MEGALODON™

DYNAMIC COMPRESSION SYSTEM

SURGICAL TECHNIQUE GUIDE

Megalodon™ Dynamic Compression System



Paragon 28®

a ZIMMER BIOMET company

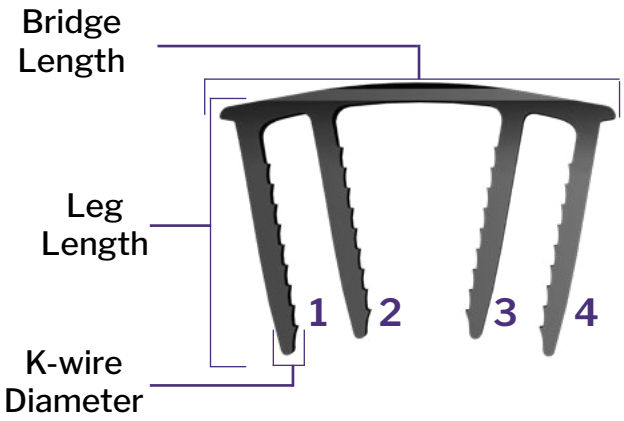
PRODUCT DESCRIPTION:

The Megalodon™ Dynamic Compression System is sterile packaged and pre-loaded on an inserter that provides a simple insertion method to help gain rigid compression across an osteotomy or fusion site. The inserter allows for the implant to be elastically deformed while stored in the inserter and immediately returns to its original shape after it is released from the inserter in the bone. The inserter allows the Megalodon™ Dynamic Compression System implant to be completely seated before it is released from the inserter, allowing final placement of the implant before it compresses the osteotomy site.

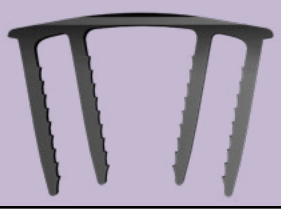
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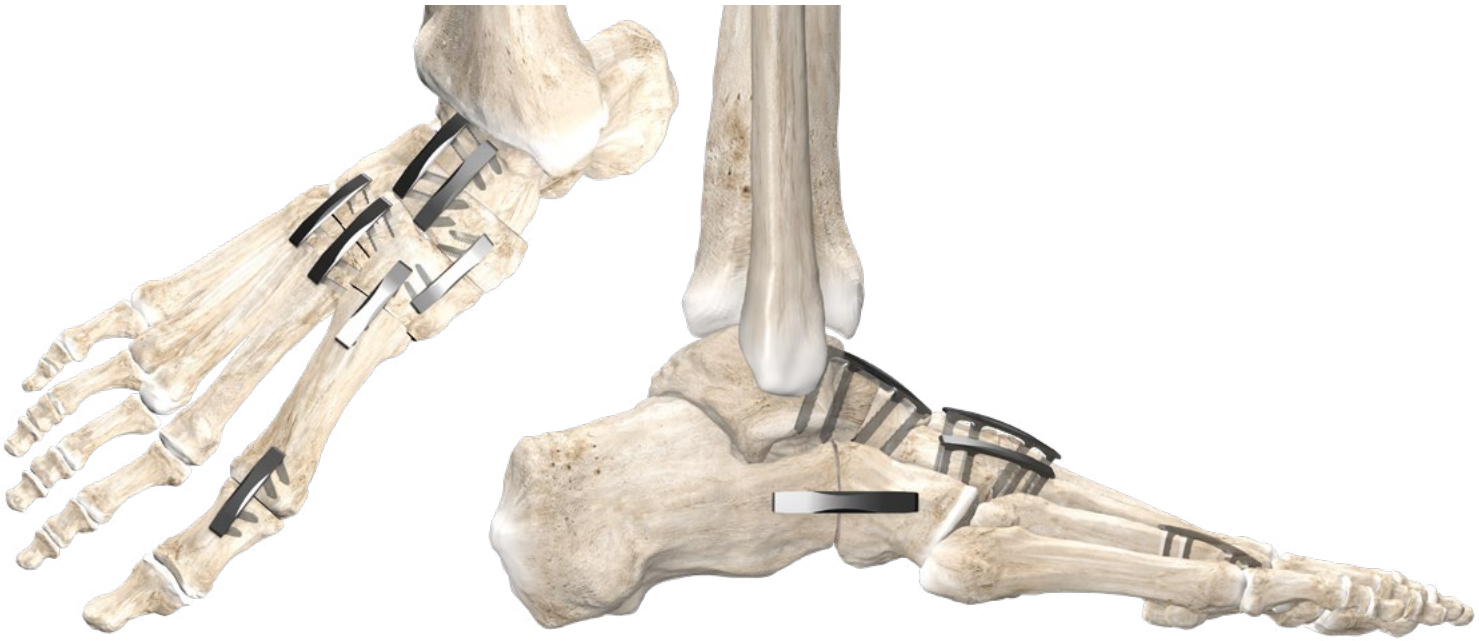
SYSTEM COMPONENTS AND FEATURES:





STAPLE SIZE	BRIDGE LENGTH	LEG 1 LENGTH	LEG 2 LENGTH	LEG 3 LENGTH	LEG 4 LENGTH	K-WIRE DIAMETER
	25 mm	12 mm	16 mm			Ø3.0 mm
	25 mm	20 mm				
	27 mm	16 mm		20 mm		
	27 mm	20 mm				
	30 mm	12 mm	16 mm			
	30 mm	20 mm				

IMPLANT OFFERINGS:



BRIDGE LENGTH	LEG LENGTH	POTENTIAL APPLICATIONS
25 mm	12 x 16 x 16 x 16 mm	• 1st MTP • 2nd/3rd TMT
25 mm	20 mm	• 1st TMT • Evans Osteotomy • Dwyer Osteotomy • Talonavicular (TN) Fusion • Calcaneocuboid (CC) Fusion • Naviculocuneiform (NC) Fusion
27 mm	16 x 16 x 20 x 20 mm	• 1st MTP • 1st/2nd/3rd TMT
27 mm	20 mm	• 1st TMT • Evans Osteotomy • Dwyer Osteotomy • Talonavicular (TN) Fusion • Calcaneocuboid (CC) Fusion • Naviculocuneiform (NC) Fusion
30 mm	12 x 16 x 16 x 16 mm	• 1st MTP • 1st/2nd TMT
30 mm	20 mm	• 1st TMT • Talonavicular (TN) Fusion • Calcaneocuboid (CC) Fusion • Naviculocuneiform (NC) Fusion

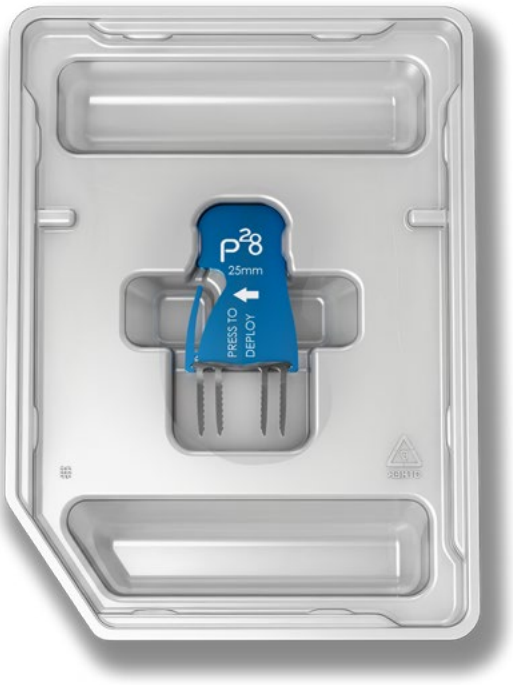
STERILE PACKED KITS:

All instruments and implants are provided sterile packed and are single-use only.

Instrument Kit

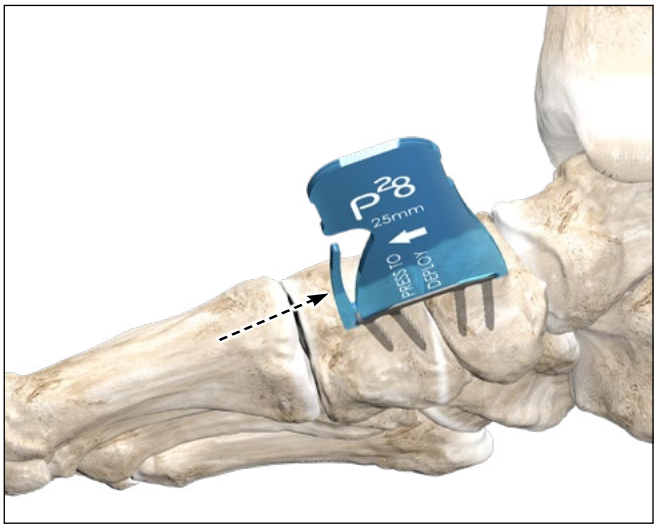


Staple Kit
25 mm, 27 mm or 30 mm Implant Kit



IMPLANT INSERTER USE:





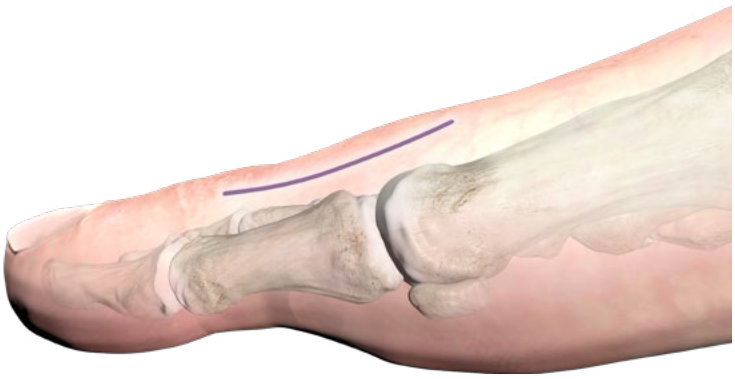
The implant comes pre-loaded onto the inserter. After preparing the osteotomy/fusion site and drilling the holes, the implant can be seated into the bone. To deploy, push the trigger on the inserter.



The surgical technique shown below is for placement of a Megalodon™ Dynamic Compression System 25 mm bridge and 12 mm x 16 mm x 16 mm x 16 mm leg implant for a 1st MTP fusion procedure. This technique is applicable to all 25, 27, and 30 mm length Megalodon™ Implants.

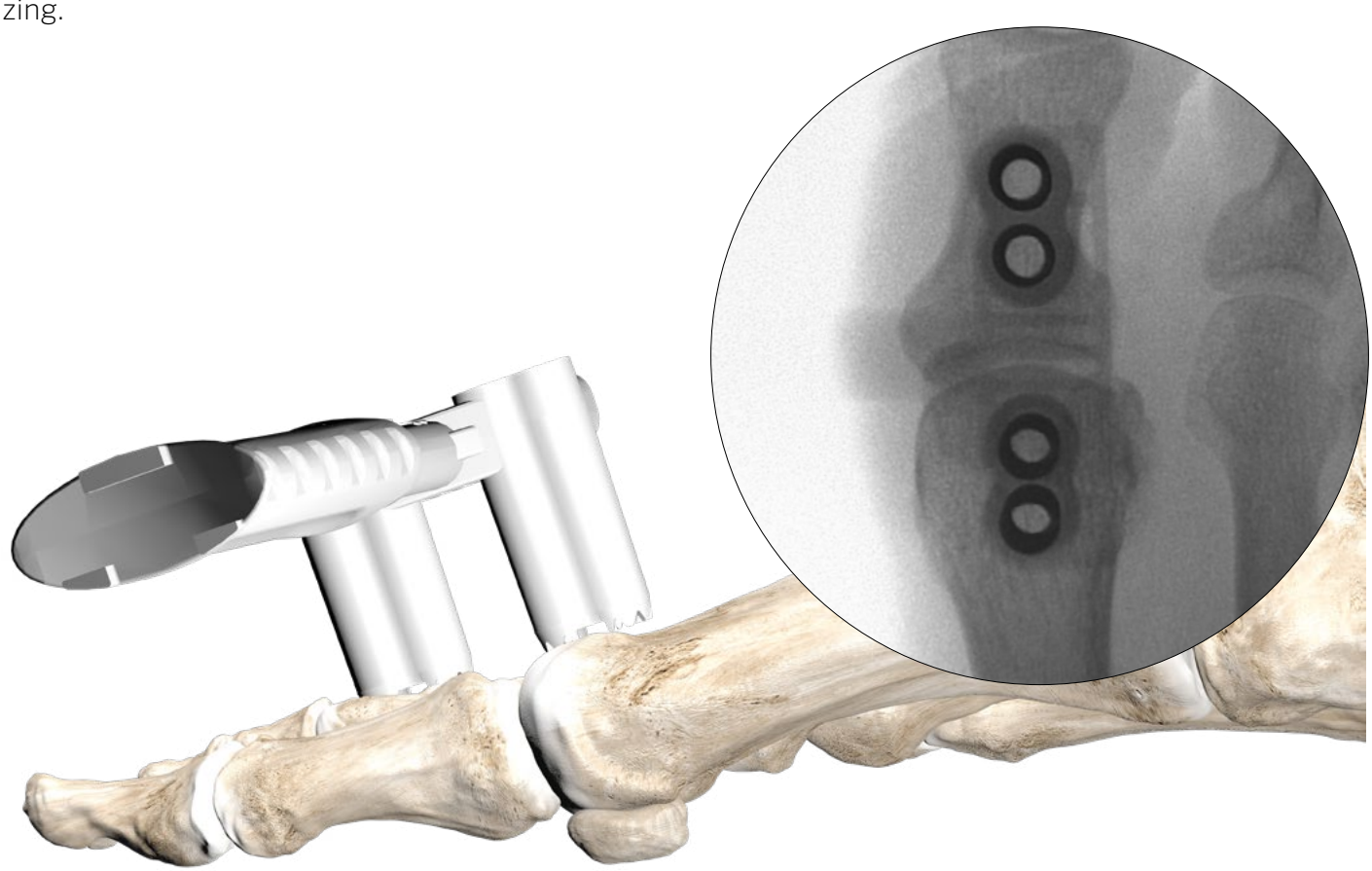
INCISION/EXPOSURE:

A dorsomedial incision over the 1st metatarsophalangeal joint is recommended. Perform soft tissue dissection down to expose the 1st metatarsophalangeal joint. Release the soft tissues to expose the articular surfaces of the 1st metatarsal head and the base of the hallux proximal phalanx. Prepare the joint for arthrodesis according to surgeon preference. A rongeur can be used to trough out some bone on the 1st metatarsal head to help the implant sit flush with the bone.



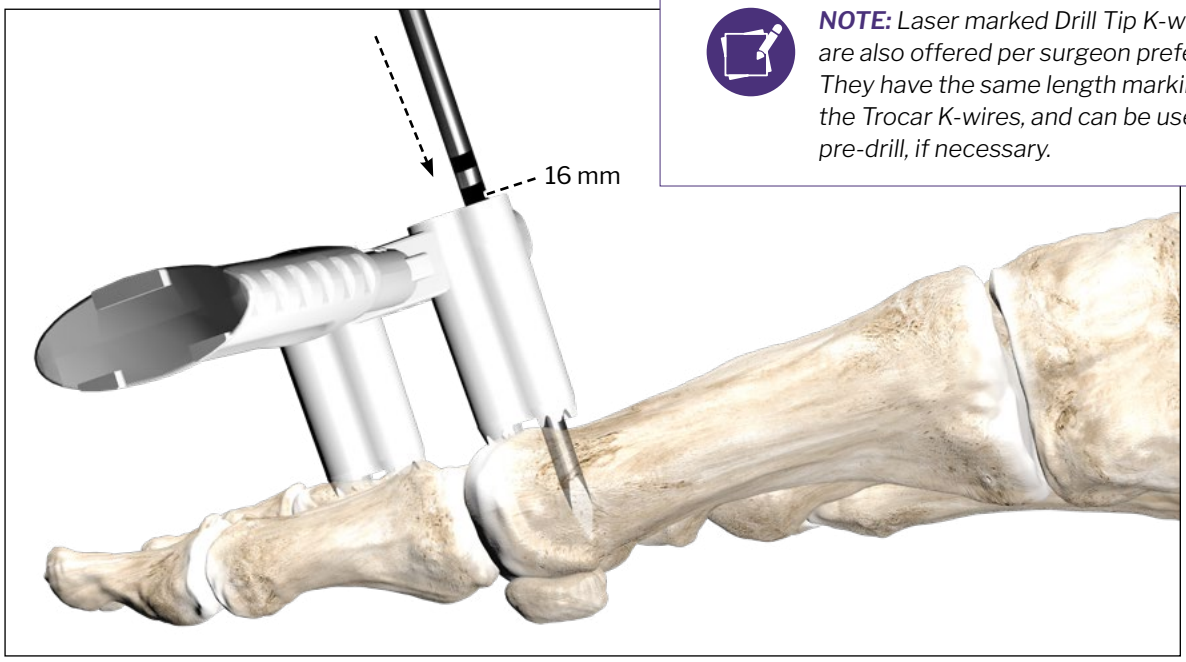
IMPLANT SELECTION AND INSERTION:

After preparing the joint for fusion, open the Instrument kit containing all Drill Guides corresponding to the three available staple bridge lengths. Select the appropriate drill guide for the bridge length of the intended implant. Center the drill guide on the joint. Fluoroscopy can be used to confirm the intended implant leg locations. If the intended location isn't appropriate, select a different size drill guide corresponding to proper implant sizing.

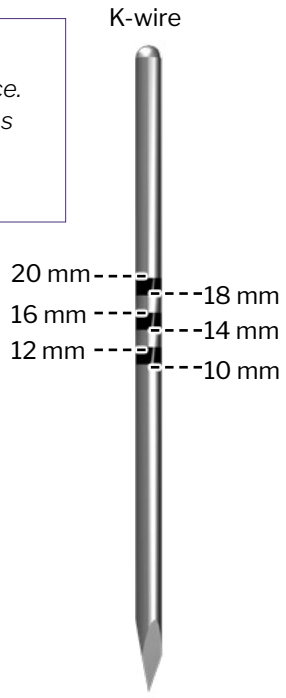


IMPLANT SELECTION AND INSERTION:

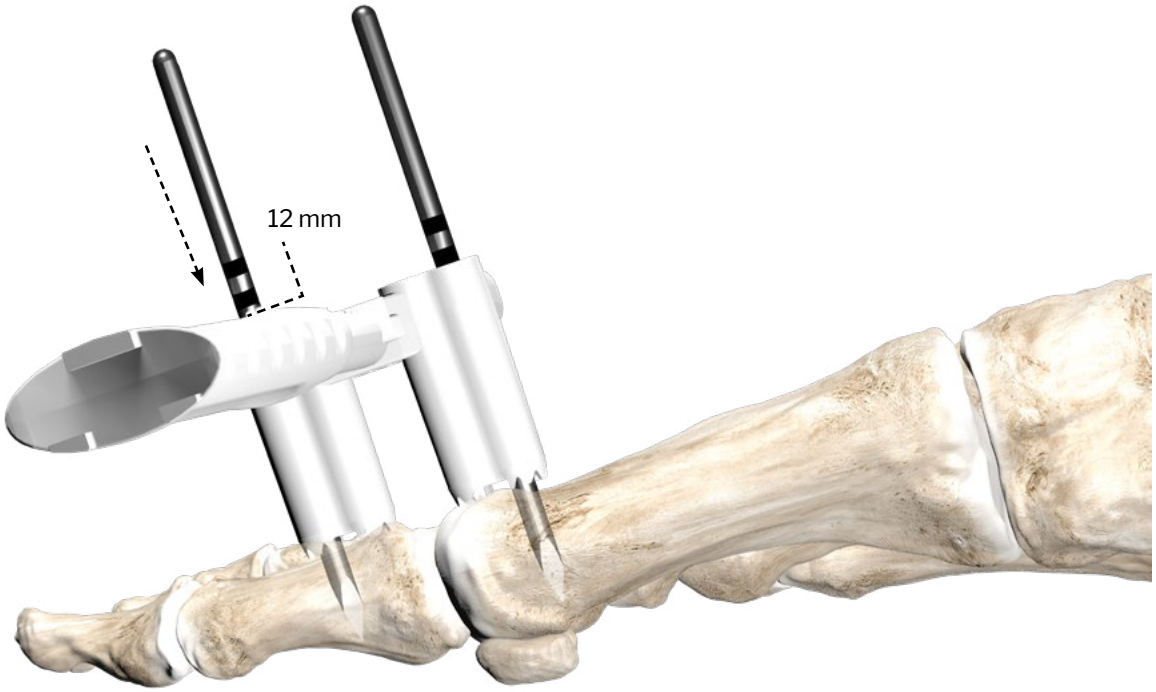
After positioning the drill guide appropriately, place the short 3.0 mm Trocar K-wire into the proximal hole of the drill guide. If there is difficulty placing the K-wire wire, pre-drill the proximal hole with the shorter 3.0 mm Drill Tip K-wire first, and drop the Trocar K-wire into the hole to hold the position. Place the wire to the appropriate depth and confirm appropriate leg length via the laser bands on the K-wire.



NOTE: *Laser marked Drill Tip K-wires are also offered per surgeon preference. They have the same length markings as the Trocar K-wires, and can be used to pre-drill, if necessary.*



With the short 3.0 Trocar K-wire placed proximally, place the remaining short 3.0mm Drill Tip K-wire into the most distal hole of the drill guide. Place the wire to the appropriate depth and confirm appropriate leg length via the laser bands on the K-wire.



IMPLANT SELECTION AND INSERTION:

After placing the proximal and distal K-wires. Use the long 3.0 mm Trocar and Drill Tip K-wires to drill the two middle holes in the drill guide. Similar to the outer holes, the Drill Tip K-wire may be used to pre-drill the hole for the Trocar K-wire position, if necessary. Confirm appropriate leg length via the laser bands on the K-wire K-wire to drill the two middle holes in the drill guide and confirm appropriate leg length via the laser bands on the K-wire.



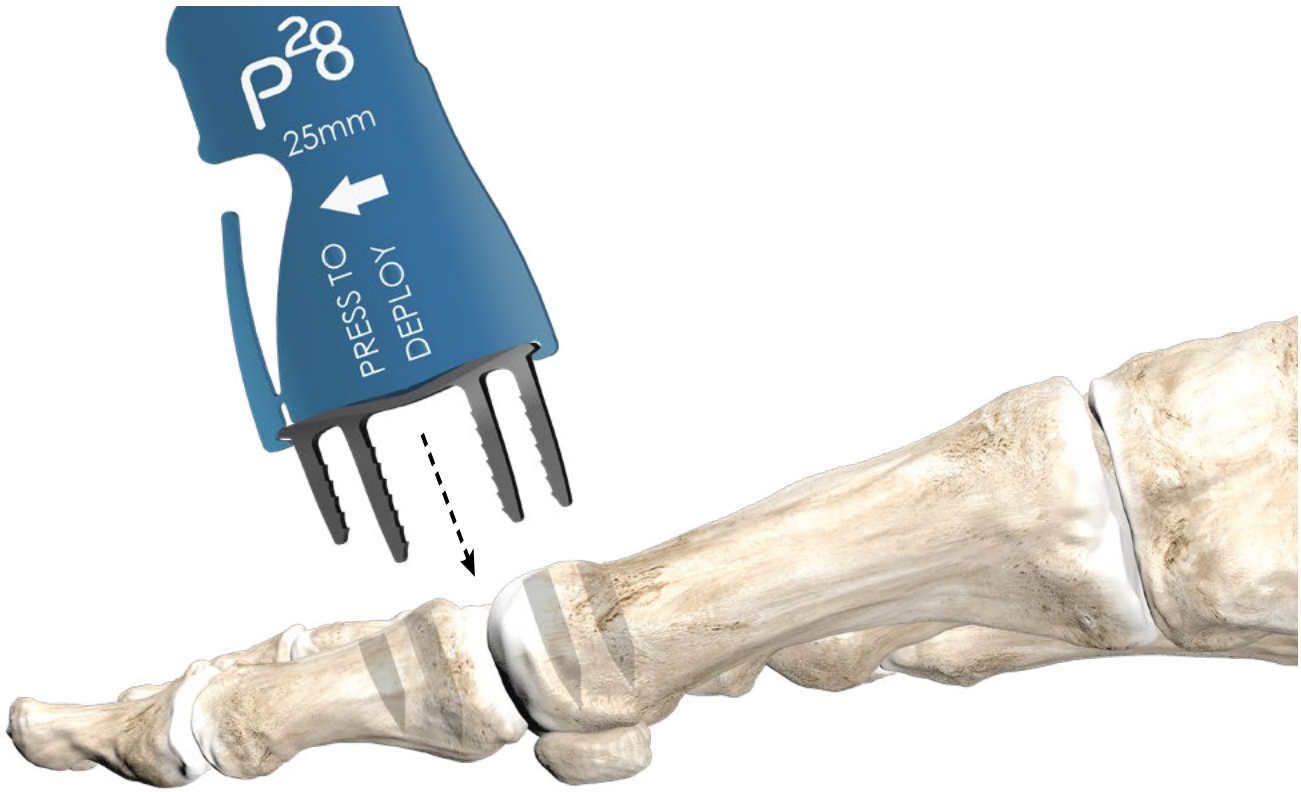


After drilling all the holes for the implant legs, remove the proximal and distal K-wires and remove the drill guide.

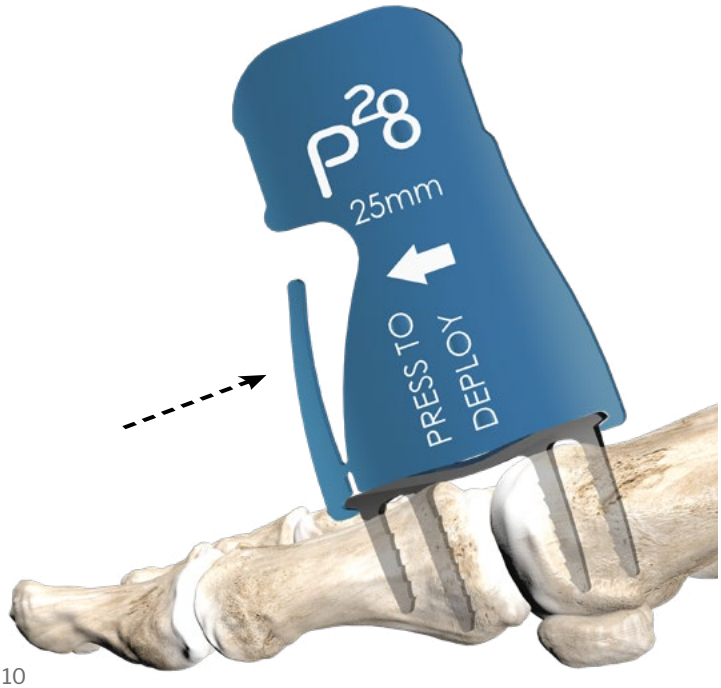


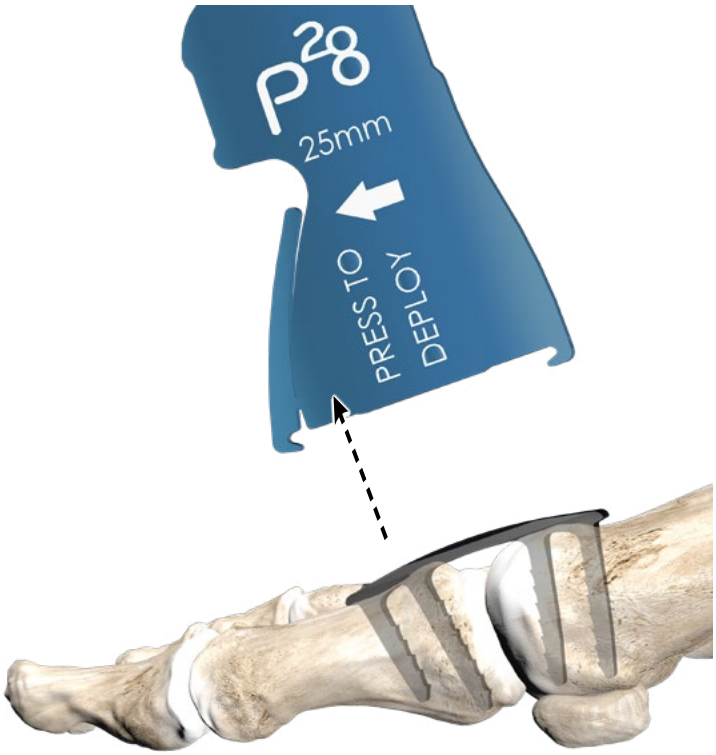
IMPLANT SELECTION AND INSERTION:

Retrieve the appropriate pre-loaded mplant determined by Drill Guide sizing and leg length measurements on an inserter and fully seat in the predrilled holes. If necessary, the inserter can be gently tapped with a mallet to help fully seat.



Push in on the inserter trigger to deploy the implant.



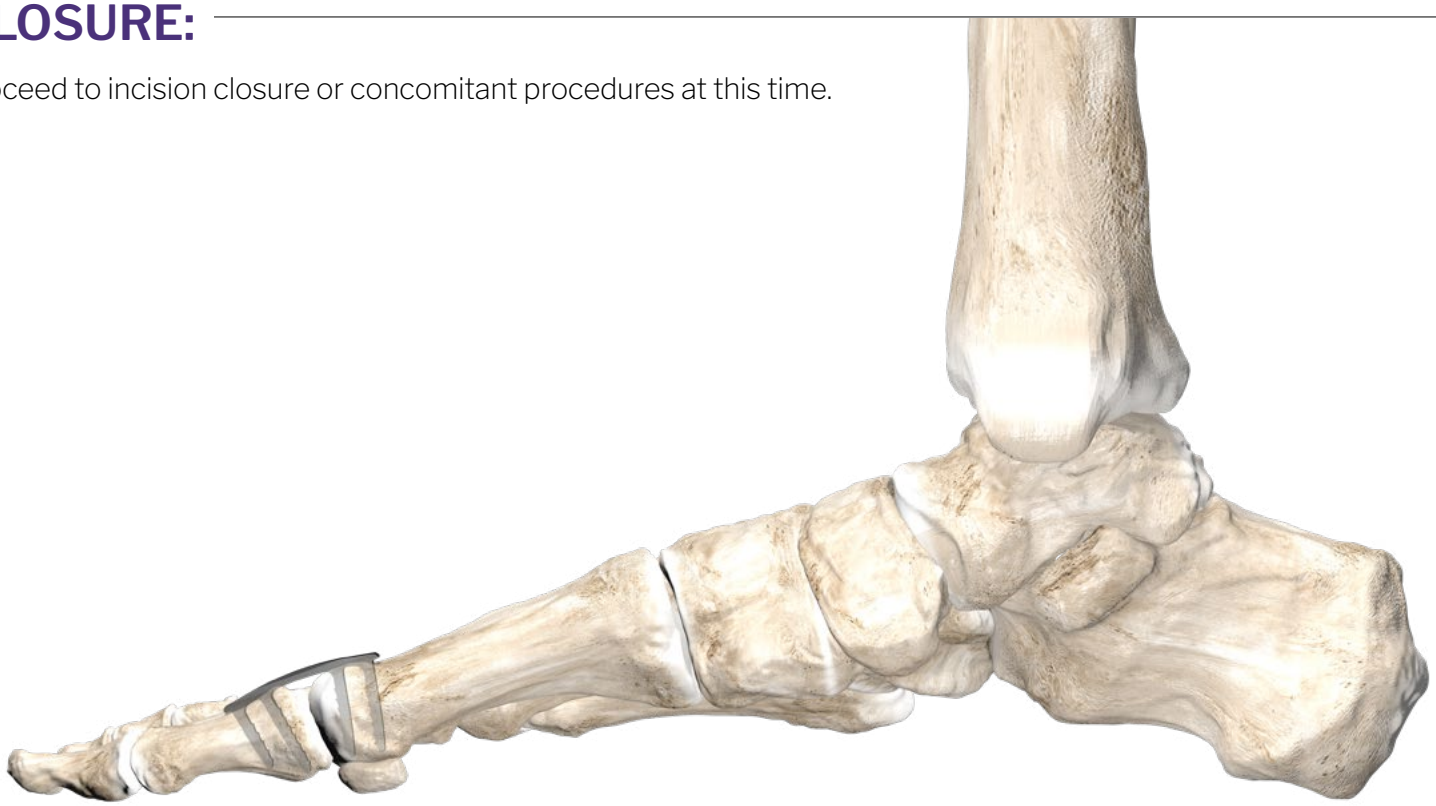


If the implant is proud after the inserter has been disengaged, the end of the drill guide can be seated on the bridge of the implant and can be used to help tamp the implant when tapping the head with a mallet. Place any additional implants according to the previously described steps.



CLOSURE:

Proceed to incision closure or concomitant procedures at this time.



REMOVAL:

Remove the placed implant by using a thin instrument such as a Hohmann or a Freer Elevator to get under the bridge of the implant and use it to lever the implant out. A rongeur/pliers can also be used to help remove the implant.

The surgical technique shown below is for placement of a Megalodon™ dynamic compression system 30 mm bridge and 20 mm x 20 mm x 20 mm x 20 mm leg length implant for a calcaneocuboid fusion procedure. This technique is applicable to all 25, 27, and 30 mm Megalodon™ Implants.

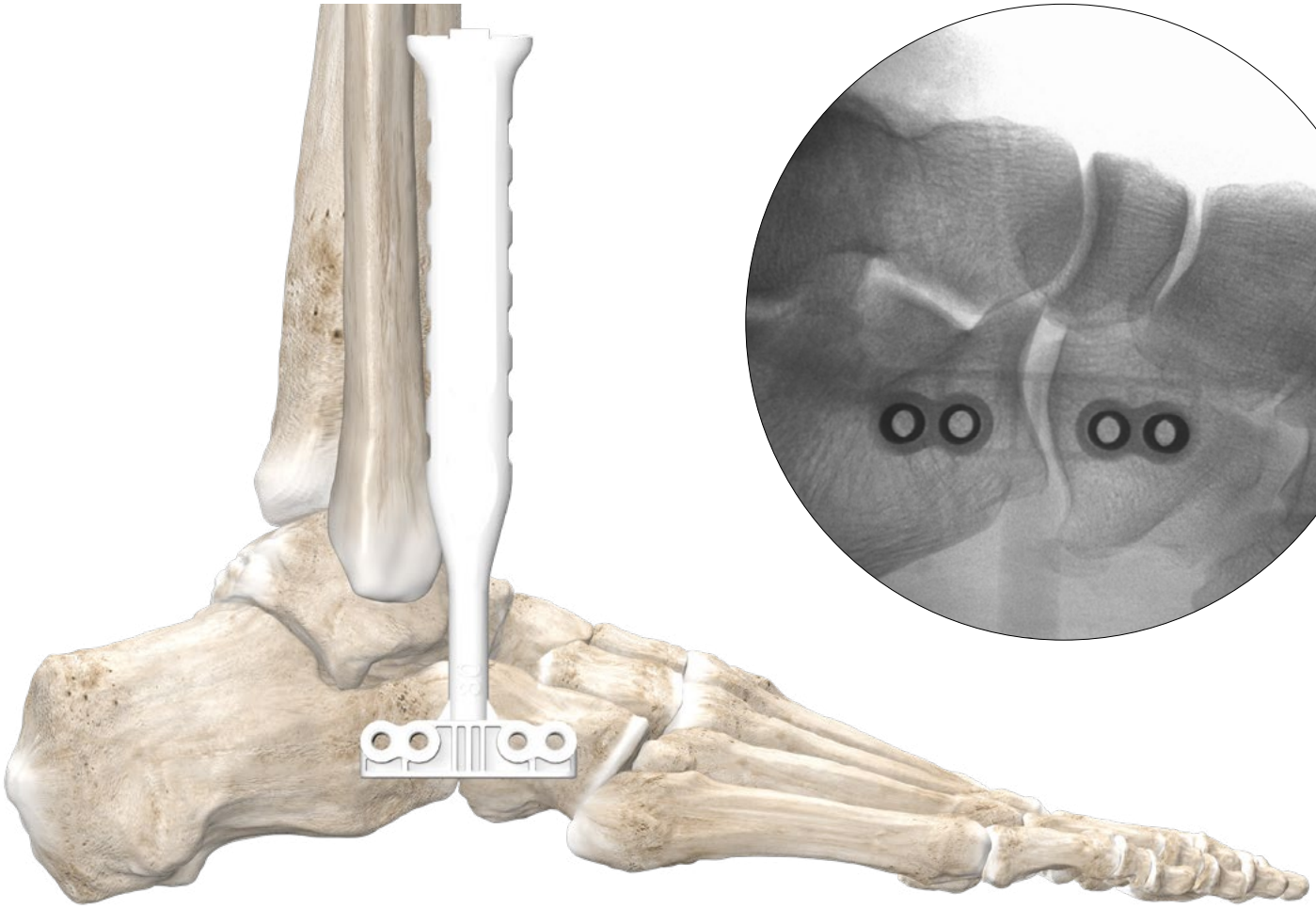
INCISION/EXPOSURE:

Make an incision over the calcaneocuboid joint. Perform soft tissue dissection down to expose the joint. Prepare the joint for arthrodesis according to surgeon preference.



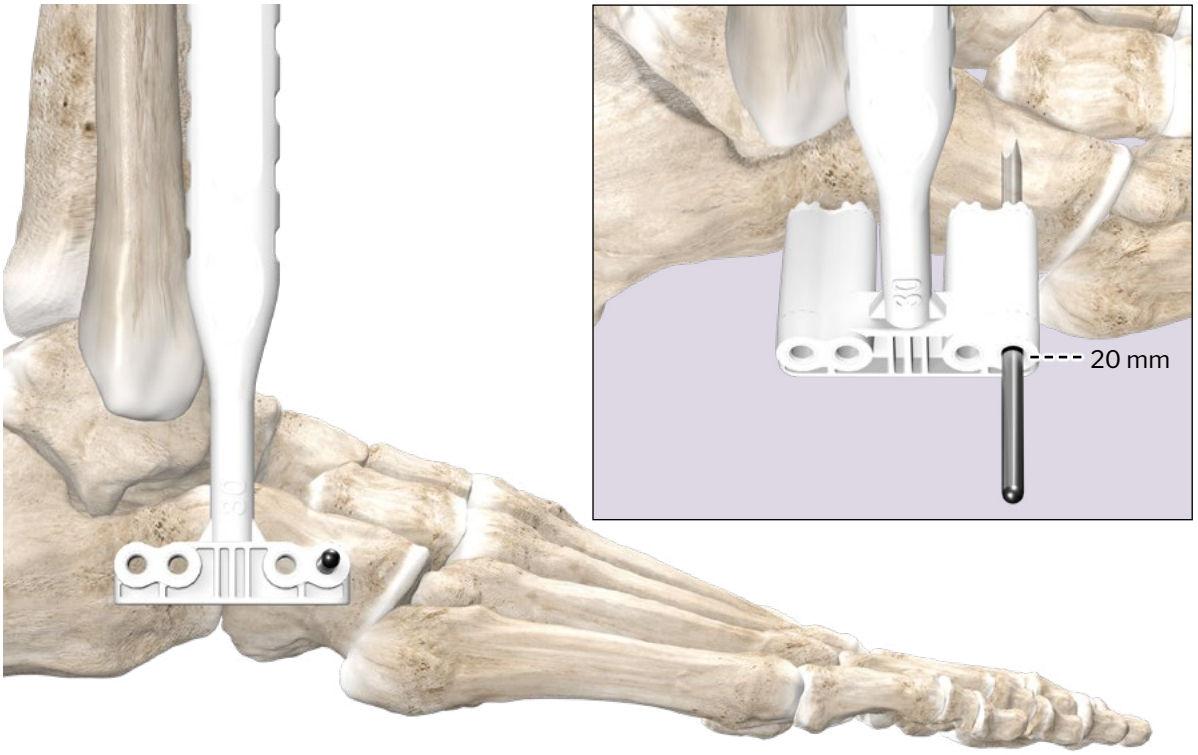
IMPLANT SELECTION AND INSERTION:

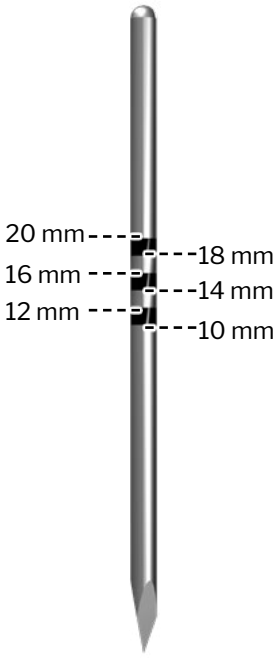
After preparing the joint for fusion, open the Instrument kit containing all Drill Guides corresponding to the three available staple bridge lengths. Select the appropriate drill guide for the bridge length of the intended implant. Center the drill guide on the joint. Fluoroscopy can be used to confirm the intended implant leg locations. If the intended location isn't appropriate, select a different size drill guide corresponding to proper implant sizing.



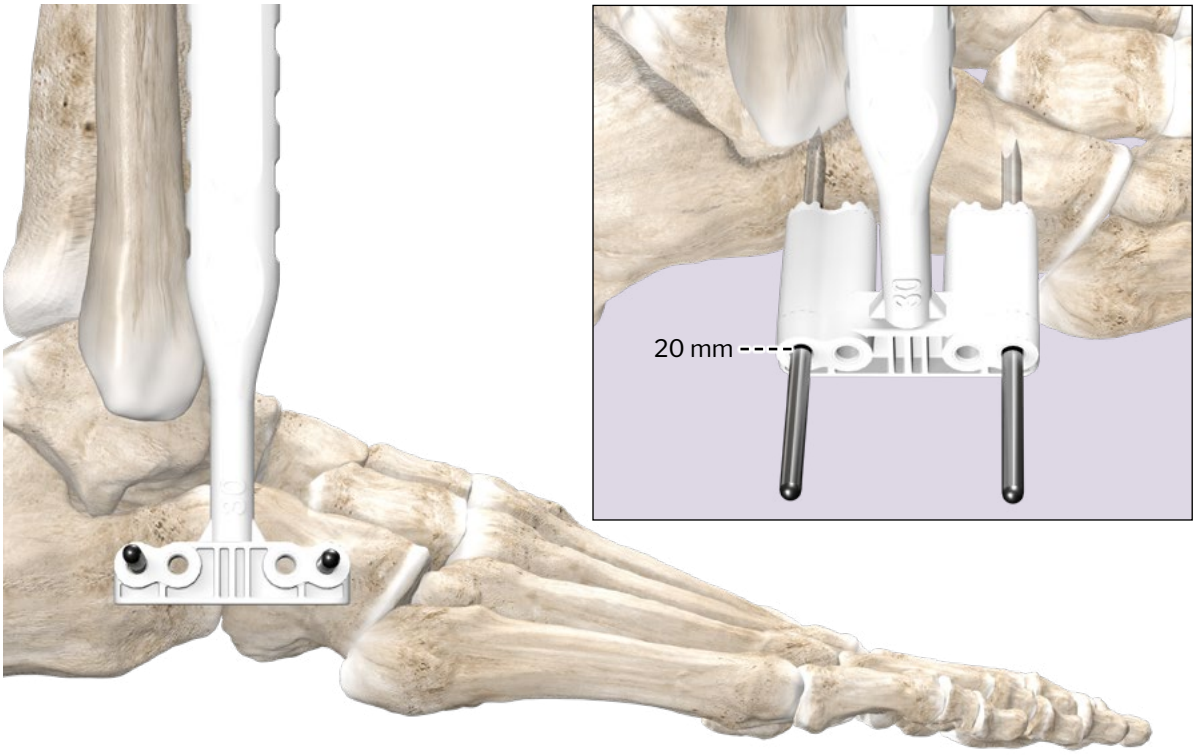
IMPLANT SELECTION AND INSERTION:

After positioning the drill guide appropriately, place the short 3.0mm Trocar K-wire into the proximal hole of the drill guide. If there is difficulty placing the K-wire wire, pre-drill the proximal hole with the shorter 3.0mm Drill Tip K-wire first, and drop the Trocar K-wire into the hole to hold the position. Place the wire to the appropriate depth and confirm appropriate leg length via the laser bands on the K-wire.



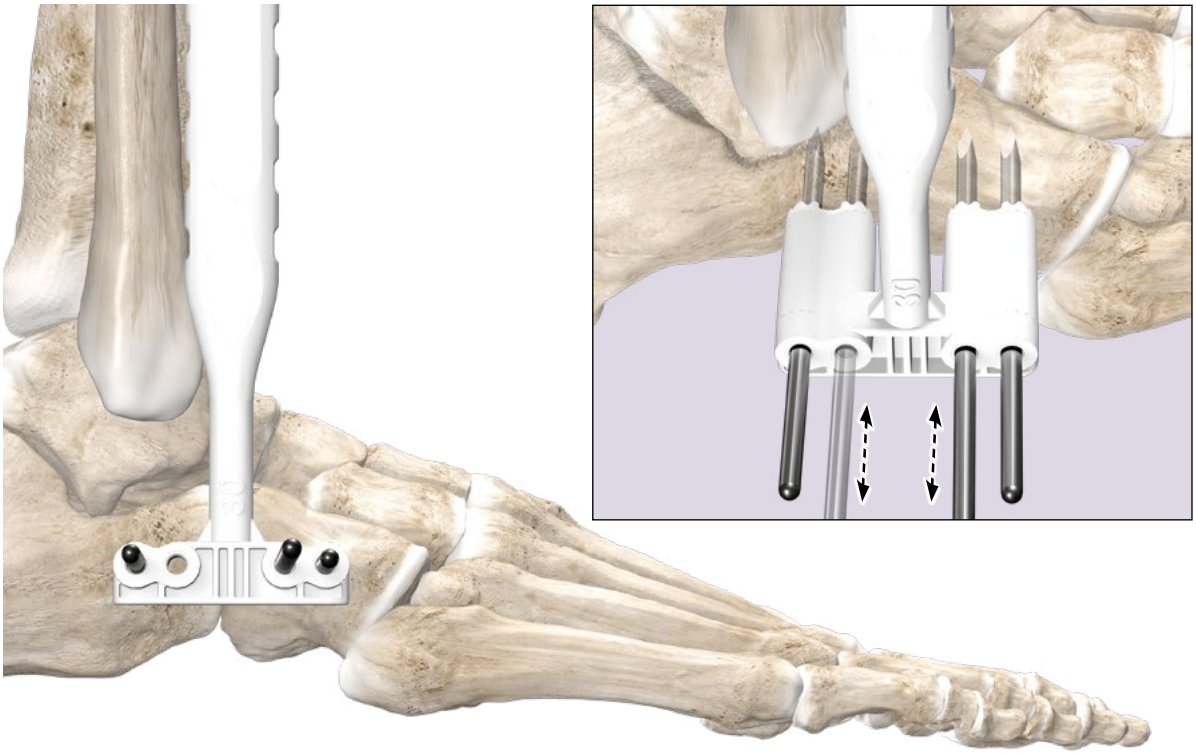


With the short 3.0 Trocar K-wire placed proximally, place the remaining short 3.0 mm Drill Tip K-wire into the most distal hole of the drill guide. Place the wire to the appropriate depth and confirm appropriate leg length via the laser bands on the K-wire.

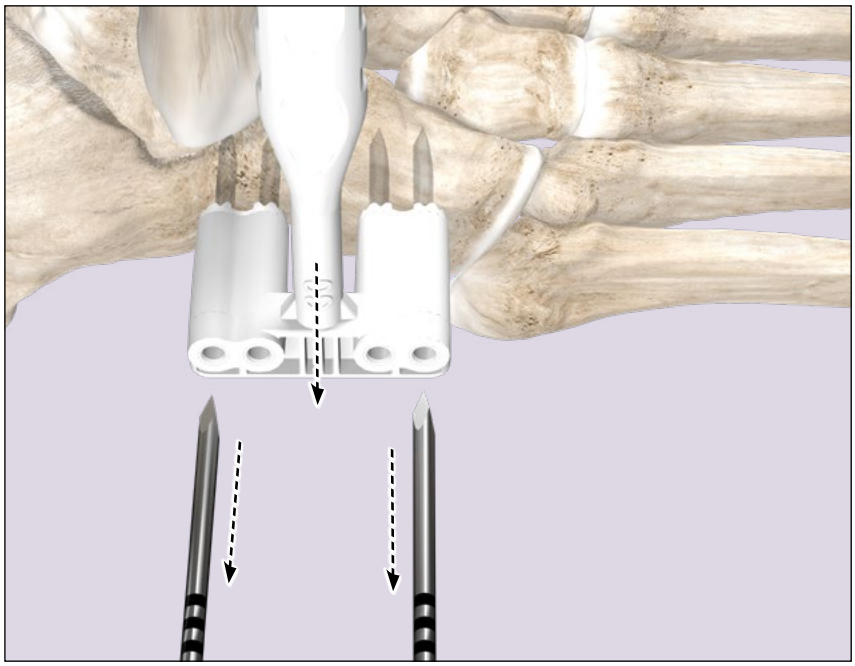


IMPLANT SELECTION AND INSERTION:

After placing the proximal and distal K-wires, use the long 3.0 mm Trocar and Drill Tip K-wires to drill the two middle holes in the drill guide. Similar to the outer holes, the Drill Tip K-wire may be used to pre-drill the hole for the Trocar K-wire position, if necessary. Confirm appropriate leg length via the laser bands on the K-wire.



After drilling all the holes for the implant legs, remove the proximal and distal K-wires and remove the drill guide.

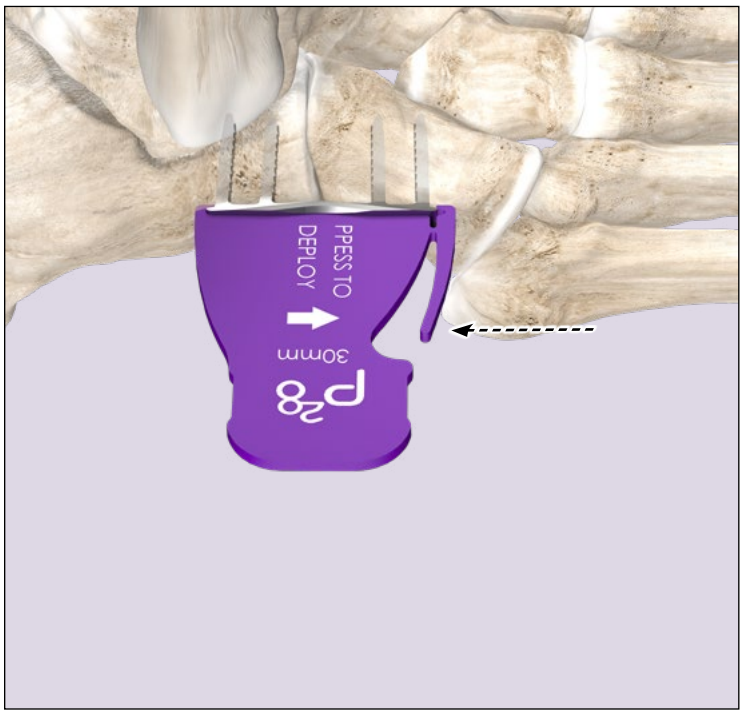


IMPLANT SELECTION AND INSERTION:

Retrieve the appropriate pre-loaded implant determined by Drill Guide sizing and leg length measurements on an inserter and fully seat in the predrilled holes. If necessary, the staple can be gently tapped with a mallet to help fully seat.



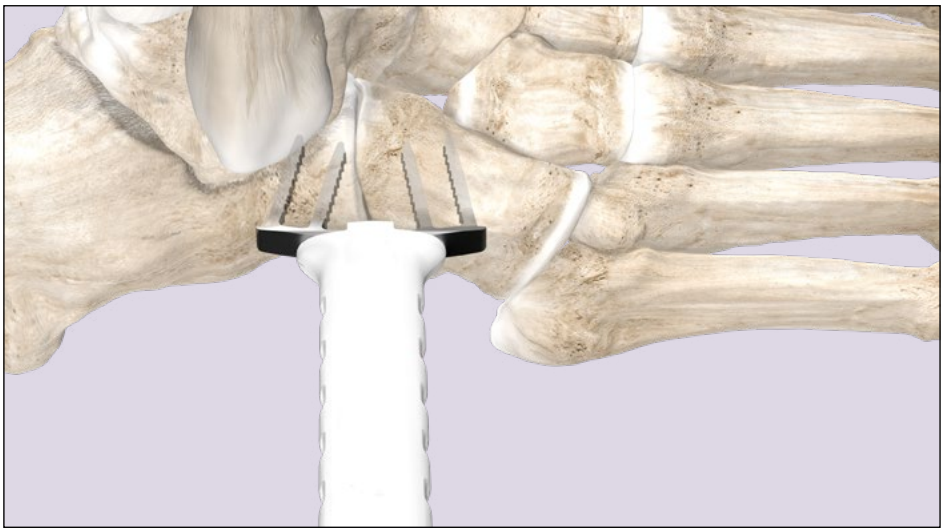
Push in on the inserter trigger to deploy the implant.





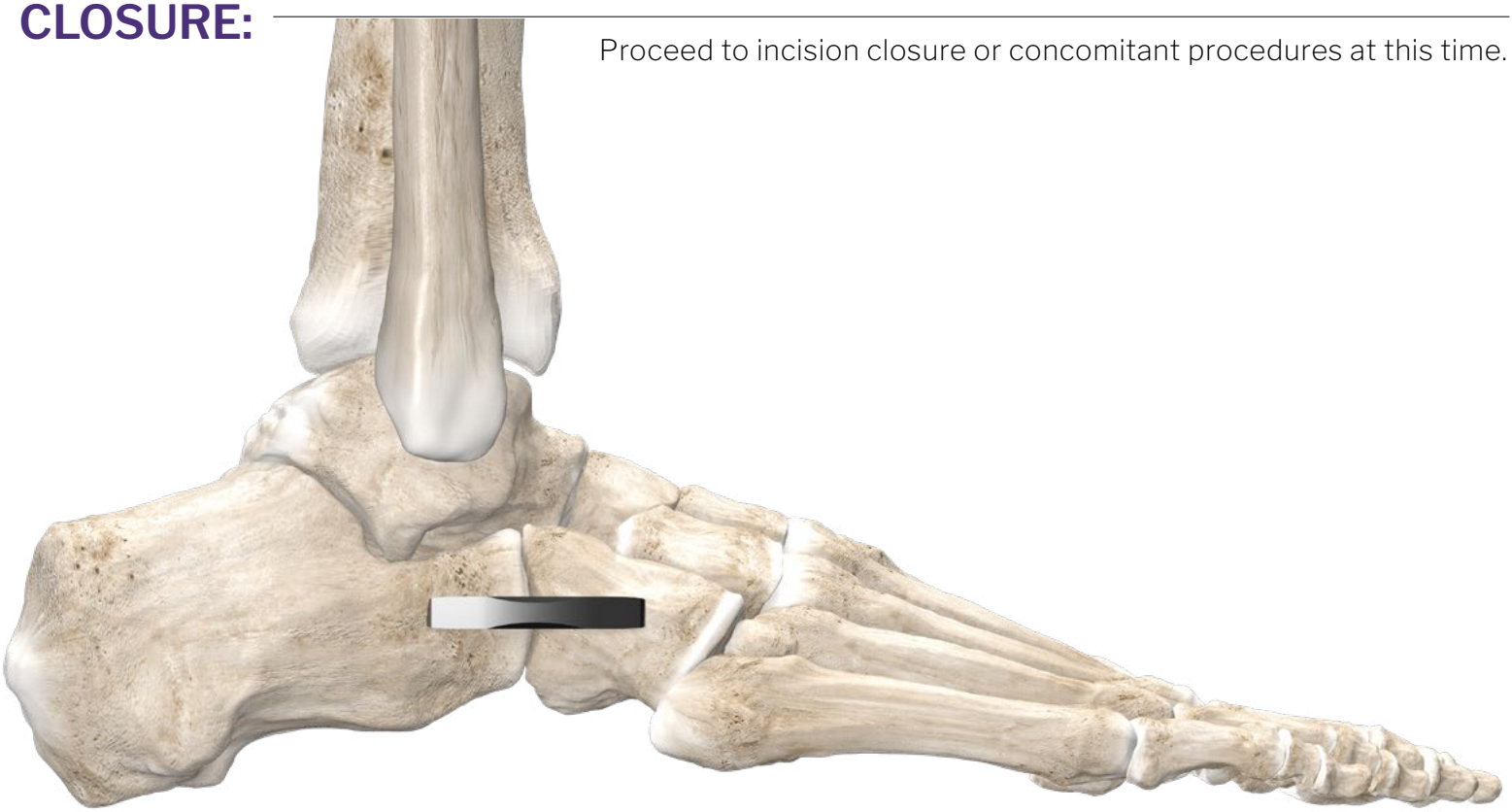
IMPLANT SELECTION AND INSERTION:

If the implant is proud after the inserter has been disengaged, the end of the drill guide can be seated on the bridge of the implant and can be used to help tamp the implant. Place any additional implants according to the previously described steps.



CLOSURE:

Proceed to incision closure or concomitant procedures at this time.



REMOVAL:

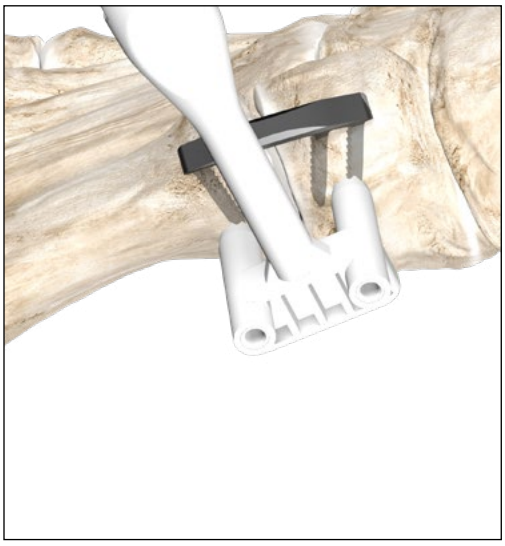
Remove the placed implant by using a thin instrument such as a Hohmann or a Freer Elevator to get under the bridge of the staple and use it to lever the implant out. A rongeur/pliers can also be used to help remove the implant.

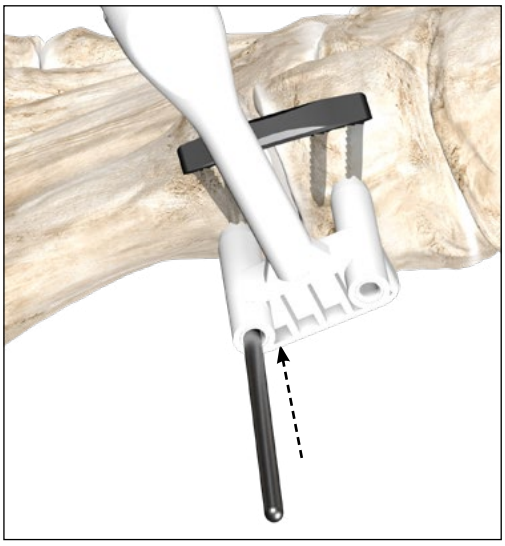
BIPLANAR 1ST TMT FUSION WITH JAWS®/JAWS® GREAT WHITE®

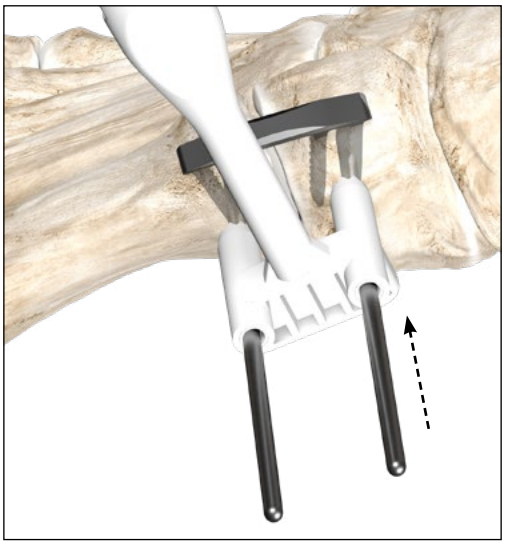
The below illustrates a biplanar 1st TMT fusion construct featuring both a Megalodon™ Dynamic Compression System 30 mm implant and a JAWS® Great White® 20 mm staple.

	MEGALODON™	JAWS®/JAWS® GREAT WHITE®
BRIDGE LENGTH COMPATIBILITY	25/27 MM	18 MM
	27/30 MM	20 MM

After placing the Megalodon™ implant, use the instrumentation provided in the JAWS® Great White® sterile kit to prepare the bone for the implant. Use fluoroscopy when aligning the Great White® Drill Guide to ensure the drill avoids the legs of the Megalodon™ implant.

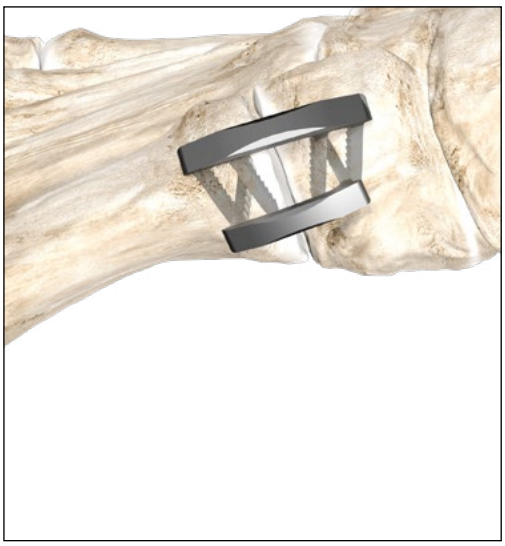






After preparing the site for implantation, seat the Great White® Staple and use fluoroscopy to ensure the staple legs do not interfere with the Megalodon™ implant legs. After confirming proper clearance, deploy the Great White® staple.

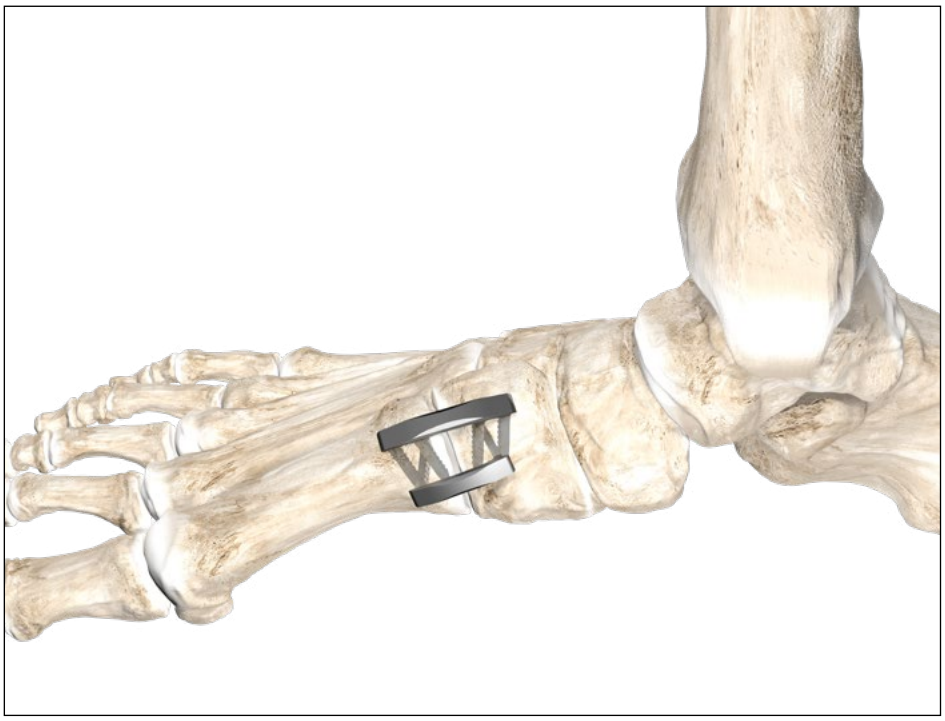




NOTE: *Refer to P72-STG-0001 for additional information about the JAWS® Great White System®*
Refer to P70-STG-0001 for additional information about the the JAWS® Staple System.

CLOSURE:

Proceed to incision closure or concomitant procedures at this time.



REMOVAL:

Remove the placed implants by using a thin instrument such as a Hohmann or a Freer Elevator to get under the bridge of the staple and use it to lever the implants out. A rongeur/pliers can also be used to help remove the implants.

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

Indications, Contraindications, Warnings and Precautions relevant to the Megalodon™ Dynamic Compression system are contained in the Instructions for Use document of the Megalodon™ Dynamic Compression System: P72-IFU-0001

INTENDED USE/INDICATIONS FOR USE:

The Megalodon™ Dynamic Compression System implants are indicated for use in osteotomy, arthrodesis and fragment fixation of bones and joint of the foot including fixation of small bone fragments (i.e., small fragments of bone which are not comminuted to the extent to preclude staple placement) located in the long bones of the lower extremities such as the fibula and tibia.

MR SAFETY INFORMATION:

The Megalodon™ Dynamic Compression System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Megalodon™ Dynamic Compression System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Indications, Contraindications, Warnings and Precautions relevant to the Jaws® Nitinol Staple system are contained in the Instructions for Use document of the JAWS® Nitinol Staple System: P70-IFU-9001

INDICATIONS FOR USE (JAWS®)

The JAWS® Nitinol Staple System implants are indicated for use in osteotomy, arthrodesis and fragment fixation of the bones and joints of the foot including fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement) located in the long bones of the lower extremities such as the fibula and tibia.

MR SAFETY INFORMATION

MR SAFETY INFORMATION

A patient with the Paragon 28® JAWS® Nitinol Staple System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	Paragon 28® JAWS® Nitinol Staple System
Nominal value(s) of Static Magnetic [T/m and gauss/cm]	1.5 T or 3 T
RF Excitation	30 T/m (3000 gauss/cm)
RF Transmit Coil Type	Circularly Polarized (CP)
Maximum Whole Body SAR [W/kg]	Whole body transmit coil, Head RF transmit-receive coil
Limits on Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may product an image artifact of 21 mm.

If information about a specific parameter is not included, there are no conditions associated with that parameter.



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