

# DynaBridge

## Superelastic Nitinol Implant

Patented - Confidential



**Fusion**  
ORTHOPEDICS

Surgical Technique

## DESCRIPTION OF THE MEDICAL DEVICE



The DynaBridge Superelastic Nitinol Implant is a Nickel-Titanium Alloy (Nitinol) bone implant intended primarily for fixation of fractures, osteotomy, and arthrodesis of the hand, foot, and bones appropriate for the size of the device. The Implant is offered in a range of sizes to address a variety of indications and patient anatomy with bridge sizes from 9mm to 25mm. The system is offered sterile and non-sterile.

## DIRECTIONS FOR USE

The implants cannot be expected to replace normal healthy bone or withstand the stresses placed upon the device by full or partial weight bearing or load bearing in the presence of nonunion, delayed union or incomplete healing. Therefore, it is important that the immobilization of the treatment site using routine methods (casting, splints, etc.) be maintained until bone healing has occurred (4-6 weeks).

Before using the DynaBridge Implant, the surgeon should be thoroughly familiar with this DynaBridge Surgical Technique Manual. Pre-Operative planning by the surgeon should determine the size of implant required and an adequate supply of the implant sizes should be available prior to surgery, including larger and smaller sizes than those expected to be used.

Reduction of the site should be achieved and maintained prior to implanting the device. The compressive force of the implant closing should not be relied upon to achieve closure or reduction of a fracture line.

## INDICATIONS FOR USE

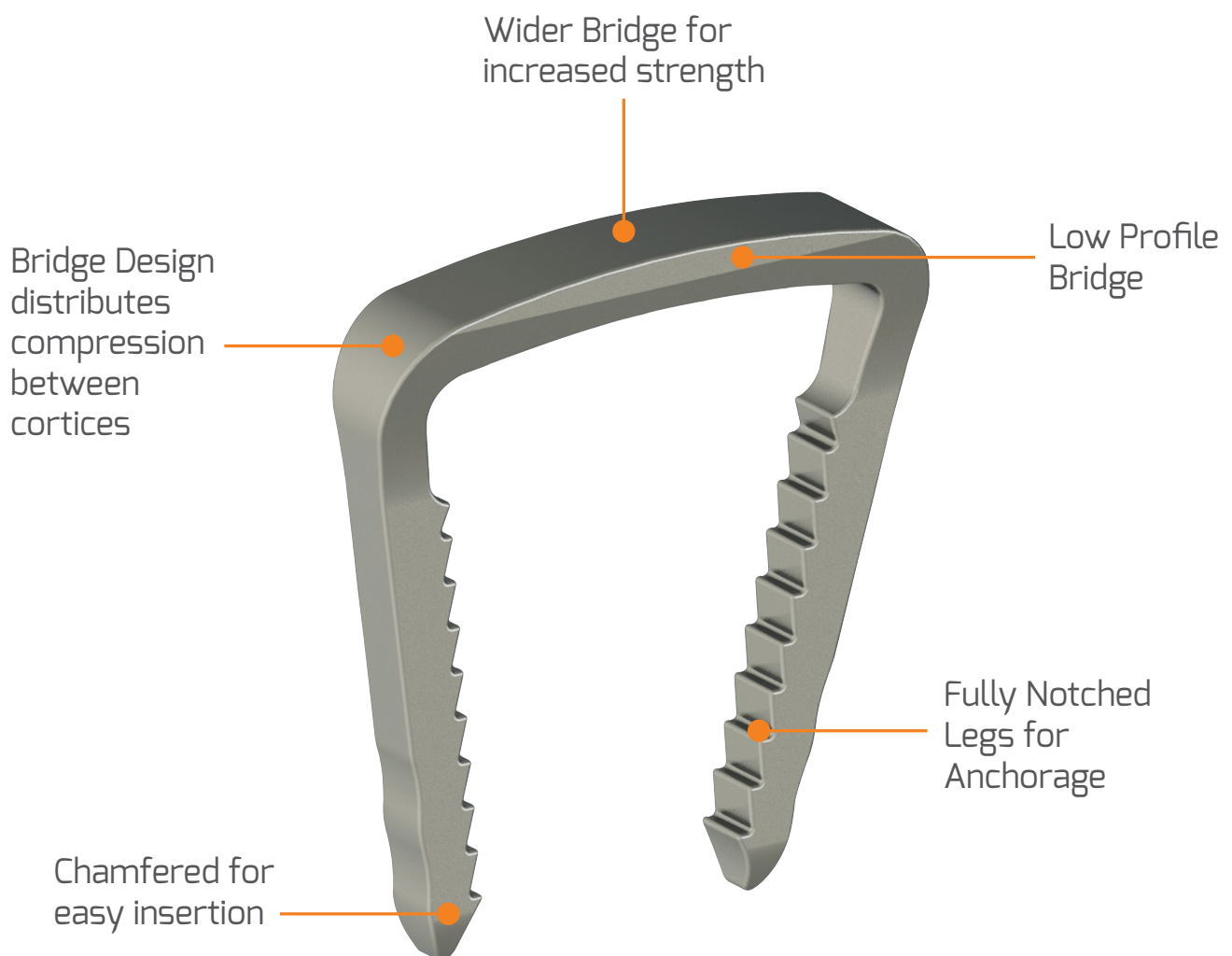
- Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.
- Fixation of proximal tibial metaphysis osteotomy.
- Hand and foot bone fragment and osteotomy fixation and joint arthrodesis.
- Fixation of small bone fragments (i.e. Small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula, and tibia in the lower extremities; the humerus, ulna, or radius in the upper extremities; the clavicle and ribs; and in flat bone such as the pelvis, scapula and sternum.

## CONTRAINDICATIONS

- Comminuted bone surface that would militate against staple placement.
- Pathologic conditions of bone such as osteopenia that would impair the ability to securely fix the implant.
- Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.
- Local or systemic, acute or chronic inflammation or infection.
- Growing patients with open Epiphyses.

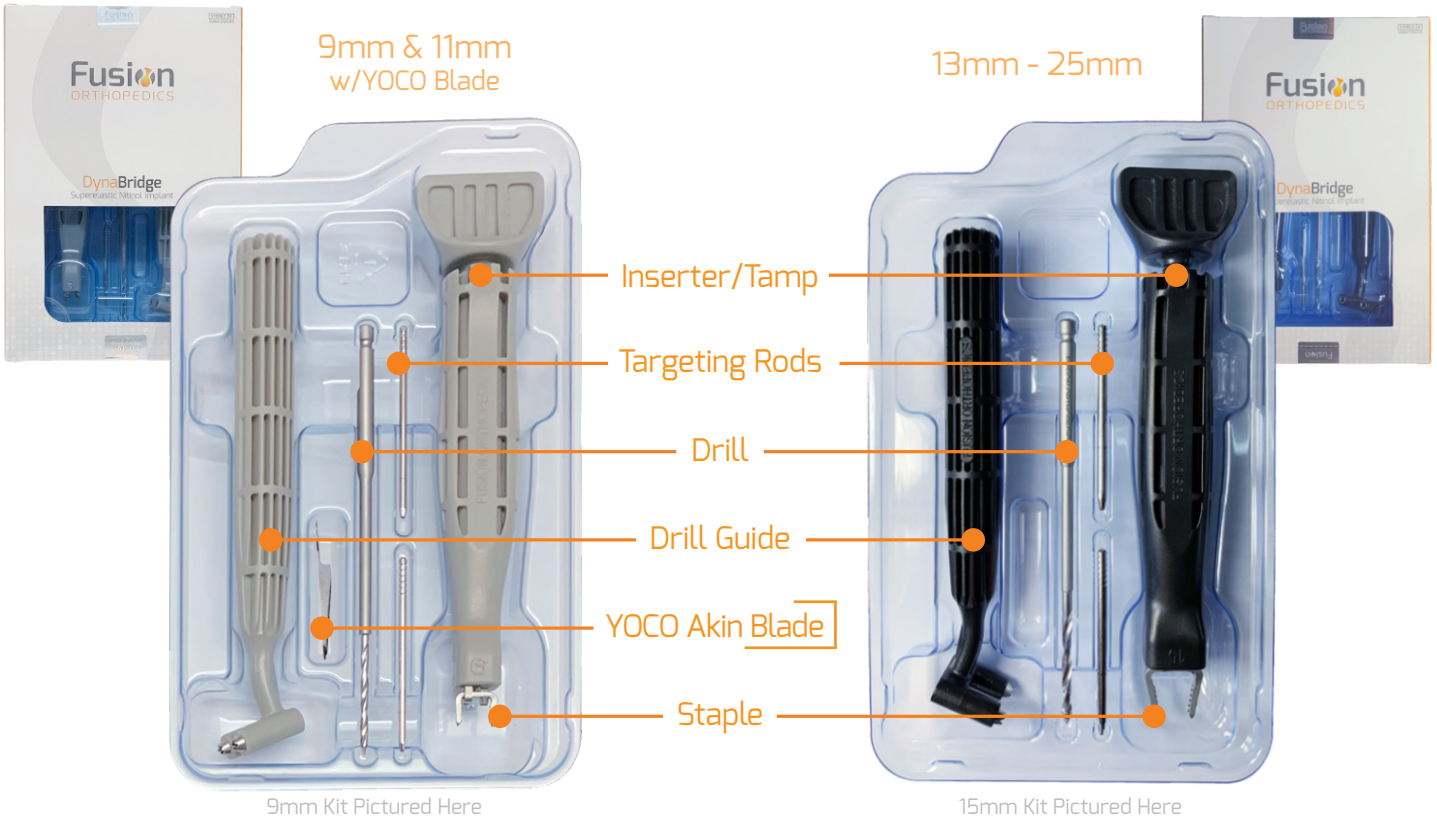
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The DynaBridge Superelastic Nitinol Implant is engineered with shape memory technology programmed to deliver constant bi-cortical compression. Complementing Wolfe's Law of Compression, DynaBridge Implants improve both fusion rates and patient outcomes.



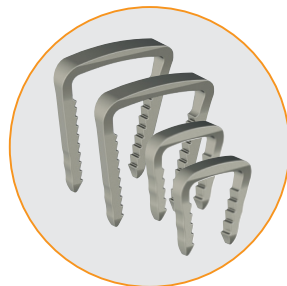
### Implant & Instrument Kits

All Sterile Kits are One-Time Use

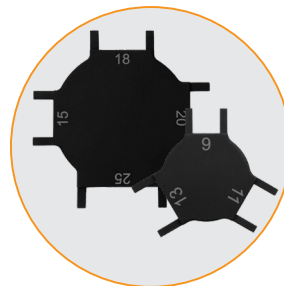


### Add-Ons

Sterile Packed and Sold Separately



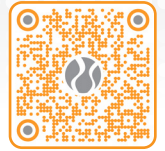
Additional Single-Packed Staples



Sizer Wheel Kit

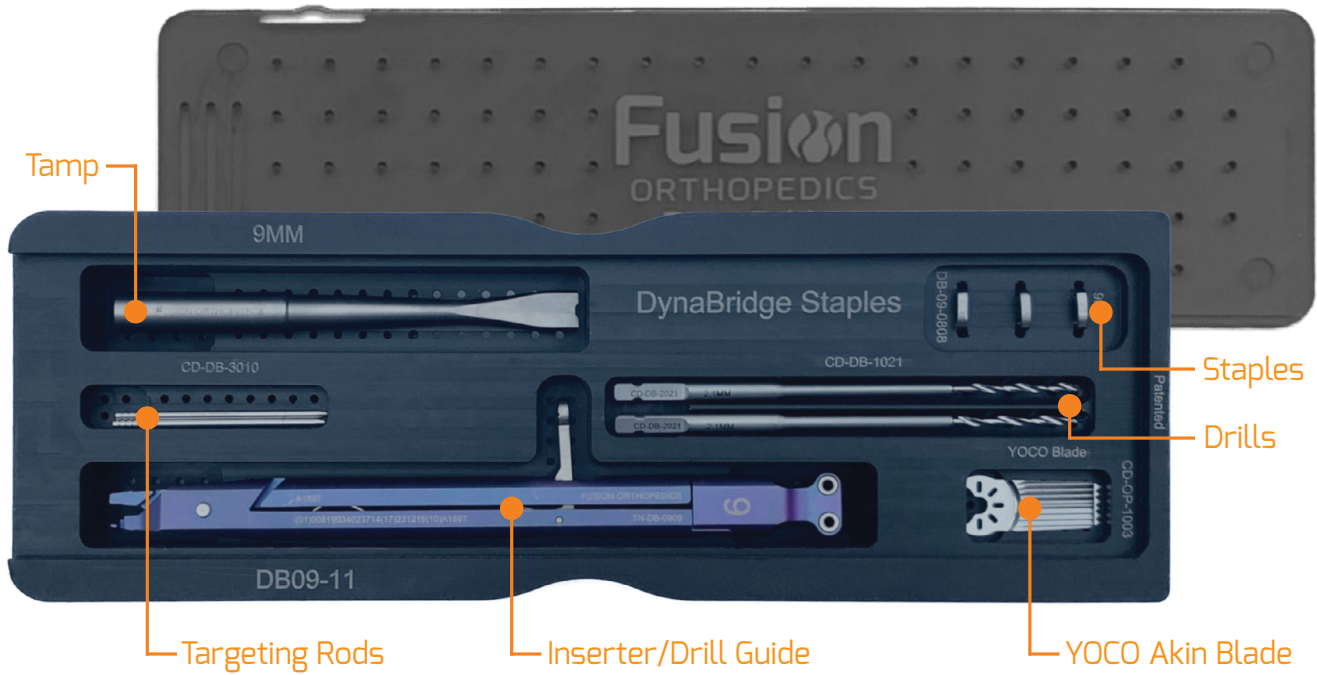
Part Of The  
FuzeFix Modular Tray

Scan to learn more  
about our Modular  
Tray Environment.



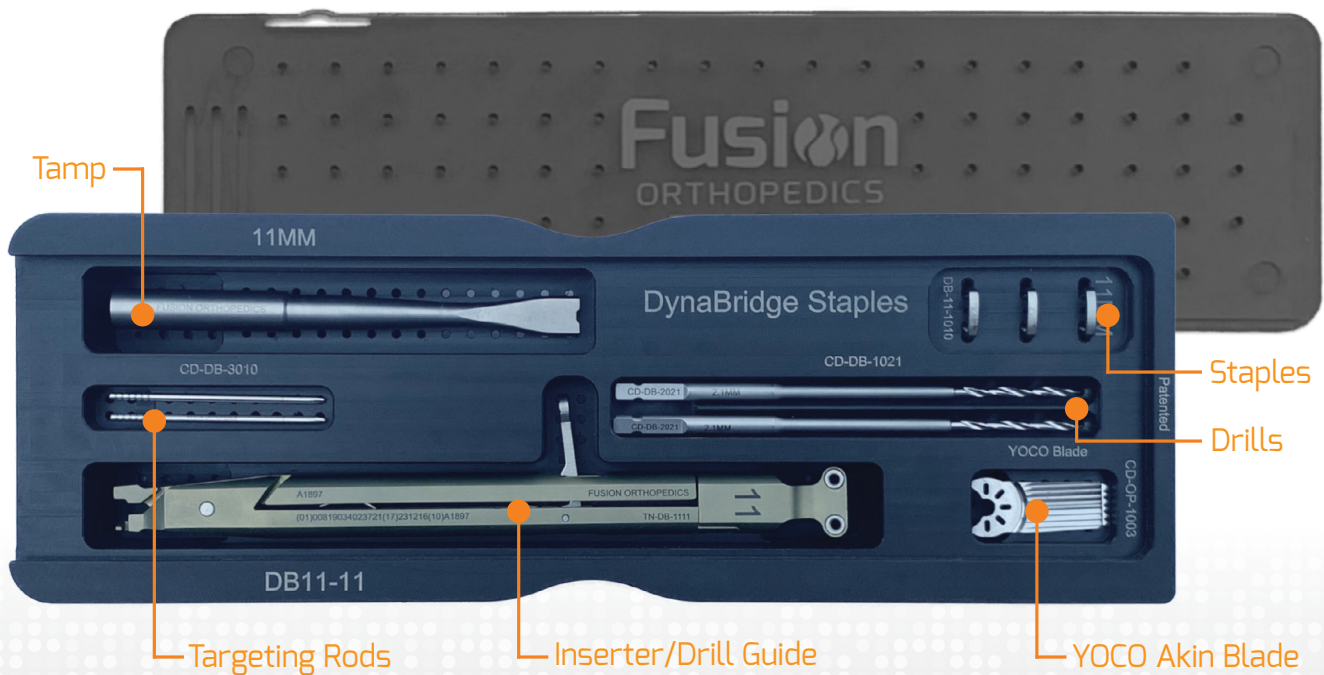
### 9mm Caddy w/YOCO

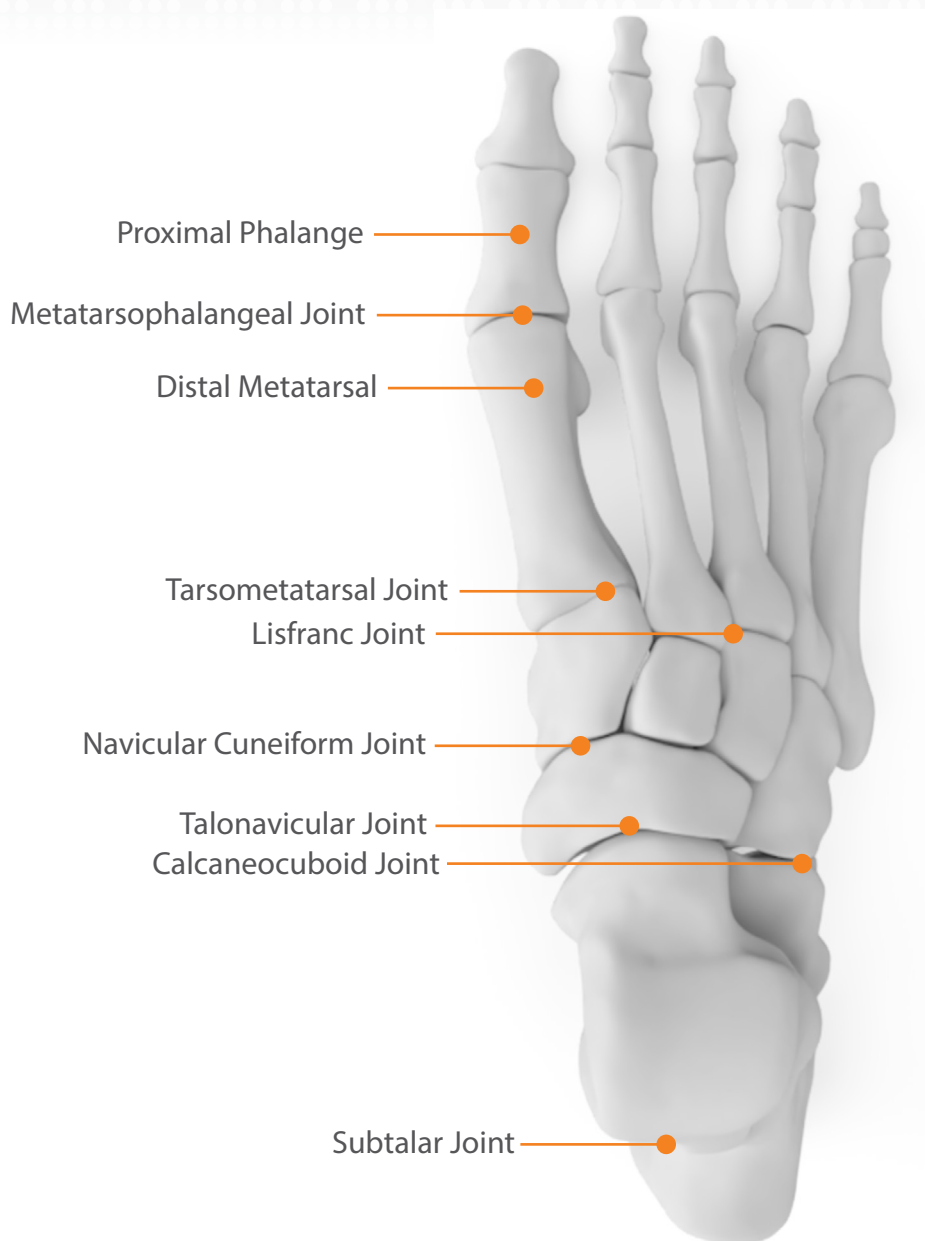
Includes 3 Staples & Reusable Instruments



### 11mm Caddy w/YOCO

Includes 3 Staples & Reusable Instruments





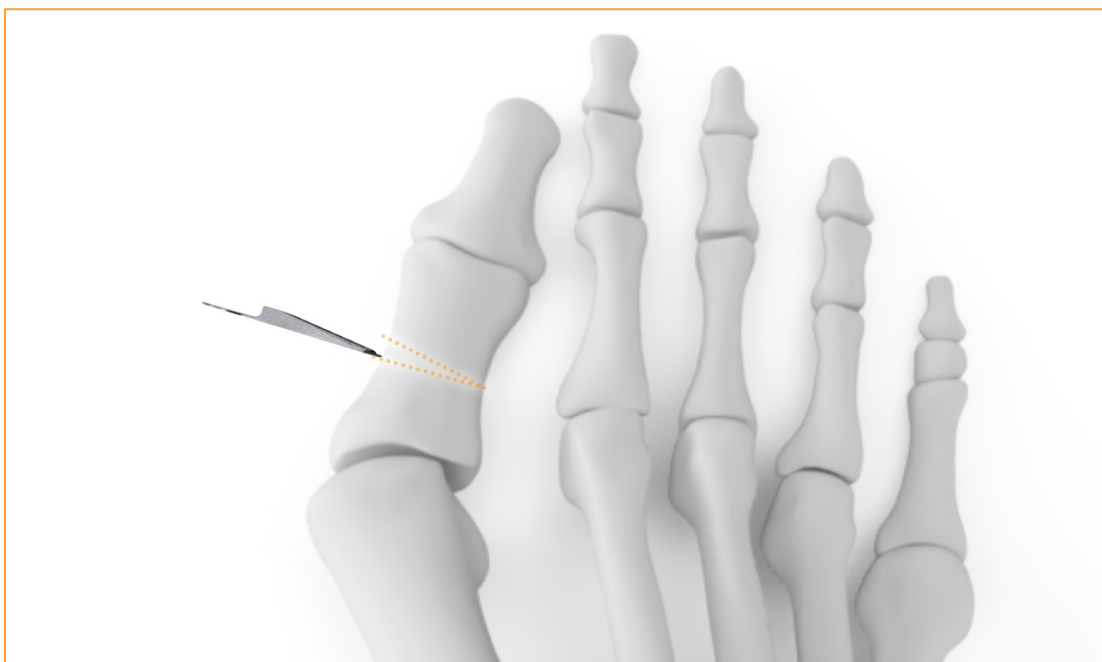
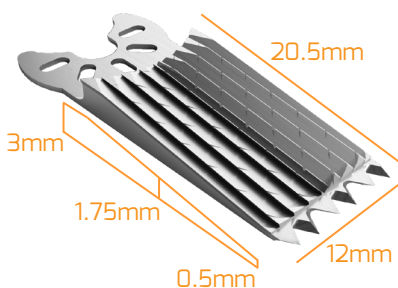
DYNABRIDGE	Location	Size
	Proximal Phalange	9mm, 11mm, 13mm
	Metatarsophalangeal Joint	15mm, 18mm
	Distal Metatarsal	11mm, 13mm, 15mm
	Tarsometatarsal Joint	15mm, 18mm, 20mm
	Lisfranc Joint	15mm, 18mm, 20mm
	Navicular Cuneiform Joint	15mm, 18mm, 20mm
	Talonavicular Joint	20mm, 25mm
	Calcaneocuboid Joint	20mm, 25mm
	Subtalar Joint	20mm, 25mm

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### Editor's Note:

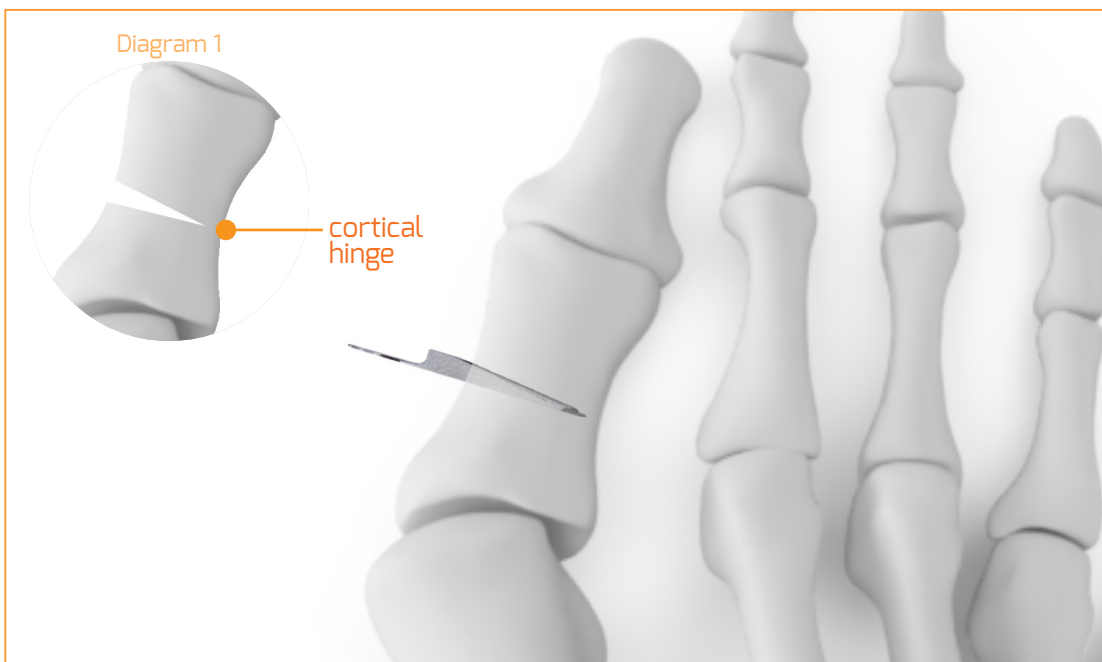
The Akin Technique can be conducted with Sterile Disposable Instrumentation -or- Tray-Based Instrumentation. Throughout the Steps you will see both types of instrumentation being utilized, for your reference.

YOCO Akin Blade  
Patent Pending



**1**

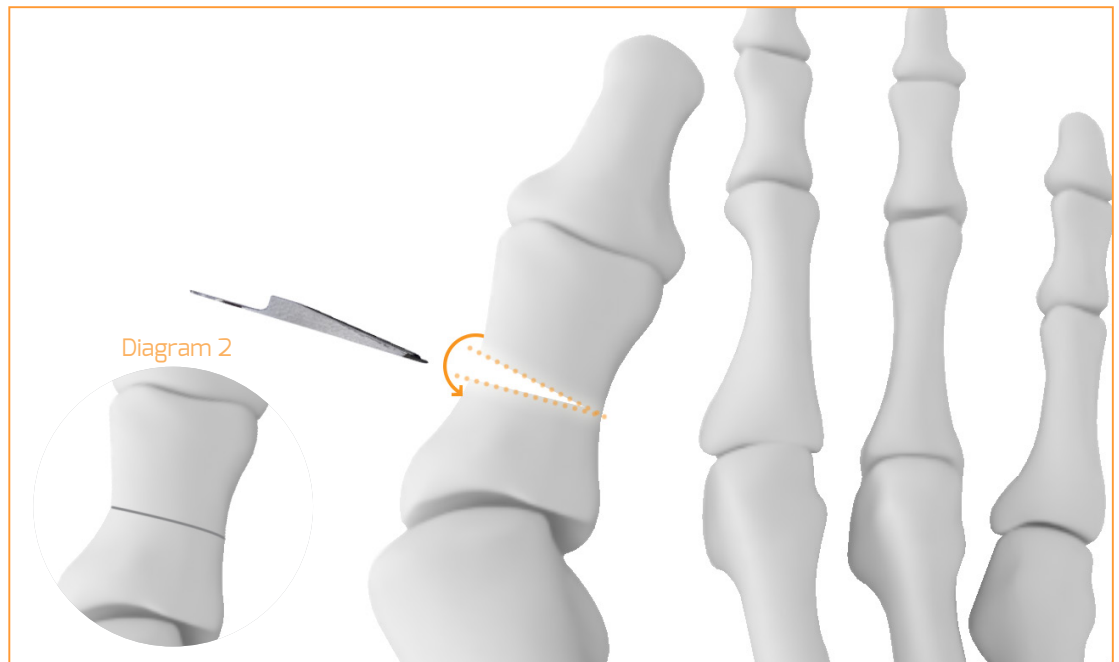
After making an incision and retracting the soft tissue, align the YOCO Akin Blade perpendicular to the proximal phalanx as shown. Assure the flat surface of the blade is proximal, while the wedged side is distal. \*The YOCO Akin blade attaches to a standard sagittal saw.



**2**

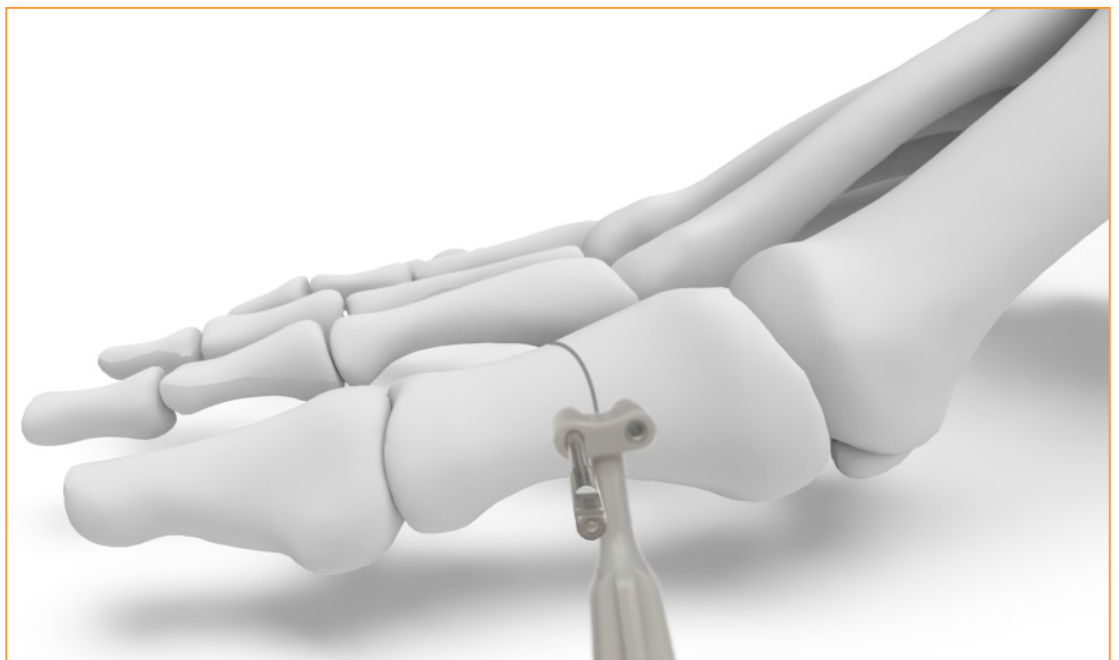
Advance the blade to create a wedge osteotomy. If the bone is larger than the width of the blade, sweep through to assure the width of the bone is being cut. It is suggested to leave a **cortical hinge** (as shown in diagram 1) at the lateral end of the proximal phalanx.

Throughout advancement focus on keeping the flat end of the blade up against the flat surface of the bone. Pressing towards the wedge end, may create a larger wedge than desired.



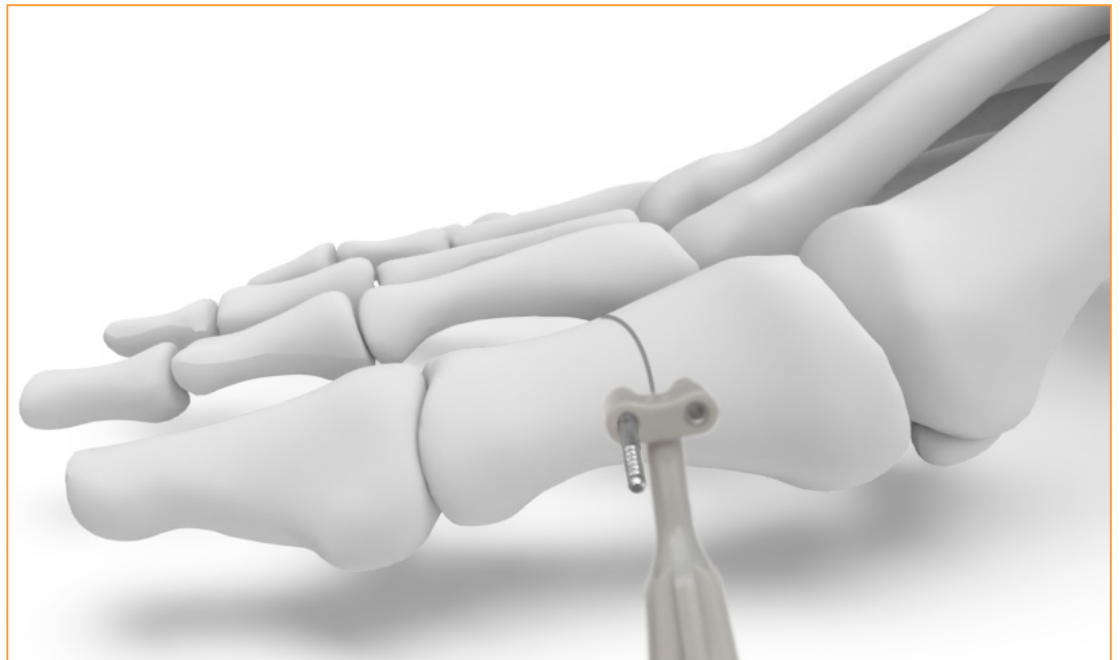
3

If greater reduction is desired: Compress the wedge osteotomy and conduct a second pass, through the same site. This should effectively double the size of the initial wedge. (This step is optional)



4

Once the Akin Osteotomy has been performed and the fusion site has been prepared, position the drill guide across the prepared joint with both prongs touching bone and equidistantly spaced from the osteotomy. While ensuring full reduction, drill the first hole using the enclosed Calibrated Drill until the hard stop is reached.



5

Insert a Targeting Rod into the first hole to maintain guide alignment and prepare to drill the second hole. The Targeting rod ensures proper alignment of the two drilled holes for the implant.

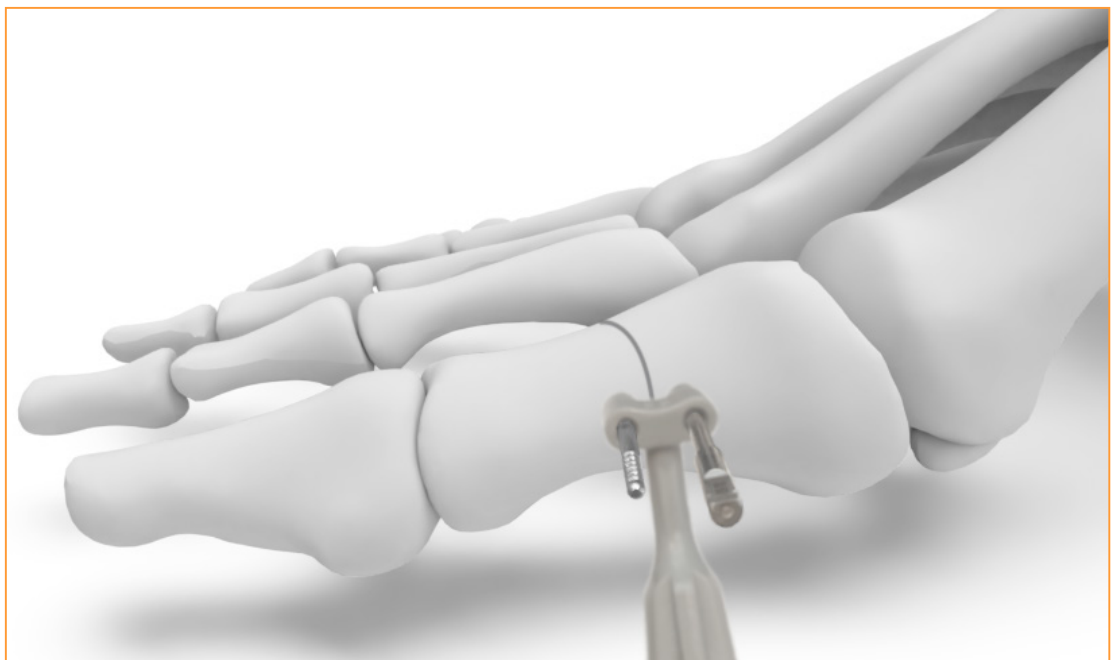
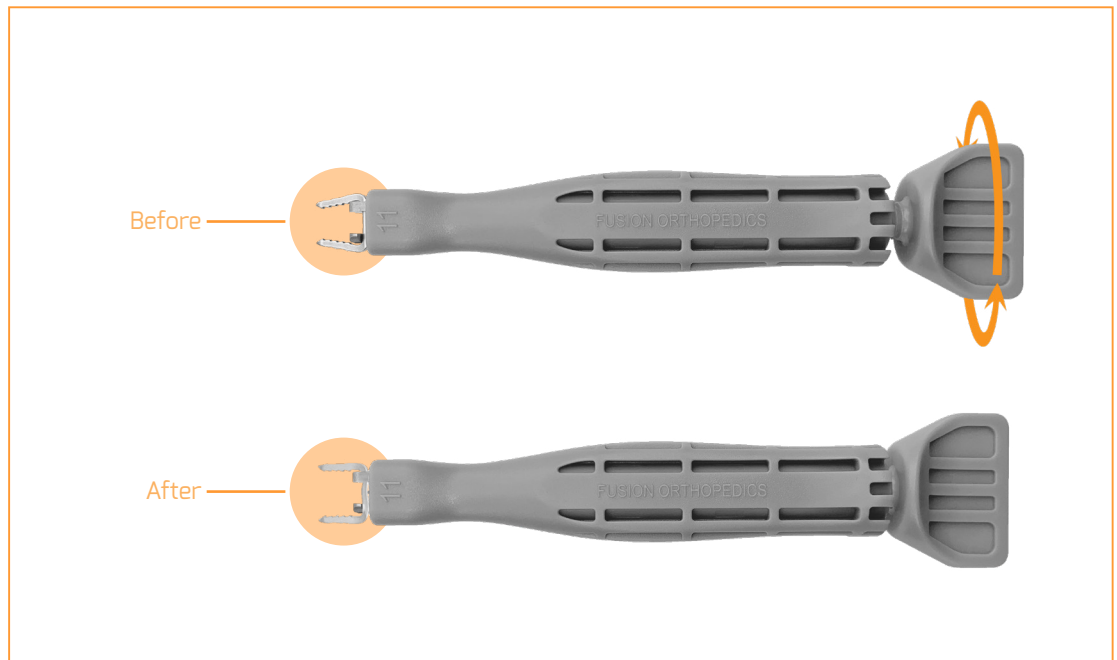


Diagram 3

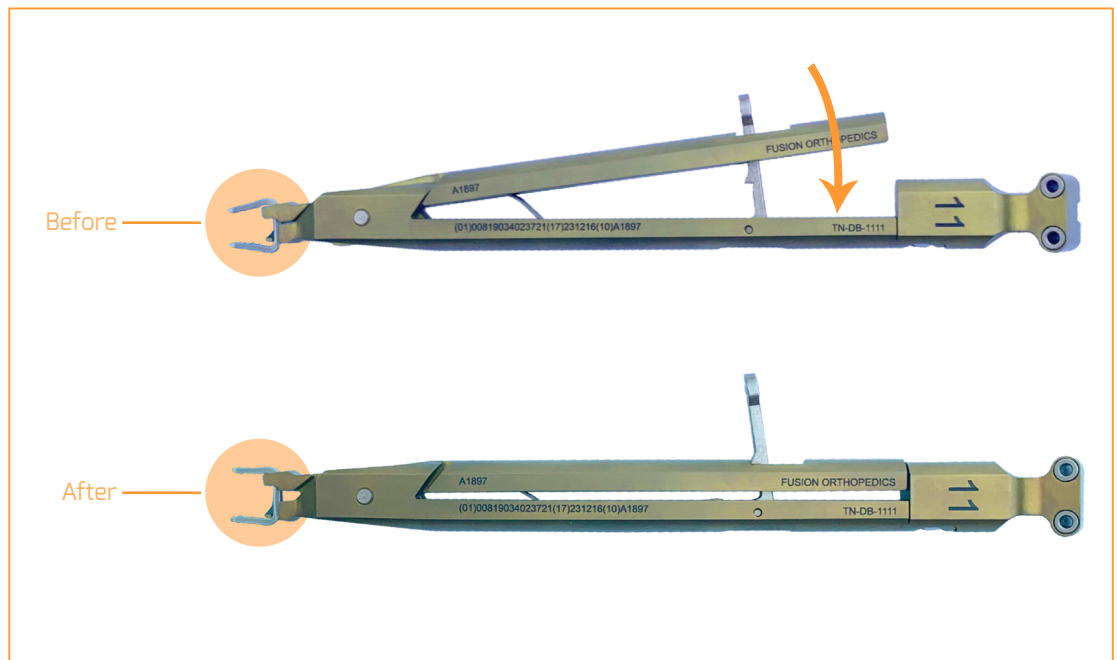


6

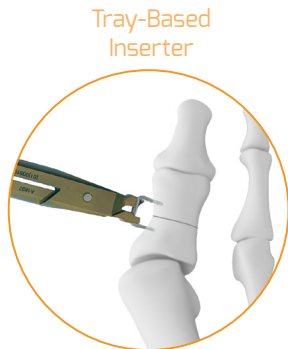
While ensuring full reduction, drill the second hole until the hard stop is reached. According to surgeon preference, an optional second Targeting Rod may be inserted into the second hole to help mark position. Remove the drill guide by sliding it off the inserted Targeting Rods (Diagram 3).



**7** Retrieve the staple inserter. Out of the package, the inserter should already be semi-loaded with the DynaBridge™ Staple. To fully-load, turn the wing end of the inserter clock-wise to tighten. Ensure that the staple has properly latched on to the teeth of the inserter. Continue tightening until the legs are in parallel position.

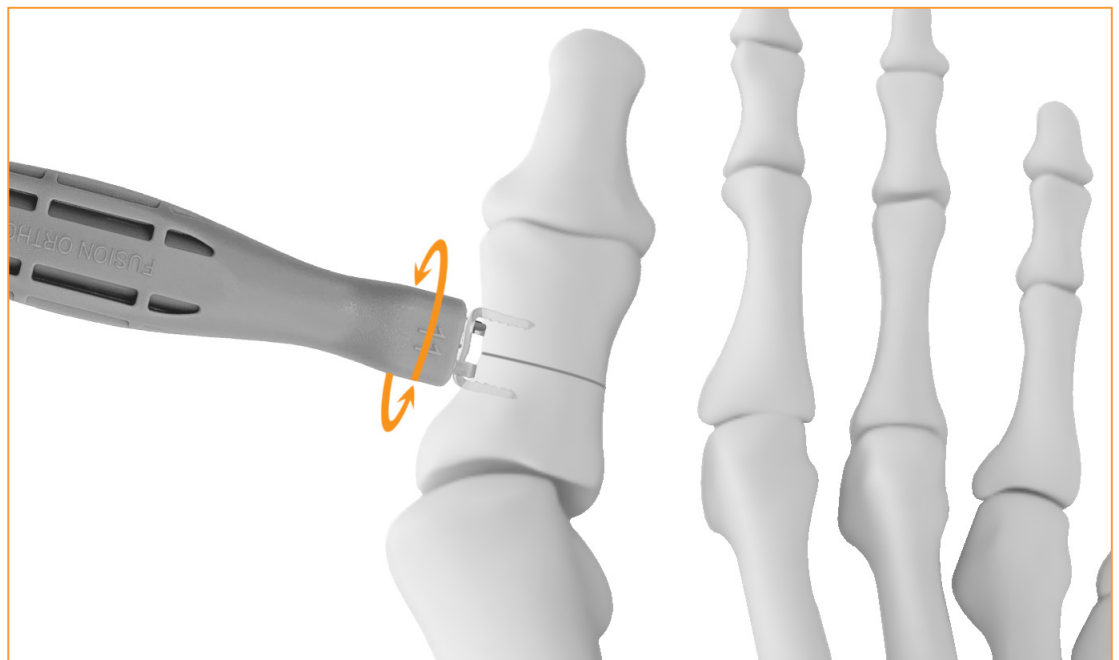


**7\*** If using the Tray-Based Inserter, latch the screw onto the teeth of the inserter while relaxed. Compress the inserter until it clicks together. This will expand the staple. It is now ready for insertion.  
\*To relax the inserter, lift the lever.



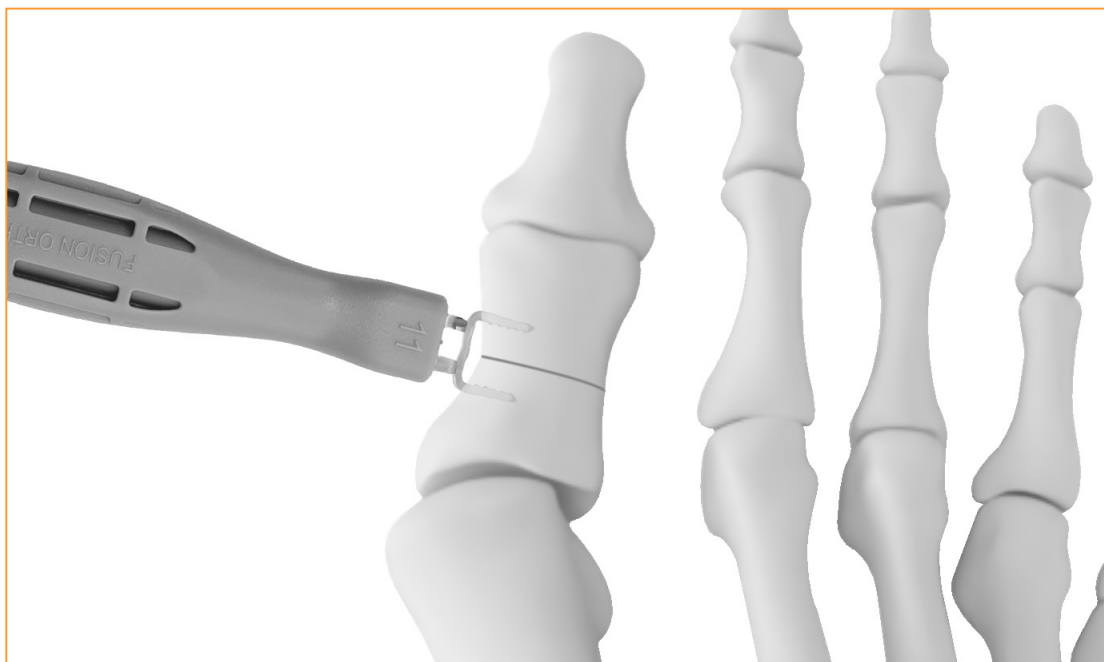
8

Remove the Targeting Rods. While maintaining reduction, align and insert the tips of the implant into the pre-drilled holes. Insert the implant as far as possible. Do not impact the inserter. To ensure proper implant placement, fluoroscopy may be used.



9

Loosen the inserter by turning the wing end counter-clockwise. Deploy the staple by rotating the inserter counter clockwise unlatching the inserter teeth from under the bridge of the implant.



Tray-Based  
Tamp

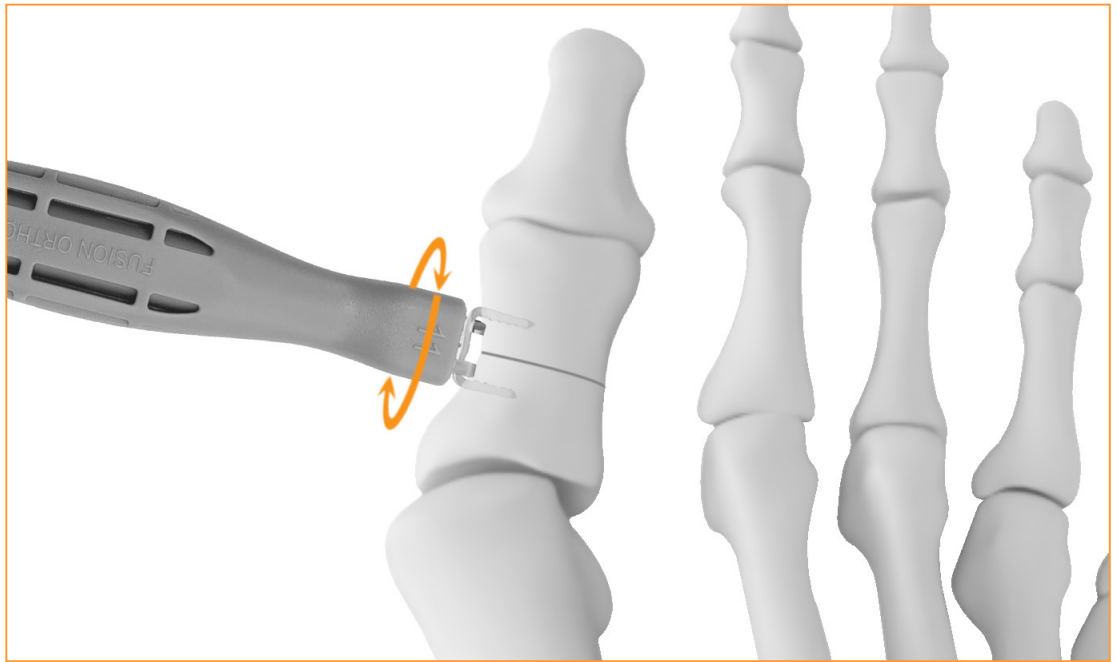
10

Using the same inserter, this time align the top of the teeth with the top of the implant. Tamp against the wing end of the inserter to completely seat the implant flush with the bone.



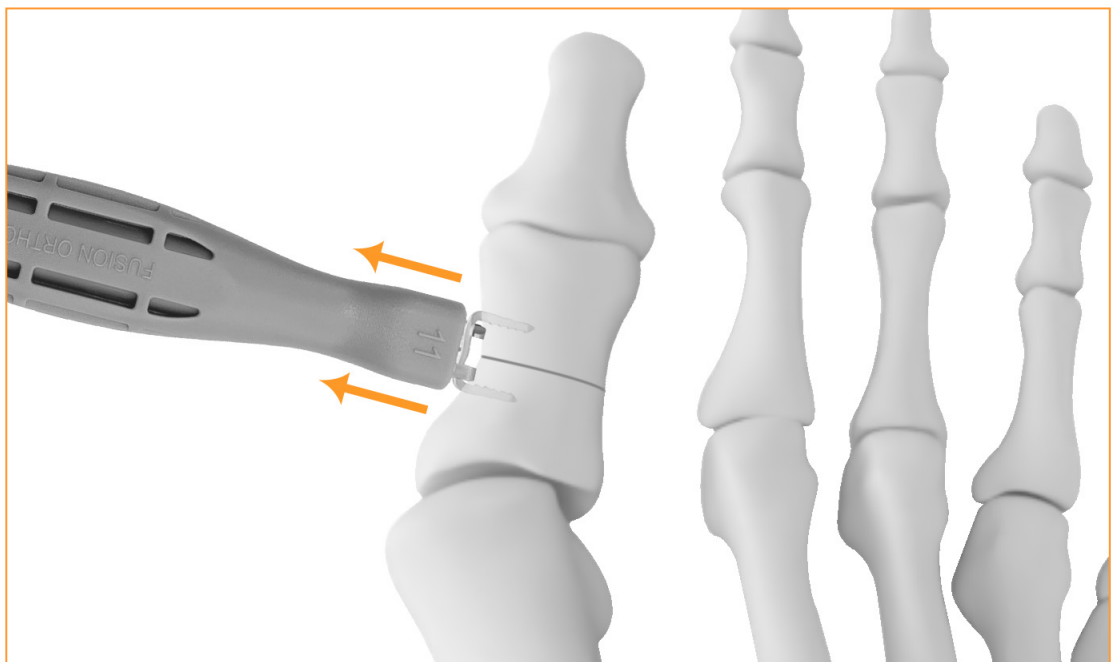
11

Final Placement.



1

Remove a small amount of bone from under the bridge of the Implant, or utilizing an osteotome or elevator, expose the bridge of the Implant to allow the inserter teeth to engage. With the inserter teeth latched on to the staple, tighten the wing-end of the inserter to constrain the staple legs to parallel position.



2

Pull the inserter away from the foot to remove the DynaBridge implant.

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### Editor's Note:

Any 13mm to 25mm Staple (and its corresponding instrumentation) is provided Sterile-Disposable Only.  
Only 9mm and 11mm systems are provided Tray-Based.



1

The incision is made on the dorsal lateral aspect of the calcaneal cuboid joint. The incision is made dorsal to the sural nerve and peroneal tendons. Distract the joint to adequately resect the joint area and debride the articular cartilage.



2

Position the drill guide across the prepared joint with both prongs touching bone and equidistantly spaced from the fusion site. While ensuring full reduction, drill the first hole using the enclosed Calibrated Drill until the hard stop is reached.



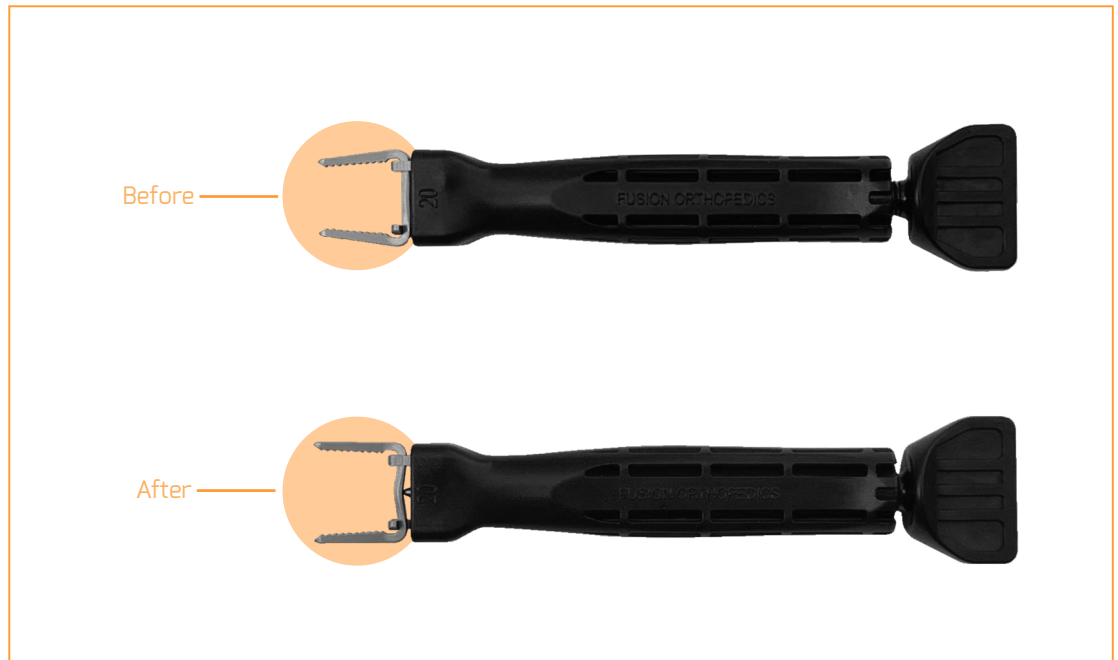
3

Insert a Targeting Rod into the first hole to maintain guide alignment and prepare to drill the second hole. While ensuring full reduction, drill the second hole until the hard stop is reached.



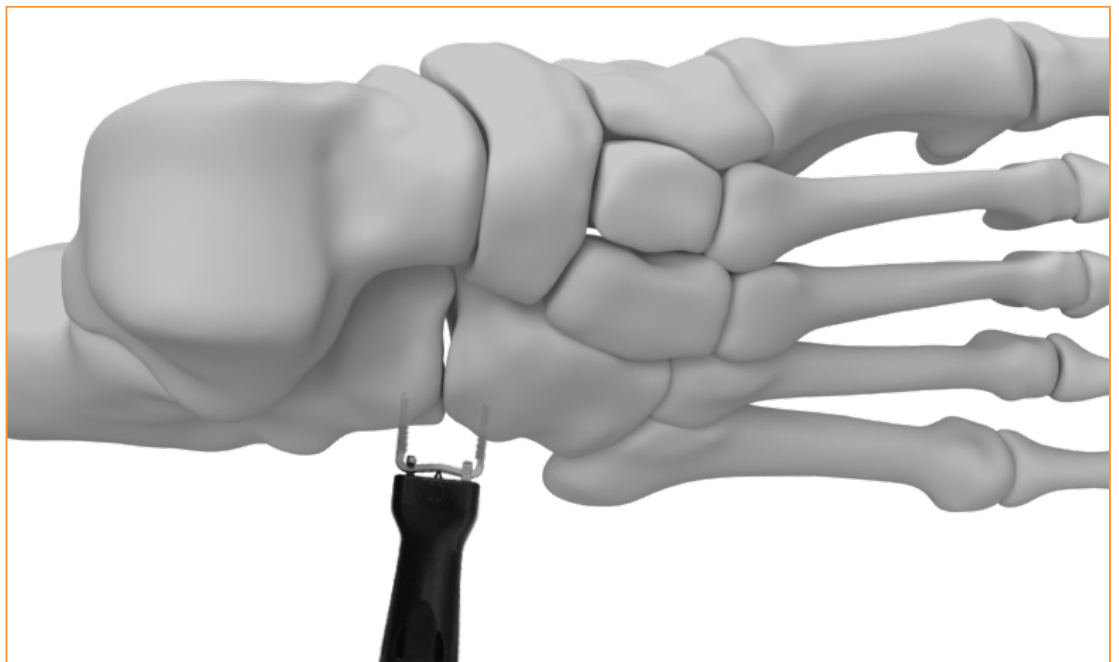
4

According to surgeon preference, an optional second Targeting Rod may be inserted into the second hole to help mark position. Remove the drill guide.



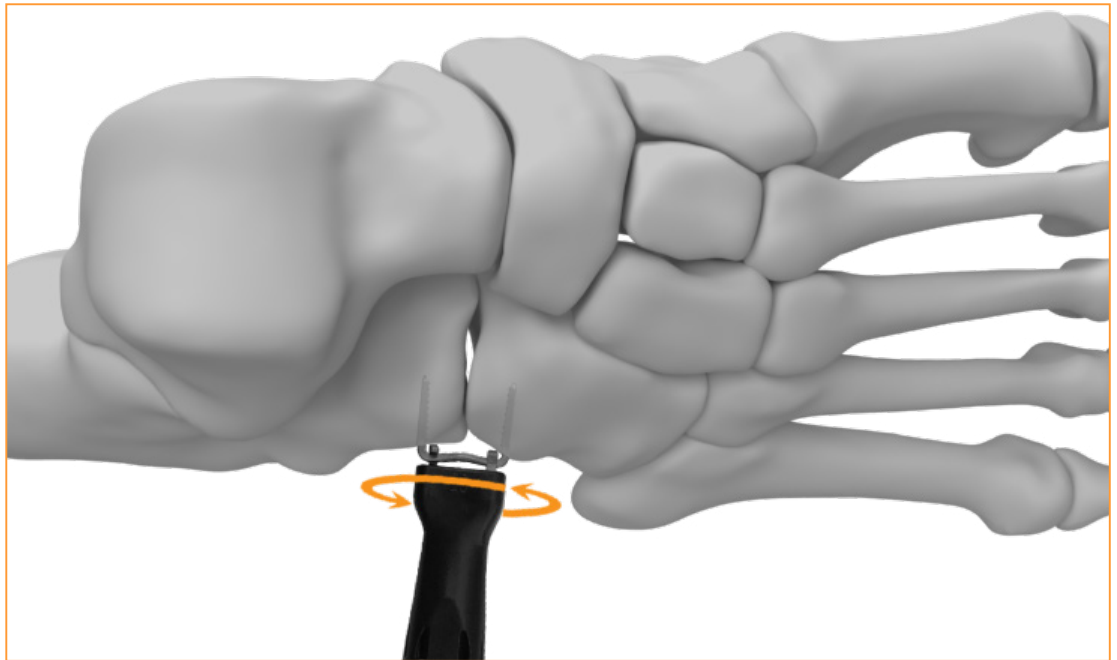
5

Retrieve the staple inserter. Out of the package, the inserter should already be semi-loaded with the DynaBridge™ Staple. To fully-load, turn the wing end of the inserter clock-wise to tighten. Ensure that the staple has properly latched on to the teeth of the inserter. Continue tightening until the legs are in parallel position.

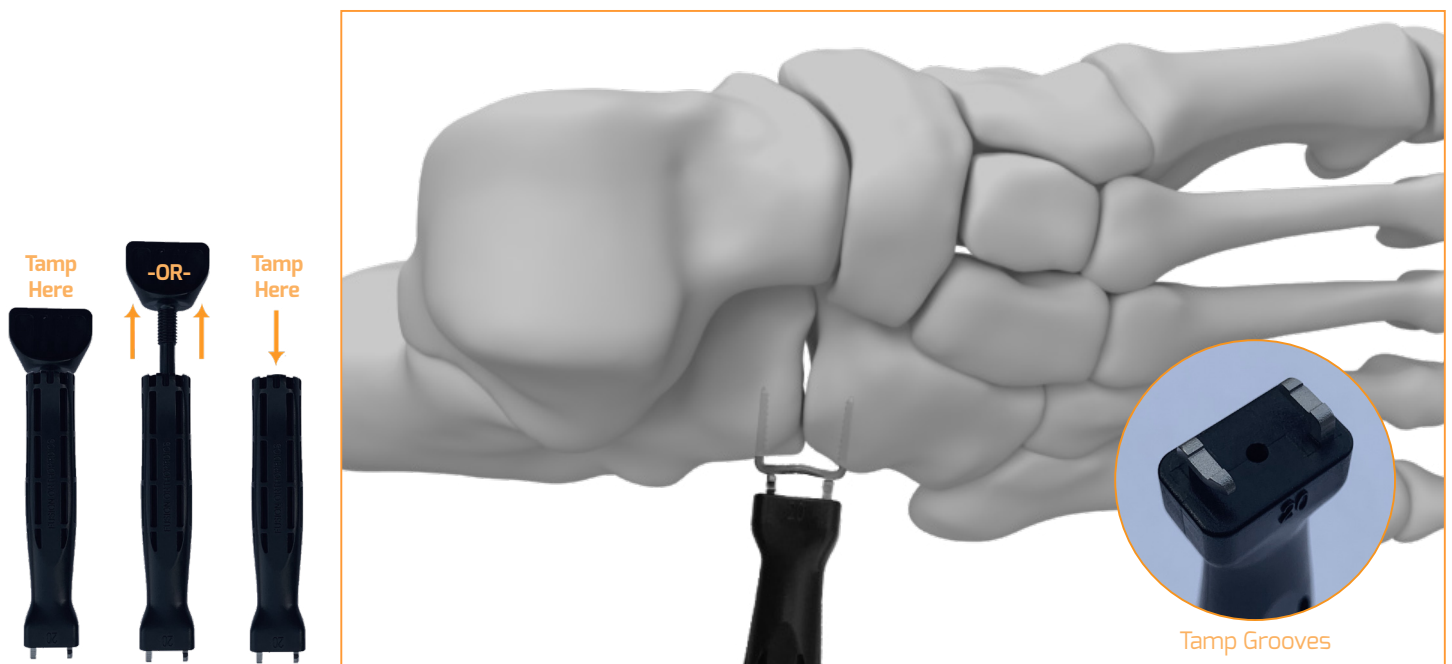


6

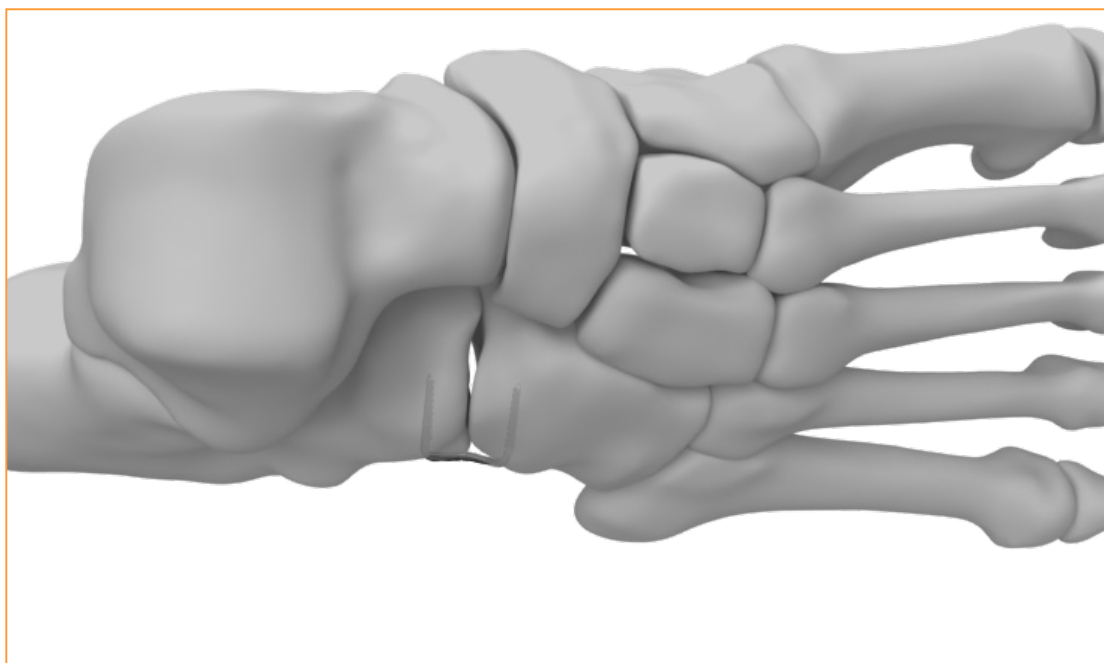
Remove any Targeting Rods if necessary. While maintaining reduction, align and insert the tips of the implant into the pre-drilled holes. Insert the implant as far as possible. Do not impact the inserter. To ensure proper implant placement, fluoroscopy may be used.



**7** Loosen the inserter by turning the wing end counter-clockwise. Deploy the staple by rotating the inserter counter clockwise unlatching the inserter teeth from under the bridge of the implant.

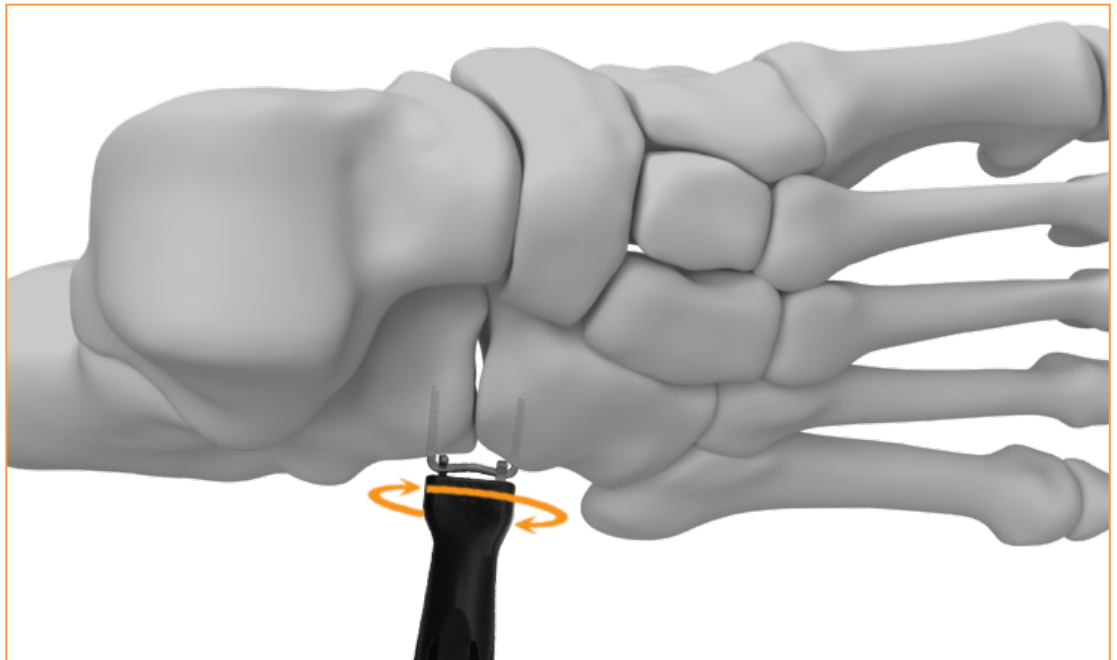


**8** Using the same inserter, transform it into a tamp by unscrewing and removing the wing insert. Align the top of the teeth with the top of the implant. Tamp to completely seat the implant flush with the bone. \* You may choose to leave the wing insert in and tamp against the the wing end.



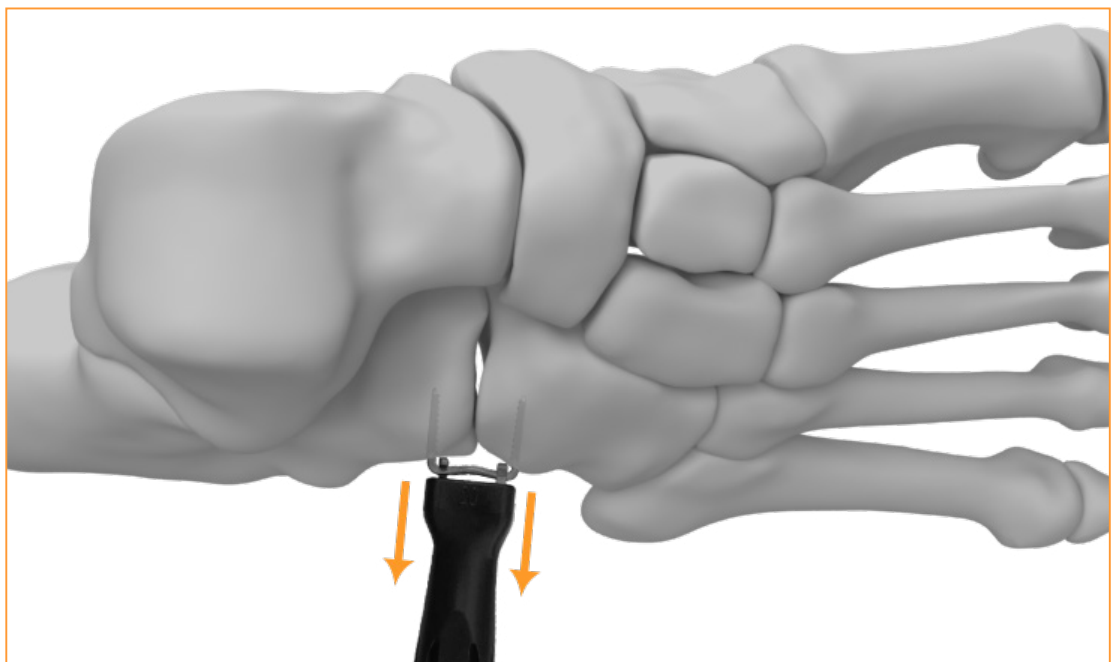
9

Final Placement.



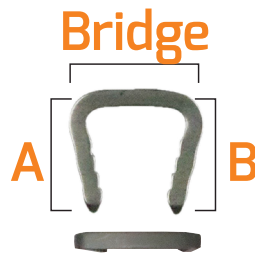
1

Remove a small amount of bone from under the bridge of the Implant, or utilizing an osteotome or elevator, expose the bridge of the Implant to allow the inserter teeth to engage. With the inserter teeth latched on to the staple, tighten the wing-end of the inserter to constrain the staple legs to parallel position.

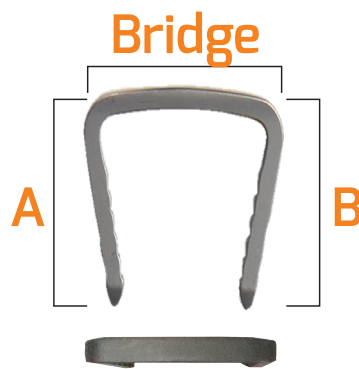


2

Pull the inserter away from the foot to remove the DynaBridge implant.



Style A Implants	Non-Sterile	Sterile-Kitted	Sterile-Single	Bridge	Leg A	Leg B
Style A 9x8x8mm	DB-09-0808-A	DB-09-0808-SA	DB-09-0808-SA1	9mm	8mm	8mm
Style A 11x10x10mm	DB-11-1010-A	DB-11-1010-SA	DB-11-1010-SA1	11mm	10mm	10mm
Style A 13x10x10mm	-	DB-13-1010-SA	DB-13-1010-SA1	13mm	10mm	10mm



Style B Implants	Non-Sterile	Sterile-Kitted	Sterile-Single	Bridge	Leg A	Leg B
Style B 15x15x15mm	-	DB-15-1515-SB	DB-15-1515-SB1	15mm	15mm	15mm
Style B 18x18x18mm	-	DB-18-1818-SB	DB-18-1818-SB1	18mm	18mm	18mm
Style B 20x20x20mm	-	DB-20-2020-SB	DB-20-2020-SB1	20mm	20mm	20mm
Style B 25x20x20mm	-	DB-25-2020-SB	DB-25-2020-SB1	25mm	20mm	20mm

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Instruments	Non-Sterile	Sterile-Kitted	Sterile-Single
Tamp DB Small	TN-DB-2050	-	-
Calibrated Drill DB 2.1mm	CD-DB-2021	CD-DB-2021-S	-
Calibrated Drill DB 2.8mm	CD-DB-2028	CD-DB-2028-S	-
Targeting Rod Small	CD-DB-3010	CD-DB-3010-S	-
Insertor Tray Based 9mm	TN-DB-0909	-	-
Insertor Tray Based 11mm	TN-DB-1111	-	-
DynaBridge Sizer Wheel Kit	-	CD-DB-6030-S	-
YOCO Akin Blade	CD-OP-1003	CD-OP-1003-S	CD-OP-1003-S1

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Sterile Kits	Sterile
9mm Implant Kit Style A Instrument Kit	CD-DB-0909-SA
11mm Implant Kit Style A Instrument Kit	CD-DB-1111-SA
13mm Implant Kit Style A Instrument Kit	CD-DB-1313-SA
15mm Implant Kit Style B Instrument Kit	CD-DB-1515-SB
18mm Implant Kit Style B Instrument Kit	CD-DB-1818-SB
20mm Implant Kit Style B Instrument Kit	CD-DB-2020-SB
25mm Implant Kit Style B Instrument Kit	CD-DB-2525-SB

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STG008

Rev. 1



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