JAWS®

NITINOL STAPLE SYSTEM

SURGICAL TECHNIQUE GUIDE

Nitinol Staple System

Exclusively foot & ankle

Paragon 28®

Acknowledgment:
Paragon 28® would like to thank Thomas San Giovanni, MD, for his contribution to the development of the surgical technique guide.

PRODUCT DESCRIPTION

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

CONTENTS

PRODUCT OFFERING

- Staple is designed to achieve compression upon insertion
- Barbed legs are designed to help resist migration and back-out during healing
- No plastic deformation required to achieve compression
- Low-profile contour and bowed bridge intended to distribute even compression

8 mm
Straight Staple

8 mm
Angled Staple

10 mm
Straight Staple

10 mm
Angled Staple

12 mm
Straight Staple

15 mm
Straight Staple

18 mm
Straight Staple

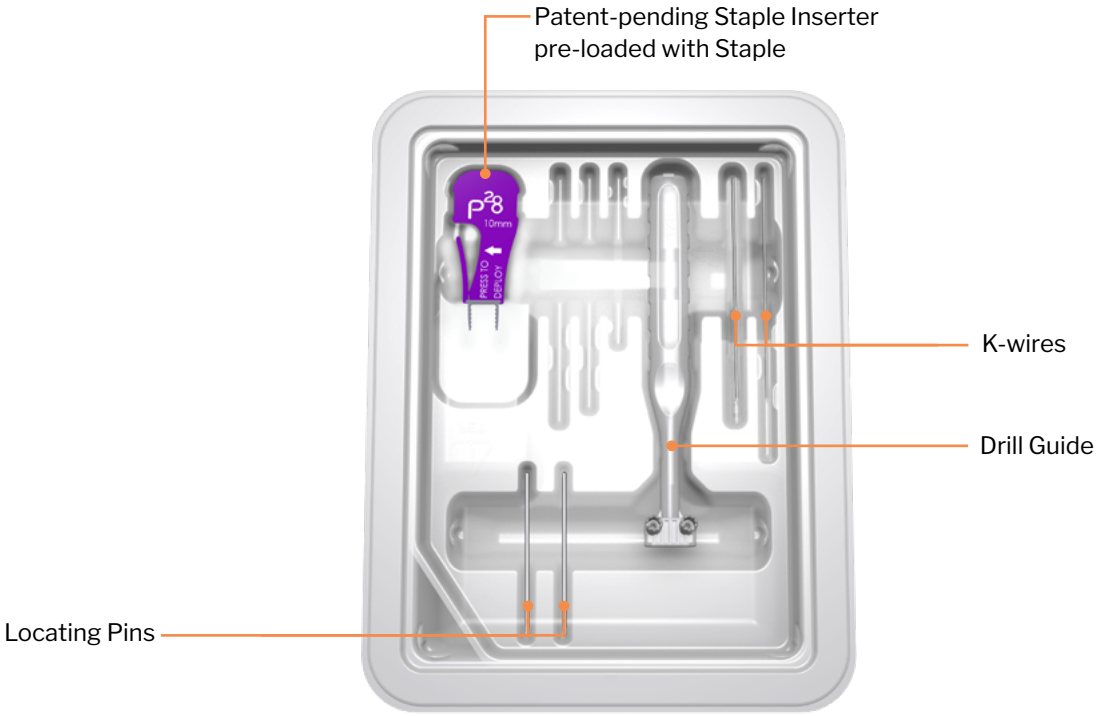
20 mm
Straight Staple

25 mm
Straight Staple

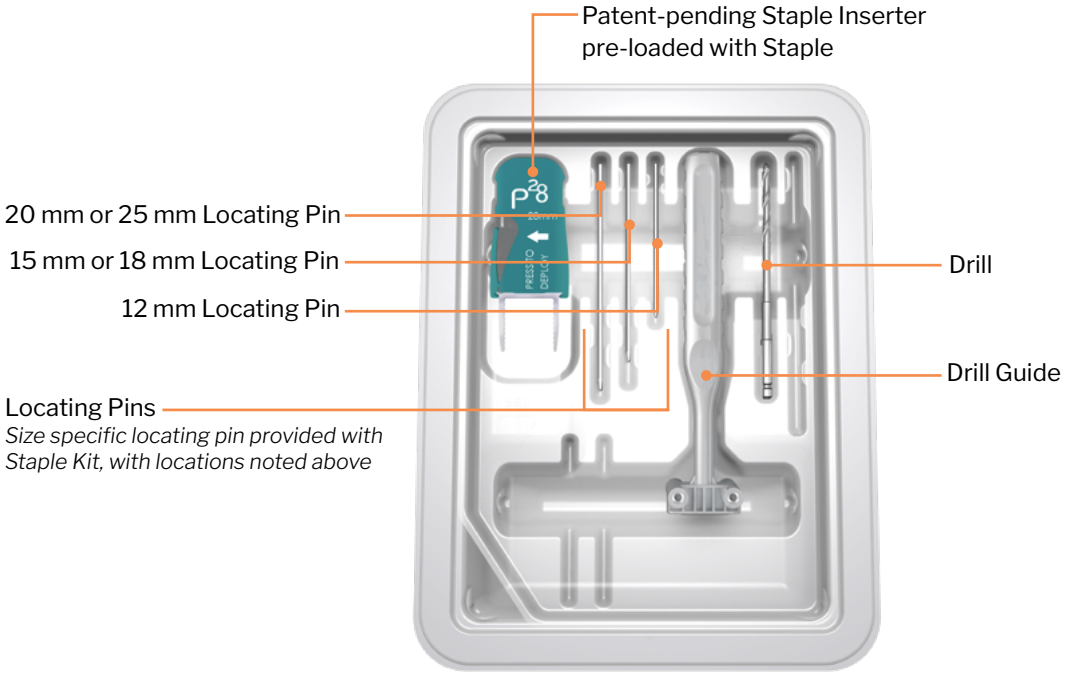
STERILE PACKED INSTRUMENTIATION

Instrumentation for JAWS™ Nitinol Staple insertion is provided in a disposable, sterile kit, configured slightly differently based on staple size.

8 mm or 10 mm Staple Kit



12 mm, 15 mm, 18 mm, 20 mm or 25 mm Staple Kit



NON-STERILE INSTRUMENTATION

Non-Sterile instrumentation is not required for JAWS™ Staple insertion, but is available to assist in the surgical procedure, if needed.

8 mm and 10 mm Trial Sizer

15 mm and 18 mm Trial Sizer

20 mm and 25 mm Trial Sizer

Osteotome, 6 mm Straight

Osteotome, 12 mm Straight

Osteotome, 19 mm Straight

Osteotome, 6 mm Curved

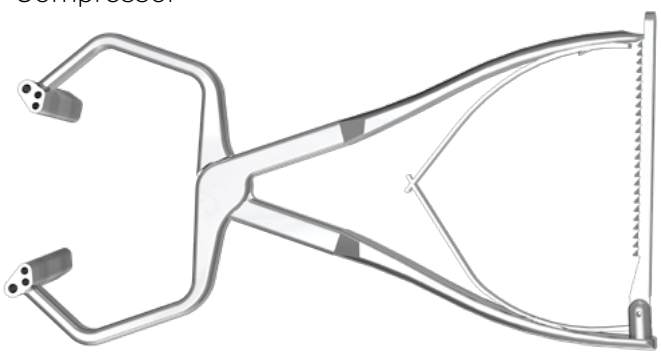
Osteotome, 12 mm Curved

Osteotome, 19 mm Curved

1.6 x 150 mm K-wire

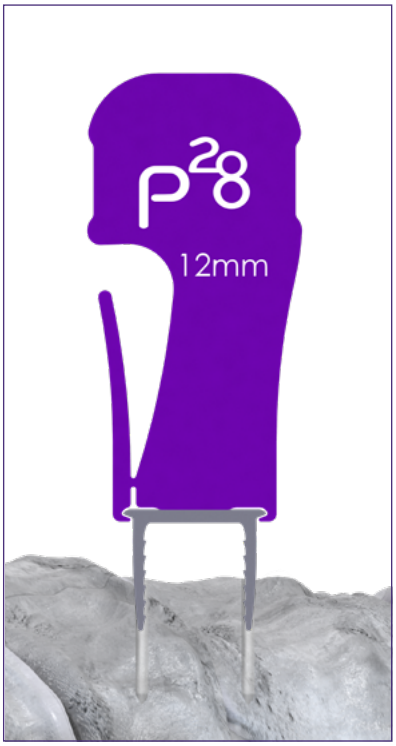
2.0 x 200 mm K-wire

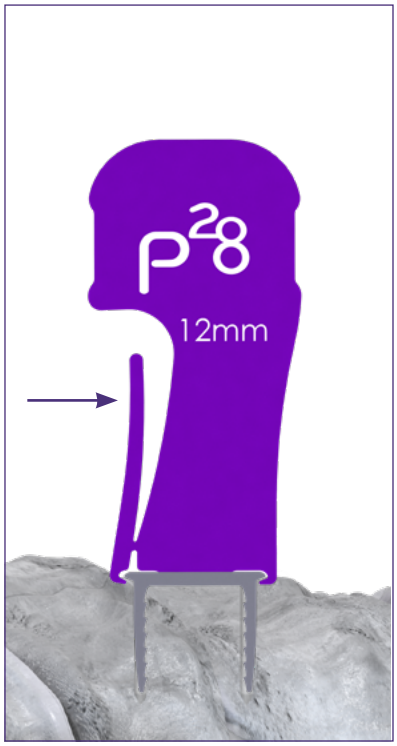
Compressor

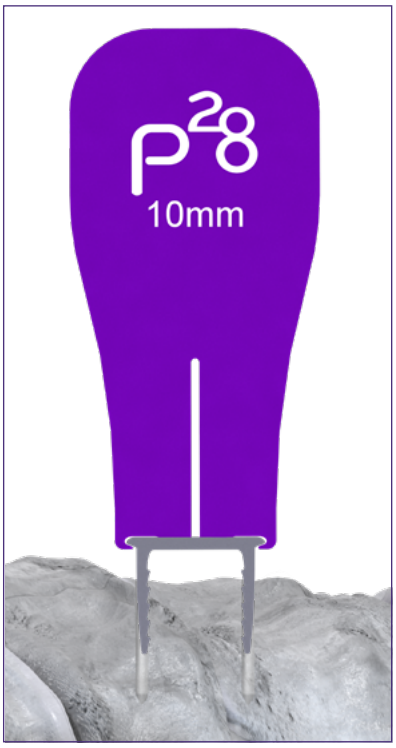


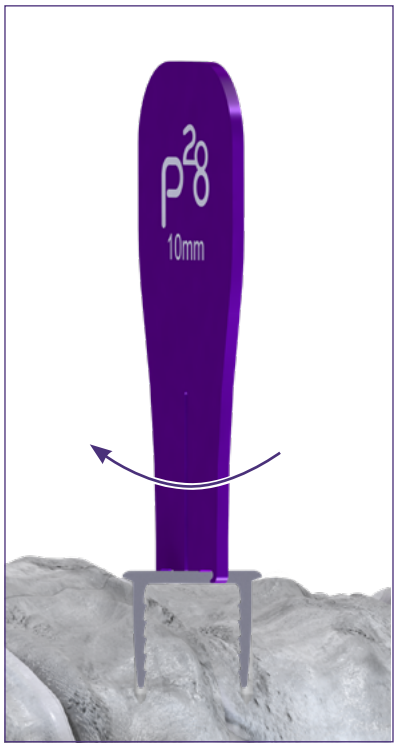
INSERTER OPTIONS

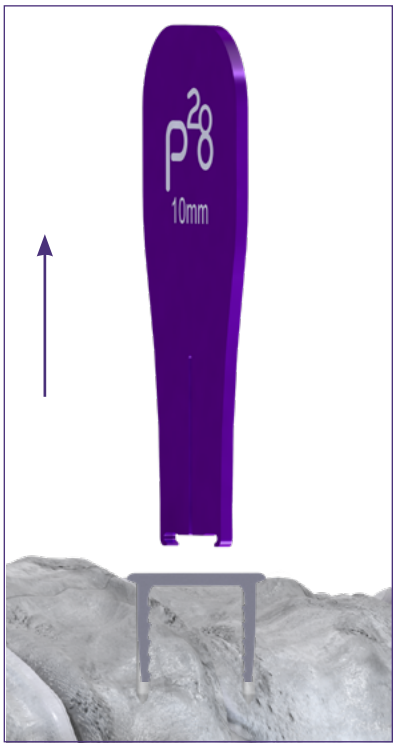
Two variations of inserters will be available depending on the distribution location. After inserting the staple in bone, the methods of JAWS™ Staple deployment are illustrated below:







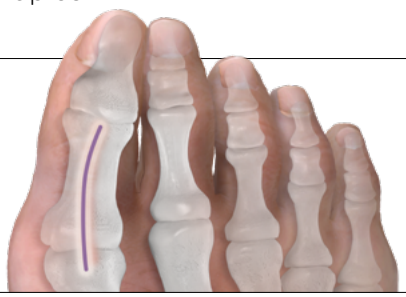




NOTE: This inserter is only available in select markets outside of the U.S..

The surgical technique shown below is for placement of a JAWS™ 8 mm x 8 mm 15° Angled Staple in an Akin Osteotomy procedure. This technique is applicable to all 8 mm and 10 mm JAWS™ Staples.

INCISION/EXPOSURE



An Akin procedure may be combined with additional procedures for correction of hallux valgus. Patient positioning in a supine position is recommended. A dorsomedial or medial incision can be performed according to surgeon preference. Dissection is carried down to expose the proximal phalanx

OSTEOTOMY

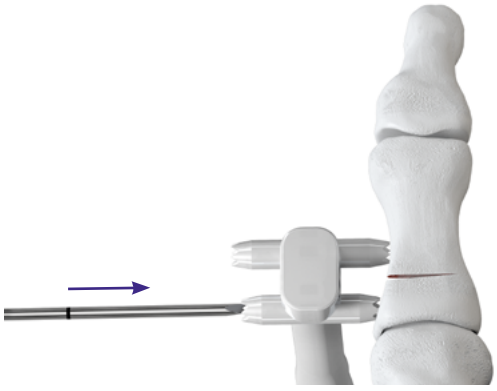
A proximal Akin osteotomy is demonstrated in this technique. A sagittal saw is used to create a medial closing wedge osteotomy of the proximal phalanx.

IMPLANT SELECTION AND INSERTION

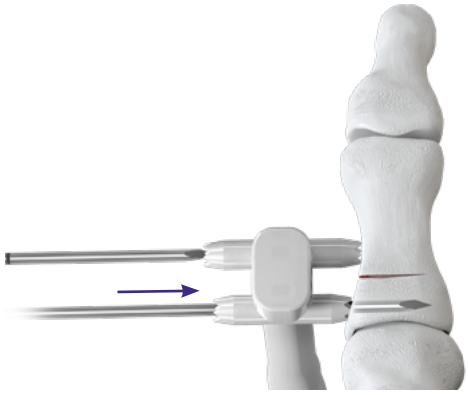
Select the preferred implant size and type. In this example, an 8 mm Angled Staple is shown. Open the implant kit by having a non-sterile member of the operating room team open the peel pack and present the sterile package to a sterile member of the operating room team.

Place the K-wire guide across the osteotomy site such that the short side of the guide is on the proximal flare of the proximal phalanx and both prongs make contact with bone.

NOTE: The K-wire guide is universal and can be rotated 180° for use on a left foot.



Once optimal position is achieved, place a K-wire through the proximal hole of the K-wire guide until the laser mark is no longer visible at the top of the guide.



Close the osteotomy and place a second K-wire through the distal hole of the K-wire guide until the laser mark is no longer visible at the top of the guide.

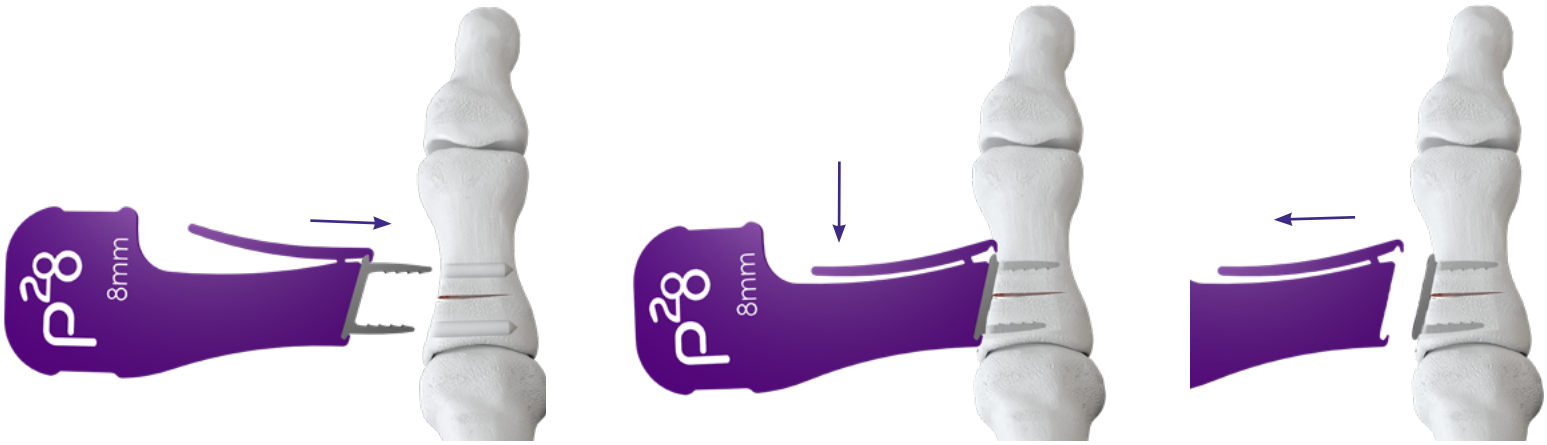
NOTE: If using a Straight Staple, the K-wires should be inserted until the laser mark is buried on both sides.

Remove the K-wire guide and K-wires. It is suggested to maintain correction of the osteotomy manually after removal of the K-wires.

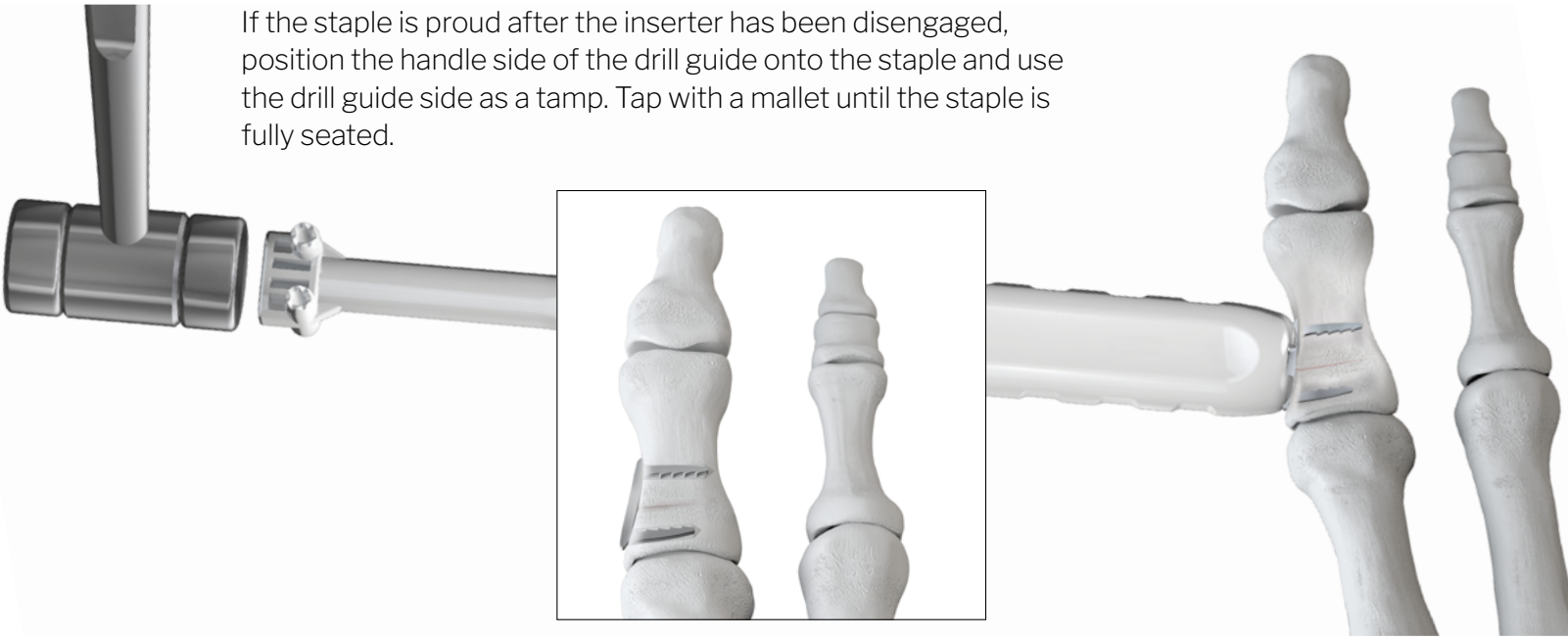
TIP: A locating pin can be used to locate the drilled holes prior to staple insertion.

IMPLANT SELECTION AND INSERTION

Retrieve the 8 mm Angled Staple and inserter from sterile pack. Position the staple over the pre-drilled holes and insert once aligned.



If the staple is proud after the inserter has been disengaged, position the handle side of the drill guide onto the staple and use the drill guide side as a tamp. Tap with a mallet until the staple is fully seated.



CLOSURE

Proceed to incision closure, additional staple placement or concomitant procedures at this time.

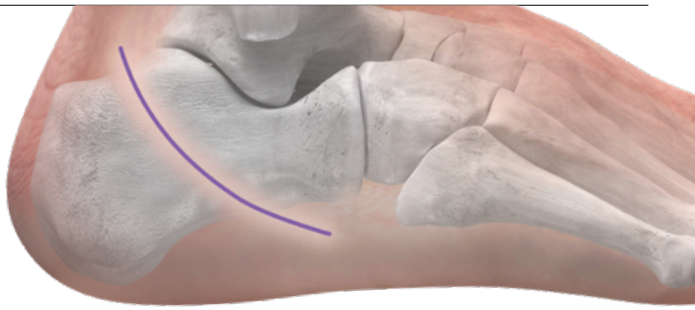
REMOVAL

If removal of staple is required, use a plate cutter instrument to cut the bridge of the staple in half. Each arm of the staple can be pulled out using a hemostat or similar instrument. Confirm removal of staple using fluoroscopy.

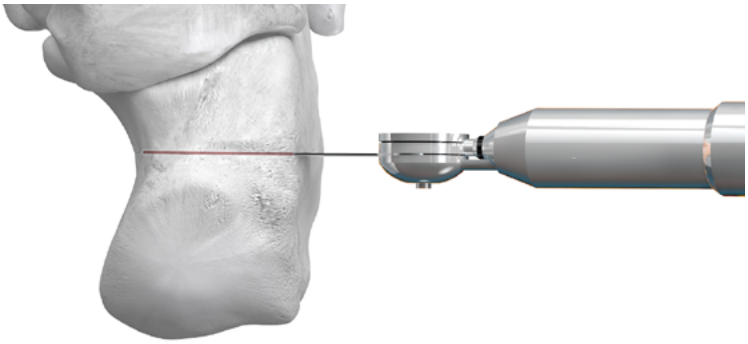
The surgical technique shown below is for placement of a JAWS™ 20 mm x 20 mm Straight Staple in a Dwyer calcaneal osteotomy procedure. These steps for JAWS™ Staple placement are applicable to 12 mm, 15 mm, 18 mm, 20 mm and 25 mm JAWS™ Staples.

INCISION/EXPOSURE

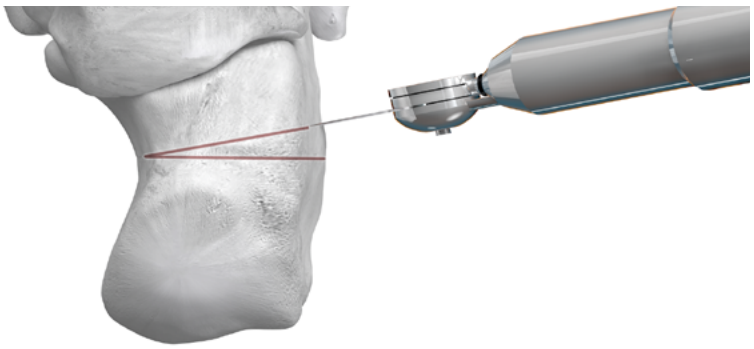
Patient is positioned in a lateral decubitus, prone or supine position, based on surgeon preference. An incision is made approximately 2 cm posterior to the tip of the fibula and carried obliquely toward the plantar aspect of the calcaneocuboid joint. Identify and protect the sural nerve and peroneal tendon sheath. Continue soft tissue dissection to the lateral wall of the calcaneus.



OSTEOTOMY

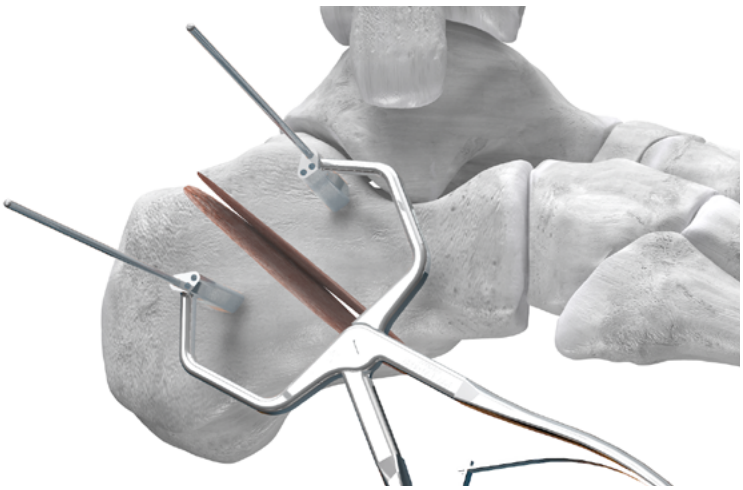


A sagittal saw is used to create a long oblique osteotomy posterior to the posterior facet of the subtalar joint and spanning distally to approximately 1 cm posterior to the calcaneocuboid joint. Leave the medial cortex of the calcaneus intact, if possible.

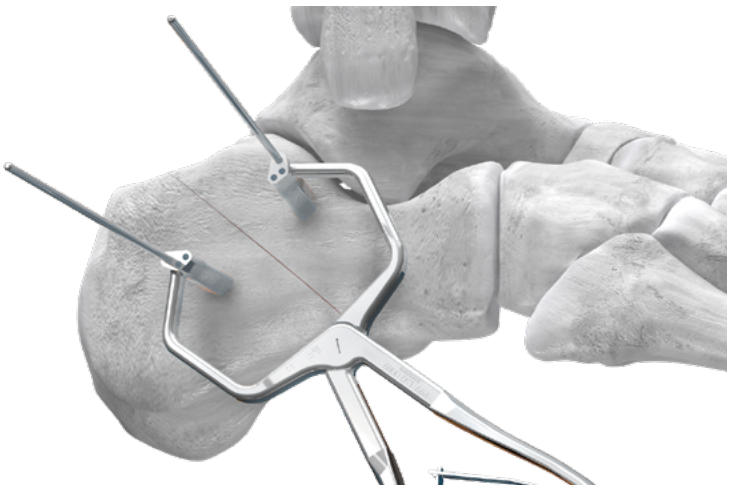


Create a second cut to form a lateral wedge from the lateral aspect of the calcaneus. The size of the wedge will depend upon the severity of deformity. The fragments are manipulated until the medial cortex is mobile enough to achieve closure of the osteotomy. If adequate correction is not achieved, additional bone resection may be required.

TEMPORARY FIXATION



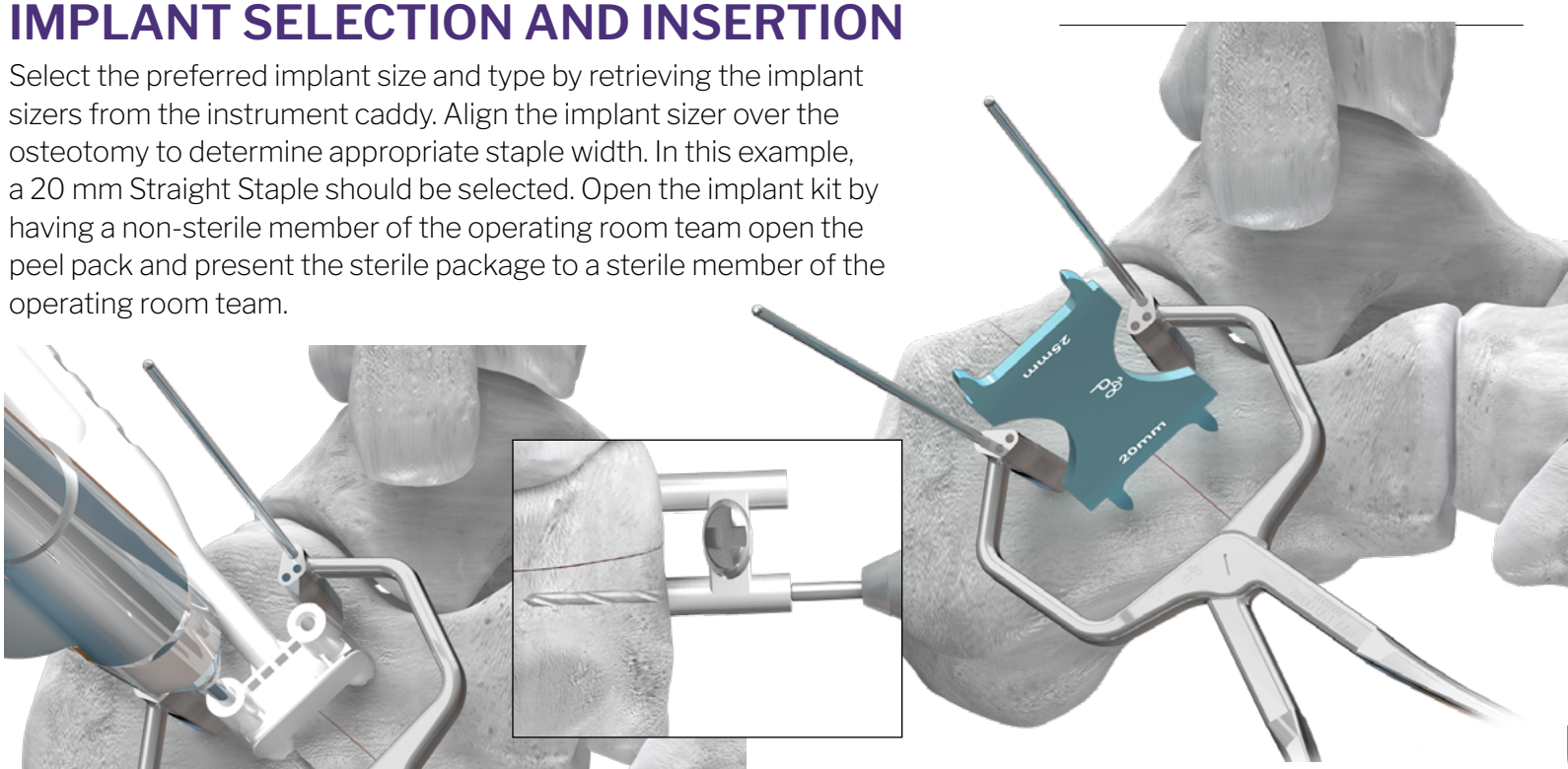
The compressor can be used to compress and provide temporary fixation of the osteotomy. Retrieve the compressor from the instrument caddy. Secure the compressor centrally on either side of the osteotomy using two K-wires.



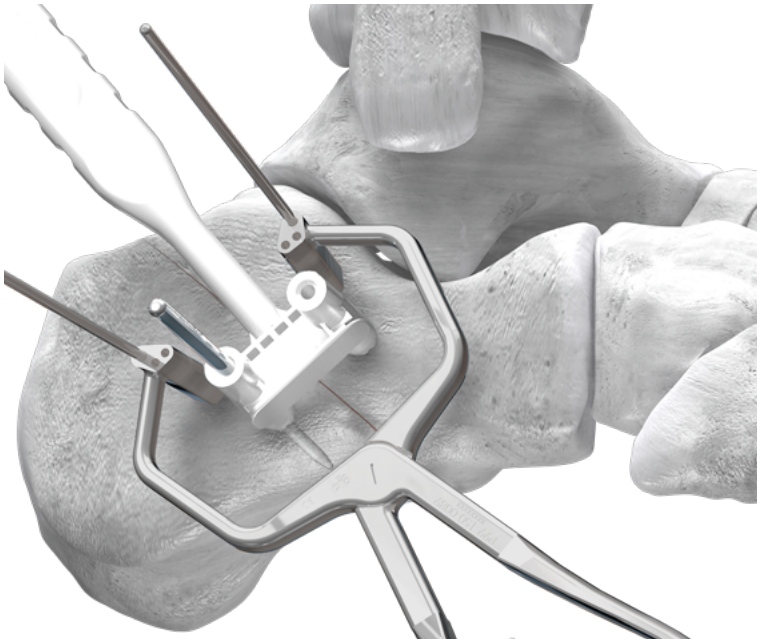
The smaller, inside holes accept up to 1.6 mm K-wires and the larger, outer holes accept up to 2.0 mm K-wires. Compress until bone apposition of the osteotomy site is achieved. Confirm reduction of deformity using fluoroscopy, if desired.

IMPLANT SELECTION AND INSERTION

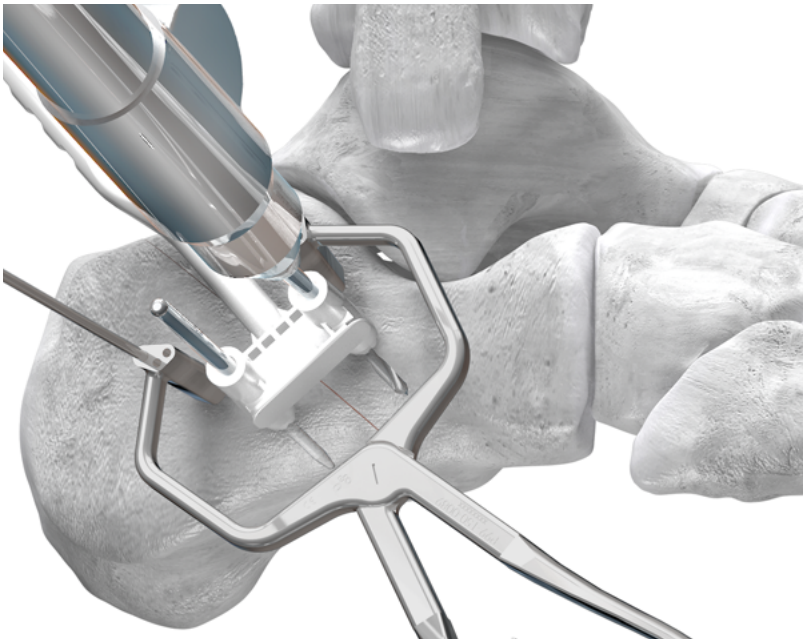
Select the preferred implant size and type by retrieving the implant sizers from the instrument caddy. Align the implant sizer over the osteotomy to determine appropriate staple width. In this example, a 20 mm Straight Staple should be selected. Open the implant kit by having a non-sterile member of the operating room team open the peel pack and present the sterile package to a sterile member of the operating room team.



Retrieve the drill guide and drill from the sterile package. Place the drill guide across the osteotomy site such that both prongs make contact with bone. Drill through one of the drill guide holes using the provided drill, allowing the drill to penetrate bone until the drill stop contacts the bone. This will ensure adequate depth for the staple leg to be inserted into bone.

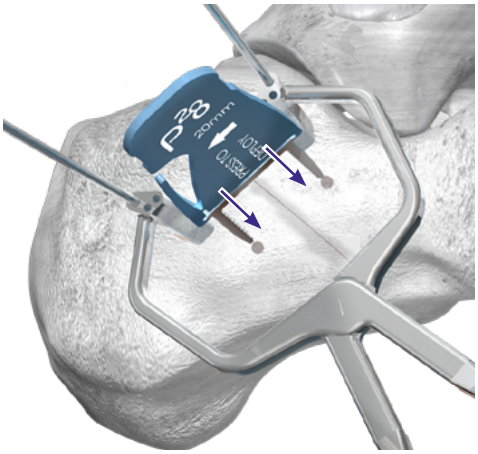


Place the provided locating pin into the drilled hole to secure the position of the drill guide across the osteotomy and allow for appropriate spacing.

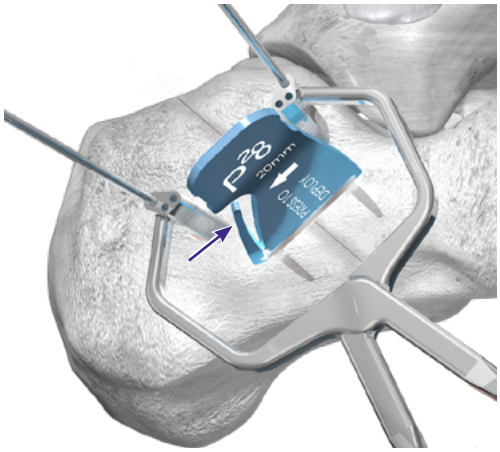


Drill a second hole through the other hole in the drill guide. Remove the locating pin and drill guide.

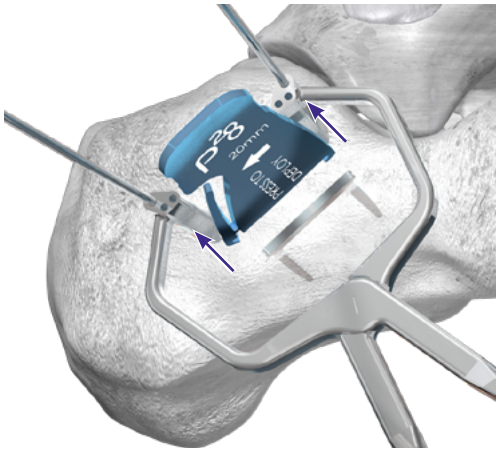
IMPLANT SELECTION AND INSERTION



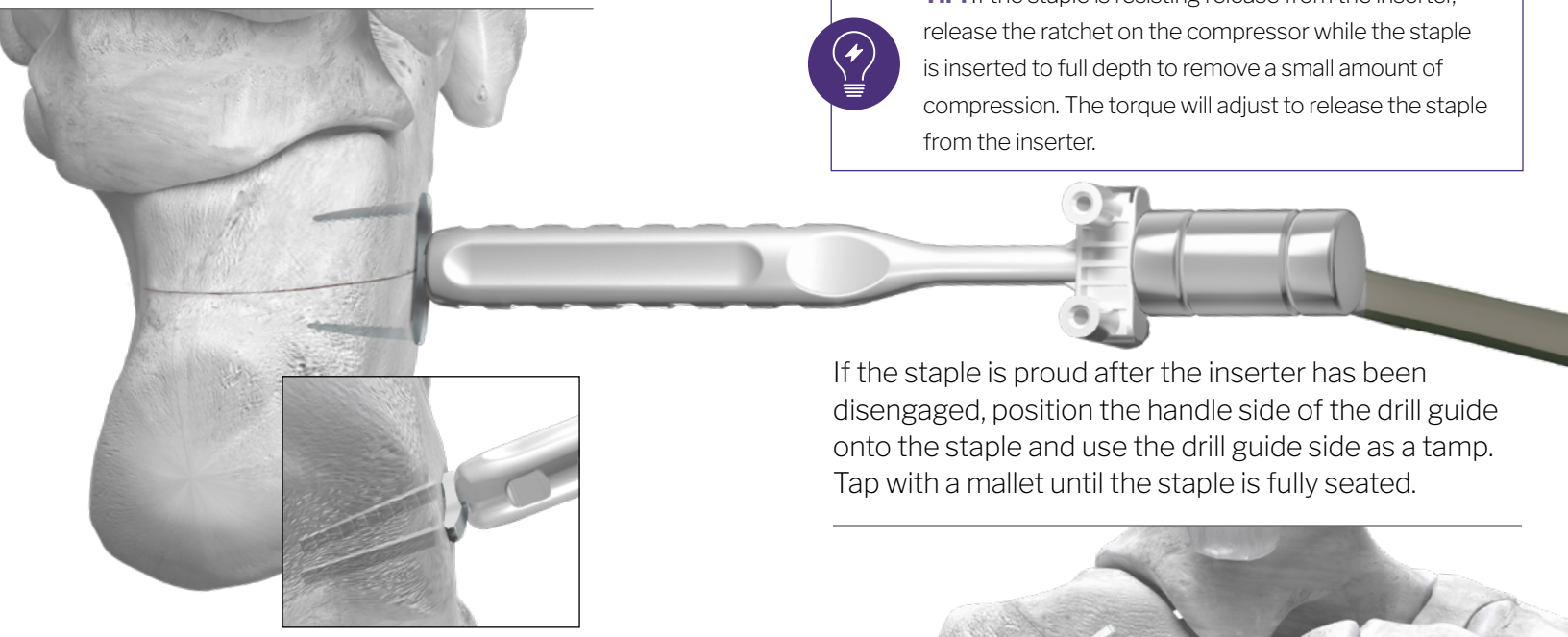
Retrieve the 20 mm Straight Staple and inserter from sterile pack. Position the staple over the pre-drilled holes and insert once aligned.



Once insertion into pre-drilled holes is complete, disengage the inserter from the staple in the manner shown on page 6, depending on the inserter in the package.

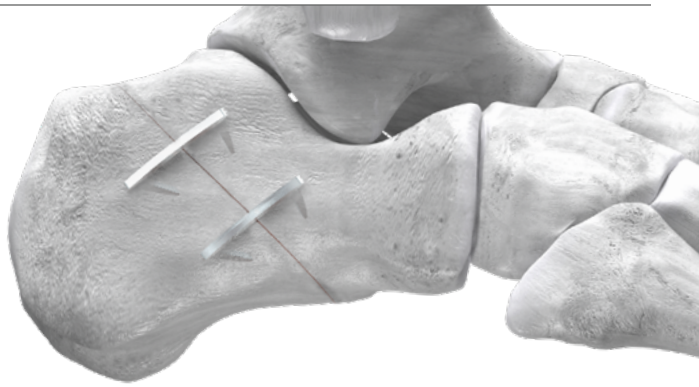


TIP: If the staple is resisting release from the inserter, release the ratchet on the compressor while the staple is inserted to full depth to remove a small amount of compression. The torque will adjust to release the staple from the inserter.



If the staple is proud after the inserter has been disengaged, position the handle side of the drill guide onto the staple and use the drill guide side as a tamp. Tap with a mallet until the staple is fully seated.

Insert a second 20 mm Straight Staple adjacent to the initial staple, if desired, using the steps just described. Remove the compressor from osteotomy site. Confirm staple size and placement using fluoroscopy.



CLOSURE

Proceed to incision closure or concomitant procedures at this time.

REMOVAL

If removal of the staple is required, use a plate cutter instrument to cut the bridge of the staple in half. Each arm of the staple can be pulled out using a hemostat or similar instrument. Confirm removal of staple using fluoroscopy.

INSTRUCTIONS FOR USE: JAWS™ NITINOL STAPLE SYSTEM

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-0001.

MR (MAGNETIC RESONANCE) SAFTEY INFORMATION

Non-clinical testing has demonstrated the JAWS Nitinol Staple System implants are MR conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3 T or 1.5 T
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, non-clinical testing results indicate the implant is expected to produce a maximum temperature rise of 3.18°C after 15 minutes of continuous scanning.

In non-clinical testing, the maximum image artifact caused by the device extends approximately 19.28 mm from the implant when imaged with a gradient echo pulse sequence and a 3 T MR system.

NOTES

JAWS®

NITINOL STAPLE SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

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DISCLAIMER

The purpose of the JAWS™ Nitinol Staple System Surgical Technique Guide is to demonstrate the use of the JAWS™ Nitinol Staple System. Although various methods can be employed for this procedure, the fixation options demonstrated were chosen for simplicity of explanation and demonstration of the unique features of our device. Federal law (U.S.A.) restricts this device to sale and use by, or on order of, a physician.