JAWS™
GREAT WHITE STAPLE SYSTEM

SURGICAL TECHNIQUE GUIDE

JAWS™ Great White™ Staple System

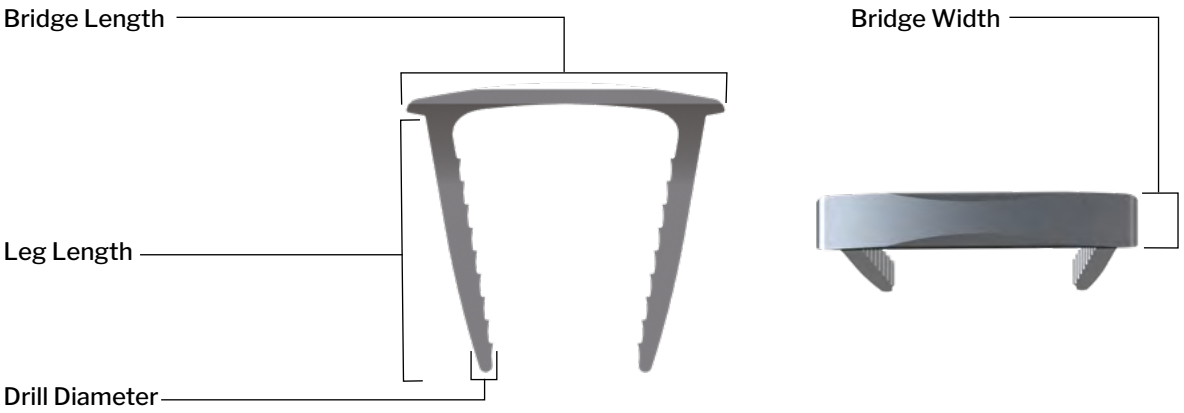
Exclusively foot & ankle
Paragon 28®

PRODUCT DESCRIPTION

The JAWS™ Great White™ Staple 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 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 Great White Staple to be completely seated before it is released from the inserter, allowing final placement of the staple before the staple compresses the osteotomy site.

CONTENTS

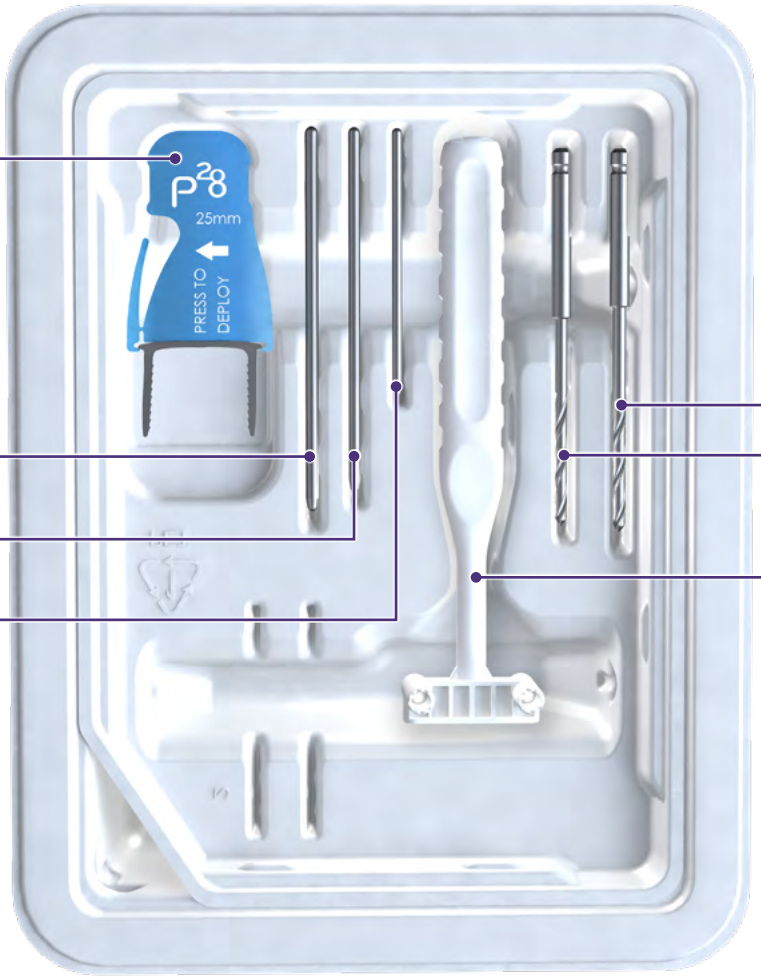
IMPLANT OFFERINGS



Staple Size	Bridge Length	Leg Length	Drill Diameter	Potential Use
12 mm 	12 mm	12 mm	2.3 mm	• Akin Osteotomy • Scarf Osteotomy • MPJ Fusion
15 mm 	15 mm	15 mm	2.7 mm	• MPJ Fusion • TMT Fusion • Navicular Cuneiform Fusion • Lisfranc Arthrodesis
18 mm 	18 mm	18 mm	2.7 mm	• TMT Fusion • Lisfranc Arthrodesis • Navicular Cuneiform Arthrodesis • Lapidus Arthrodesis
20 mm 	20 mm	20 mm	3.0 mm	• Calcaneocuboid Fusion • Talonavicular Fusion • Calcaneal Osteotomy
25 mm 	25 mm	20 mm	3.0 mm	• Calcaneocuboid Fusion • Talonavicular Fusion • Subtalar Arthrodesis

STERILE PACKED INSTRUMENTATION

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



Patent-pending Staple Inserter pre-loaded with Staple

Locating Pins
Size specific locating pin provided with Staple Kit, with locations noted below

20 mm or 25 mm Locating Pins

15 mm or 18 mm Locating Pins

12 mm Locating Pins

Drills
Size specific drills provided with Staple Kit, with locations noted below

Ø3.0 mm Drill

Ø2.7 mm Drill

Drill Guide

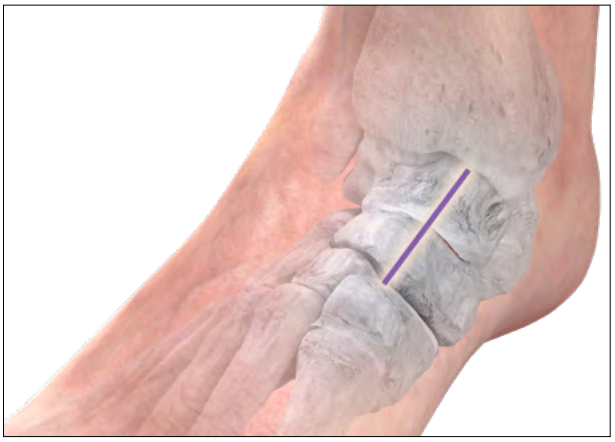
STAPLE INSERTER USE

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

The surgical technique shown below is for placement of a JAWS™ Great White™ Staple 20 mm x 20 mm for a talonavicular fusion procedure. This technique is applicable to all 12, 15, 18, 20, and 25 mm JAWS Great White Staples.

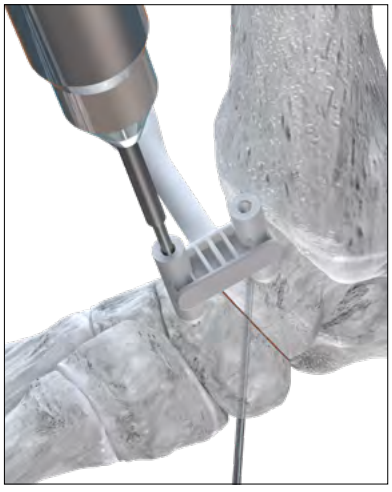
INCISION/EXPOSURE

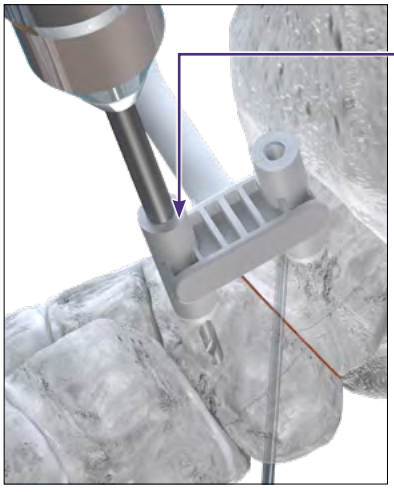
A medial, dorsal, or dorsomedial (shown) incision may be performed over the joint according to surgeon preference. Dissection is carried down to expose the joint, taking care to preserve nearby tendons and neurovascular bundles. Prepare the talonavicular joint for arthrodesis and position according to surgeon preference.



Provisionally fix the talonavicular joint while preparing placement of the implants.

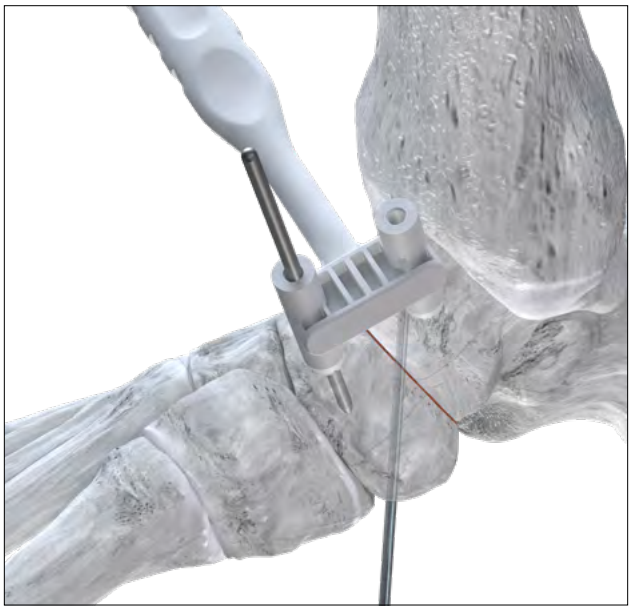
IMPLANT SELECTION AND INSERTION



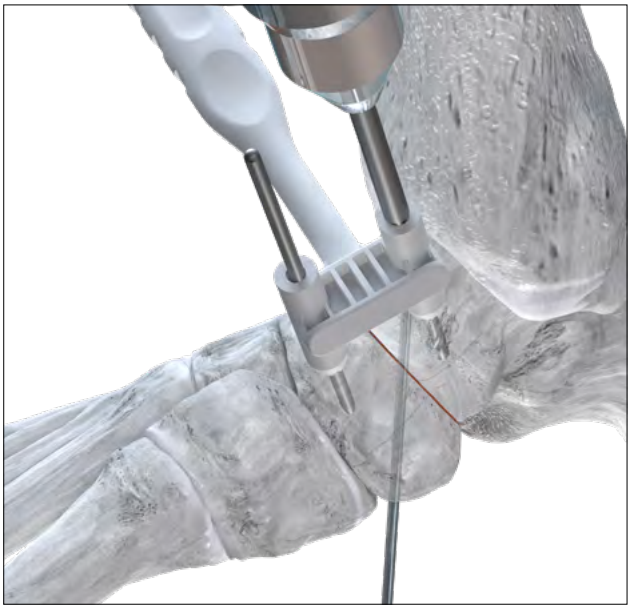


Place the drill guide for the appropriate staple size across the fusion site such that both prongs make contact with the bone. Drill through one side using the appropriate provided drill. Continue drilling until the drill stop contacts the guide.

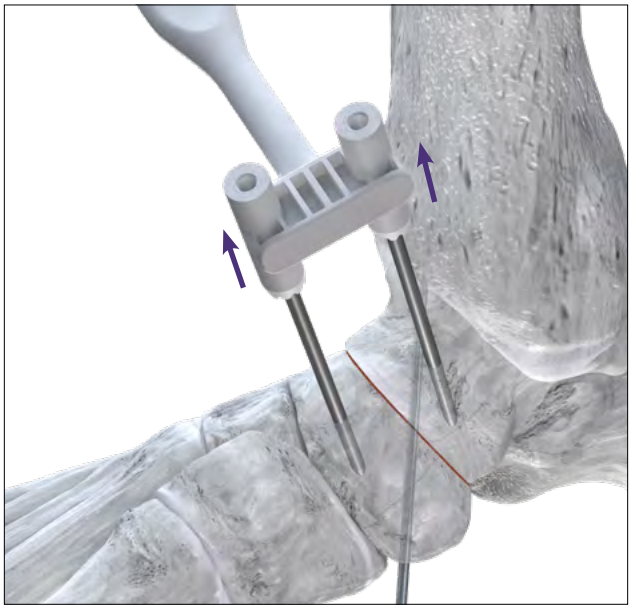
IMPLANT SELECTION AND INSERTION



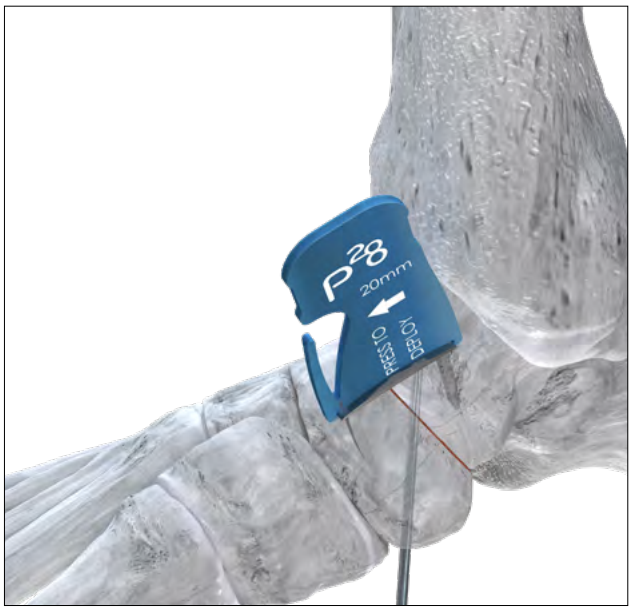
Place the provided locating pin into the drilled hole to secure the position of the drill guide across the joint.



Drill a second hole through the other side of the drill guide.

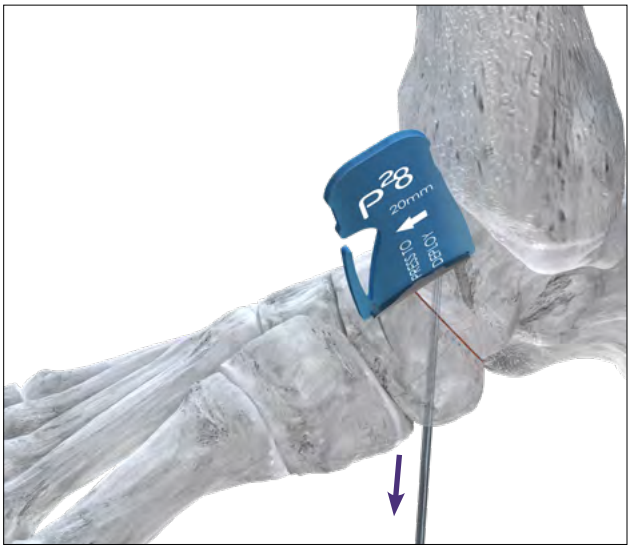


Place the second locating pin in the newly drilled hole and slide the drill guide off the pins.

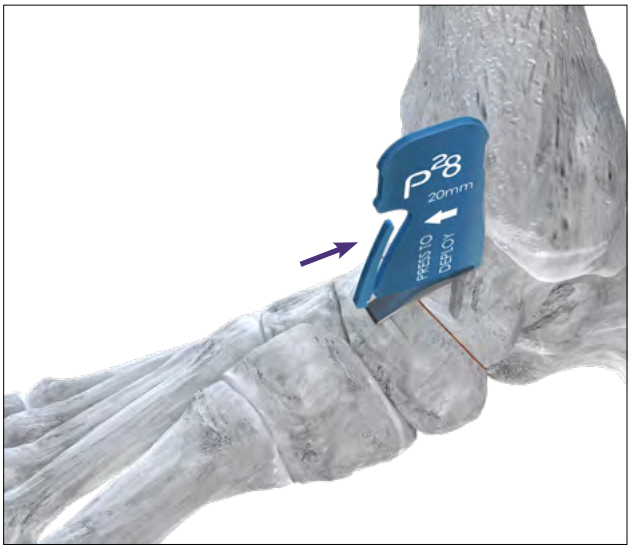


Retrieve the intended staple that is preloaded onto an inserter. Remove the locating pins and fully seat the staple into the pre-drilled holes. If necessary, the staple can be gently tapped with a mallet to help fully seat.

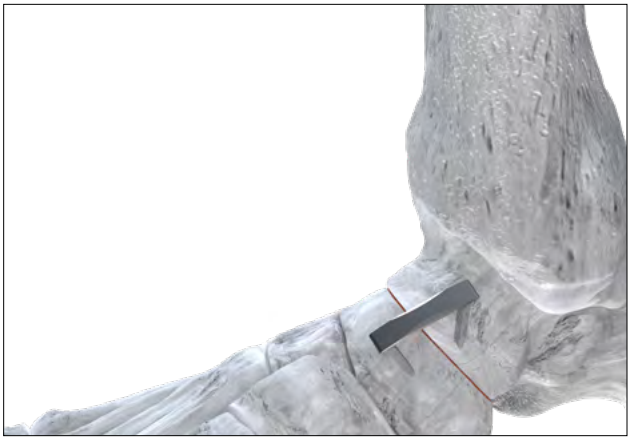
IMPLANT SELECTION AND INSERTION



Remove any provisional fixation across the joint prior to releasing the staple

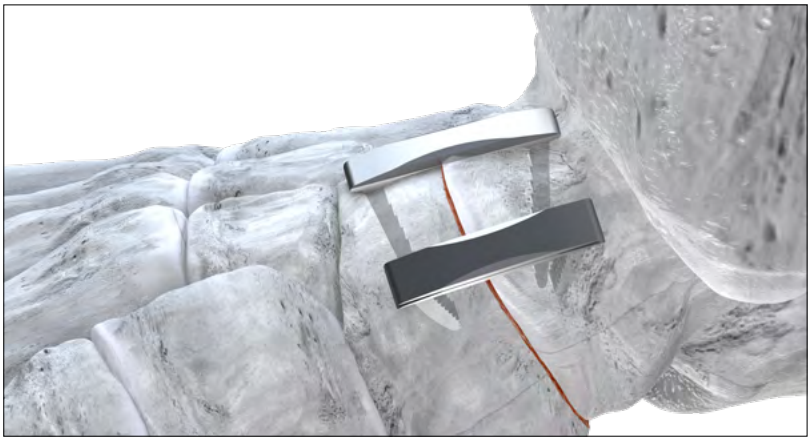


Push in the inserter trigger to deploy the staple.



If the staple is proud after the inserter has been disengaged, tamp according to surgeon preference. If additional fixation is required, place additional staples according to the previously described steps.

CLOSURE



Proceed to incision closure or concomitant procedures at this time.

REMOVAL

If removal of the staple is required, use 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 staple out.

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

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.

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

IMPLANT MATERIALS

The JAWS™ Staple System implants are manufactured from Nickel Titanium Alloy (Nitinol).

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

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.

JAWS™ GREAT WHITE™ STAPLE SYSTEM KIT

Part #	Description	Quantity
P72-015-1515-S	JAWS Great White Nitinol Staple System, 15 x 15 x 15mm, Straight Staple Kit	3
P72-018-1818-S	JAWS Great White Nitinol Staple System, 18 x 18 x 18mm, Straight Staple Kit	4
P72-020-2020-S	JAWS Great White Nitinol Staple System, 20 x 20 x 20mm, Straight Staple Kit	4

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Exclusively foot & ankle
Paragon 28®

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

DISCLAIMER

The purpose of the JAWS™ Great White™ Surgical Technique Guide is to demonstrate the optionality and functionality of the JAWS Great White implants and instrumentation. CAUTION: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.