SURGICAL TECHNIQUE GUIDE:

JAWS™ NITINOL STAPLE SYSTEM

JAWS™

NITINOL STAPLE SYSTEM

Exclusively foot & ankle

Paragon 28®

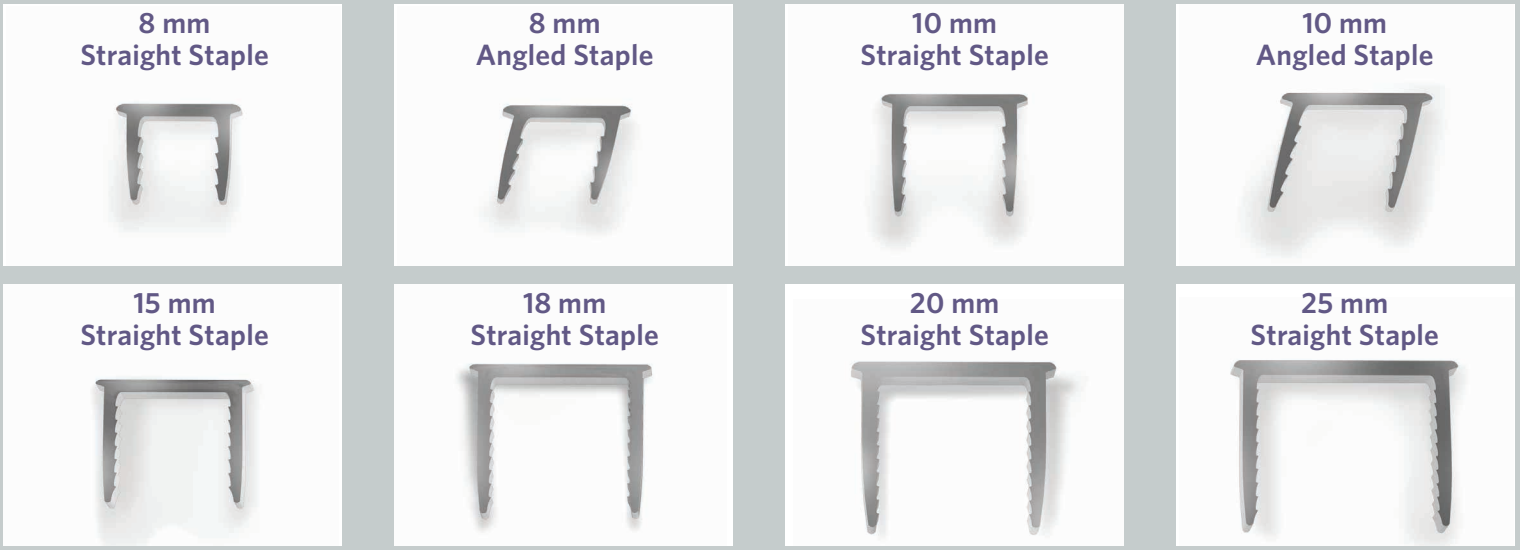
PRODUCT DESCRIPTION

The JAWS™ Nitinol Staple System provides a high strength, superelastic Nitinol staple that is designed to provide continuous, active compression for bone fixation.

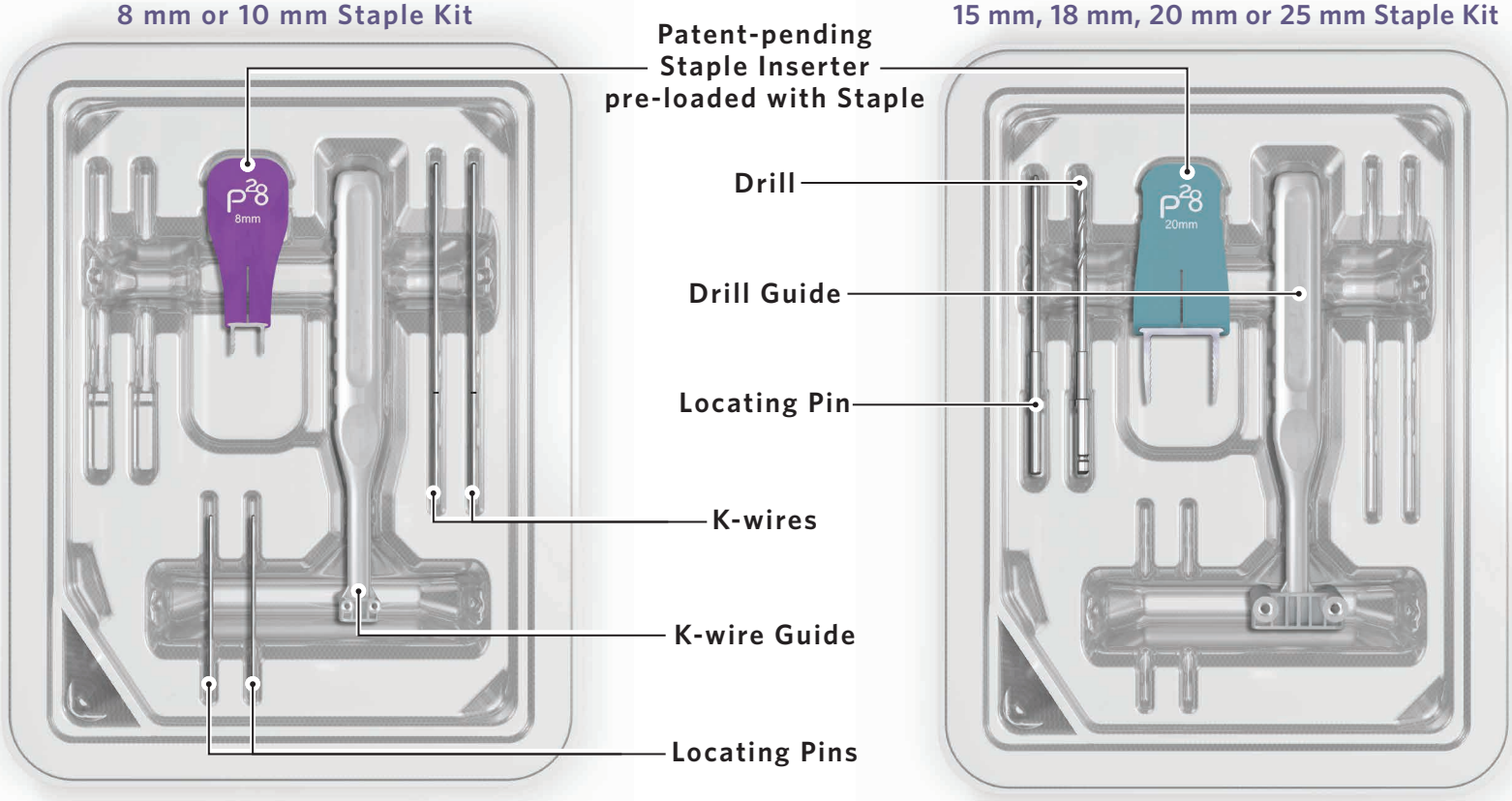
PRODUCT OFFERING

JAWS™ Nitinol Staple Features:

- 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

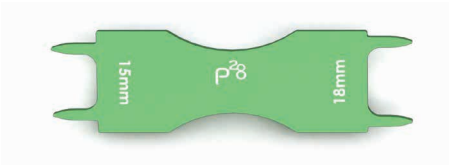


STERILE-PACKED INSTRUMENTATION

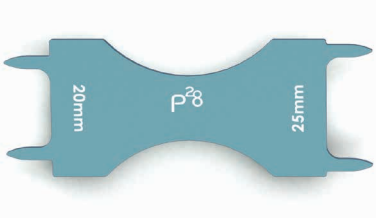


NON-STERILE INSTRUMENTATION

8 mm and 10 mm Trial Sizer



15 mm and 18 mm Trial Sizer



20 mm and 25 mm Trial Sizer

Osteotome, 6mm Straight

Osteotome, 12 mm Straight

Osteotome 19 mm Straight

Osteotome, 6 mm Curved

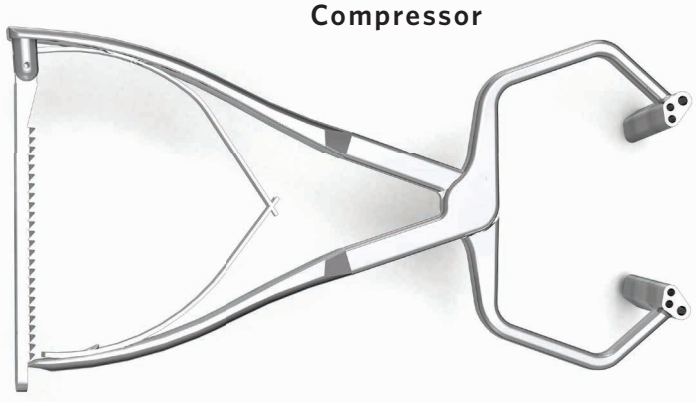
Osteotome, 12 mm Curved

Osteotome, 19 mm Curved

1.6 x 150 mm K-wire

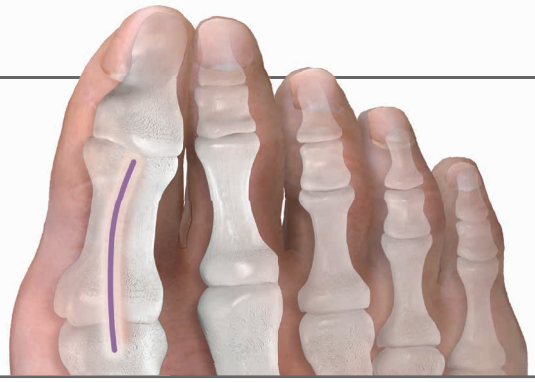
2.0 x 200 mm K-wire

Compressor



SURGICAL TECHNIQUE GUIDE:
AKIN OSTEOTOMY USING THE JAWS NITINOL STAPLE SYSTEM

The surgical technique shown below is for placement of a JAWS 10 mm x 10 mm 15° 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

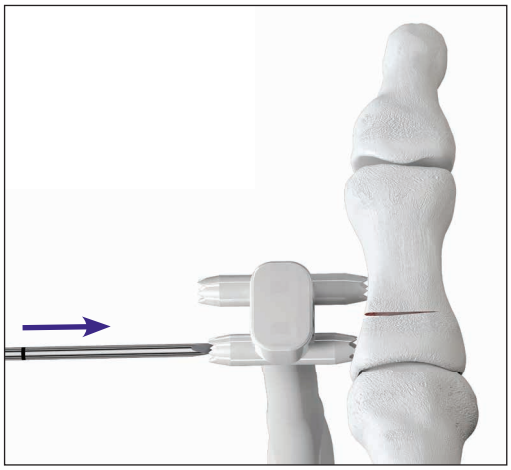
A proximal Akin osteotomy is demonstrated in this technique. A sagittal saw is used to create a medial closing wedge osteotomy of the proximal phalanx.

IMPLANT SELECTION AND INSERTION

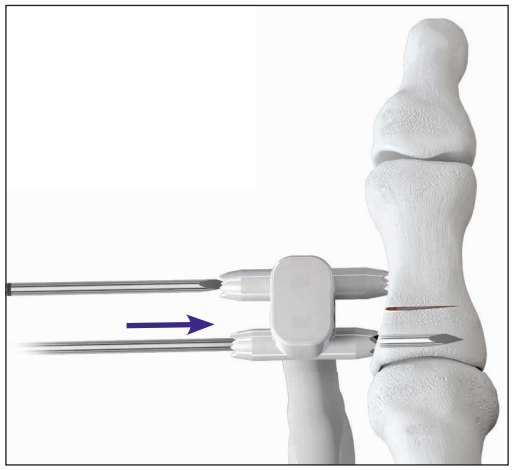
Select the preferred implant size and type. In this example, a 10 mm Angled Staple is shown. Open the implant kit by having a non-sterile member of the operating room team open the peel pack and present the sterile package to a sterile member of the operating room team.

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.

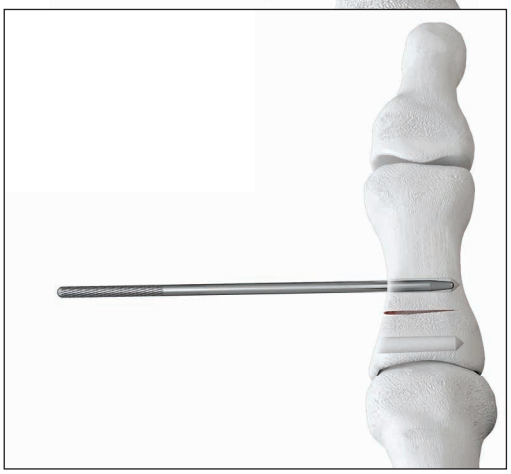


Once optimal position is achieved, place a K-wire through the proximal hole of the K-wire guide until the laser mark is no longer visible at the top of the guide.



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.

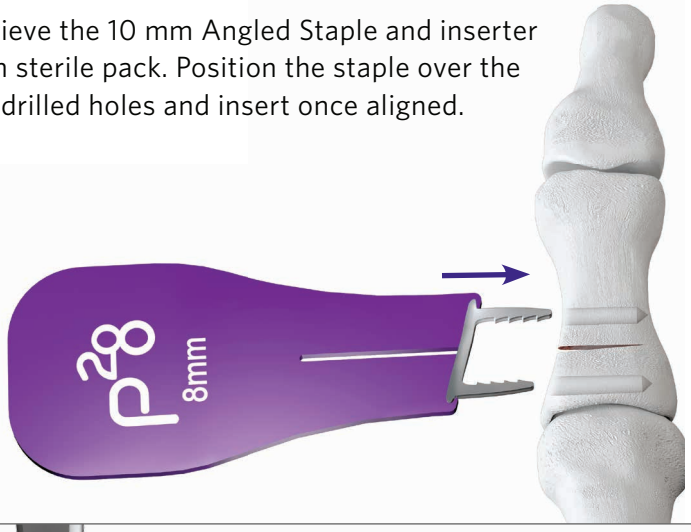


Remove the K-wire guide and K-wires. It is suggested to maintain correction of the osteotomy manually after removal of the K-wires.

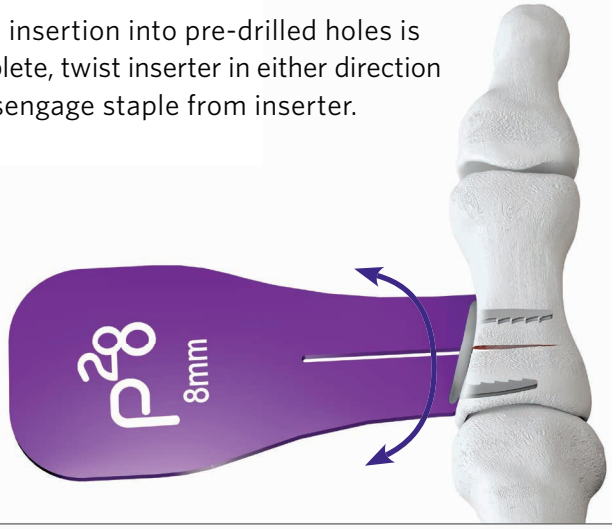
TIP: A locating pin can be used to locate the drilled holes prior to staple insertion.

IMPLANT SELECTION AND INSERTION

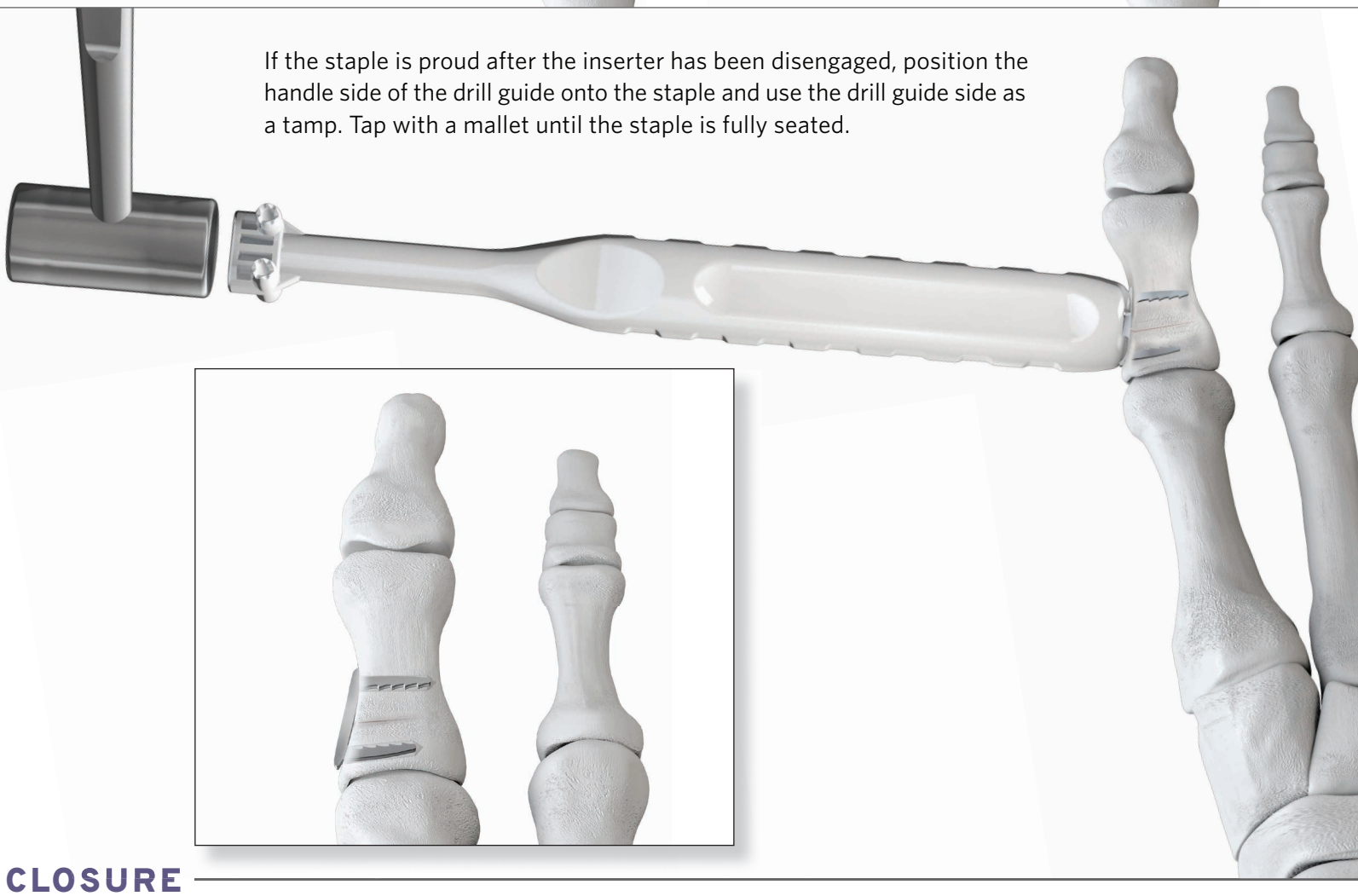
Retrieve the 10 mm Angled Staple and inserter from sterile pack. Position the staple over the pre-drilled holes and insert once aligned.



Once insertion into pre-drilled holes is complete, twist inserter in either direction to disengage staple from 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.



CLOSURE

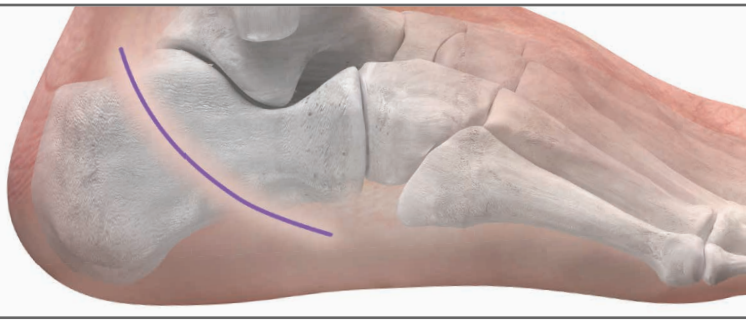
Proceed to incision closure, additional staple placement or concomitant procedures at this time.

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. This technique is applicable to 15 mm, 18 mm, 20 mm and 25 mm JAWS staples.

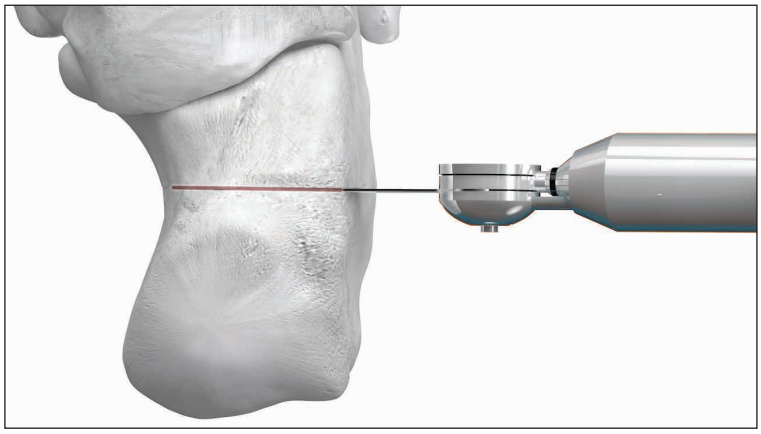
INCISION/EXPOSURE



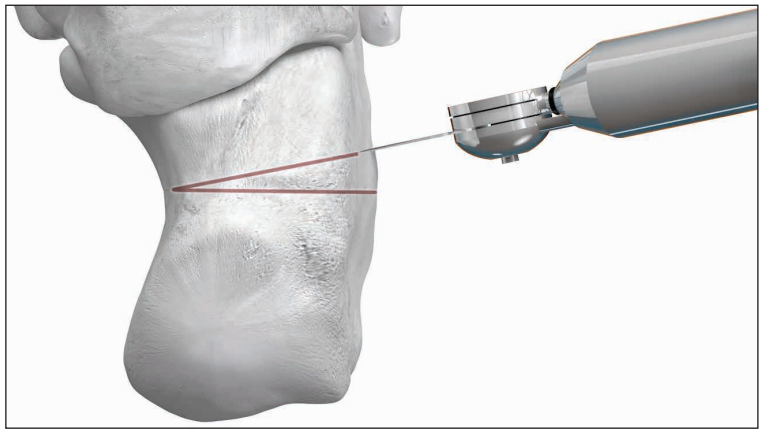
Patient is positioned in a lateral decubitus, prone or supine position, based on surgeon preference. An incision is made approximately 2 cm posterior to the tip of the fibula and carried obliquely toward the plantar aspect of the calcaneocuboid joint.

Identify and protect the sural nerve and peroneal tendon sheath. Continue soft tissue dissection to the lateral wall of the calcaneus.

OSTEOTOMY

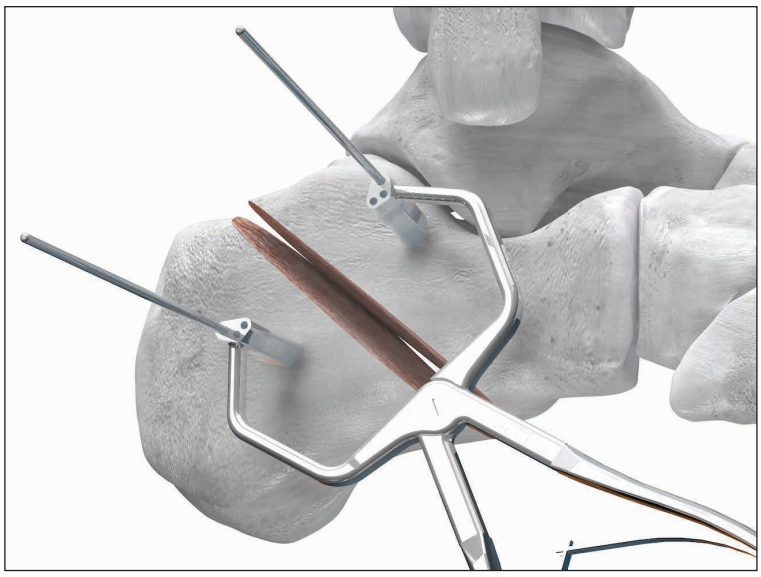


A sagittal saw is used to create a long oblique osteotomy posterior to the posterior facet of the subtalar joint and spanning distally to approximately 1 cm posterior to the calcaneocuboid joint. Leave the medial cortex of the calcaneus intact, if possible.

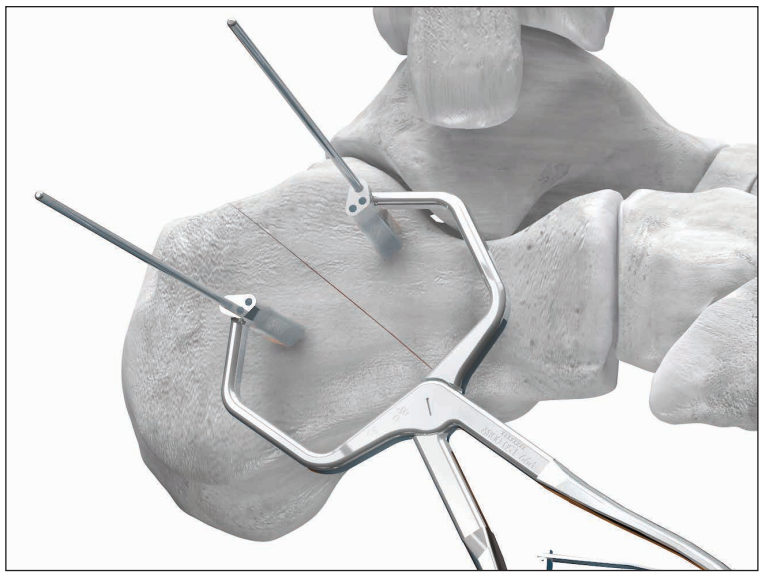


Create a second cut to form a lateral wedge from the lateral aspect of the calcaneus. The size of the wedge will depend upon the severity of deformity. The fragments are manipulated until the medial cortex is mobile enough to achieve closure of the osteotomy. If adequate correction is not achieved, additional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

TEMPORARY FIXATION



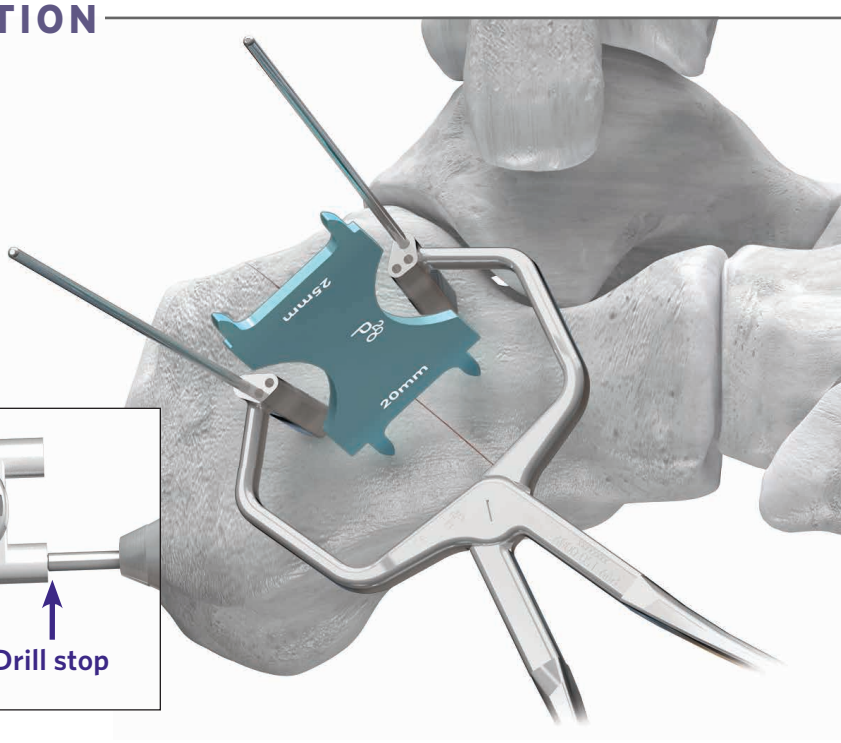
The compressor can be used to compress and provide temporary fixation of the osteotomy. Retrieve the compressor from the instrument caddy. Secure the compressor centrally on either side of the osteotomy using two K-wires.

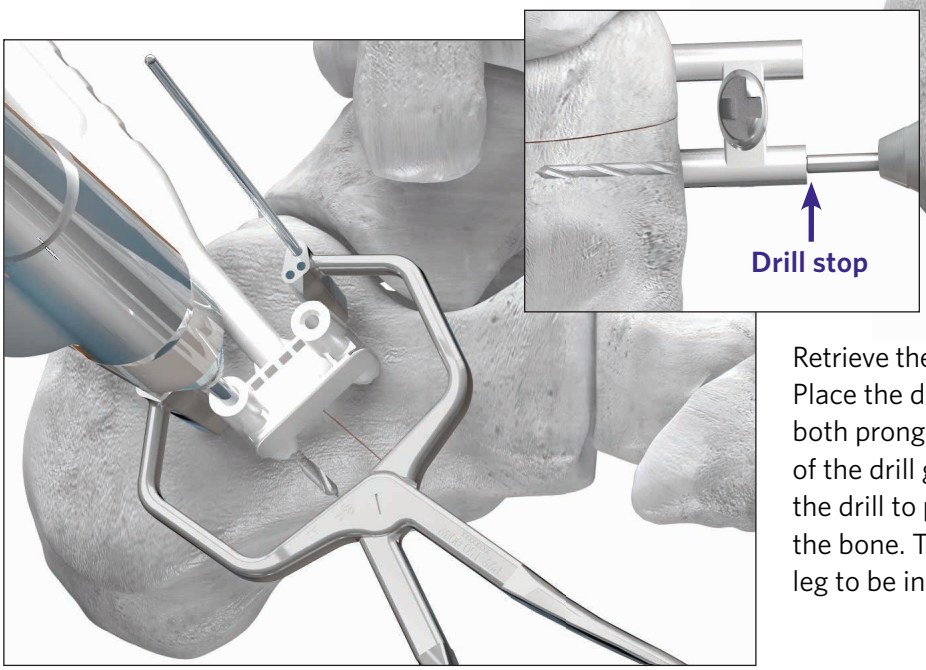


The smaller, inside holes accept up to 1.6 mm K-wires and the larger, outer holes accept up to 2.0 mm K-wires. Compress until bone apposition of the osteotomy site is achieved. Confirm reduction of deformity using fluoroscopy, if desired.

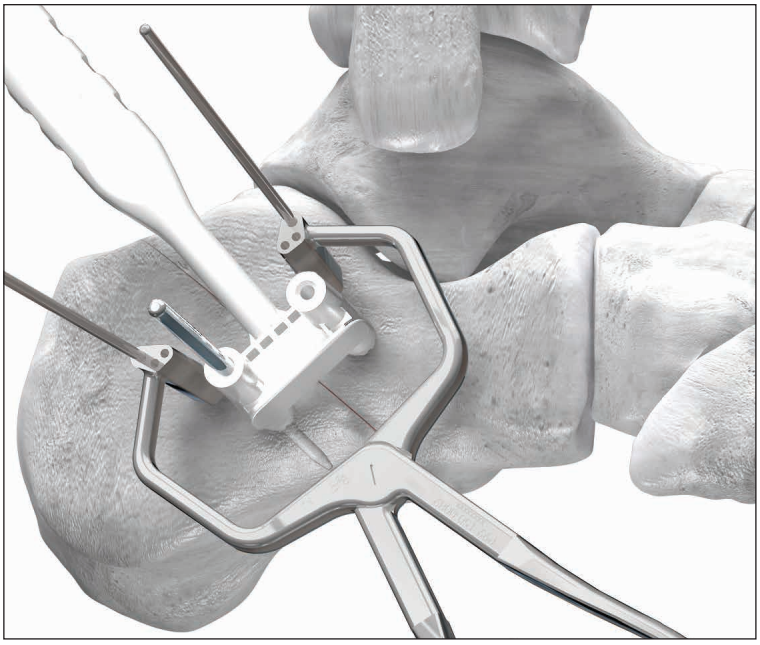
IMPLANT SELECTION AND INSERTION

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 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.

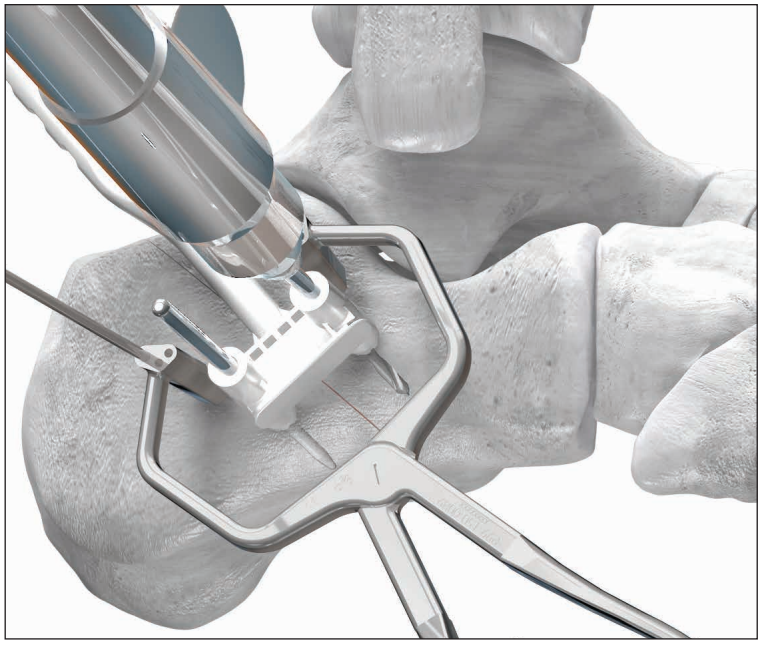




Retrieve the drill guide and drill from the sterile package. Place the drill guide across the osteotomy site such that both prongs make contact with bone. Drill through one of the drill guide holes using the provided drill, allowing the drill to penetrate bone until the drill stop contacts the bone.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

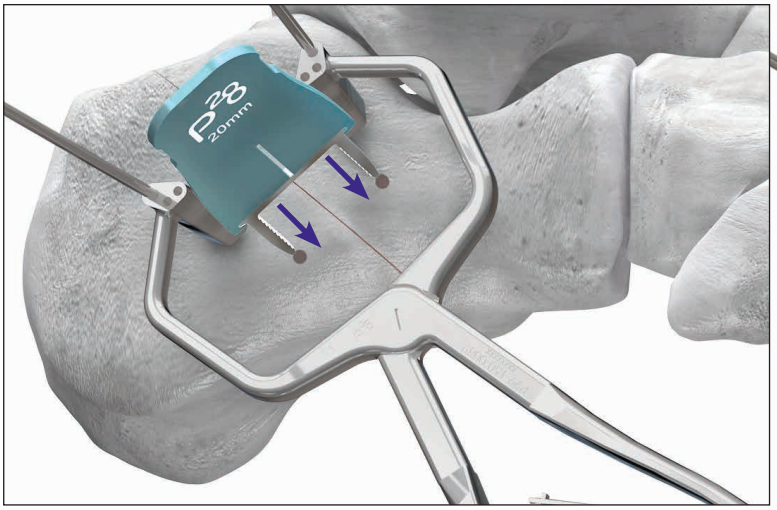


Place the provided locating pin into the drilled hole to secure the position of the drill guide across the osteotomy and allow for appropriate spacing.

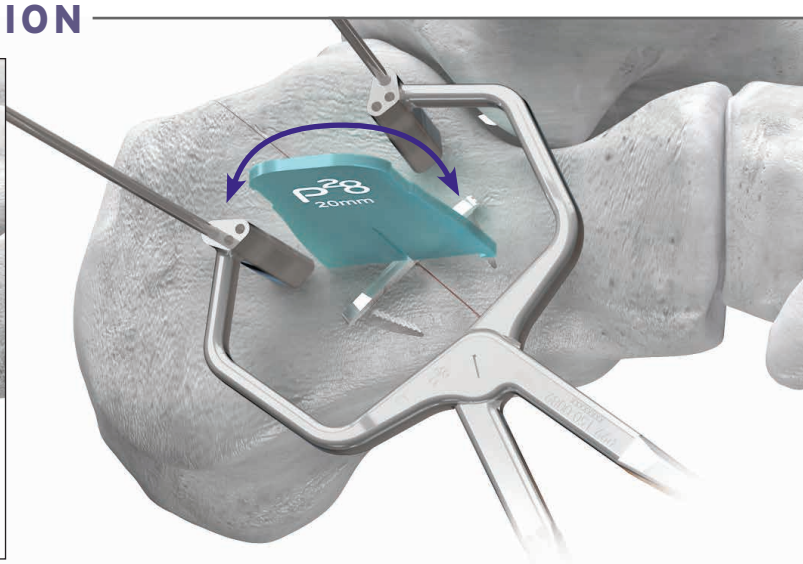


Drill a second hole through the other hole in the drill guide. Remove the locating pin and drill guide.

IMPLANT SELECTION AND INSERTION

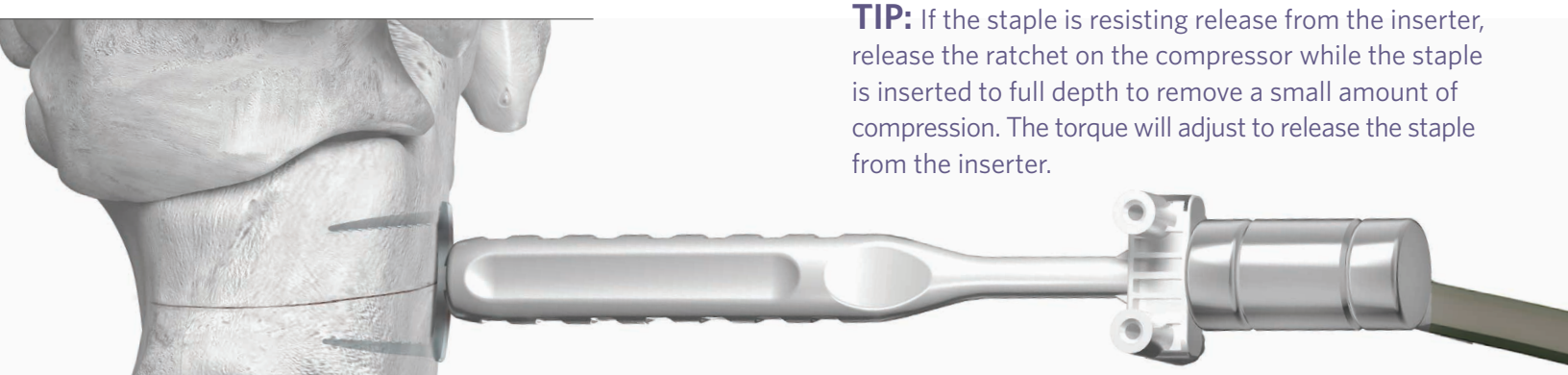


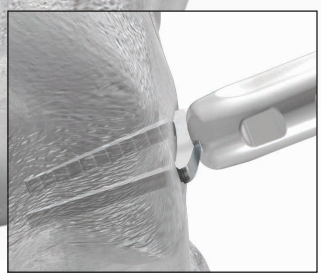
Retrieve the 20 mm staple and inserter from sterile pack. Position the staple over the pre-drilled holes and insert once aligned.



Once insertion into pre-drilled holes is complete, twist the inserter in either direction to disengage staple.

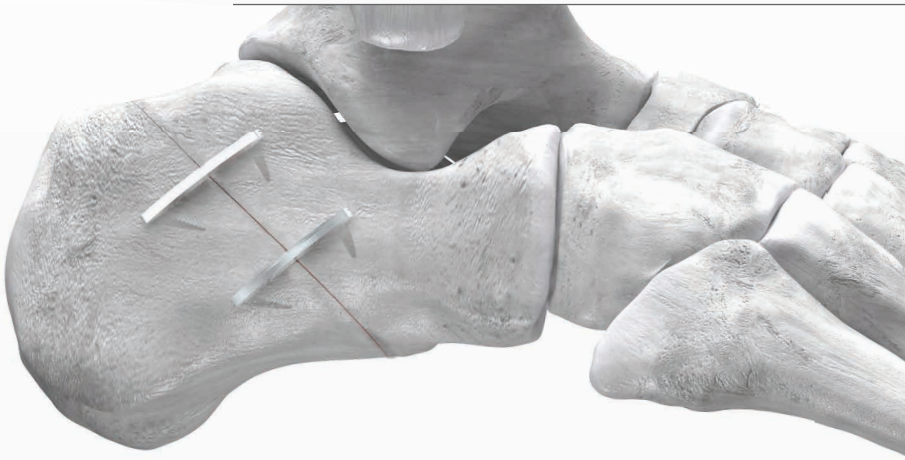
TIP: If the staple is resisting release from the inserter, release the ratchet on the compressor while the staple is inserted to full depth to remove a small amount of compression. The torque will adjust to release the staple from the inserter.





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 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.

INDICATIONS FOR USE

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.

CONTRAINDICATIONS

Use of the JAWS™ Nitinol Staple System is contraindicated in the following instances:

- Active or suspected infection or osteomyelitis
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- Poor bone quality, i.e. osteoporotic bone that is susceptible to fracture
- Known or suspected sensitivity to metal or foreign bodies
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Physical conditions that may hinder the healing process
- Conditions that limit the patient's ability or willingness to follow postoperative instructions
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exist. These do not include all adverse effects which can occur with surgery, but are important considerations particular to metallic internal stabilization devices.

- Infection
- Loosening, deformation, migration or fracture of the implant
- Fractures resulting from unilateral joint loading
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

Complications and adverse effects listed here are not typical of Paragon 28® Inc. products but are in principle observed with any implant. Promptly inform Paragon 28® as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28® with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28® cannot accept any other returns of used implants.

WARNINGS AND PRECAUTIONS

- For safe and effective use of the JAWS™ Nitinol Staple System, the surgeon should be familiar with the procedure and devices and must exercise reasonable judgment in use of the device. Improper selection, placement or positioning may result in reduced lifetime of the implant(s).
- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Do not resterilize the JAWS™ Nitinol Staple System implants or instruments. The implants and instruments are intended for single use only.
- Instruments are to be treated as sharps.
- Do not use other manufacturer's instruments or implants in conjunction with the JAWS™ Nitinol Staple System. Failure to use the provided, unique JAWS™ Nitinol Staple System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the implants, instruments and packaging prior to use to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.

MR SAFETY 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.

JAWS™

NITINOL STAPLE SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle

Paragon 28®

www.PARAGON28.com

P70-STG-0001 RevD
™Trademarks and ®Registered Marks of Paragon 28®, Inc.
© Copyright 2020 Paragon 28®, Inc. All rights reserved.
Patents: www.paragon28.com/index.php/patents

Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112
(855) 786-2828

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.