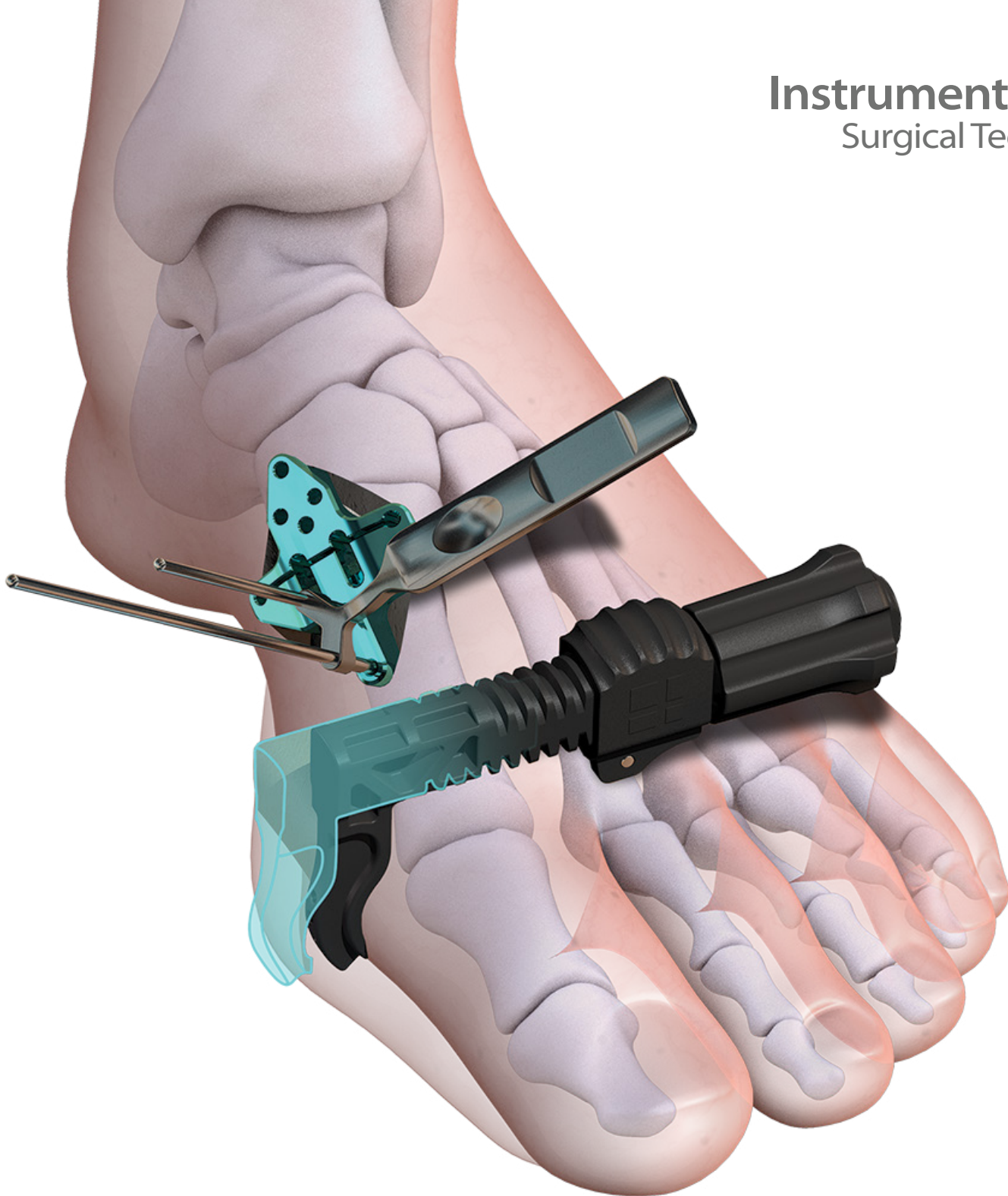


Instrumented 4D

Surgical Technique



DYNABUNION™ 4D

Instrumented Lapidus System

FEATURING PERSPECTIVES FROM:

Craig Breslauer, DPM David Oji, MD Michael Campbell, MD
Murray Butler, DPM Patrick Briggs, DPM Scott Shawen, MD

 **DePuy Synthes**
THE ORTHOPAEDICS COMPANY OF *Johnson & Johnson*

Lapidus Should Be4D Stress Free

DYNABUNION™ System instrumentation secures each plane individually. This allows for fine tuning of alignment in each plane.¹



Traditional Procedures
Multiple Hands Used



DYNABUNION™
Instruments Hold Position

“The 4th Dimension” Compression That Doesn’t Quit

Compression is addressed by utilizing a unique RAC (re-alignment and compression) block and DYNAFORCE™ Staple Compression Plate (SCP). SCPs have a patented design that utilizes a powerful nitinol staple to provide compression.

This provides these primary advantages:

Gap Recovery^{1, 2}

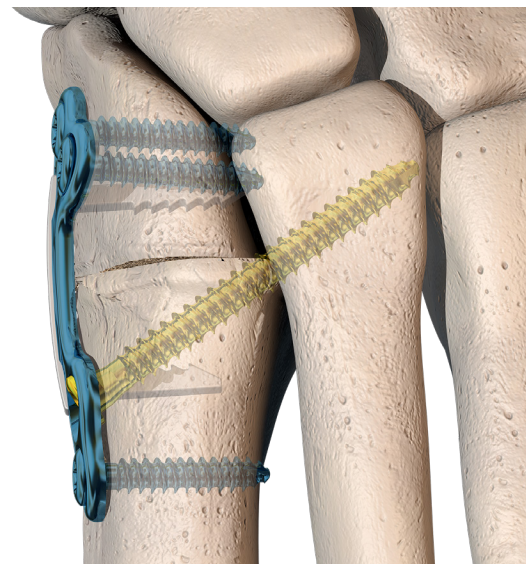
Continuous staple compression overcomes space between the fusing bones (i.e. gapping) caused by natural osteoclast resorption or patient non-compliance.

Apposition¹

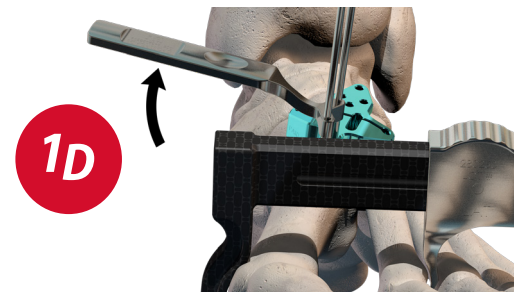
Staple compression allows for increased bony apposition and surface area to optimize fusion compared to a transarticular lag screw.¹

Speed¹

Staple insertion requires less steps compared to conventional independent lag screw techniques.¹



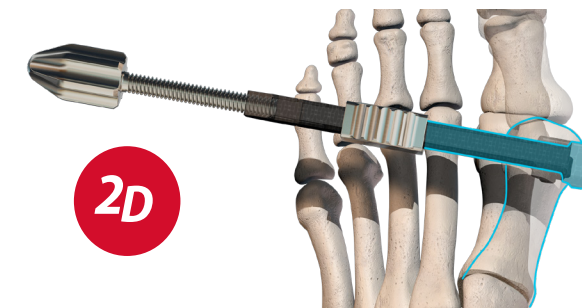
The 4 Dimensions



Rotation

The DYNABUNION™ Frontal Plane Joystick allows two-point control proximally at the joint which generates strong leverage to correct rotation.¹

A wire can be placed into the distal reducer to secure rotation.



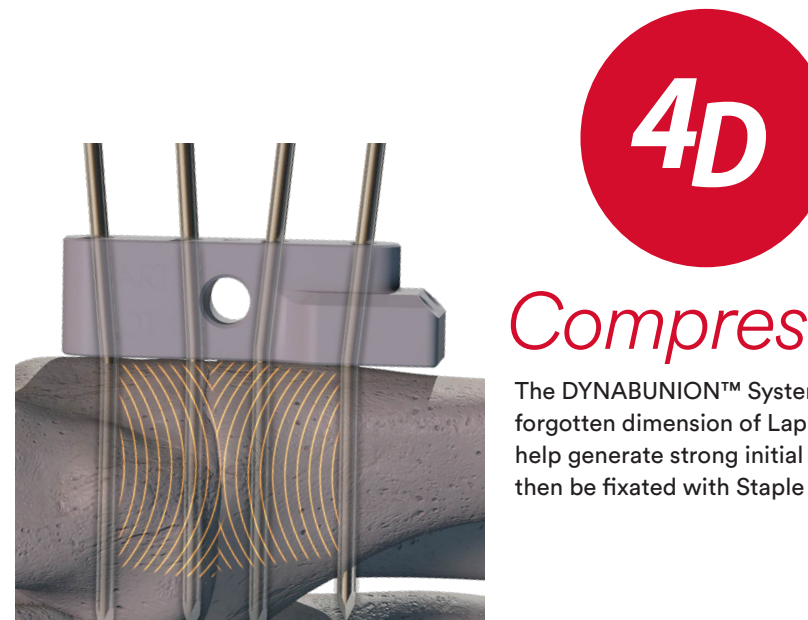
Reduction

The DYNABUNION™ Reducer provides distal IMA reduction directly at the metatarsal head. Unlike competitive reducers, the medial arm of the DYNABUNION™ System reducer can be placed directly over the skin.¹ Once tightened, it will hold the IM reduction in place.



Alignment

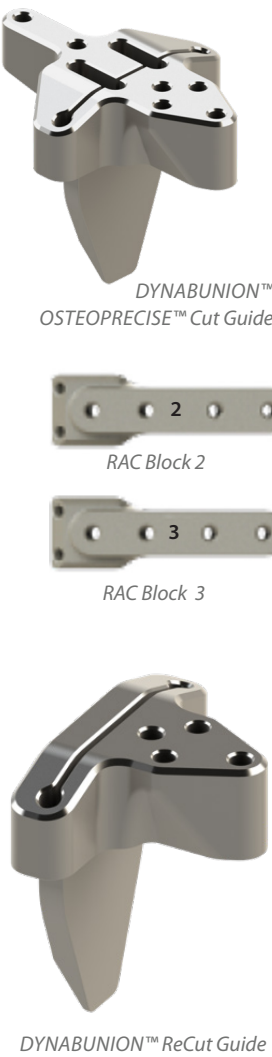
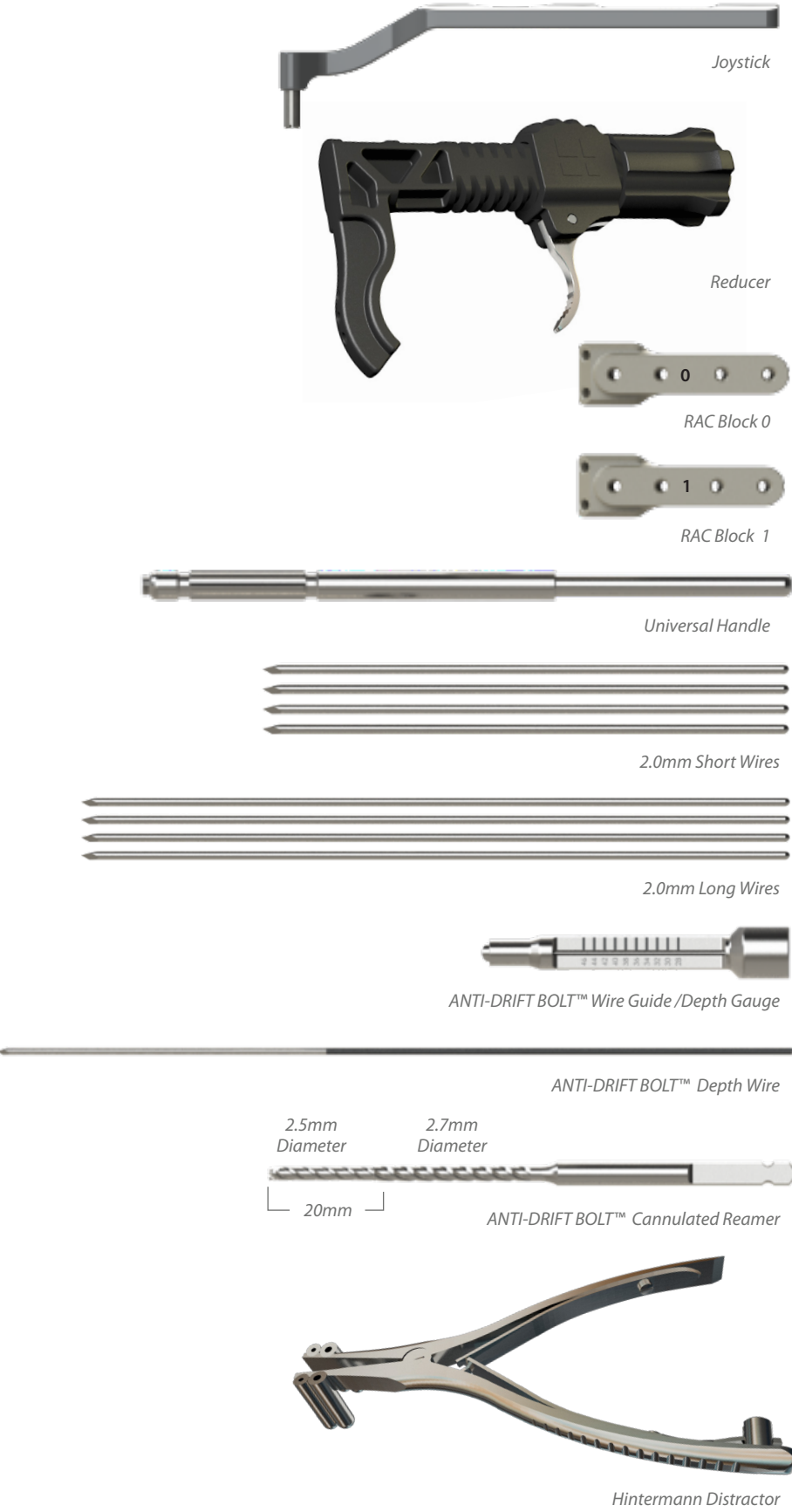
The radiolucent DYNABUNION™ RAC Block finalizes and secures the correction. The RAC block is designed to provide a platform to optimize sagittal alignment and avoid transfer metatarsalgia.¹



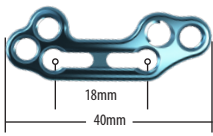
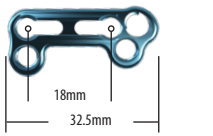
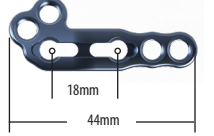
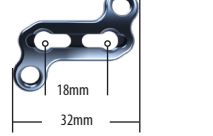
Compression

The DYNABUNION™ System addresses compression, a critical but commonly forgotten dimension of Lapidus. The RAC block features convergent holes to help generate strong initial compression and bony apposition.¹ The joint can then be fixated with Staple Compression Plate technology.

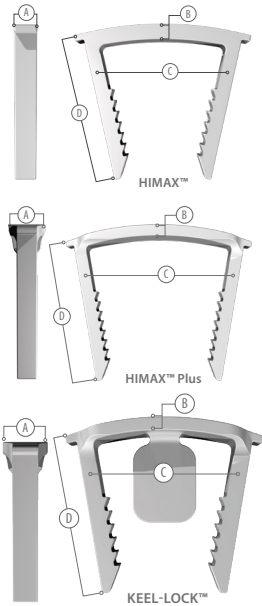
DYNABUNION™ Lapidus System
Key Instrumentation



DYNAFORCE™ Staple
Compression Plate
Options

								
	DYNABUNION™ SCP (Standard)		DYNABUNION™ SCP (Short)		LC SCP		LZ SCP	
TYPE	Right	Left	Right	Left	Alpha	Beta	Alpha	Beta
PART NUMBER	7108-DST-R	7108-DST-L	7108-DSH-R	7108-DSH-L	7100-LC18-A	7100-LC18-B	7100-LZ18-A	7100-LZ18-B
SLOT LENGTH/STAPLE SIZE	18mm	18mm	18mm	18mm	18mm	18mm	18mm	18mm
OVERALL LENGTH	40mm	40mm	32.5mm	32.5mm	44mm	44mm	32mm	32mm
THICKNESS	1.5mm	1.5mm	1.5mm	1.5mm	1.7mm	1.7mm	1.7mm	1.7mm
PLATE CURVATURE (DISTAL/PROXIMAL)	10 Degrees	10 Degrees	10 Degrees	10 Degrees	10 Degrees	10 Degrees	10 Degrees	10 Degrees
COMPATIBLE STAPLE	HIMAX™ C Implant	HIMAX™ C Implant	HIMAX™ C Implant	HIMAX™ C Implant	HIMAX™ C Implant	HIMAX™ C Implant	HIMAX™ C Implant	HIMAX™ C Implant
ANTI-DRIFT BOLT™ COMPATIBLE	YES	YES	YES	YES	NO	NO	NO	NO

Nitinol Options



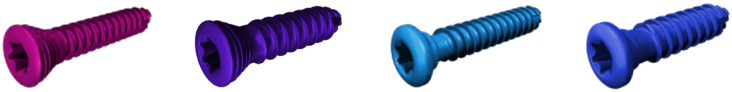
	For use with Staple Compression Plates				
					
	HIMAX™ C Implant (18x18x18mm)	HIMAX™ C Implant (18x14x14mm)	HIMAX™ C Implant (18x18x14mm)	HIMAX™ Plus Implant	KEEL-LOCK™ Implant
PART NUMBER	7118-1818-C	7118-1414-C	7118-1814-C	7415-1515 thru 7425-2222	7318-1818, 7320-2020
BRIDGE WIDTH	A	2.7mm	2.7mm	2.7mm	5mm
BRIDGE THICKNESS	B	1.8mm	1.8mm	1.8mm	1.3-1.6mm
INTERAXIS LENGTH	C	18mm	18mm	18mm	15,18, 20, 25mm
LEG LENGTH	D	18mm	18mm	18x14mm	15,18, 20,22 mm
REAMER SIZE		3.2mm	3.2mm	3.2mm	3.2mm
COMPRESSION		27lbs.	27lbs.	27lbs.	28lbs.
CURVATURE WHEN LEGS ARE STRAIGHT		10°	10°	10°	10°

ANTI-DRIFT BOLT™ Implant
(For use with DYNABUNION™ Plate only)



3.5mm, Non-Locking, Solid
FullyThreaded, 14mm
32-42mm Lengths, 2mm Increments

Plate Screws



	3.0mm POLYAXIAL LOCKING	3.5mm POLYAXIAL LOCKING	3.0mm NON-LOCKING	3.5mm NON-LOCKING
PART NUMBER	15PL-3010 thru 15PL-3030	15PL-3510 thru 15PL-3530	15NL-3010 thru 15NL-3030	1500-3510 thru 1500-3550
SIZE RANGE*	10mm-30mm	10mm-30mm	10mm-30mm	10mm-50mm
DRIVER	H10 (Hexalobe)	H10 (Hexalobe)	H10 (Hexalobe)	H10 (Hexalobe)
DRILL SIZE	2.0mm	2.5mm	2.0mm	2.5mm

*2mm increments

Cut Metatarsal

- 1

Create a dorsomedial incision that is approximately 45 degrees from direct dorsal and well medial to the extensor hallucis longus.
- i

The incision should be approximately the length of the cut guide which is 3-4cm long.
- 2

It is critical to utilize a slim osteotome to mobilize the joint and release any plantar soft tissue attachments.

Incision Location: Dorsomedial

Direct Dorsal

45°

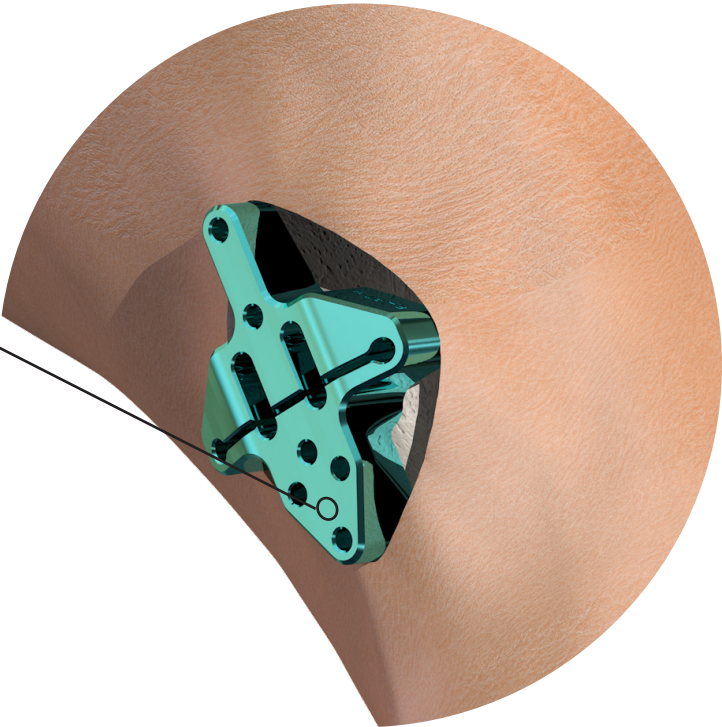


- 3

Place the paddle of the cut guide into the joint with the cutting side (marked with a circle) facing the metatarsal. Firmly press down on the center of cut guide to seat it closely to bone with the keel parallel to the proximal joint surface of the metatarsal.
- i

Do NOT apply pressure to the distal end of the cut guide. It is NOT critical that the distal end of the cut guide is touching bone.
- 4

The cut guide should be oriented approximately at 45 degrees relative to the direct dorsal and aligned directly in between true dorsal and true medial. For a more severe bunion, the cut guide will be positioned slightly closer to medial than to true dorsal.



Cut Guide



2.0 Short Wire



2.0 Long Wire



40mm Saw Blade

INSTRUMENTS REQUIRED

Cut Metatarsal

- 5

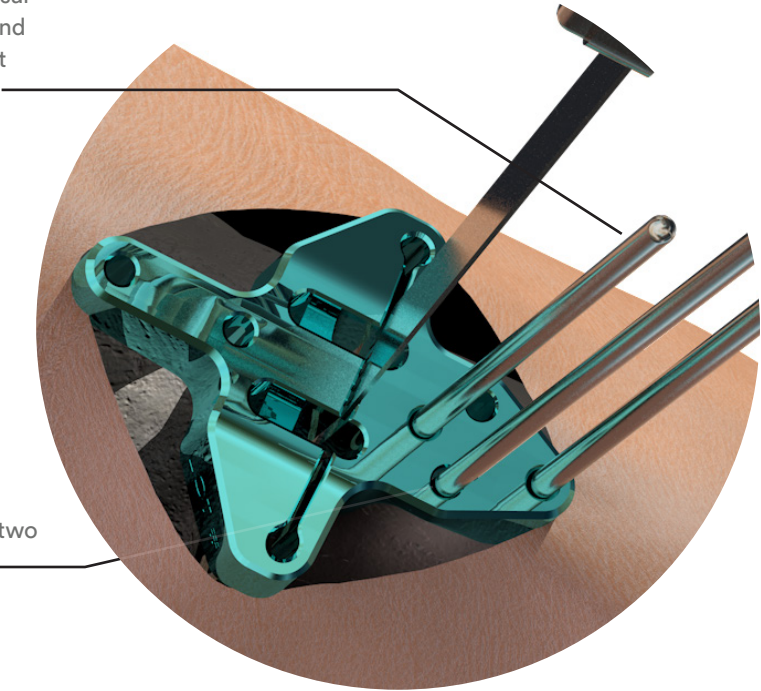
Ensuring the cut guide paddle is flush with the metatarsal joint surface, place the short 2.0mm wire into the second most distal hole. Place a long 2.0mm wire into the most distal hole.
- i

Ensure both wires are bicortical but not into the 2nd metatarsal.
- 6

Utilize one of the provided extra long 40mm saw blades to complete the metatarsal cut.
- i

There are two blade options for different power systems. Listed on pages 21 and 23.
- 7a

To prevent the cut guide from being displaced during resection, a 2.0mm wire can be placed into one of the two convergent distal holes to hold the guide in place.

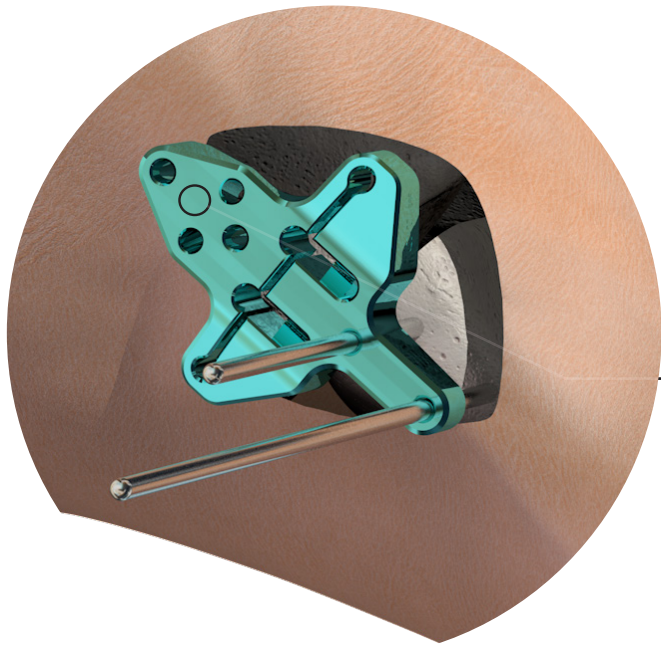


- i

Care should be taken not to cut into the second metatarsal base. Ensure surrounding tissue and the extensor hallucis longus (EHL) are retracted away from the cut guide prior to the resection.

- i

The maximum theoretical thickness of the metatarsal bone sliver is 1.6mm.



- 8

Once the metatarsal cut is complete, remove the cut guide from the two k-wires in order to remove the bone sliver.
- 9

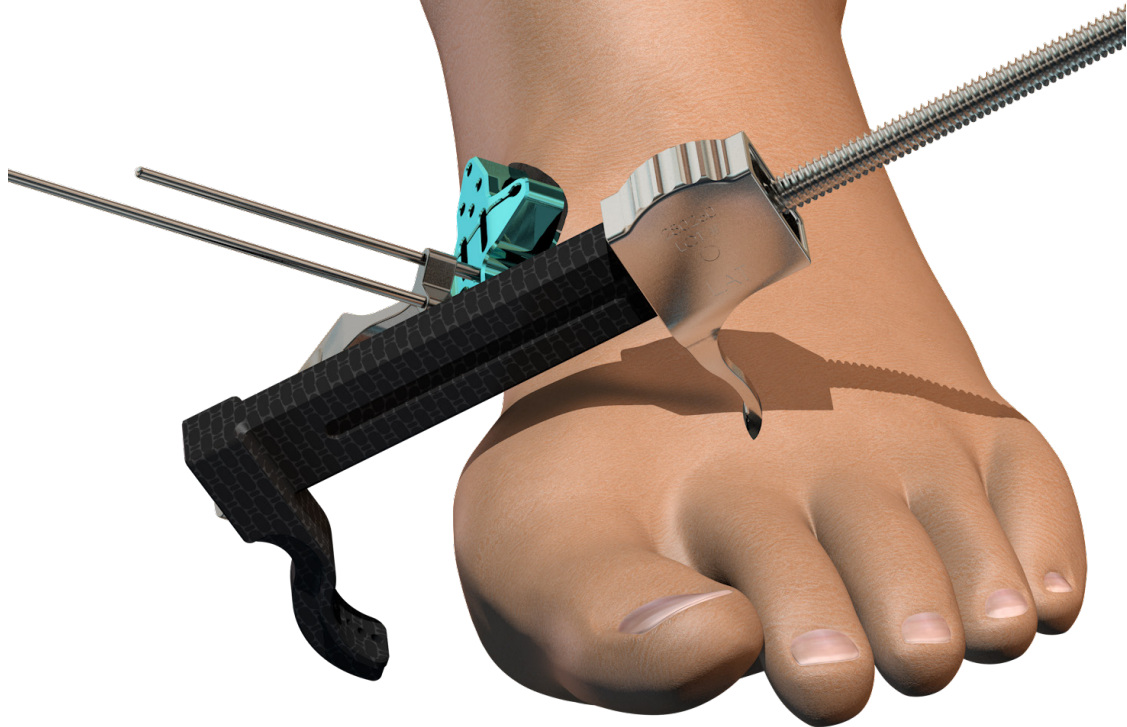
Flip the cut guide 180 degrees and place it back into the joint and over the existing wires. The cutting slot and circle should now be facing the medial cuneiform.

WHY IS THE DYNABUNION™ INCISION DORSOMEDIAL? IS THERE ANY SPECIFIC ANATOMY TO BE WARY OF DUE TO THE DORSOMEDIAL INCISION?

Surgeon Perspective from Michael Campbell, MD

The dorsomedial incision for the DYNABUNION™ Procedure was chosen to allow for excellent access to the entire first tarsometatarsal joint in addition to the interspace between the bases of the first and second metatarsals and distal portion of the medial intercuneiform joint. This incision allows for work to be done in the interval between the tibialis anterior tendon insertion and the extensor hallucis longus tendon. A common structure encountered with this exposure is the terminal sensory branch to the great toe and often a traversing vein branch - both easily mobilized or, in the case of the vein, ligated or coagulated.

CrossRoads Staple Compression Plates are designed with the biomechanical goal of achieving a tension band type construct away from the plate. By design, the DYNABUNION™ Medial Plate placement creates a dynamic construct which not only resists plantar gapping, but also resists widening of the intermetatarsal angle, with an intent of providing the ideal Lapidus construct.



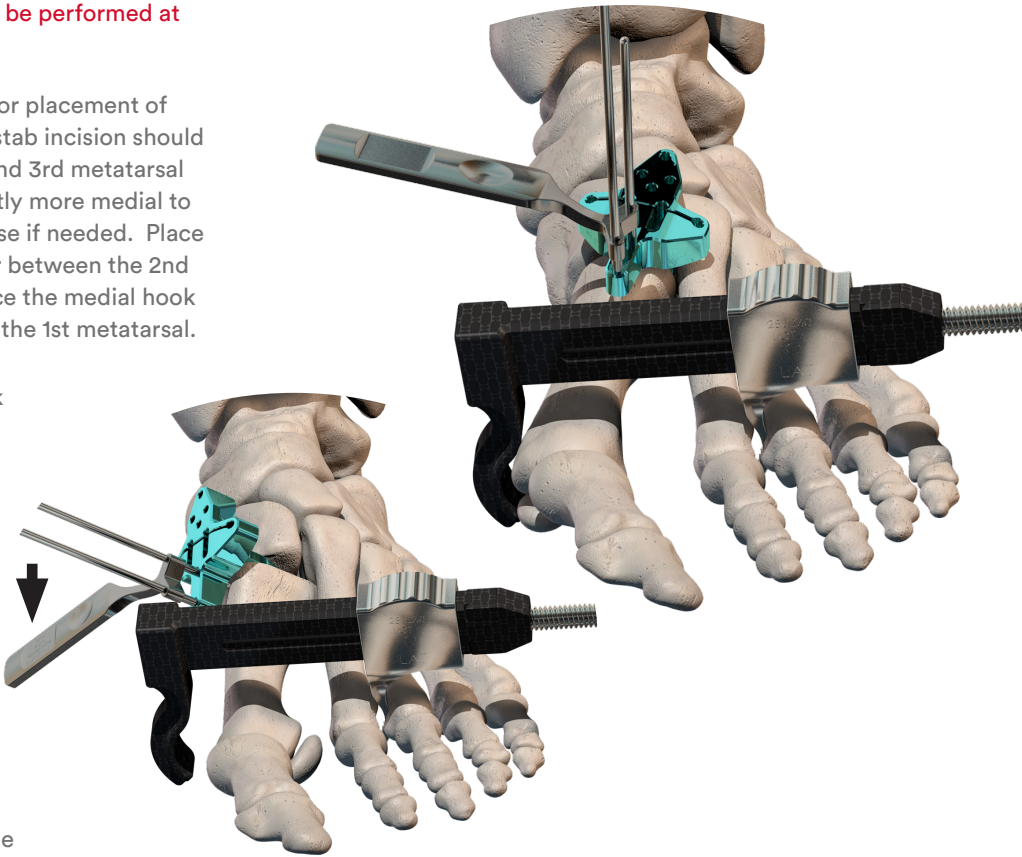
Utilize the frontal plane joystick to attempt rotation of the metatarsal. If complete rotation and ideal sesamoid position cannot be achieved, then a lateral soft-tissue release may be performed at this time.

1 Perform a small stab incision for placement of the lateral reducer hook. The stab incision should be located between the 2nd and 3rd metatarsal necks or may be created slightly more medial to be also used for a lateral release if needed. Place the lateral hook of the reducer between the 2nd and 3rd metatarsal necks. Place the medial hook over the skin onto the head of the 1st metatarsal.

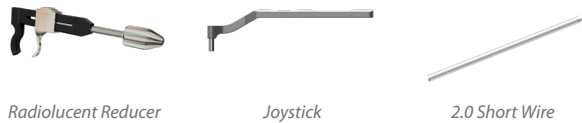
2 Place the frontal plane joystick over the two distal wires with the handle facing in either direction.

3 While holding the reducer in place, tighten the reducer knob clockwise until it is snug but do not close down all of the intermetatarsal (IM) angle.

4 With one hand, utilize the joystick to generate frontal plane correction by rotating the sesamoids into proper placement directly under the head of the metatarsal



INSTRUMENTS REQUIRED

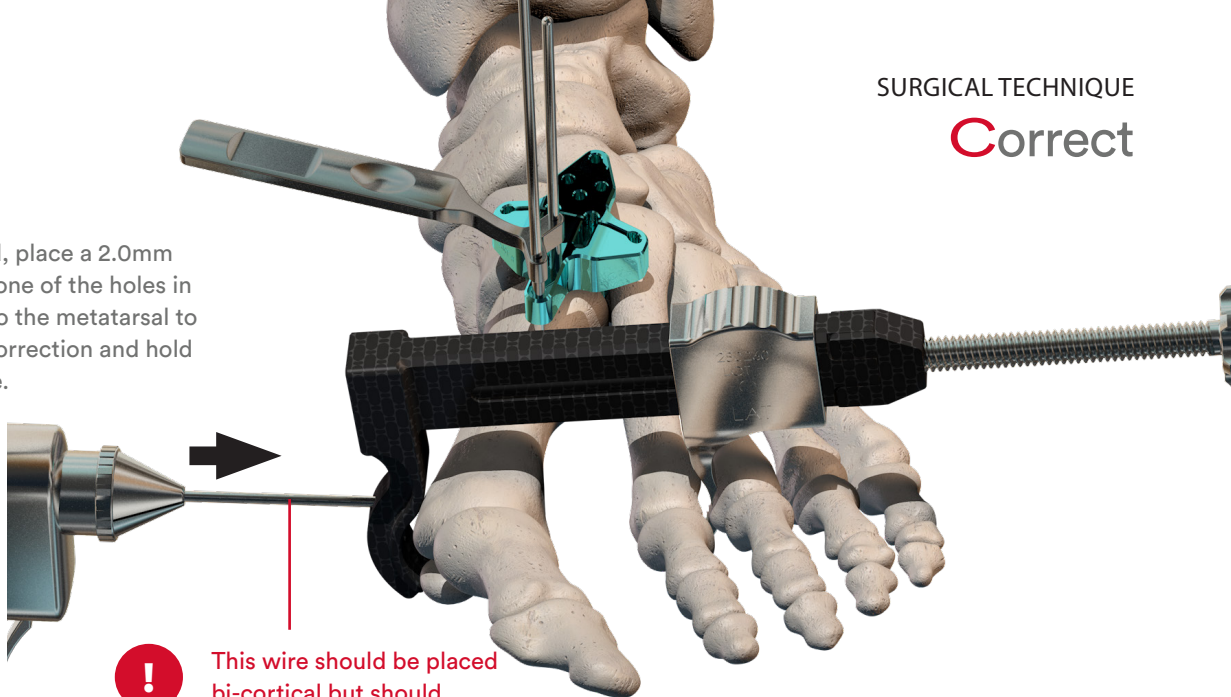


Radiolucent Reducer

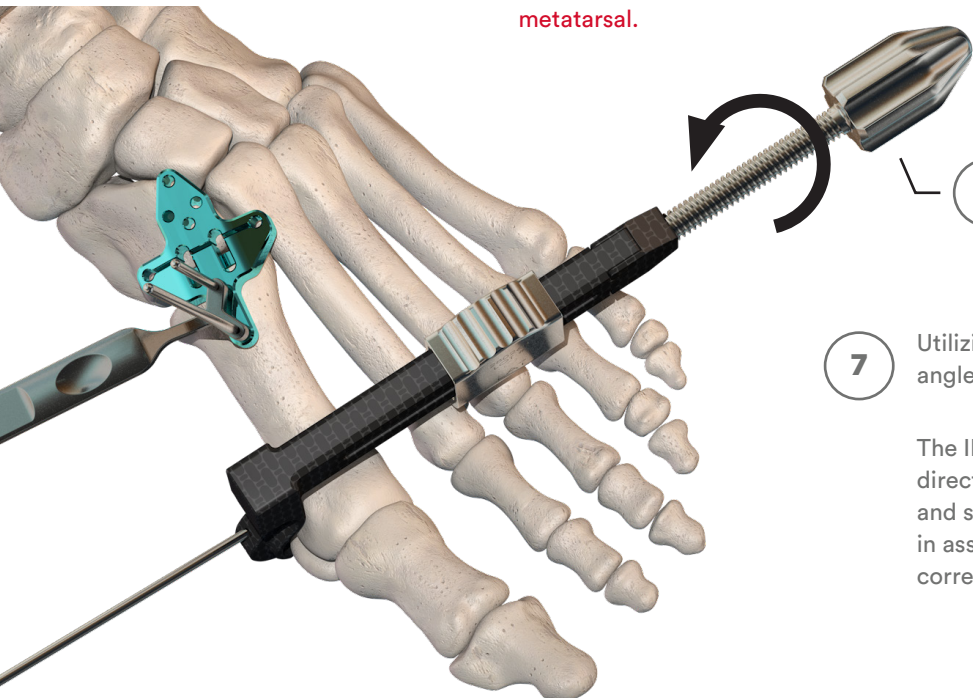
Joystick

2.0 Short Wire

5 With a second hand, place a 2.0mm short wire through one of the holes in the medial hook into the metatarsal to lock frontal plane correction and hold the reducer in place.



This wire should be placed bi-cortical but should not penetrate the 2nd metatarsal.



6 Dial-in the IM angle by turning the reducer knob clockwise until desired reduction is achieved.

7 Utilizing AP fluoroscopy, confirm the desired IM angle and sesamoid position is achieved.

The IM Reducer is radiolucent which allows direct visualizations of the metatarsal head and sesamoids. These structures are critical in assessing proper frontal plane rotation correction.

WHEN SHOULD I PERFORM A LATERAL RELEASE?
Surgeon Perspective From David Oji, MD

My main consideration on whether to do open or percutaneous lateral release is the flexibility of the patient's great toe MTP joint. In older patients with hallux rigidus, the bunion deformity is typically more rigid, and a lateral release may be needed to make the joint congruent. In those patients, I may also consider an akin osteotomy to provide a better clinical result. Regardless of age and/or arthritis, or reduced ROM, I perform the DYNABUNION™ Lapidus arthrodesis to get 4D correction.

In 60% of patients, I do not have to do a lateral release. The DYNABUNION™ System's unique ability to fully correct the IMA and frontal plane deformity, minimize shortening, and compress in a simplified step wise approach reduces the need for lateral soft tissue release, modified McBride, or Akin osteotomies. In the 40% of patients that need a lateral release, I notice that the great toe is still in valgus after correction of the IMA and frontal plane even though the distal 1st MT is directly over the sesamoids. These patients tend to be older (>50 years old), long standing moderate to severe hallux valgus deformity, there's evidence of hallux rigidus, and tend to have reduced flexibility to varus.

I typically start with a percutaneous release rather than an open release. If the joint is still rigid and tight, then I do an open release and release the adductor hallucis off the lateral sesamoid. I find that in 30% of patients, the great toe needs additional correction and I have a very low threshold to include an akin osteotomy. Finally, if a last bit of correction is needed, then I do an excision of the medial eminence and plication of the medial capsule. I find that with the ability to have such a precise correction system like The DYNABUNION™ System's where all deformities can be corrected to a normal position/ value, there is less of a need to do a McBride.

Cut Cuneiform

1

Dorsiflex the hallux to engage the windlass mechanism of the plantar fascia, which will compress the first TMT joint and provide apposition of the cut guide paddle to the medial cuneiform joint surface.

!

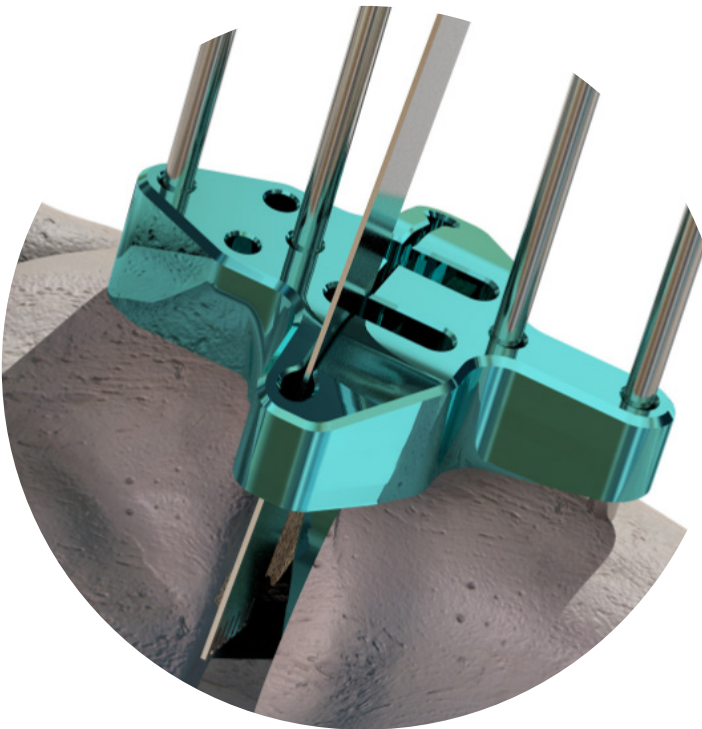
Be careful to not lose any frontal plane correction, while dorsiflexing the hallux and engaging the windlass mechanism. TIP: Have an assistant hold the frontal plane joystick to help ensure sesamoid position is maintained while performing this portion of the procedure.

2

While still performing windlass, place a short 2.0mm wire into the 2nd most proximal hole. Place the long 2.0mm wire into the most proximal hole.

!

Ensure both wires are bicortical.



3

Utilize one of the provided 40mm saw blades to complete the cuneiform cut. Making sure that the surrounding soft tissue has been retracted from under the cut guide.

INSTRUMENTS REQUIRED



Cut Cuneiform

4

Once the cut is complete, remove the cut guide while leaving only the four wires and distal reducer in place.

5

Remove the cuneiform resection. If needed, utilize an osteotome or rongeur to remove any remaining plantar bone.

i

The maximum theoretical thickness of the cuneiform bone sliver is 1.6mm. The cuneiform bone sliver may be thicker on the lateral side.

!

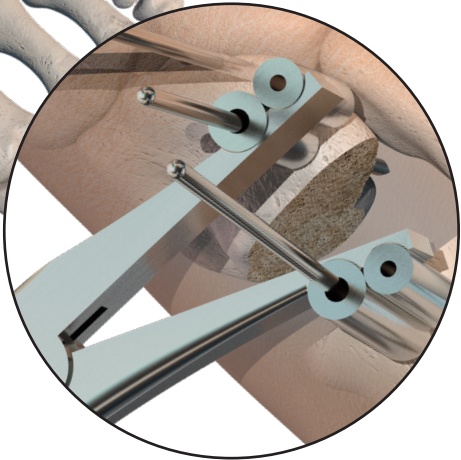
If an additional cut is needed, see the optional ReCut technique below.

6

Preparation of the metatarsal and cuneiform joint surfaces should be completed at this time per the surgeon's preferred technique. If desired, preparation of the articulation between the proximal 1st and 2nd metatarsals or distal portion of the intercuneiform joint can be completed.

!

A hintermann distractor is provided and can be placed over the two inner wires to distract the joint in order to access the joint surfaces.



Optional: Recut

!

Before the Re-Cut guide is used, ensure both metatarsal and cuneiform cuts have been made using the standard cut guide. A re-cut prior to making both cuts will cause misalignment of the wire pattern for proper instrument placement.

7

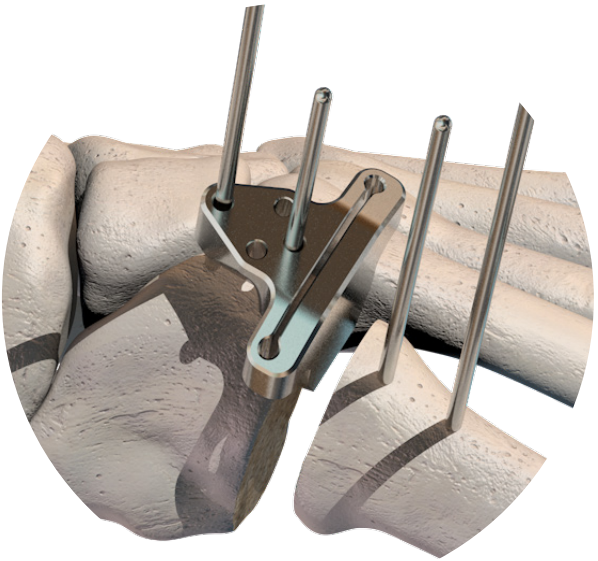
The ReCut Guide should be placed over the existing two wires until in contact with the bony surface.

8

Next, the cut can be taken with the provided blades.

i

The maximum theoretical thickness of each re-cut bone sliver is 1.1mm.



INSTRUMENTS REQUIRED



WHEN IS A "RE-CUT" TYPICALLY REQUIRED?
Surgeon Perspective From Michael Campbell, MD

A recut is often necessary in cases with significantly convex/concave joint surfaces or for a significantly atavistic cuneiform. Typically, only one joint surface would require a re-cut and minimizing bony resection will maximize the maintenance of metatarsal length. There may be a small amount of cartilage on the medial side of the cuneiform that did not get removed from the initial cut. It is not necessary to re-cut that portion of the joint surface as it should not be part of the fusion surface.

1

Starting with RAC Block 0, align the 4 dorsal holes of the block over the four dorsal wires with the two angled holes facing distally.

!

Apply plantar counter-pressure to ensure the force from the block does not plantar shift the metatarsal.

3

When the RAC block is approximately half way down the wires, any sagittal plane alignment adjustments can be made. Confirm with palpation and fluoroscopy that the weight bearing surface under the sesamoids is not dorsally or plantarly translated in relation to the lesser metatarsal heads.

i

The RAC Block should be flush against the dorsal surface of the cuneiform but may be hanging above the surface of the metatarsal.

2

The blunt side of the universal handle can be slid into the large hole on the RAC Block to push the compressor block down to bone.

4

Visually confirm bony apposition of the first TMT joint and confirm under lateral fluoroscopy if desired. The RAC Block is PEEK and radiolucent to aid in visualization of the correction and bony apposition.

i

If additional bony apposition is needed, remove RAC Block 0 and place one of the additionally provided blocks. Increasing number corresponds with increased compression.

INSTRUMENTS REQUIRED



!

Due to its final dorsal position, the RAC Block can be left in place while placing the DYNABUNION™ Staple Compression Plate. However, if the block is in the way of desired plate placement, it can be removed by following the steps listed below.

5

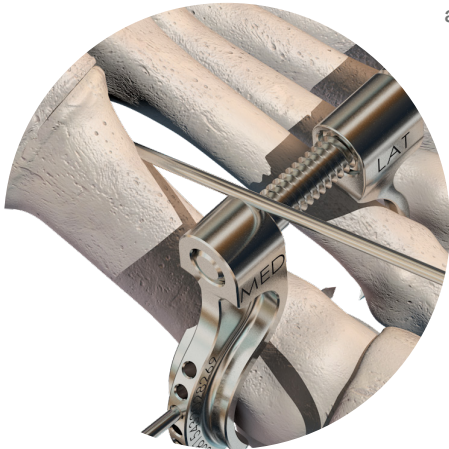
Place a cross-joint wire by driving a long 2.0mm wire through one of the holes of the RAC Block.

i

The lateral hole is recommended to avoid the plate.

!

If the user is not confident in the bone quality or bony purchase, a second wire can be placed in the remaining hole or freehand to ensure correction and apposition will be maintained.

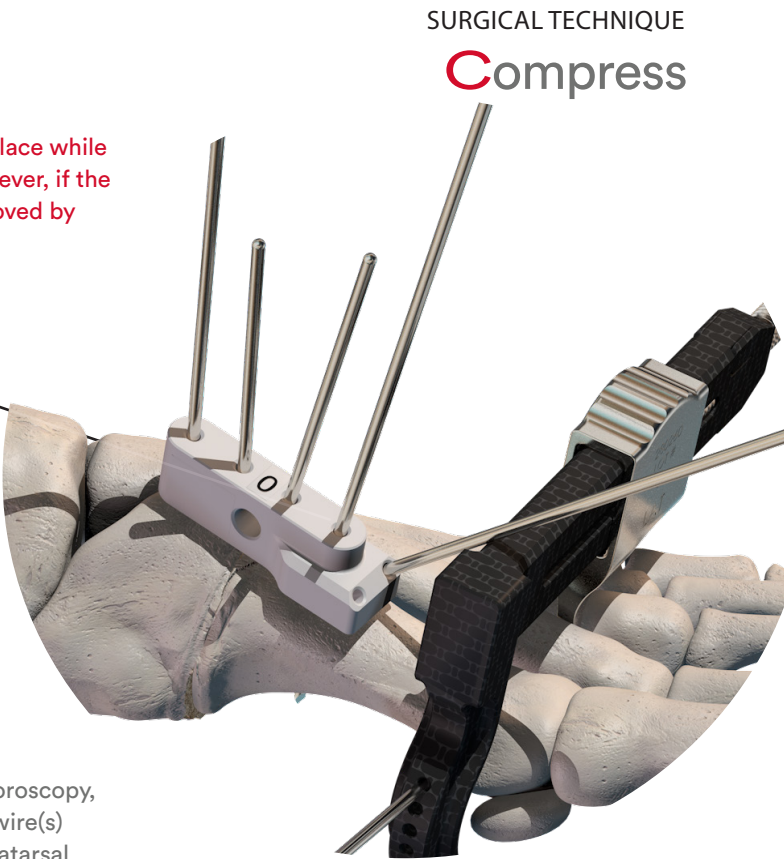


6

Using AP and lateral fluoroscopy, confirm the cross-joint wire(s) has purchase in the metatarsal and cuneiform.

7

Remove all 4 dorsal wires and slide the RAC block off of the cross-joint wire.



IF THERE IS A LATERAL FLARE OF THE METATARSAL BASE, SHOULD I BEND MY PLATE OR SHAVE THE BONE?
Surgeon Perspective From Michael Campbell, MD

When performing the Lapidus procedure, especially one with significant metatarsal rotational correction, the plantar-medial flare of the first metatarsal often becomes very prominent. Personally, I'm a major proponent shaving this medial surface of the proximal first metatarsal and if necessary medial aspect of the cuneiform to become flat surface. This, in my experience, not only decreases prominence and improves cosmesis, but has completely obviated the need for hardware removal. Additionally, it allows for the plate to be applied without any contouring. By avoiding the need to contour the plate, staple and screw interaction with the plate is optimized. It is also far easier and quicker to make the bone fit the plate than make the plate fit the bone.

WHAT IS THE MOST SECURE FREEHAND WIRE TRAJECTORY?
Surgeon Perspective From Patrick Briggs, DPM

If a second wire is needed to cross the 1st TMT to stabilize prior to fusion, the easiest and most reproducible throw is from plantar/distal to dorsal proximal. This allows the surgeon to take advantage of plantar curvature of the 1st metatarsal and can facilitate direct aiming into the medial cuneiform. This temporary fixation also has the advantage with being on the tension side of the joint and will prevent any gapping plantarly while counterbalancing the 1st point of fixation through the RAC block. This technique also prevents any temporary fixation to be well out of the way of the permanent fixation.

Staple Compression Plate Placement

CrossRoads fixation options such as Staple Compression Plates (SCP) or staples can be utilized to fixate the 1st TMT joint. If using a SCP, select between the DYNABUNION™, LC, or LZ plate. See page 5 for details on plate options.



1 If additional plate contour is required, utilize the 2nd most curved slot in the plate bender to add contour. **DO NOT REVERSE BEND THE PLATE.**

2 Align the plate by centering the staple slot over the joint and positioning the plate medial (DYNABUNION™ Implant) or dorsomedial (LC/LZ).

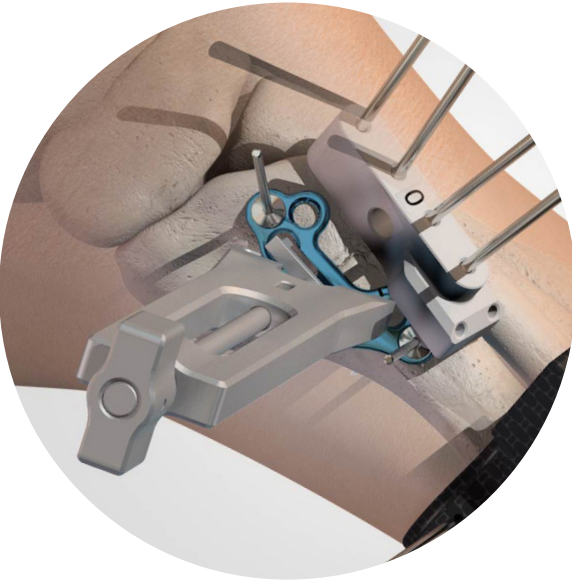
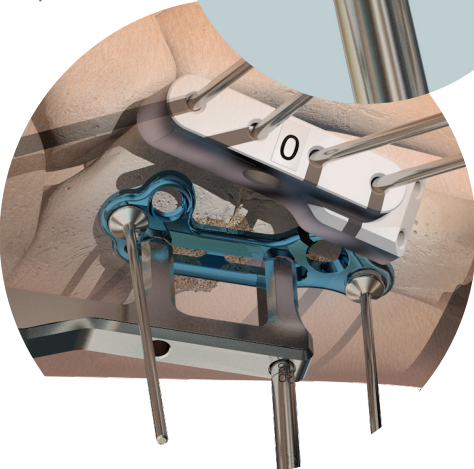
3 Place two olive wires into the most proximal and distal holes of the plate.

4 Align the 18mm drill guide to the center slot of the plate and use the 3.2mm reamer to drill for one of the staple legs. Place a temporary fixation pin in the prepared hole. Use the 3.2mm reamer to drill for the second staple leg.

5 Remove the temporary fixation pin.

6 Ensuring the legs are parallel, utilize the inserter to implant the HIMAX™ Staple through the plate until the staple is almost flush with the plate surface. The 18x18x14 staple is recommended with the 14mm leg being placed into the cuneiform.

7 Rotate the inserter knob counter-clockwise until pressure is released, then rotate the inserter counter-clockwise until the staple releases.



i During reaming, ensure each hole depth matches the desired staple leg length by reading the depth markings on the 3.2mm reamer.

! **Reminder:** The DYNABUNION™ Plate should be used with the standard HIMAX™ Staple. The standard Lapidus plates (LZ/LC) should be used with the HIMAX™-C Staple. If a notable bend is added to the DYNABUNION™ Plate, a HIMAX™-C Staple can be used. See page 5 for staple options.

INSTRUMENTS REQUIRED



Staple Compression Plate Placement

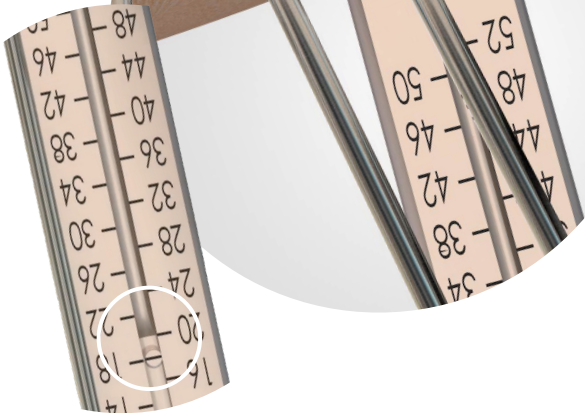
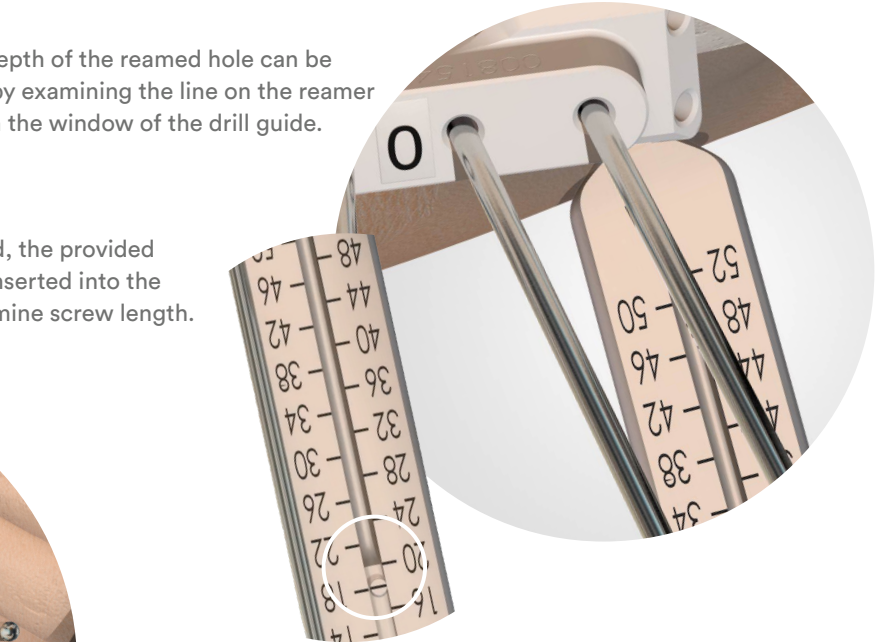
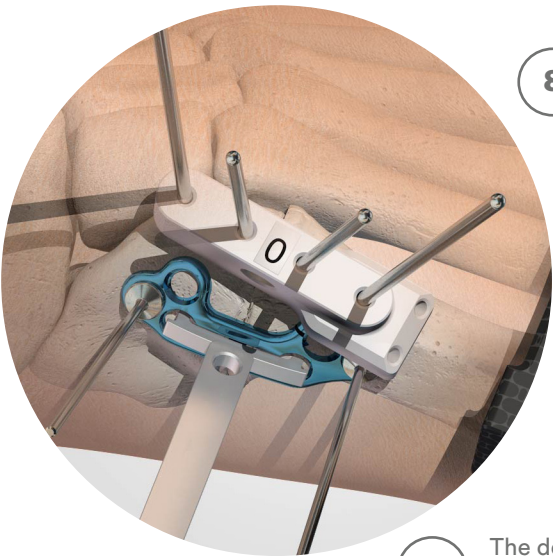
8 If needed, a tamp can be used to ensure the staple is flush to plate. The end of the tamp features a cut out that fits the staple bridge.

i Determine if locking or non-locking or locking screws will be utilized. The use of non-locking screws is recommended to allow maximum continuous compression for gap recovery.

9 Place the drill guide onto the most distal hole first. Use the appropriate reamer to prepare a hole for the screw.

3.0mm Screw ▶ 2.0mm Reamer

3.5mm Screw ▶ 2.5mm Reamer



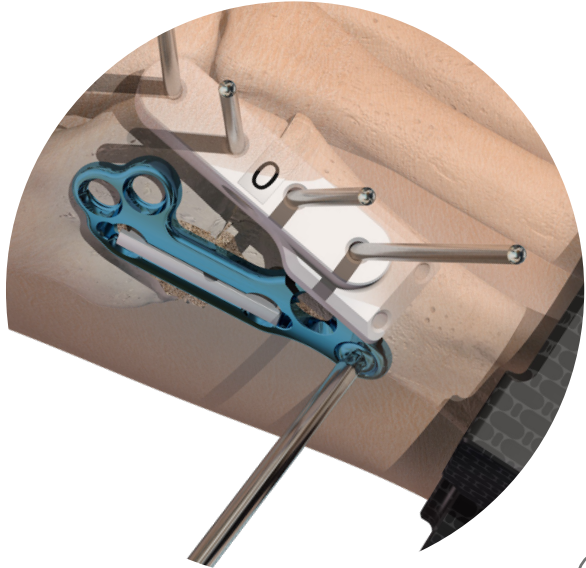
10 The depth of the reamed hole can be read by examining the line on the reamer within the window of the drill guide.

11 Additionally, if desired, the provided depth gauge can be inserted into the reamed hole to determine screw length.

12 Attach the provided H10 self retaining driver to the handle. Load the selected screw onto the self-retaining driver and insert into hole.

! Once the screw is placed, it is critical to toggle the driver side to side to remove it from the placed screw. **DO NOT PULL THE DRIVER STRAIGHT OFF THE SCREW WITHOUT TOGGLING.**

13 Repeat the previously described screw preparation and placement steps for the two proximal screw holes.



WHY AND WHEN SHOULD I USE THE 18x18x14 STAPLE?

Surgeon Perspective From Michael Campbell, MD

The 18 by 18 x 14 staple is a fantastic option for the average size patient. Unless the patient has a relatively large or small foot, the size option fits the base of the metatarsal and the cuneiform nicely. The 18 mm leg provides stable fixation over the vast majority of the metatarsal base without crossing through the lateral cortex or impeding close down of the intermetatarsal angle. The 14 mm leg which is typically placed in the cuneiform provides excellent coverage across the cuneiform typically without crossing into the intercuneiform joint.

IF I WANT TO PLACE SOME LOCKING SCREWS, WHICH SIDE SHOULD THEY BE PLACED?

Surgeon Perspective From Murray Butler, DPM

If I ever have a need to use locking screws, I use them on the proximal holes of the plate into the medial cuneiform. The non-locking distal screw is always bicortical and provides good apposition of the plate to the metatarsal. The proximal screws are often only in the medial cuneiform and are unicortical so, in patients with compromised bone density, locking screws can be placed unicortically with confidence.

ANTI-DRIFT BOLT™ Implant Placement

THE FOLLOWING STEPS ARE FOR DYNABUNION™ PLATES ONLY.

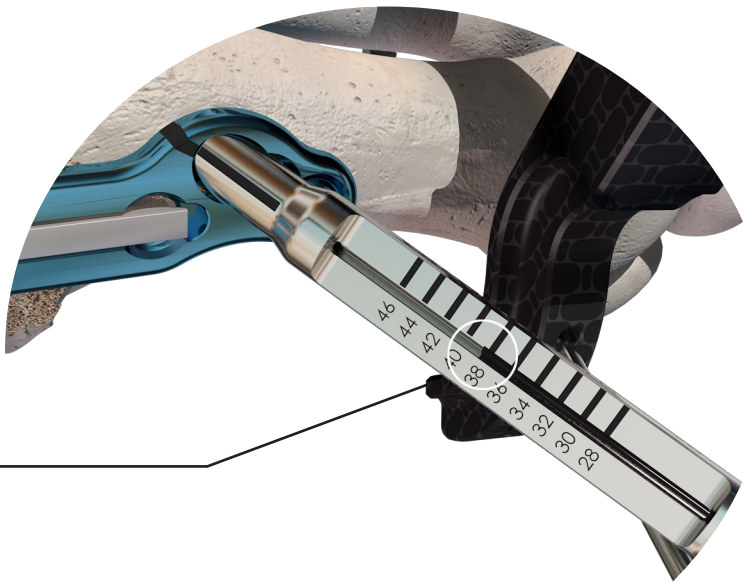


- !** At this time, the RAC Block and/or any crossjoint wires can be removed.
- i** If the ANTI-DRIFT BOLT™ Implant will NOT be used, a 3.5mm non-locking screw may be placed into that hole. A locking screw is not able to be placed into this hole.
- 1** Dock the ANTI-DRIFT BOLT™ Implant wire guide into the plate and ensure the laser mark line on both parts is aligned. If desired attach the universal handle to the ANTI-DRIFT BOLT™ Wire Guide by threading the handle tip into the top of the guide.

- 2** Under fluoroscopy, place the ANTI-DRIFT BOLT™ Depth Wire through the guide until the tip of wire is in the base of the second metatarsal and through the lateral cortex.

- !** Be careful to not penetrate the 1st or 2nd TMT joints when placing this wire. It is critical the bolt placement is through the lateral cortex.
- i** If a more distal trajectory is desired, the handle can be rocked proximally to aim the guide more distally.

- 3** Examine the window of the wire guide to determine which bolt size will be needed.



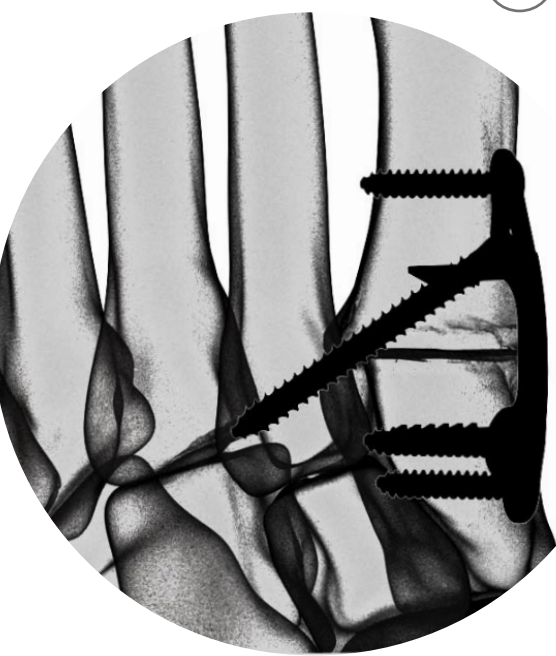
INSTRUMENTS REQUIRED



ANTI-DRIFT BOLT™ Implant Placement

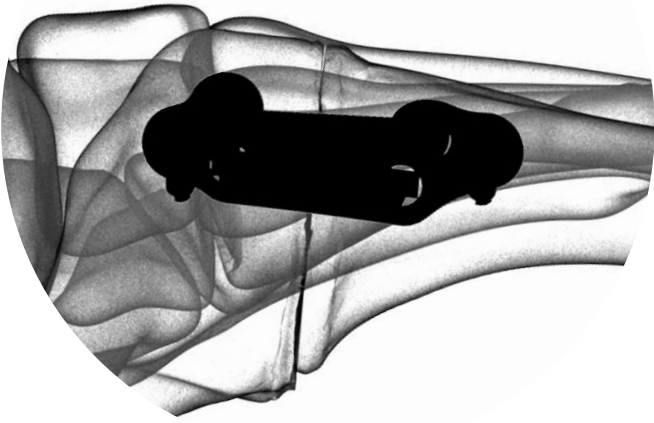
- 4** Use the ANTI-DRIFT BOLT™ Cannulated Reamer to drill over the wire. At a minimum, ensure the medial cortex of the 2nd metatarsal is penetrated.
- 5** Remove the depth wire and attach the selected ANTI-DRIFT BOLT™ Implant to the provided H10 driver and place it through the plate and into the prepared hole.

- i** The most common lengths of the ANTI-DRIFT BOLT™ Implant are 34-40mm.
- !** An internal oblique C-arm image visualizing the interspace between the proximal 2nd and 3rd metatarsals, parallel to the 2nd TMT joint, is critical to accurately determine wire position and appropriate screw length.



- 6** Verify the final construct placement with both AP and ML imaging; confirming both anatomic correction as well as proper screw trajectory of ANTI-DRIFT BOLT™ Implant

- !** DO NOT OVERTIGHTEN THE ANTI-DRIFT BOLT™ IMPLANT. THE ANTI-DRIFT BOLT™ IMPLANT IS A POSITIONAL SCREW AND NOT INTENDED TO BE USED FOR REDUCTION OR COMPRESSION.



WHAT ARE THE BENEFITS OF USING AN ANTI-DRIFT BOLT™ IMPLANT? Surgeon Perspective From Patrick Briggs, DPM

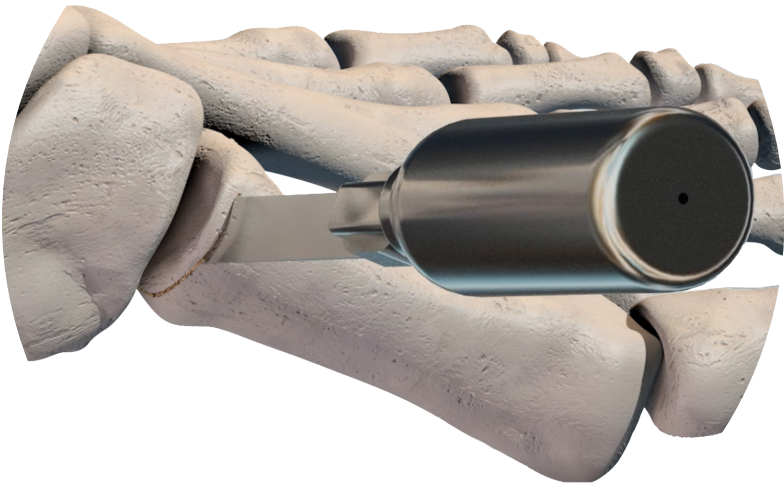
We know from the literature that upwards of 30% of Lapidus can reoccur. Aligning the 1st ray parallel to the second ray with arthrodesis at the 1st TMT, does not guarantee prevention of medial deviation of the 1st ray even if the surgeon elects to “wedge” the medial cuneiform on the lateral side. As we have seen with our ANTI-DRIFT BOLT™ Implant, the intercuneiform and intermetatarsal gapping or “diastasis” is eliminated. Prior to throwing our ANTI-DRIFT BOLT™ Implant, we can demonstrate this on fluoroscopy by applying pressure in the first intermetatarsal space (after our fixation is in place at the 1st TMT). This most often leads to medial deviation of the entire 1st ray. From anecdotal evidence, the most stable and tolerated direction is from mid shaft (from dorsal to plantar on metatarsal) aiming toward the base of the second. I have found placing the ANTI-DRIFT BOLT™ Implant into the intermediate cuneiform will not always prevent diastasis occurring between the intermetatarsals. Furthermore, if you angle the bolt perpendicular to the 1st and 2nd metatarsals, this at times will not be tolerated by the patient and will require removal.

WHAT PATIENTS ARE A CANIDATE FOR AN ANTI-DRIFT BOLT™? Surgeon Perspective From Scott Shawen, MD

The ANTI-DRIFT BOLT™ Implant, in my opinion, provides increased stability to the construct, which clinically increases the chance for a successful arthrodesis, but also decreases the possibility of late deformity recurrence. I think that all patients undergoing a Lapidus or first tarsometatarsal fusion procedure are candidates for the ANTI-DRIFT BOLT™ Implant. It provides increased stability to the fusion construct which cannot be ignored.

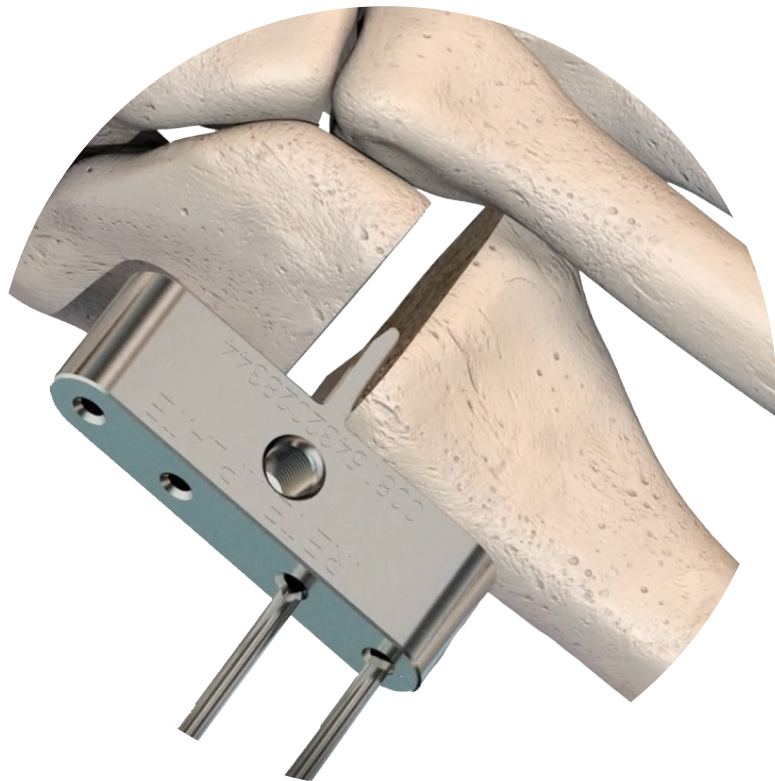
Freehand / Curettage Technique

This portion of the technique is only for users who use a curettage technique or wish to complete their cuts freehand without a cut guide.



1 Complete the metatarsal and cuneiform cuts freehand or perform the curettage technique.

2 Place the freehand wire guide into the joint at a dorsomedial position. While ensuring the paddle is flush with the metatarsal surface, pin a short 2.0mm wire into the second most distal hole of the wire guide. Place a long 2.0mm wire into the most distal hole of the wire guide.

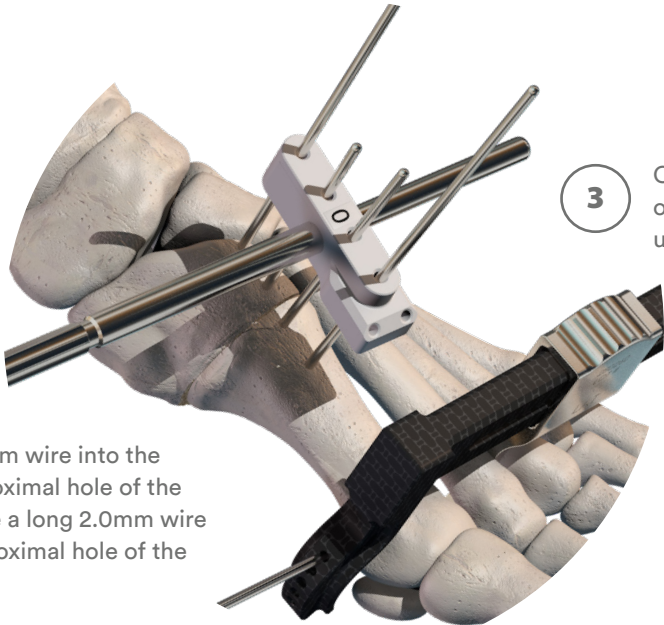


INSTRUMENTS REQUIRED



Freehand Wire Guide

Freehand / Curettage Technique



3 Complete step: “CORRECT” with the only difference being the wire guide is used in place of the cut guide.

4 Pin a short 2.0mm wire into the second most proximal hole of the wire guide Place a long 2.0mm wire into the most proximal hole of the wire guide.

5 Perform the remaining steps as previously described in the standard technique: Starting with step: “COMPRESS”. Perform step: “Staple Compression Plate Placement”



WHEN WOULD A FREEHAND TECHNIQUE BE NECESSARY?

Surgeon Perspective From Craig Breslauer, DPM

The freehand technique can be utilized at the surgeon’s discretion and personal preferences. Prior to the The DYNABUNION™ System, I greatly favored a freehand joint resection on all of my Lapidus bunionectomies. There are still some occasions when freehand joint resection might be chosen. The first indication for the freehand technique involves the presence of an atavistic medial cuneiform. In this scenario, joint resection can require a significant wedge resection of the distal cuneiform in order to create two parallel surfaces for fusion. I prefer to approach the medial cuneiform from a dorsal approach to allow proper visualization of the intended wedge to be removed. A minimum sliver of cartilage is taken medially with the base of the wedge laterally. One caveat to keep in mind. Caution should be used to not take too much bone laterally as this can create unnecessary shortening. Instead, I prefer to fish scale the lateral aspect of the cuneiform with a 1/4” curved osteotome as this allows compression of the cancellous bone and additional correction.

Another situation where the freehand technique may be utilized involves a surgeon who prefers this method over the others. This boils down to what the individual physician is the most comfortable with. When performing this type of joint preparation, one can use a Hintermann type distractor to access and visualize the joint more readily. The same distal pin hole from the distractor may then be used to apply the freehand pin guide from the DYNABUNION™ Set. At this point, the wires in the distal holes of the pin guide can be used to distract the 1st metatarsal distally while resecting the medial cuneiform.

A final circumstance that can lead one to use the freehand technique is in the case of an atypical small foot. Here, the cut guide might be too large to sit inside the 1st TMTJ. Although this is infrequent, surgeons should be prepared to abandon the cut guide and move on to the freehand approach when encountered.



WHAT ITEMS ARE IN EACH SUITCASE?

ECOSMART™ Surgery All Instrument and Implants Sterile Packaged

What sets do I need to
bring to the case?



Staple Utility Kit



Plate Utility Kit



DYNABUNION™
Procedure Module (Sterile)

Part Number	Description	Qty
7100-1500	15mm Staple Prep Kit	1
7100-1800	18mm Staple Prep Kit	2
7100-2000	20mm Staple Prep Kit	1
7100-2500	25mm Staple Prep Kit	1
7115-1515	HIMAX™ Implant 15mm x 15mm x 15mm	2
7115-1818	HIMAX™ Implant 15mm x 18mm x 18mm	1
7118-1414	HIMAX™ Implant 18mm x 14mm x 14mm	2
7118-1814	HIMAX™ Implant 18mm x 18mm x 14mm	1
7118-1818	HIMAX™ Implant 18mm x 18mm x 18mm	2
7115-1515-C	HIMAX™ C Implant 15 x 15 x 15	2
7115-1818-C	HIMAX™ C Implant 15 x 18 x 18	2
7118-1414-C	HIMAX™ C Implant 18 x 14 x 14	2
7118-1814-C	HIMAX™ C Implant 18 x 18 x 14	2
7118-1818-C	HIMAX™ C Implant 18 x 18 x 18	2
7415-1515	HIMAX™ Plus Implant 15mm x 15mm x 15mm	2
7418-1818	HIMAX™ Plus Implant 18mm x 18mm x 18mm	2
7420-2020	HIMAX™ Plus Implant 20mm x 20mm x 20mm	2
7425-2222	HIMAX™ Plus Implant 25mm x 22mm x 22mm	1
7000-0032	3.2mm Drill Bit	1

Part Number	Description	Qty
1500-3510	Non-Locking Screw, 3.5mm x 10mm	1
1500-3512 to 1500-3526	Non-Locking Screw, 3.5mm x 12mm -26mm (2mm Increments)	3ea
1500-3528 to 3540	Non-Locking Screw, 3.5mm x 28mm	2
1500-3545	Non-Locking Screw, 3.5mm x 45mm	2
1500-3550	Non-Locking Screw, 3.5mm x 50mm	2
15NL-3010	Non-Locking Screw, 3mm x 10mm	1
15NL-3012 to 15NL-3026	Non-Locking Screw, 3mm x 12mm-26mm (2mm Increments)	3ea
15NL-3028	Non-Locking Screw, 3mm x 28mm	2
15NL-3030	Non-Locking Screw, 3mm x 30mm	2
15PL-3010	Polyaxial Locking Screw, 3.0mm x 10mm	1
15PL-3012 to 15PL-3026	Polyaxial Locking Screw, 3.0mm x 12mm-26mm (2mm Increments)	3ea
15PL-3028	Polyaxial Locking Screw, 3.0mm x 28mm	2
15PL-3030	Polyaxial Locking Screw, 3.0mm x 30mm	2
15PL-3510	Polyaxial Locking Screw, 3.5mm x 10mm	1
15PL-3512 to 15PL-3526	Polyaxial Locking Screw, 3.5mm x 12mm-26mm (2mm Increments)	3ea
15PL-3528	Polyaxial Locking Screw, 3.5mm x 28mm	2
15PL-3530	Polyaxial Locking Screw, 3.5mm x 30mm	2
1500-4700	Plate Sterile Instrument Kit	2
7001-BEND	Plate Benders	1
7000-40SB	40mm Saw Blade - Stryker	2
PC5023.140 STE	40mm Saw Blade - Conmed/Hall	2
1500-SPSK	General Staple Plate Sharps Kits	2
7000-16KW	1.6mm x 6in Wire Pack(x3)	2
7000-HNDL	Sterile Ratchet Handle	1

Part Number	Description	Qty
1500-4801	DYNABUNION™ Instrument Kit	1
1500-48RC	DYNABUNION™ Re-Cut Instrument Kit	1
1500-48FH	DYNABUNION™ Freehand Wire Template Single Pack	1
1500-4850	ANTI-DRIFT BOLT™ Instrument Kit	1
7100-LP18-L	Implant, DYNABUNION™ Plate 18mm - LEFT	2
7100-LP18-R	Implant, DYNABUNION™ Plate 18mm - RIGHT	2
7100-LZ18-A	Lapidus Plate LZ Alpha 18mm	1
7100-LZ18-B	Lapidus Plate LZ Beta 18mm	1
7100-LC18-A	Lapidus Plate LC Alpha 18mm	1
7100-LC18-B	Lapidus Plate LC Beta 18mm	1
15FT-3532 to 3542	ANTI-DRIFT BOLT™ Fully Threaded 3.0x32	2

ECOSMART™ Surgery All Instrument and Implants Sterile Packaged

What do I need to open?



REQUIRED



DYNABUNION™ Kit
1500-4801

- OSTEOPRECISE™ Cut Guide
- IM Reducer
- Frontal Plane Joystick
- RAC Block 0
- RAC Block 1
- Short 2.0mm Wire x 4
- Long 2.0mm Wire x 4
- Universal Handle



Plate Instrument Kit
1500-4700

- AO Handle
- Olive Wire x 2
- H10 Driver
- Locking Drill Guide
- Non-Locking Drill Guide
- Depth Gauge
- 2.5 Reamer
- 2.0 Reamer



18mm Staple Prep Kit
(implant not included)
7100-1800

- 18mm Staple Drill Guide
- 18mm Staple Insertor
- Tamp
- Fixation Pins x 2
- 3.2 Reamer



40mm Saw Blade

TWO OPTIONS
For Stryker/MicroAir
Connection Use:
7000-40SB

For Conmed/Hall
Connection Use:
PC5023.140 STE or
7001-40SB

OPTIONAL

Using An ANTI-DRIFT BOLT™ Implant? Open This:



ANTI-DRIFT BOLT™ Instrument Kit
1500-4850

- ANTI-DRIFT BOLT™ Wire Guide
- 2.5 Cannulated Reamer
- ANTI-DRIFT BOLT™ Depth Wire

Need To Re-Cut? Open This:



DYNABUNION™ ReCut Kit
1500-48RC

- ReCut Guide
- RAC Block 2
- RAC Block 3

Need To Bend A Plate? Open This:

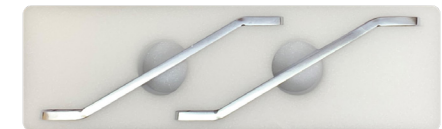


Plate Bender Kit
7000-BEND

- Plate Bender x 2

Sterile Packed Implants



DYNABUNION™ Standard Plate



DYNABUNION™ Short Plate



LC SCP



LZ SCP



18mm Staple
HIMAX™ for DYNABUNION™ Plate
HIMAX™ C for LC & LZ Plate
18x18,14x14, or 18x14
Leg Lengths Available



ANTI-DRIFT BOLT™ Implant
For Use With DYNABUNION™
Plate Only



2- 4 Screws
3.0 or 3.5 NL or PAL

Kit Back-Ups

We know things don't always go as planned, so we provide backups of all key instruments and sharps to ensure you are covered!

7000-20K4	2.0 Short Wire 4 Pack 1
7000-20K6	2.0 Long Wire 4 Pack 1
7000-ADK6	ANTI-DRIFT BOLT™ Depth Wire Single Pack 1
7000-LVWR	Olive Wire 1
7000-0032	3.2 Reamer 1
1500-5025	2.5 Reamer 1
1500-5050	H10 Driver 1

Sterile ratchet handles are available by request.

NON-ECOSMART™ Surgery
ONLY Sharps and Implants Are Sterile Packaged

What sets do I need to bring to the case?



DYNABUNION™
Sterile Surgical Set – PARTIAL



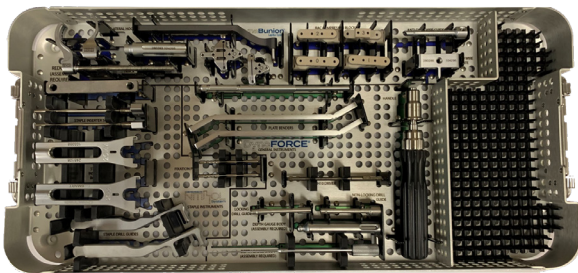
Staple Utility Kit



Plate Utility Kit



DYNABUNION™
Procedure Module (Sterile)

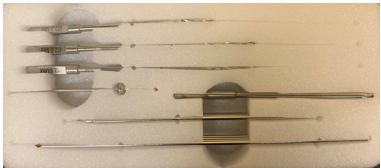


DYNABUNION™ Non-Sterile Surgical Tray

NON-ECOSMART™ Surgery
ONLY Sharps and Implants Are Sterile Packaged

What do I need to open?

REQUIRED



DYNABUNION™ Sharps Kit
1500-5060

- Short 2.0 Wire x 4
- Long 2.0 Wire x 4
- Olive Wire x 2
- H10 Driver
- 2.0 Reamer
- 2.5 Reamer
- 3.2 Reamer



40mm Saw Blade

TWO OPTIONS
For Stryker/MicroAir
Connection Use:
7000-40SB

For Conmed/Hall
Connection Use:
PC5023.140 STE or
7001-40SB

OPTIONAL

Using An ANTI-DRIFT BOLT™ Implant? Open This:



ANTI-DRIFT BOLT™ Instrument Kit
1500-4850

- ANTI-DRIFT BOLT™ Wire Guide
- 2.5 Cannulated Reamer
- ANTI-DRIFT BOLT™ Depth Wire

Sterile Packed Implants



DYNABUNION™ Standard Plate



DYNABUNION™ Short Plate



LC SCP



LZ SCP



18mm HIMAX™ C Staple
HIMAX™ for DYNABUNION™ Plate
HIMAX™ C for LC & LZ Plate
18x18,14x14, or 18x14
Leg Lengths Available



ANTI-DRIFT BOLT™
Implant
For Use With DYNABUNION™
Plate Only



2- 4 Screws
3.0 or 3.5 NL or PAL

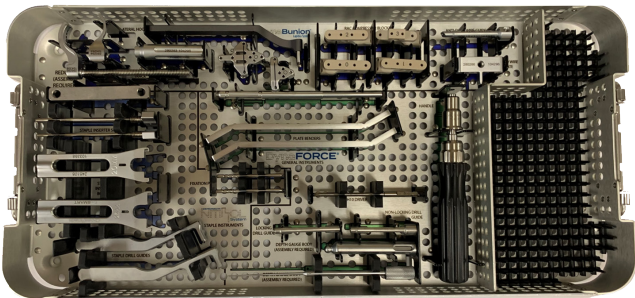
Kit Back-Ups

We know things don't always go as planned, so we provide backups of all key instruments and sharps to ensure you have your case covered!

- | | |
|-----------|---|
| 7000-20K4 | 2.0 Short Wire 4 Pack 1 |
| 7000-20K6 | 2.0 Long Wire 4 Pack 1 |
| 7000-ADK6 | ANTI-DRIFT BOLT™ Depth Wire Single Pack 1 |
| 7000-LVWR | Olive Wire 1 |
| 7000-0032 | 3.2 Reamer 1 |
| 1500-5025 | 2.5 Reamer 1 |
| 1500-5050 | H10 Driver 1 |

Sterile ratchet handles are available by request.

DYNABUNION™ Non-Sterile Surgical Tray

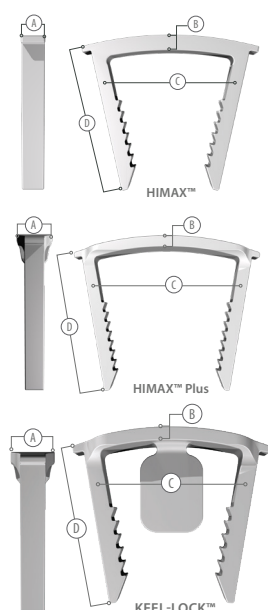


Name	Quantity	Name	Quantity
Radiolucent Reducer	1	ANTI-DRIFT BOLT™ Wire Guide	1
OSTEOPRECISE™ Cut Guide	1	18mm Staple Insertor	1
ReCut Guide	1	18mm Staple Drill Guide	1
Frontal Plane Joystick	1	Tamp	1
RAC Block 0	1	Fixation Pins	2
RAC Block 1	1	H10 Driver	1
RAC Block 2	1	New Plate Bender	2
RAC Block 3	1	Depth Gauge	1
Freehand Wire Template	1	Non-Locking Drill Guide	1
Universal Handle	1	Ratchet Handle	1
Hintermann Distractor	1		

DYNAFORCE™ Staple Compression Plate Options

	DYNABUNION™ SCP (Standard)		DYNABUNION™ SCP (Short)		LC SCP		LZ SCP	
TYPE	Right	Left	Right	Left	Alpha	Beta	Alpha	Beta
PART NUMBER	7108-DST-R	7108-DST-L	7108-DSH-R	7108-DSH-L	7100-LC18-A	7100-LC18-B	7100-LZ18-A	7100-LZ18-B
SLOT LENGTH/STAPLE SIZE	18mm	18mm	18mm	18mm	18mm	18mm	18mm	18mm
OVERALL LENGTH	40mm	40mm	32.5mm	32.5mm	44mm	44mm	32mm	32mm
THICKNESS	1.5mm	1.5mm	1.5mm	1.5mm	1.7mm	1.7mm	1.7mm	1.7mm
PLATE CURVATURE (DISTAL/PROXIMAL)	10 Degrees	10 Degrees	10 Degrees	10 Degrees	10 Degrees	10 Degrees	10 Degrees	10 Degrees
COMPATIBLE STAPLE	HIMAX™ C Implant	HIMAX™ C Implant	HIMAX™ C Implant	HIMAX™ C Implant	HIMAX™ C Implant	HIMAX™ C Implant	HIMAX™ C Implant	HIMAX™ C Implant
ANTI-DRIFT BOLT™ COMPATIBLE	YES	YES	YES	YES	NO	NO	NO	NO

Nitinol Options



For use with Staple Compression Plates

	HIMAX™ C Implant (18x18x18mm)	HIMAX™ C Implant (18x14x14mm)	HIMAX™ C Implant (18x18x14mm)	HIMAX™ Plus Implant	KEEL-LOCK™ Implant
PART NUMBER	7118-1818-C	7118-1414-C	7118-1814-C	7415-1515 thru 7425-2222	7318-1818, 7320-2020
BRIDGE WIDTH A	2.7mm	2.7mm	2.7mm	5mm	5mm
BRIDGE THICKNESS B	1.8mm	1.8mm	1.8mm	1.3-1.6mm	1.3-1.6mm
INTERAXIS LENGTH C	18mm	18mm	18mm	15, 18, 20, 25mm	18 or 20mm
LEG LENGTH D	18mm	18mm	18x14mm	15, 18, 20, 22 mm	18 or 20mm
REAMER SIZE	3.2mm	3.2mm	3.2mm	3.2mm	3.2mm
COMPRESSION	27lbs.	27lbs.	27lbs.	28lbs.	28lbs.
CURVATURE WHEN LEGS ARE STRAIGHT	10°	10°	10°	10°	10°

ANTI-DRIFT BOLT™ Implant

(For use with DYNABUNION™ Plate only)



3.5mm, Non-Locking, Solid
Fully Threaded, 14mm
32-42mm Lengths, 2mm Increments

Plate Screws



	3.0mm POLYAXIAL LOCKING	3.5mm POLYAXIAL LOCKING	3.0mm NON-LOCKING	3.5mm NON-LOCKING
PART NUMBER	15PL-3010 thru 15PL-3030	15PL-3510 thru 15PL-3530	15NL-3010 thru 15NL-3030	1500-3510 thru 1500-3550
SIZE RANGE*	10mm-30mm	10mm-30mm	10mm-30mm	10mm-50mm
DRIVER	H10 (Hexalobe)	H10 (Hexalobe)	H10 (Hexalobe)	H10 (Hexalobe)
DRILL SIZE	2.0mm	2.5mm	2.0mm	2.5mm

*2mm increments

Indications & Risks

The MotoBAND™ CP Implant System includes DynaBunion™ 4D Minimal-incision Bunion System and DynaMet™ Lesser TMT Fusion System, which include plates and screws indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. DynaBunion™ 4D Minimal-incision Bunion System and DynaMet™ Lesser TMT Fusion plates are compatible with fracture fixation staples from the MotoCLIP™ M/HiMAX™ Implant System cleared in K142727, K181410 and K193452.

Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions. US Patents: D870,284 & 10,492,841

Data on File for All Information & Data Listed

References

1. CrossRoads Extremity Systems Report: CrossRoads Extremity Claims Substantiation Memo, 2022. Ref: EM23- 0010.

2. Lee KT, Park YU, Jegal H, Park JW, Choi JP, Kim JS. Prognostic classification of fifth metatarsal stress fracture using plantar gap. Foot Ankle Int. 2013;34(5):691-696.

* Pre-clinical test data are not necessarily indicative of clinical performance

255970-230808 DSUS



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