

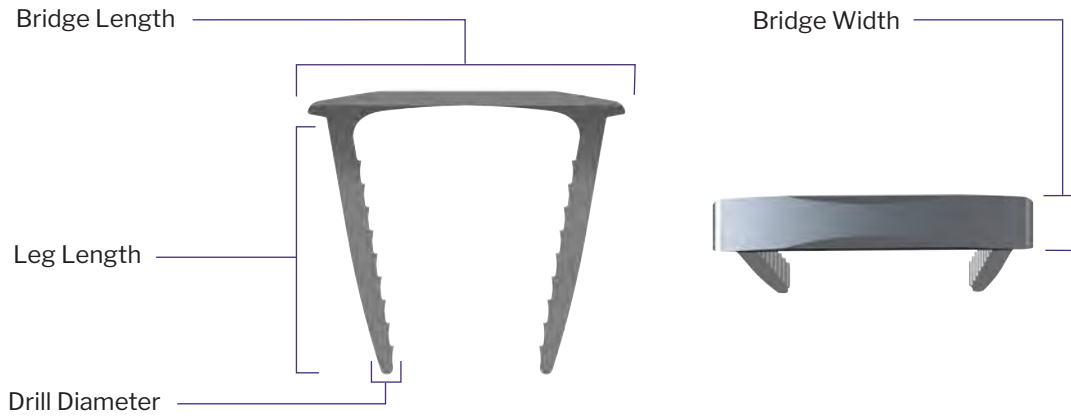
JAWS[®]
NITINOL STAPLE SYSTEM

JAWS[™]
GREAT WHITE STAPLE SYSTEM

Nitinol and Great White Staple Systems



IMPLANT OFFERINGS



**Top View Shown to the Right of each Staple*

STAPLE SIZE	BRIDGE LENGTH	LEG LENGTH	DRILL DIAMETER	POTENTIAL USE
12 mm	12 mm	12 mm	2.3 mm	<ul style="list-style-type: none"> • Akin Osteotomy • Scarf Osteotomy • MPJ Fusion
15 mm	15 mm	15 mm	2.7 mm	<ul style="list-style-type: none"> • MPJ Fusion • TMT Fusion • Navicular Cuneiform Fusion • Lisfranc Arthrodesis
18 mm	18 mm	18 mm	2.7 mm	<ul style="list-style-type: none"> • TMT Fusion • Lisfranc Arthrodesis • Navicular Cuneiform Arthrodesis • Lapidus Arthrodesis
20 mm	20 mm	20 mm	3.0 mm	<ul style="list-style-type: none"> • Calcaneocuboid Fusion • Talonavicular Fusion • Calcaneal Osteotomy
25 mm	25 mm	20 mm	3.0 mm	<ul style="list-style-type: none"> • Calcaneocuboid Fusion • Talonavicular Fusion • Subtalar Arthrodesis

STAPLE INSERTER USE



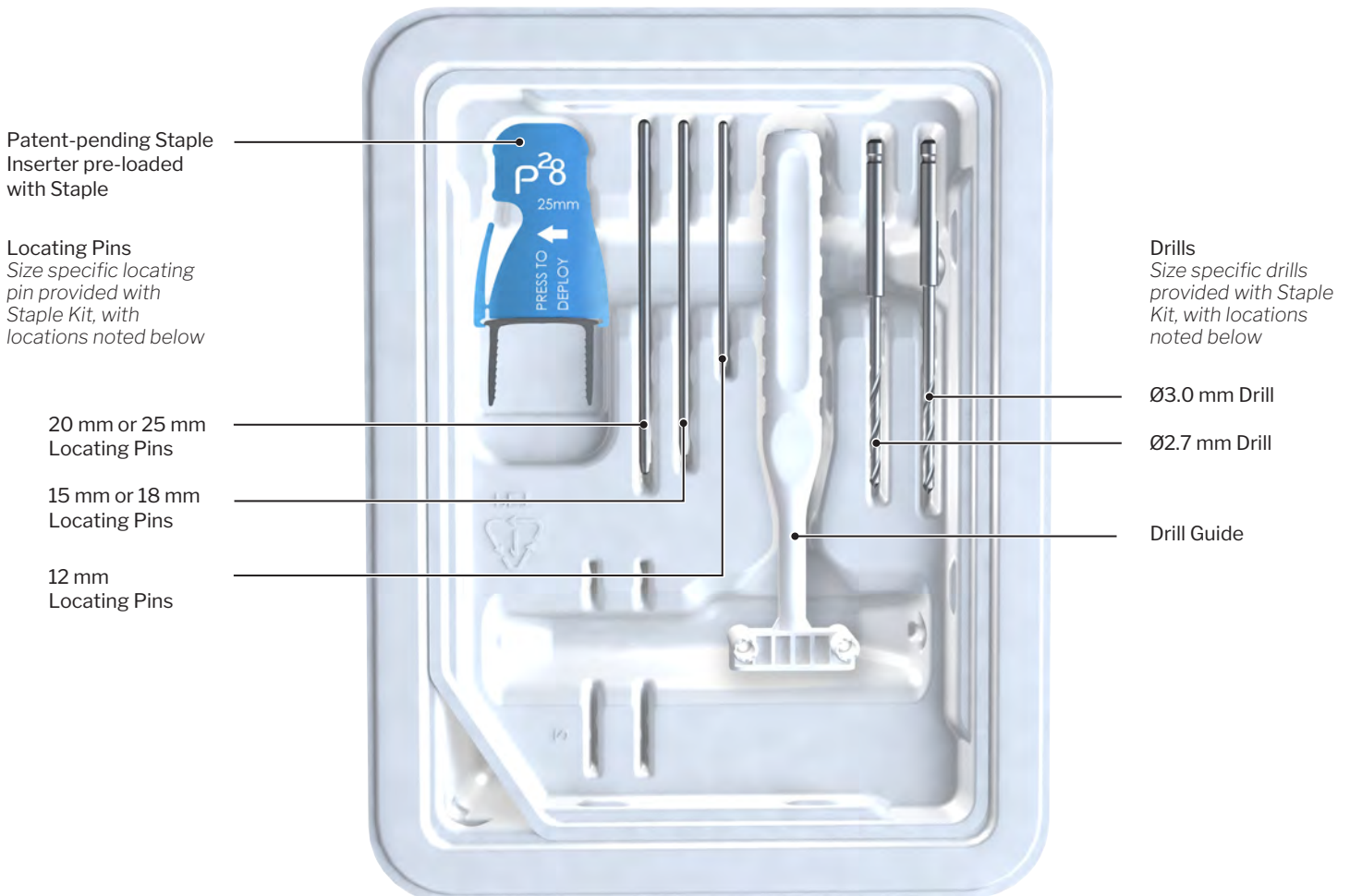
The staple comes pre-loaded onto the inserter. After preparing the osteotomy/fusion site and drilling the holes, the staple can be seated into the bone. To deploy the staple, push the trigger, push the leg into the bone. To deploy the staple, push the trigger on the inserter.

IMPLANT FEATURES

- ▶ The JAWS™ Great White staples exhibit a wider bridge thickness (between 4.00–5.00 mm) and a wider leg thickness (between 1.80–2.30 mm) designed for superior strength and durability
- ▶ The bridge to leg interface is reinforced to increase strength where the staples may be subjected to the most strain
- ▶ The wider bridge design aids in resistance of torsional and bending forces
- ▶ The JAWS™ Great White staples provide a 169% compressive force compared to competitive two-prong, nitinol staple subjected to the same load parameters¹
- ▶ The JAWS™ Great White staples have at least 400X fatigue life compared to competitive nitinol staples subjected to the same load parameters¹

JAWS™ GREAT WHITE STERILE INSTRUMENTATION KIT

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

PRODUCT INFORMATION

The JAWS™ Nitinol Staple System uses superelastic nitinol and a simple insertion method to gain rigid compression across an osteotomy site. The staple is elastically deformed while stored in the inserter and immediately returns to its original shape after it is released from the inserter.

JAWS™ GREAT WHITE STAPLE SYSTEM TECHNIQUE



Figure 1: Incision

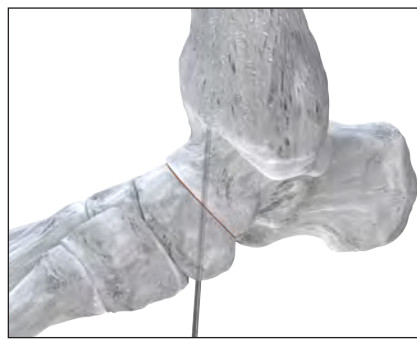


Figure 2: Provisional Fixation

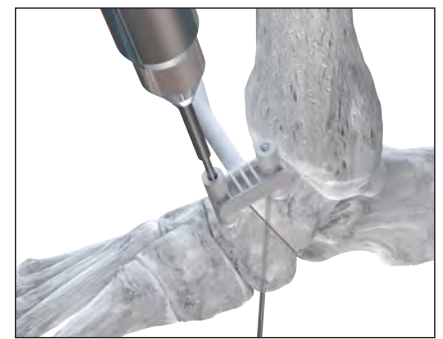


Figure 3: Drill for Implant through Guide

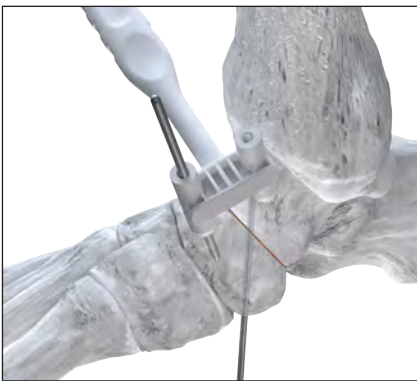


Figure 4: Complete Drilling

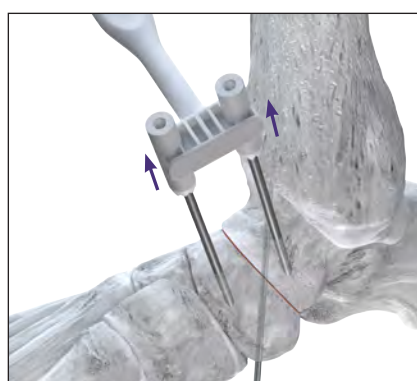


Figure 5: Remove Drill Guide



Figure 6: Insert Staple



Figure 7: Remove Provisional Fixation Wire

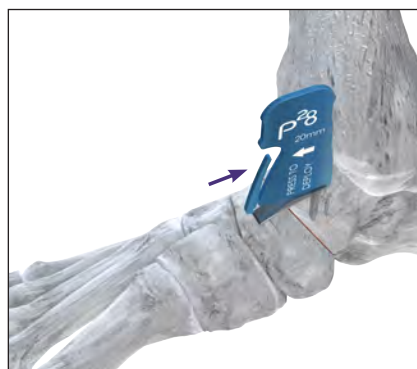


Figure 8: Deploy Staple by Pushing Inserter Trigger












Figure 9 (Optional): If Staple is Proud, Use Drill Guide to Tamp and Seat Staple

IMPLANT FEATURES

- ▶ Sharp tooth geometry increases pull out resistance
- ▶ Lower surface profile than competitive designs to help minimize soft tissue irritation
- ▶ Staple achieves compression upon insertion; no heating required
- ▶ No plastic deformation required to achieve compression
- ▶ 15° angle staple option replicates the medial surface of the proximal phalanx
- ▶ Staple inserter helps eliminate the need to tamp
- ▶ Implant is biocompatible and doesn't need to be removed

STAPLE SYSTEM OFFERING

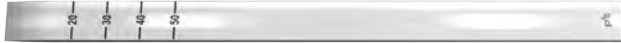
STAPLE SIZE	BRIDGE LENGTH	LEG LENGTH	DRILL DIAMETER	POTENTIAL USE
8 mm 	8 mm	8 mm	1.6 mm	<ul style="list-style-type: none"> • Akin Osteotomy • Scarf Osteotomy • PIPJ Fusion
8 mm Angled 	8 mm	8 mm	1.6 mm	<ul style="list-style-type: none"> • Akin Osteotomy • Scarf Osteotomy • PIPJ Fusion
10 mm 	10 mm	10 mm	1.6 mm	<ul style="list-style-type: none"> • Akin Osteotomy • Scarf Osteotomy • PIPJ Fusion
10 mm Angled 	10 mm	10 mm	1.6 mm	<ul style="list-style-type: none"> • Akin Osteotomy • Scarf Osteotomy • PIPJ Fusion
12 mm 	12 mm	12 mm	2.0 mm	<ul style="list-style-type: none"> • Akin Osteotomy • Scarf Osteotomy • MPJ Fusion
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20 mm 	20 mm	20 mm	2.7 mm	<ul style="list-style-type: none"> • Calcaneocuboid Fusion • Talonavicular Fusion • Calcaneal Osteotomy
25 mm 	25 mm	20 mm	2.7 mm	<ul style="list-style-type: none"> • Calcaneocuboid Fusion • Talonavicular Fusion • Subtalar Arthrodesis

INSTRUMENTATION

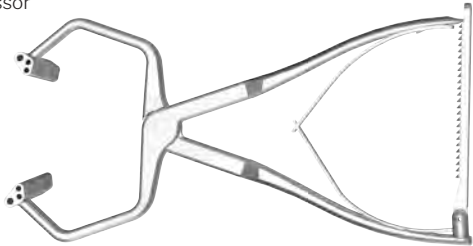
Osteotome, 6 mm Straight



Osteotome, 12 mm Straight



Compressor



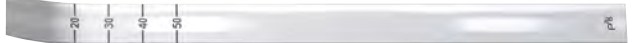
Osteotome, 19 mm Straight



Osteotome, 6 mm Curved



Osteotome, 12 mm Curved



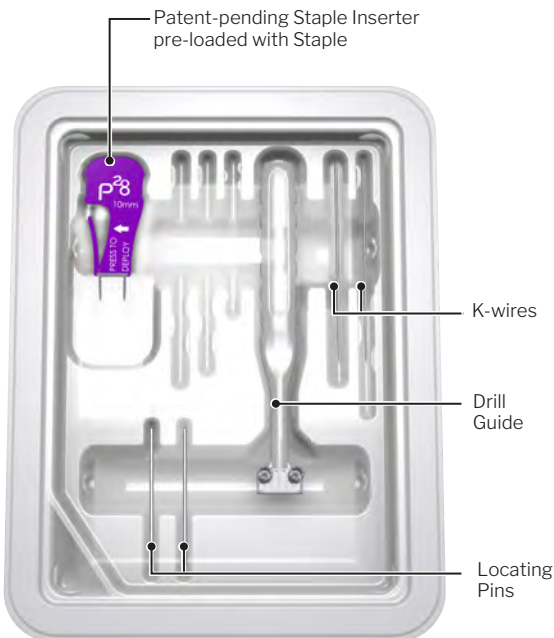
Osteotome, 19 mm Curved



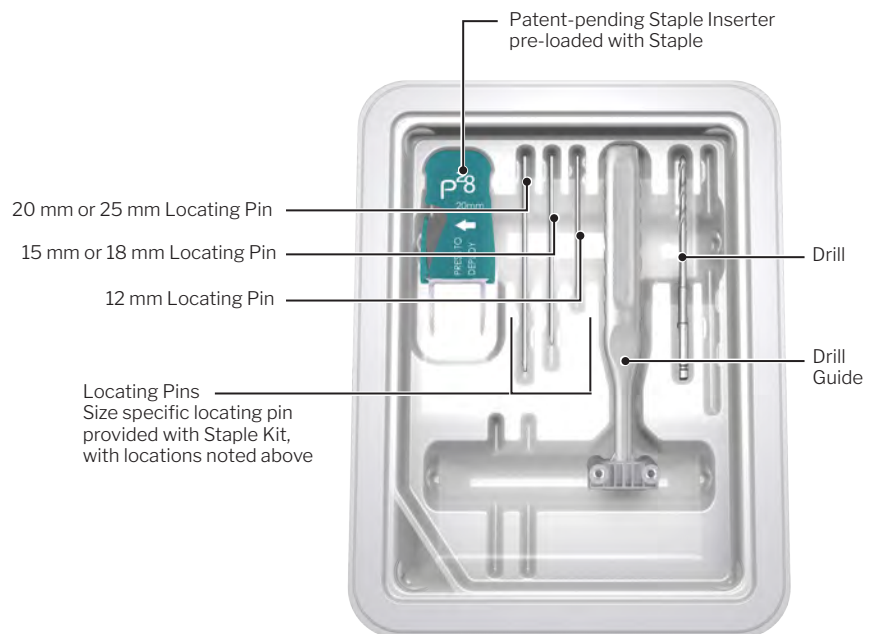
JAWS™ STERILE PACKED INSTRUMENTATION

All instrumentation for the JAWS™ Nitinol Staple System comes in a simple, disposable, sterile kit. The staple comes pre-loaded on the inserter to help facilitate a quick and simple surgery.

8 mm or 10 mm Staple Kit



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



JAWS® NITINOL STAPLE SYSTEM TECHNIQUE

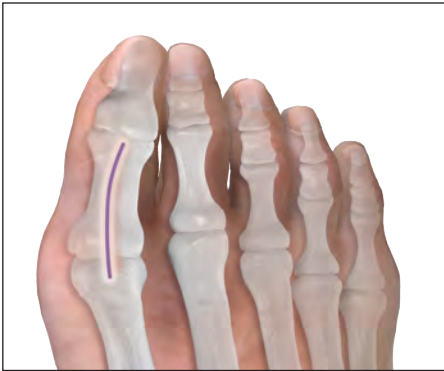


Figure 1: Incision



Figure 2: Complete Osteotomy

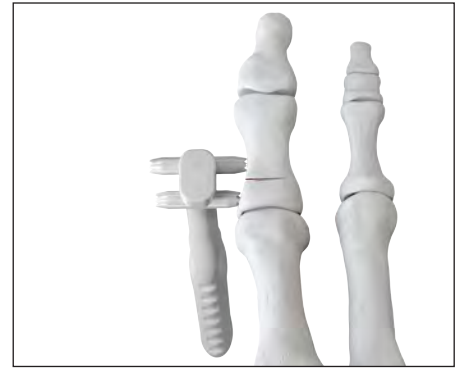


Figure 3: Close Osteotomy and Place K-Wire Drill Guide Across Osteotomy so that Short Side of Guide is on the Proximal Flare of the Proximal Phalanx

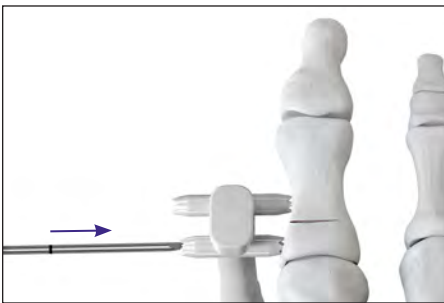


Figure 4: Place a K-wire through the Proximal Hole of the K-wire Guide Until the Laser Mark is no Longer Visible at the Top of the Guide

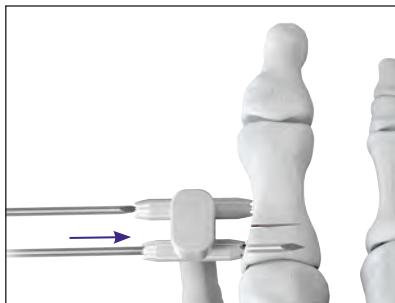


Figure 5: Place a Second K-wire through the Distal Hole of the K-wire Guide Until the Laser Mark is no Longer Visible at the Top of the Guide

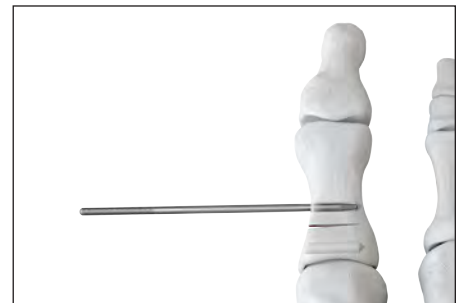
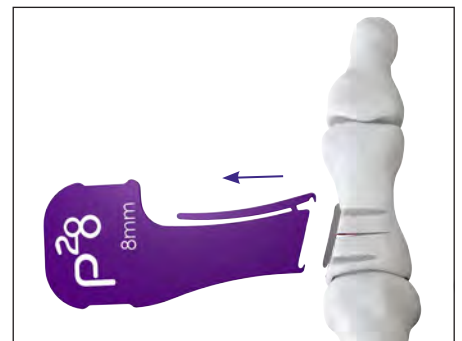
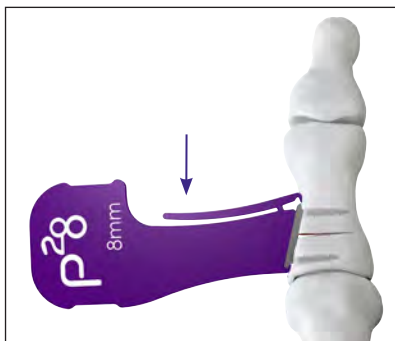
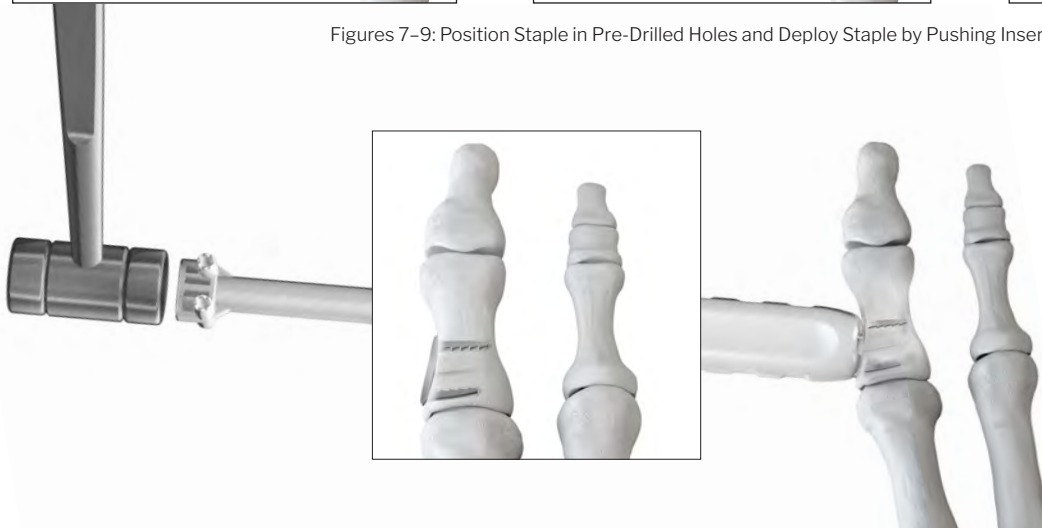


Figure 6: Remove Drill Guide—Locating Pins may be used to Aid in Placement



Figures 7-9: Position Staple in Pre-Drilled Holes and Deploy Staple by Pushing Inserter Trigger



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.




Nitinol and Great White Staple Systems

References:

1. Internal Test Data on File

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2023-10-10

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