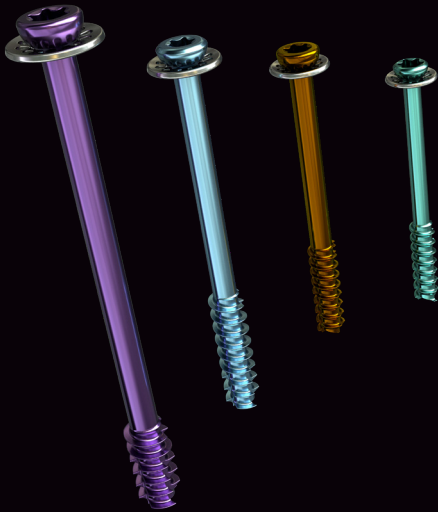
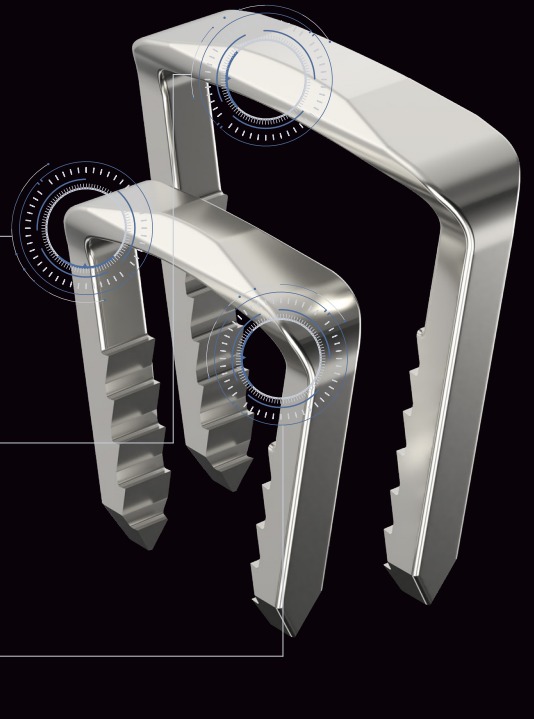
Reinforced shoulders
improve strength in highest strain area



Curved bridge design
for even compression across the fusion site

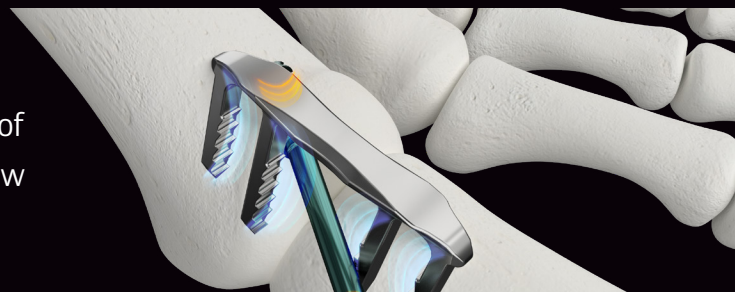


Ultra-low profile wide bridge for enhanced stability and minimal prominence

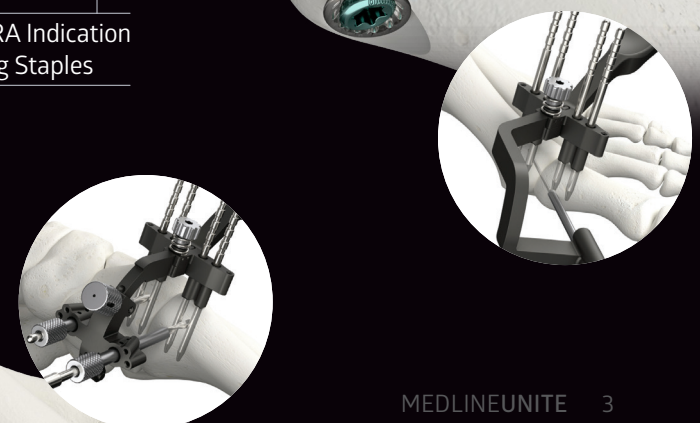


REFLEX Nitinol Dynamic Disc is an innovative implant that transforms a traditional static lag screw into a dynamic construct. REFLEX disc provides continuous compression and gap recovery up to 4.0 mm to address bone resorption occurring during the post-operative healing phase. The disc is available in Ø4.0mm, Ø4.5mm, Ø5.5mm, and Ø7.0mm sizes.

Patent-pending targeting guides allow for medial placement of an interdigitating 2-leg ULTRA staple or a cannulated lag screw with a Dynamic Disc through the TETRA staple's inner legs.



REFLEX TETRA Indication Specific 4-Leg Staples



Instrumentation tips



Staple Inserters

Non-sterile staple inserters require the staple to be loaded by rotating the knob clockwise to expand the inserter tips, expanding the staple legs. Sterile staple inserters come with a pre-loaded staple which is held under tension. For both inserters, carefully rotate the inserter knob clockwise until the staple legs are parallel.

	Pre-Loaded	Expandable	Reloadable
Non-Sterile (Reusable)	No	Yes	Yes
Sterile (Single Patient)	Yes	Yes	Yes

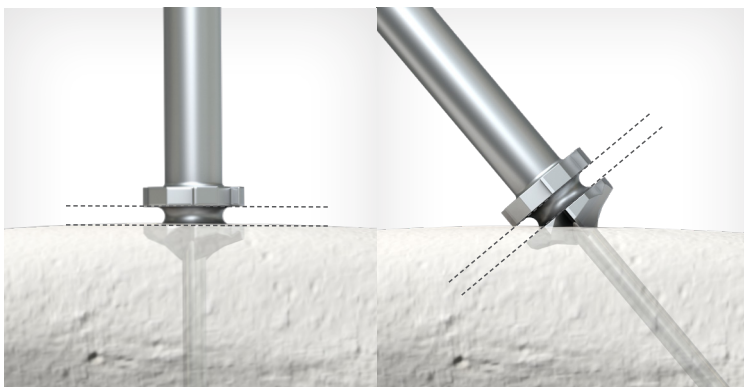
Tip: The sterile (disposable) inserter features a mechanical release feature. Following delivery into the pre-drilled holes in the bone, rotate the knob counter clockwise until an audible 'click' is heard or an interruption is overcome.



Akin Stepped Saw Blade

The 2.5 mm blade allows for easy, reproducible closing wedge osteotomies of the proximal phalanx.

Tip: When compared to a traditional small sawblade, a noticeably different tactile feel may be observed due to the dual-cutting features of the sawblade. Care should be taken when advancing the sawblade to avoid sawing through the far cortex.








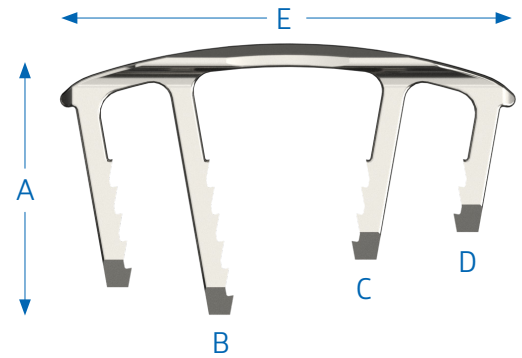
Dynamic Disc Countersink

Following wire placement, measurement and drilling, a specially designed countersink is used to create a pocket in the cortex to accommodate the disc.

Tip: The countersink features an interruption just proximal to the leading cutting feature, which can be seen under direct visualization or fluoroscopically. This serves as a visual reference point for proper countersinking depth. When screw placement is nearly perpendicular to the surface of the bone, advance the countersink under manual power until the leading cutting feature is flush with the cortex. Avoid over-countersinking which may compromise the proximal cortex.

Staple options

4-Leg	REFLEX TETRA	A	B	C	D	E
26mm MTP		16mm	18mm	14mm	12mm	26mm
26mm TMT		20mm	20mm	16mm	14mm	26mm
26mm Lapidus/TN		20mm	20mm	20mm	20mm	26mm
30mm MTP		16mm	18mm	14mm	12mm	30mm
30mm Lapidus		20mm	20mm	20mm	20mm	30mm



REFLEX MINI	REFLEX MAX	REFLEX ULTRA
8 x 8mm	15 x 15mm	18 x 18mm
10 x 10mm	15 x 18mm	20 x 14mm
12 x 12mm	18 x 18mm	20 x 16mm
	18 x 20mm	20 x 20mm
	20 x 20mm	23 x 16mm
		25 x 20mm

	Bridge Width	Bridge Thickness
MINI	1.5mm	1.2mm
MAX	4.0mm	1.4-1.5mm
ULTRA	5.0mm	1.5-1.7mm
TETRA	5.0mm	1.5-1.7mm

Device Description

The Medline UNITE REFLEX® Nitinol Staples and Dynamic Discs are manufactured from nickel titanium alloy (Nitinol). Staples are offered in different bridge lengths and include 2-leg and 4-leg staples. Dynamic Discs are manufactured from nickel titanium alloy (nitinol) and are offered in various diameters to be used in conjunction with UNITE cannulated screws of various diameters. The system also includes disposable and reusable instrumentation necessary to implant the staples and discs, e.g. drill guides, drills, countersinks, locating pins, staple inserter and tamp. The system also includes targeting guides and instrumentation to prepare the joint surfaces for arthrodesis, including metatarsal and phalangeal joint reamers, joint fenestration drill pins, arthrotomes and curettes.

Indications For Use

The Medline UNITE REFLEX® Nitinol Staples are intended to provide fixation for fractures, fusions or osteotomies of the bones of the hand and foot such as: First metatarsalcuneiform arthrodesis, First metatarsophalangeal arthrodesis, Talo-Navicular fusion, and LisFranc arthrodesis. Staples are intended for single use only.

The Medline UNITE REFLEX™ Dynamic Discs are indicated for use in bone reconstruction, osteotomies, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Discs are intended for single use only.

MTP Joint Fusion with TETRA staple and cannulated screw

Step 1. Joint Prep

Prep the joint using the metatarsal and phalangeal cup and cone reamers. Expose the metatarsal head by displacing the phalanx plantarly. Place a $\varnothing 1.6\text{mm}$ guidewire into the center of the metatarsal head using a power driver. Place the metatarsal reamer over the wire and begin to ream. The reamer should be spinning prior to touching bone. Use progressively smaller reamers to remove all articular cartilage, exposing bleeding bone (Fig. 1).

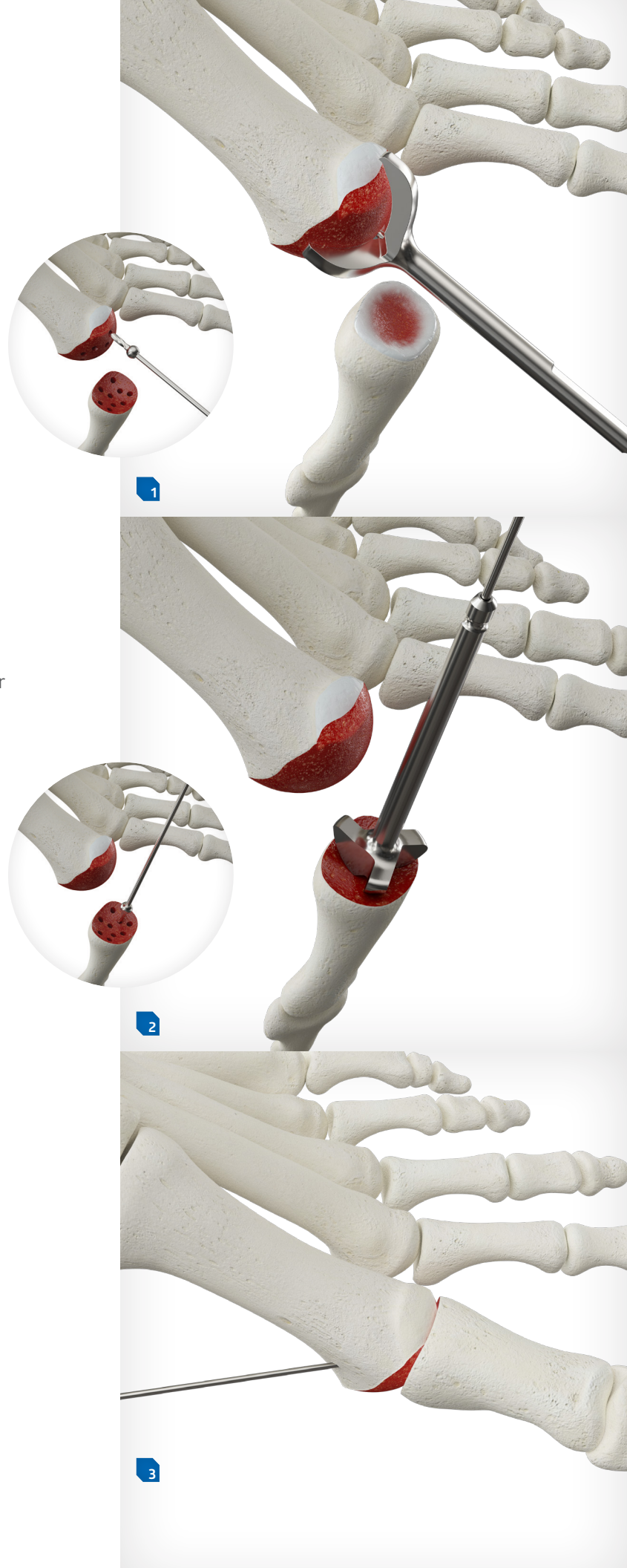
Expose the proximal phalanx by displacing the phalanx plantarly. Place a $\varnothing 1.6\text{mm}$ guidewire into the center of the proximal phalanx using a power driver. Place the phalangeal reamer over the wire and begin to ream. Reamer should be spinning prior to touching bone. Use progressively larger reamers, finishing with the same diameter as previously used for the metatarsal reaming to ensure congruent joint surfaces. Remove all articular cartilage exposing bleeding bone (Fig. 2).

A fenestration drill pin may be used to perforate the reamed surfaces of the metatarsal head and base of the proximal phalanx. Bone graft may be used as needed to facilitate joint fusion.

Step 2. Provisional Pinning

Following joint preparation, provisionally pin the 1st MTP joint in the desired final position with a k-wire (Fig. 3).

Biplanar fixation is recommended for adequate stability and to aid in compression across the plantar aspect of the joint. It is recommended to place a cross screw first then a 4-leg staple dorsally.

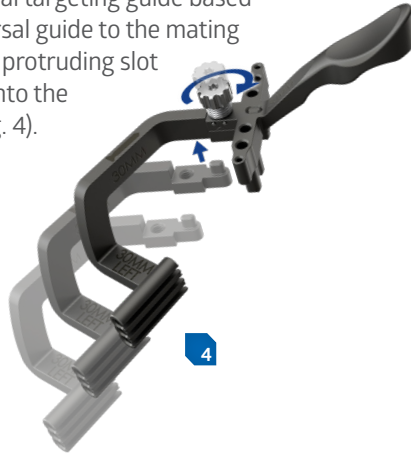


Step 3. Targeting Guide Assembly

Select the dorsal 4-leg staple size most appropriate for the patient's anatomy.

Dorsal targeting guides are available in 26mm and 30mm bridge lengths. Select the appropriate dorsal targeting guide based on the staple size. Assemble the dorsal guide to the mating medial screw guide by inserting the protruding slot feature on the medial screw guide into the keyhole slot on the dorsal guide (Fig. 4). Then, thread the dorsal guide knob by hand or with a T15 driver into the medial guide until the knob is tight. The guides should be not be loose after assembly.

Note: Either of the two medial guides (left/right) may be used in placing the cannulated screw. When using the left guide on a left foot, the screw placement is distal to proximal. Alternatively, the right guide can be used to place from proximal to distal, depending on the surgeon's preference.



Step 4. 4-Leg Staple Bone Preparation

Place the drill guide assembly on the bone so that the drill holes of the dorsal guide are symmetric with respect to the joint line (Fig. 5). Optional: Place Ø1.4mm k-wires through the most proximal and distal k-wire holes for temporary fixation of guide.

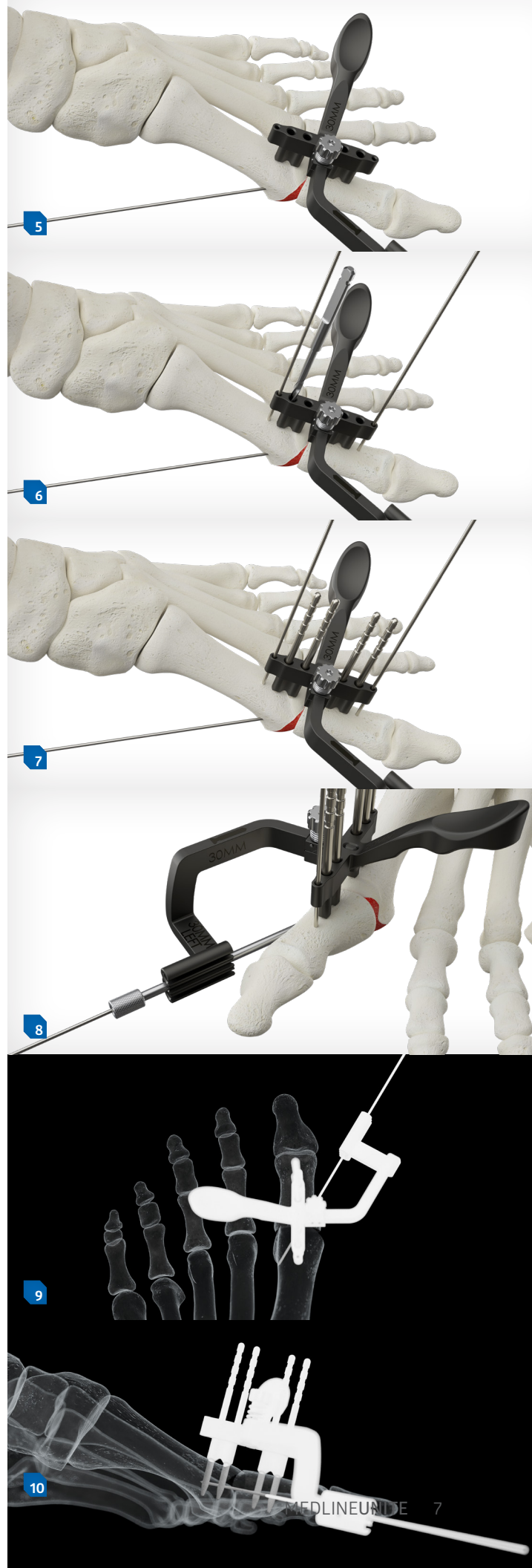
K-wires may also be used in the drill holes prior to drilling to verify placement.

Drill the first hole through the dorsal guide in the most proximal hole (metatarsal) with the Ø3.0mm drill bit and place the Ø3.0mm locator pin through the guide into the drilled hole. Repeat for the remaining holes in the dorsal guide (Fig. 6-7).

Step 5. Cannulated Screw Preparation

Remove the k-wire for provisional fixation. With the dorsal guide still fixed in position with the locator pins, insert the Ø1.1 or Ø1.4mm wire sleeve (Ø1.1mm for Ø3.0/3.5mm screw; Ø1.4mm for Ø4.0mm screw) into the medial targeting guide until the sleeve contacts the bone surface. Three positions are available for the wire sleeve to achieve the optimal position for the screw.

Insert the appropriate guidewire in the bone through the wire sleeve (Fig. 8). Verify pin and guidewire placement visually and fluoroscopically, as their location will indicate the definitive positioning of the staple legs and cannulated screw (Fig. 9-10).



Step 6. Remove Medial Screw Guide

Remove the wire sleeve. Unscrew the dorsal guide knob by hand or with a T15 driver and disconnect the medial guide, leaving the dorsal guide in position. Remove the medial screw guide by disengaging from the dorsal guide and translating so that the guidewire slides through the open slots in the medial screw guide.

Step 7. Final Screw Prep

Place the cannulated depth gauge over the guidewire until fully seated on the bone. The depth gauge shows the depth of the guidewire to the surface of the bone; if the screw head will be left proud, add the screw head height to the selected screw (Fig. 11).

Place the appropriate size cannulated drill over the guidewire and drill under power past the fusion site. Consider pre-drilling for hard cortical bone or bicortical fixation (Fig. 12).

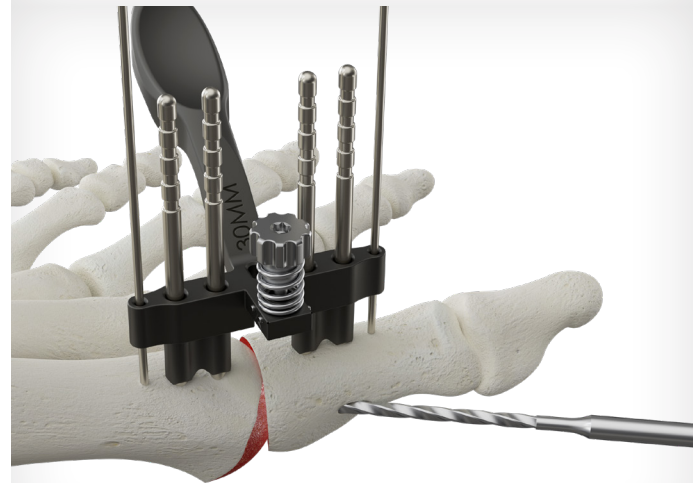
Place the appropriate countersink over the guidewire and countersink under manual power to recess the head of the screw into the proximal cortex, or to prepare for placement of a Dynamic Disc. Avoid over-countersinking, which may compromise the proximal cortex (Fig. 13).

Verify the length of the screw with the screw caddy prior to inserting the screw.

Step 8. Implant Screw

When using the dynamic disc, the disc is loaded onto the screw, with the convex side directly against the screw head, and inserted in typical fashion. Place the screw over the guidewire and engage the screw with the appropriate driver. Drive the screw until the threads of the screw are engaged with the far bone segment, but the head of the screw is not seated against the near cortex of the bone. **DO NOT FULLY SEAT OR TIGHTEN THE SCREW.** Verify the final placement of the screw fluoroscopically (Fig. 14).

Remove the dorsal guide, locating pins, and k-wires from the bone.



Step 9. Load 4-Leg Staple

Twist the staple inserter knob counter-clockwise to contract the expanding tips, allowing the instrument to fit under the staple bridge and between the two inner legs.

Position the staple inserter tips just beneath the bridge of the selected staple, then twist the knob clockwise to grasp and retain the implant. Continue to twist the knob clockwise until the staple legs are parallel to one another.

Step 10. Implant 4-Leg Staple

The proximal and distal leg lengths differ to accommodate the anatomy. Advance the 4-leg staple legs into the pre-drilled holes until the inserter tips are flush with the bone, and then twist the inserter knob counter-clockwise to release the inserter from the staple (Fig. 15).

Use the provided tamp and a mallet to seat the 4-leg staple until flush with the bone (Fig. 16).

Step 11. Final Screw Insertion

Continue advancing the lag screw until fully seated. Upon final seating and tightening, the screw head deforms the dynamic disc. Avoid over-tightening the screw. Remove the guidewire (Fig. 17-18).



Lapidus

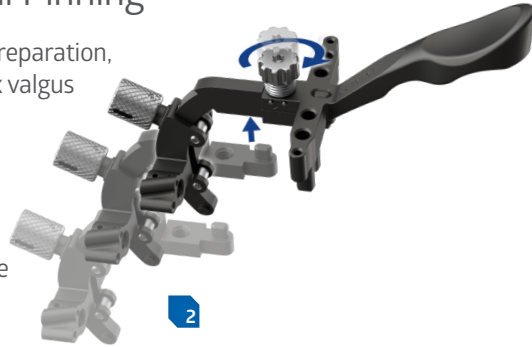
with TETRA and ULTRA staple

Step 1. Provisional Pinning

Following exposure, joint preparation, and correction of the hallux valgus deformity, provisionally pin the 1st TMT joint using a k-wire (Fig. 1).

Biplanar fixation is recommended for adequate stability and to aid in compression across the plantar aspect of the joint.

It is recommended to place a 4-leg TETRA staple first, in a dorsal position, followed by a 2-leg ULTRA staple in a medial position.



Step 2. Targeting Guide Assembly

Select the 4-leg staple size most appropriate for the patient's anatomy.

Dorsal targeting guides are available in 26mm and 30mm bridge lengths. Select the appropriate dorsal targeting guide based on the staple size. Assemble the dorsal guide to the mating medial staple guide by inserting the protruding slot feature on the medial staple guide into the keyhole slot on the dorsal guide. Then, thread the dorsal guide knob by hand or with a T15 driver into the medial guide until the knob is tight. The guides should not be loose after assembly (Fig. 2).

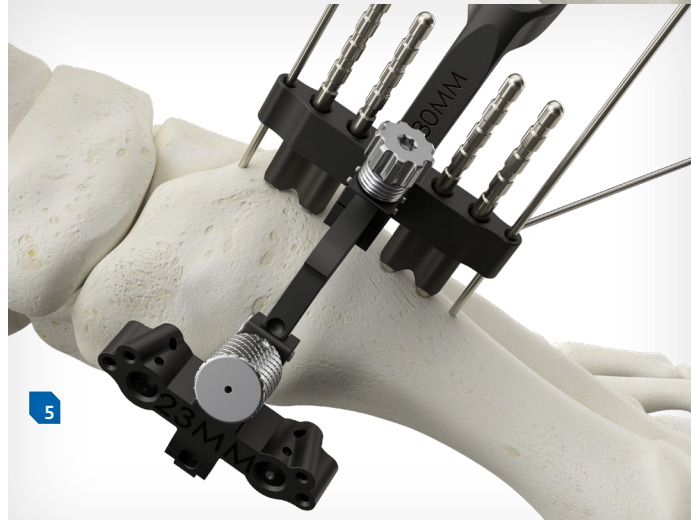


Step 3. 4-Leg Staple Bone Preparation

Place the targeting guide assembly on the bone so the drill holes of the dorsal guide are symmetric with respect to the joint line (Fig. 3). Optional: Place $\text{\O}1.4\text{mm}$ k-wires through the most proximal and distal k-wire holes for temporary fixation of the guide.

K-wires may also be used in the drill holes prior to drilling to verify placement.

Drill the first hole through the dorsal guide in the most proximal hole (cuneiform) with the $\text{\O}3.0\text{mm}$ drill bit and place the $\text{\O}3.0\text{mm}$ locator pin through the guide into the drilled hole (Fig. 4-5). Repeat for the remaining holes in the dorsal guide.



Step 4. 2-Leg Staple Bone Preparation

If desired, adjust the placement of the medial staple guide with the knob on the guide. The guide provides adjustability from 80-110° (Fig. 6). With the guide in the final position, Ø1.4mm k-wires can be placed through the k-wire holes in the medial drill guide to hold position of the guide.

With the dorsal guide still fixed in position with the locator pins, insert the drill sleeves into the medial drill guide until the sleeves contact the bone surface. Drill the first hole through the medial guide with the Ø3.0mm long drill bit and place a Ø3.0mm locator pin in the hole. Repeat for the second hole (Fig. 7). Verify pin placement visually and fluoroscopically, as the locator pins will indicate the definitive positioning of the staple legs (Fig. 8-9).

Step 5. Remove Dorsal Guide

Remove the locator pins and k-wires (if applicable) from the dorsal guide. Leave any locator pins and k-wires (if applicable) in place in the medial guide.

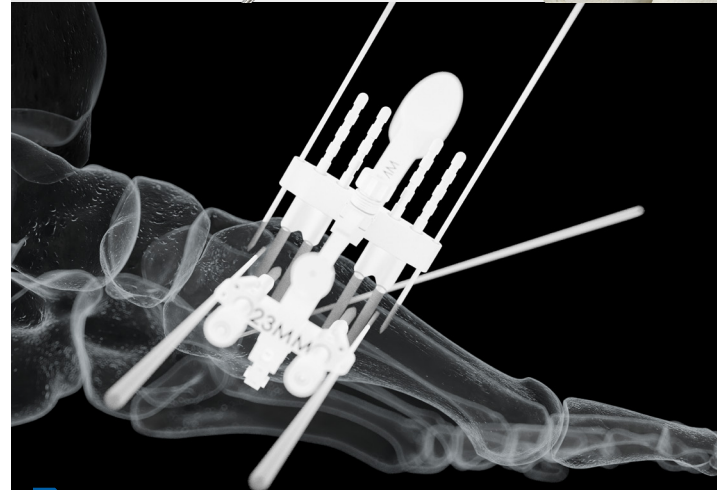
Unscrew the dorsal guide knob by hand or with a T15 driver and disconnect the medial guide, leaving the medial guide in position. Remove the dorsal guide.



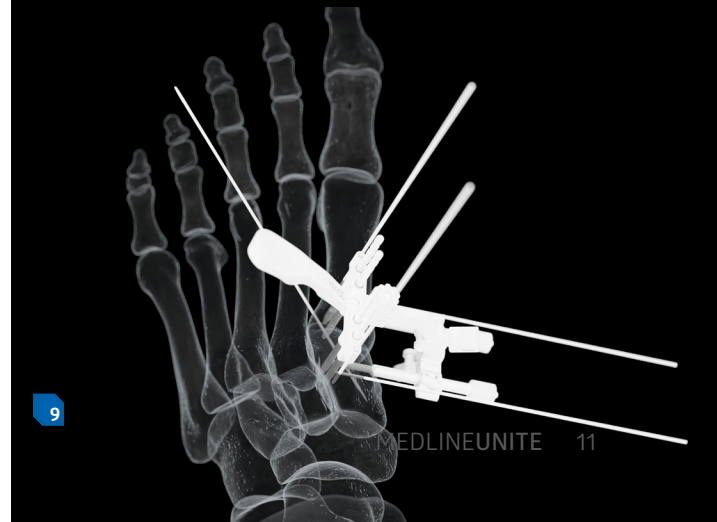
6



7



8

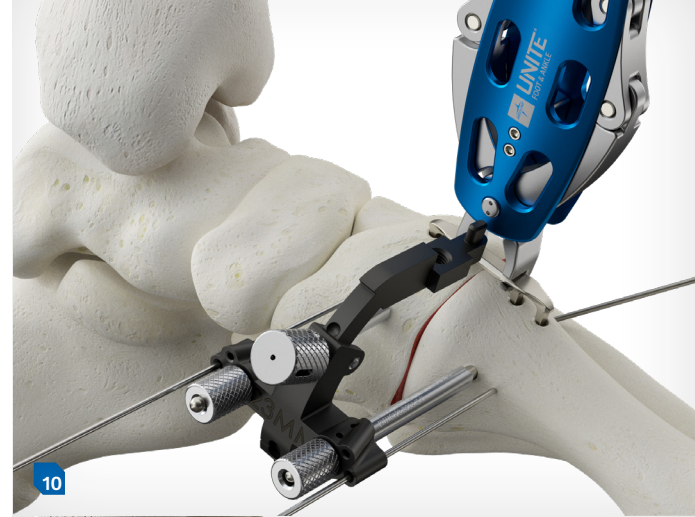


9

Step 6. Load 4-Leg Staple

Twist the staple inserter knob counter-clockwise to contract the expanding tips, allowing the instrument to fit under the staple bridge and between the two inner legs of the applicable 4 leg staple.

Position the staple inserter tips just beneath the bridge of the selected staple and twist the knob clockwise to grasp and retain the implant. Continue to twist the knob clockwise until the staple legs are parallel.



Step 7. Implant 4-Leg Staple

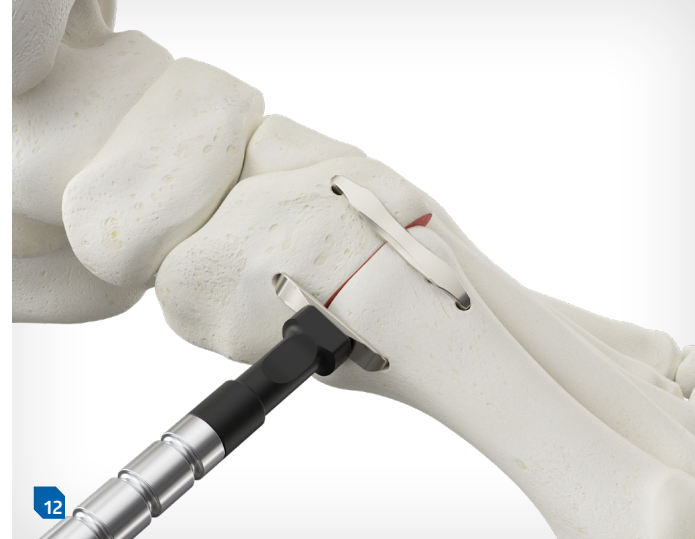
Advance the 4-leg staple legs into the pre-drilled holes until the inserter tips are flush with the bone, and then twist the inserter knob counter-clockwise to release the inserter from the staple (Fig. 10). It is recommended to orient the inserter so it can be removed laterally to avoid interference from the medial guide.

Verify placement of the dorsal staple visually and fluoroscopically, but avoid tamping until the second staple is implanted.



Step 8. Implant 2-Leg Staple

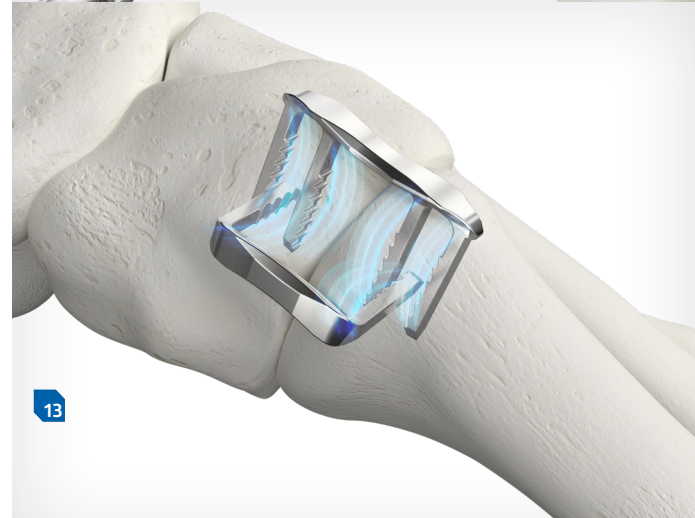
Remove the medial staple guide, locating pins, and k-wires (if applicable). Select the 2-leg staple size most appropriate for the patient's anatomy for dorsomedial or medial placement. The compatible bridge lengths are laser marked on the medial targeting guide. Place the medial staple in the same fashion as the dorsal 4-leg staple (Fig. 11).



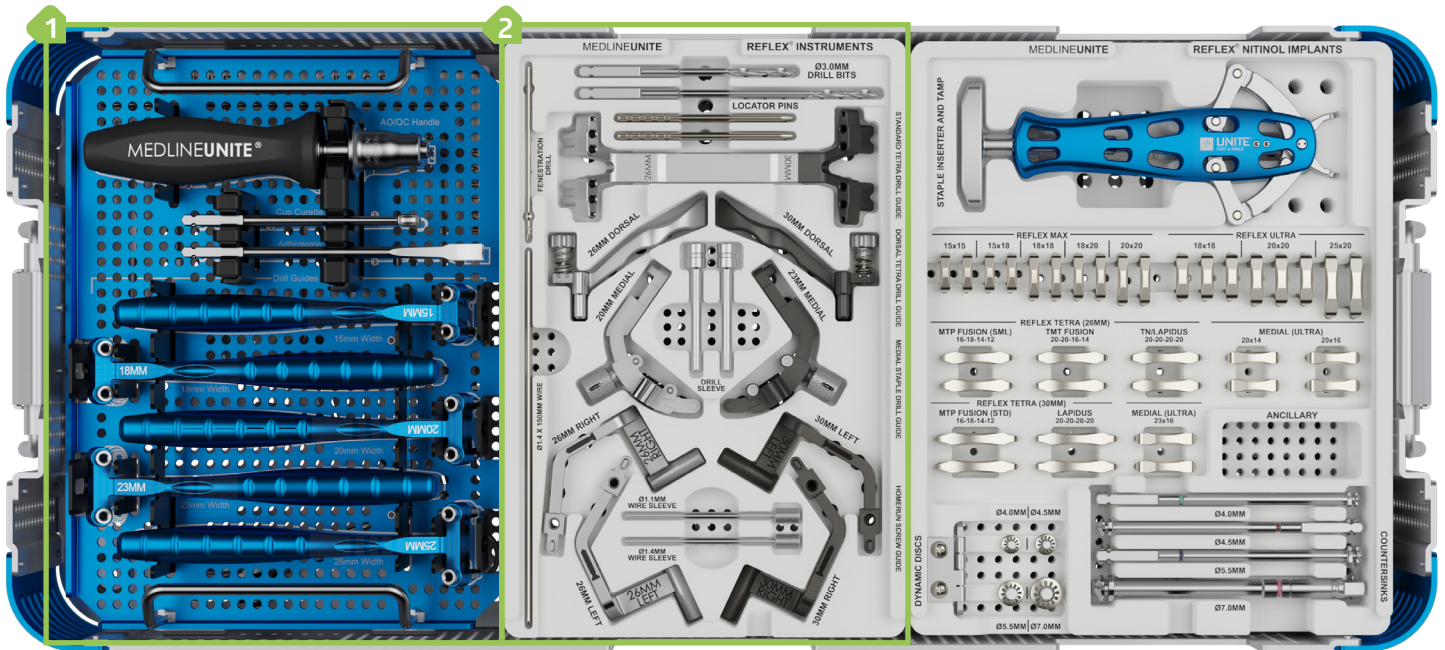
Step 9. Final Impaction

Use the provided tamp and a mallet to seat both staples until flush with the bone (Fig. 12-13).

If either staple requires repositioning or removal, the inserter's sharp, low-profile elevator tips allow the surgeon to pry, expand, and lift the staple from its seated position.



Tray Layout



Section 1

Instrument Tray

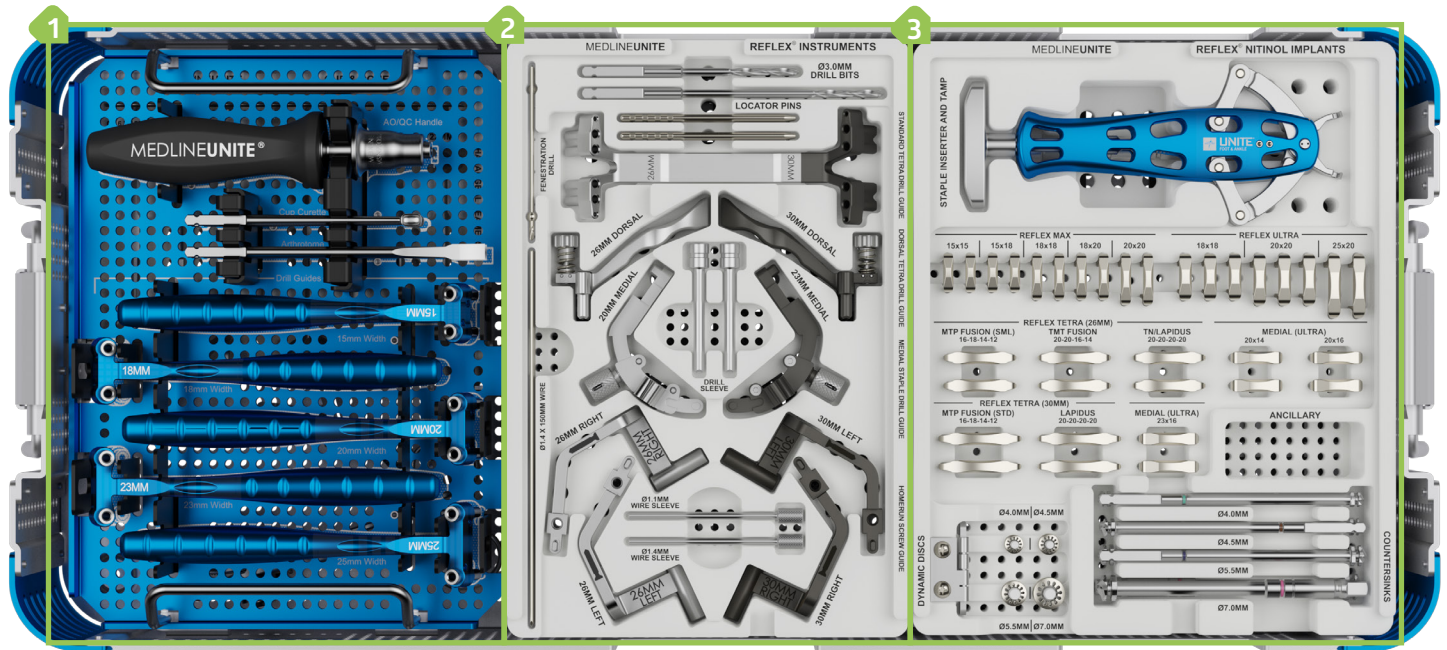
Item No.	Description	Qty.
MSN90006	Non-Ratcheting Handle	1
MPN52012	Small Joint Arthrotome	1
MSTC0000	Straight Cup Curette	1
MSTG0015	15mm Drill Guide	1
MSTG0018	18mm Drill Guide	1
MSTG0020	20mm Drill Guide	1
MSTG0023	23mm Drill Guide	1
MSTG0025	25mm Drill Guide	1
MPN53000	Pointed Reduction Forceps (located in 2nd level)	1

Section 2

Instrument Caddy

Item No.	Description	Qty.
MSTD1030	Ø3.0mm Drill Bit, short	2
MSTD1130	Ø3.0mm Drill Bit, long	2
MSTP0030	Ø3.0mm Locator Pin	6
MPDP0020	Ø2.0mm Fenestration Drill Pin	2
MSG14150	Ø1.4 x 150mm Guidewire	2
MSTG2630	26/30mm Double Ended Tetra Drill Guide	1
MSTG2600	26mm Dorsal Staple Targeting Guide	1
MSTG2620	26mm x 20mm Medial Staple Targeting Guide	1
MSTG2601	26mm Medial Screw Targeting Guide, left	1
MSTG2602	26mm Medial Screw Targeting Guide, right	1
MSTG3000	30mm Dorsal Staple Targeting Guide	1
MSTG3023	30mm x 23mm Medial Staple Targeting Guide	1
MSTG3001	30mm Medial Screw Targeting Guide, left	1
MSTG3002	30mm Medial Screw Targeting Guide, right	1
MSTN0003	Drill Sleeve	2
MSTN0004	Ø1.1mm Wire Sleeve	1
MSTN0005	Ø1.4mm Wire Sleeve	1

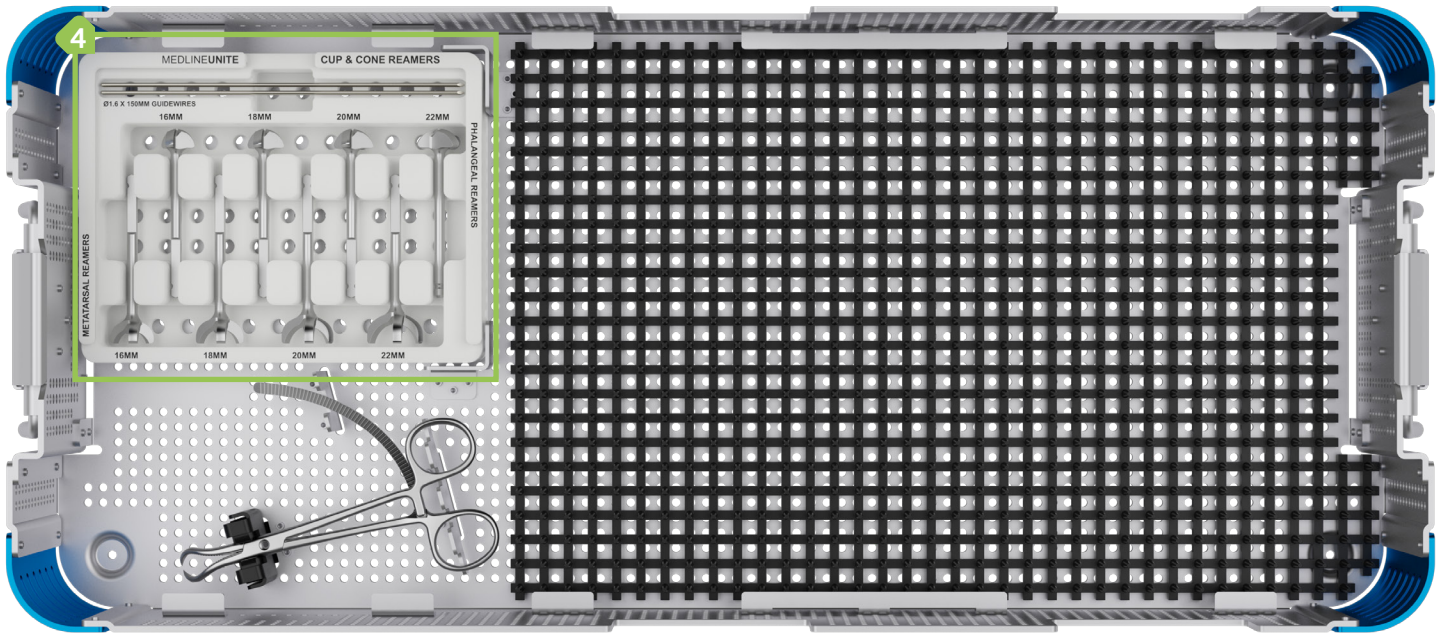
Tray Layout



Section 3

Implant Caddy

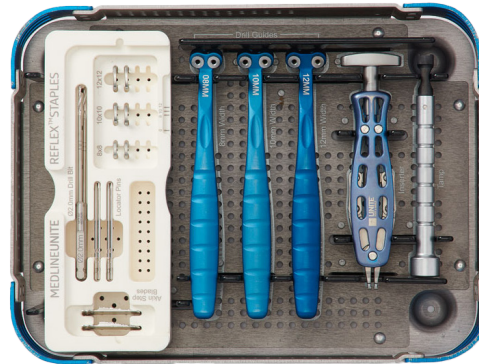
Item No.	Description	Qty.	Item No.	Description	Qty.
MSTN0002	Staple Inserter	1	MSTX2600NS	26mm MTP Fusion TETRA Staple	2
MSTTAMP1	Staple Tamp	1	MSTX2601NS	26mm TMT Fusion TETRA Staple	2
MST41515NS	15 x 15mm MAX Staple	2	MSTX2602NS	26mm TN/Lapidus TETRA Staple	2
MST41518NS	15 x 18mm MAX Staple	2	MSTX3000NS	30mm MTP Fusion TETRA Staple	2
MST41818NS	18 x 18mm MAX Staple	2	MSTX3002NS	30mm Lapidus TETRA Staple	2
MST41820NS	18 x 20mm MAX Staple	2	MSN21000	Ø4.0mm Disc Countersink	2
MST42020NS	20 x 20mm MAX Staple	2	MSN21001	Ø4.5mm Disc Countersink	2
MST51818NS	18 x 18mm ULTRA Staple	2	MSN21002	Ø5.5mm Disc Countersink	2
MST52014NS	20 x 14mm ULTRA Staple	2	MSN21003	Ø7.0mm Disc Countersink	2
MST52016NS	20 x 16mm ULTRA Staple	2	MSWN0000	Ø4.0mm Dynamic Disc	4
MST52020NS	20 x 20mm ULTRA Staple	2	MSWN1000	Ø4.5mm Dynamic Disc	4
MST52316NS	23 x 16mm ULTRA Staple	2	MSWN2000	Ø5.5mm Dynamic Disc	4
MST52520NS	25 x 20mm ULTRA Staple	2	MSWN3000	Ø7.0mm Dynamic Disc	4



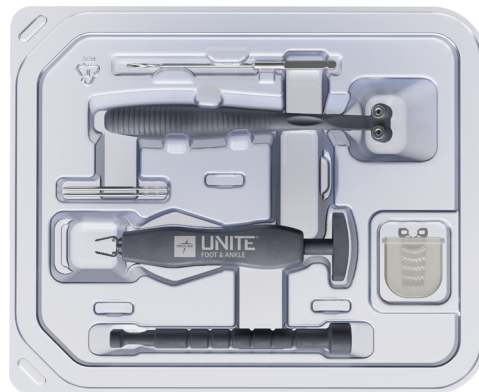
Section 4

MTP Fusion Reamer Caddy

Item No.	Description	Qty.
MPN20016	16mm Phalangeal Reamer	1
MPN20018	18mm Phalangeal Reamer	1
MPN20020	20mm Phalangeal Reamer	1
MPN20022	22mm Phalangeal Reamer	1
MPN20116	16mm Metatarsal Reamer	1
MPN20118	18mm Metatarsal Reamer	1
MPN20120	20mm Metatarsal Reamer	1
MPN20122	22mm Metatarsal Reamer	1
MSG16150	Ø1.6mm Non-Threaded Guidewire	6



Kitted for your convenience
Staples are available in both non-sterile trays and single use kits.



To schedule a case, contact your Medline UNITE Representative or visit medlineunite.com for more information.



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