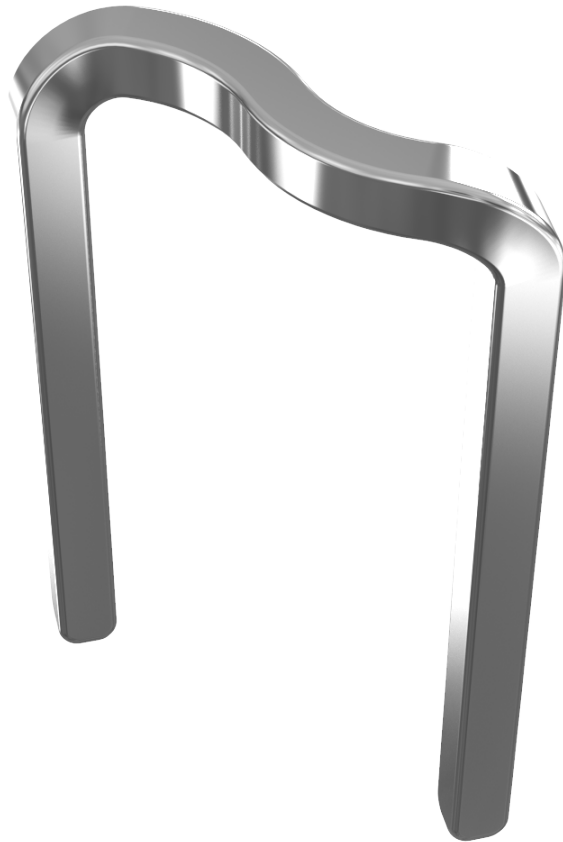




BPSS Memory Staple

Surgical Technique



Contents

Table of contents

Indications & Contraindications	1
Implant Specifications	2
Instrument Specifications	3-4
Handling Instructions	5
Surgical Technique	6-8
Foot and Ankle Procedures	9
Hand and Wrist Procedures	10
Implant Ordering	11
Instrument Ordering	12-13

Indications and Contraindications

Indications for use:

1. Hand and foot bone fragment and osteotomy fixation and joint arthrodesis.

Contraindications:

2. A debilitating general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure.
3. Comminuted bone surface which would militate against staple placement.
4. Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the staple.
5. Foreign body sensitivity to metals including nickel or titanium. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

Warning:

- Immobilization in addition to this internal fixation until bone healing should be achieved by routine methods (casting, splints, etc.)
- Reduction of the site should be achieved and maintained prior to implanting the staple. The compressive force of the staple closing should not be relied upon to achieve closure or reduction of the fracture line.

Precautions and Handling:

- Inspect the sterile blisters used for the implants prior to use. Sterilization cannot be assured, and staples should not be used if blister or seal is damaged.
- Staples should be stored at 24°C (75° F) or less. Staples should be cooled to 24°C (75° F) prior to removing from the shipping block. Placing staples at -20°C (-5°F) will return staples to original position.
- The staples are a single use device
- Do not autoclave staples

Potential Complications and Adverse Effects:

- Allergic reactions to metal (titanium or nickel)
- Delayed or Non-union of bone
- Delayed Healing
- Staples may break
- Staples may extrude or back out of the surgical site

Contact surgeon if a change in performance or pain level is noticed.

Implant Specifications

Description

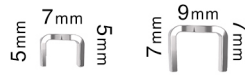
The BPSS Memory Staple is a 2-leg nitinol memory-alloy staple designed for bone fixation in the hand and foot. The unique S-Bend bridge of the BPSS Memory Staple ensures even compression across the fusion site, while maintaining a low profile against the bone.

The BPSS Memory Staple is individually sterile packaged and available in 17 standard sizes. The packaging features a color coding system that coordinates staple leg size with drill diameter. The system offers standard legs or offset legs where standard leg staples are utilized when a flush surface exists while the offset staples offer different leg lengths to accommodate uneven bone surfaces.

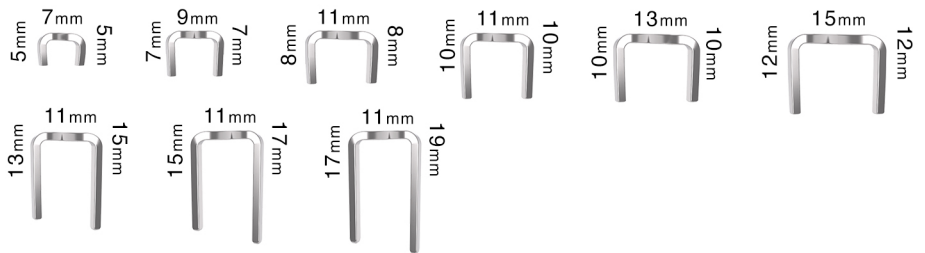
Material

Manufactured from Nitinol, a memory metal comprised of approximately 50% nickel (Ni) and 50% titanium (Ti). The alloy's unique properties allow the staple full activation at body temperature or 98.6°F (37°C).

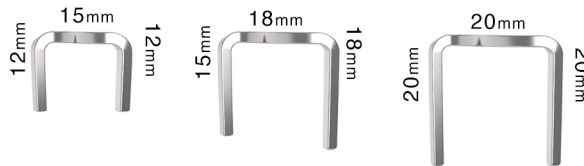
Sizing



• 1.2MM LEGS



• 1.5MM LEGS



• 2.0MM LEGS



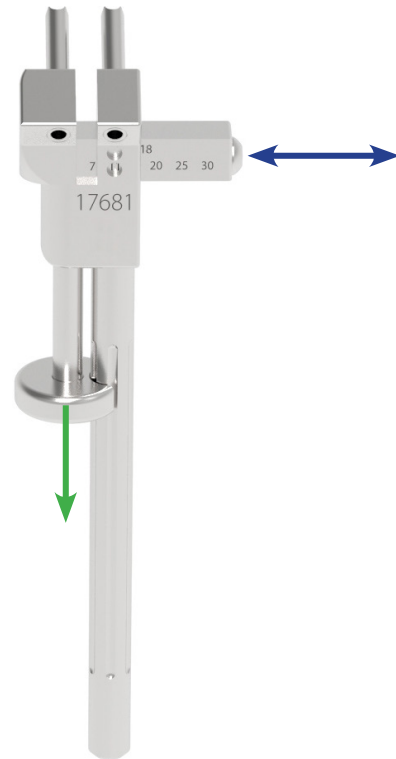
• 3.0MM LEGS

Instrument Specifications

Drill Guides

The adjustable drill guide accommodates all staple sizes.

Set the adjustable drill guide by pulling down on the set pin (green arrow), with the set pin pulled down, slide the top guide bar (blue arrow) until the desired staple bridge width shows in the engraving window.



Static drill guides

The instrument kit includes double sided drill guides with size markings to indicate bridge width.



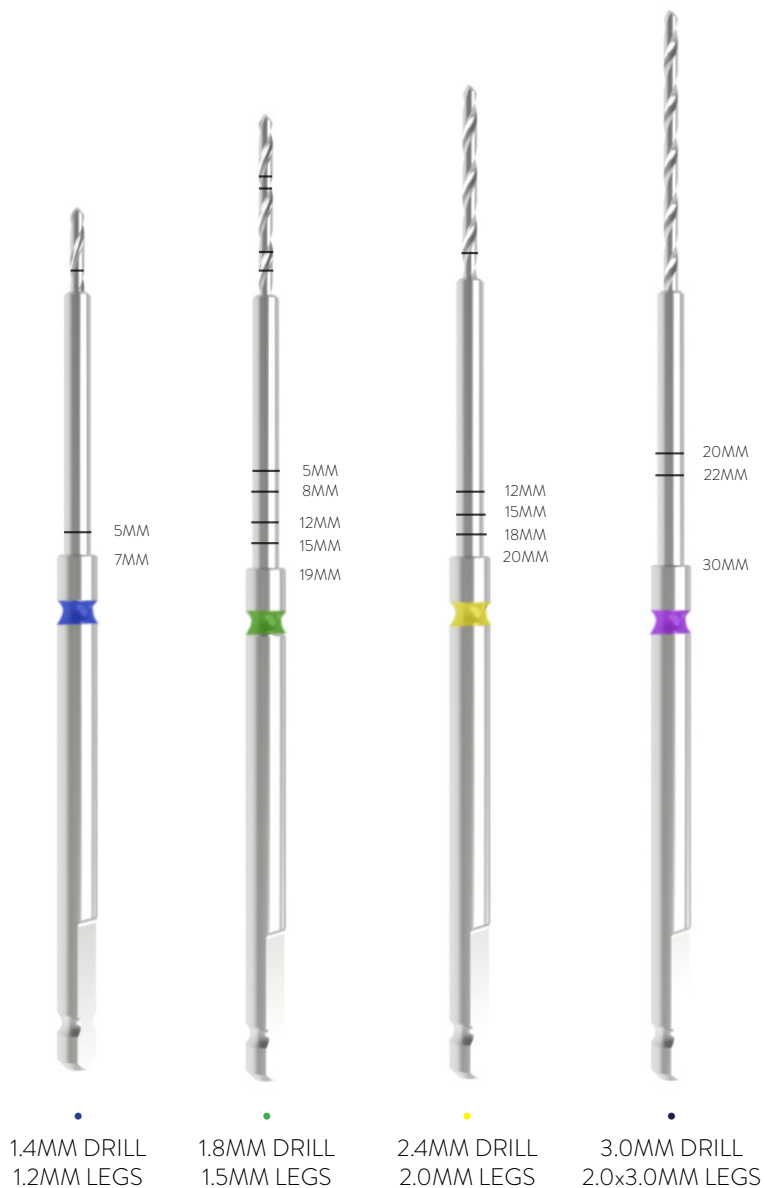
Instrument Specifications

Drill bits

Ø1.4mm, 1.8mm, 2.4mm, and 3.0mm color coded drill bits feature etched lines that indicate drill depth, corresponding to available staple leg lengths.

Note:

Drill bits may be provided sterile packaged and may not be included in your instrument kit.



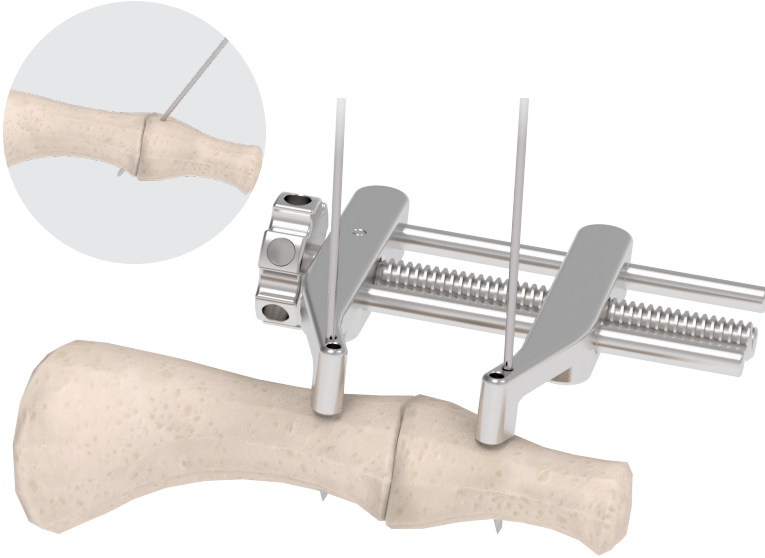
Handling Instructions

Caution

It is important to always handle the staple with the provided clamps, never by hand, as this may result in premature activation. The instrument kit includes two specially designed staple clamps to securely handle all sizes of the BPSS Memory Staple.

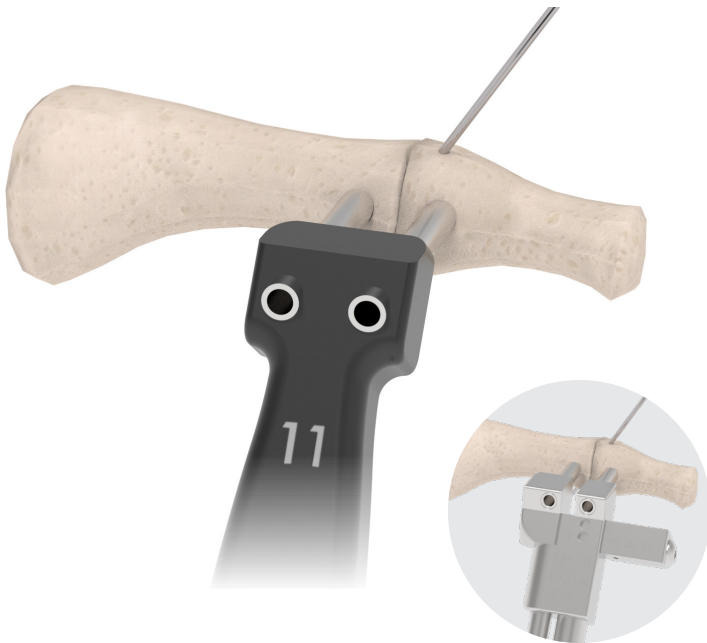


Surgical Technique



Step One:

Prepare the surgical site by tightly opposing bone fragments. This can be accomplished with a compression+distraction device or a k-wire.

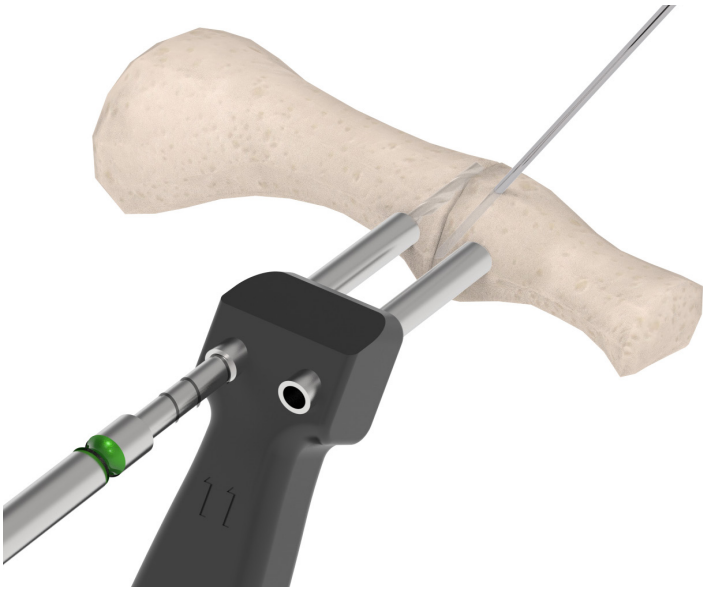


Step Two

Determine optimal staple size ensuring the legs capture both bone fragments.

Note:

The drill guides can act as a sizer when determining the correct staple size. If using the adjustable drill guide, refer to page 3 on how to adjust for different bridge widths.

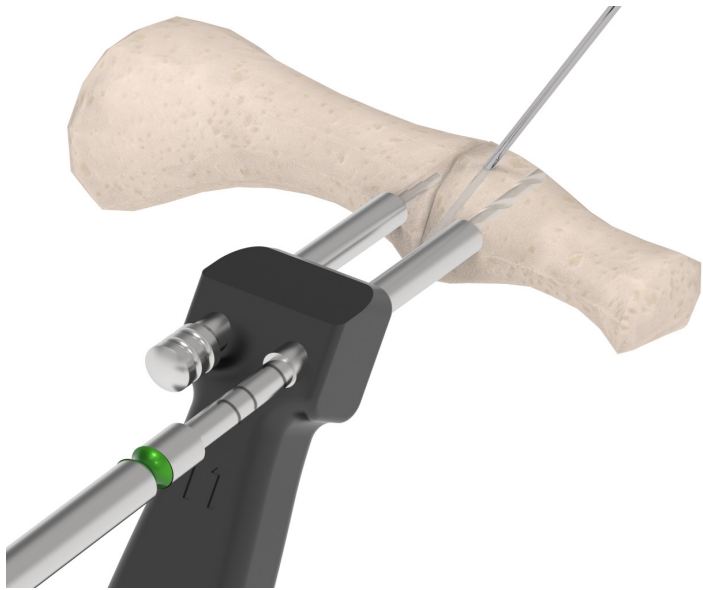


Step Three:

After determining the staple size, utilize the appropriately sized drill guide and drill bit to drill on one side of the fusion site.

Note:

The drill bits feature etched lines that indicate drill depth. Refer to page 5 for details on the leg lengths each line corresponds to.



Step Four:

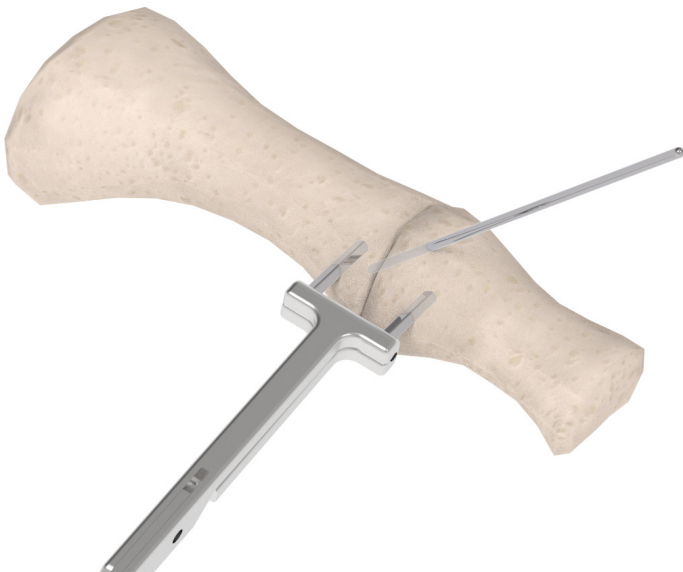
Insert the provided anchor pin into the drill hole to maintain position; drill for the opposite leg.

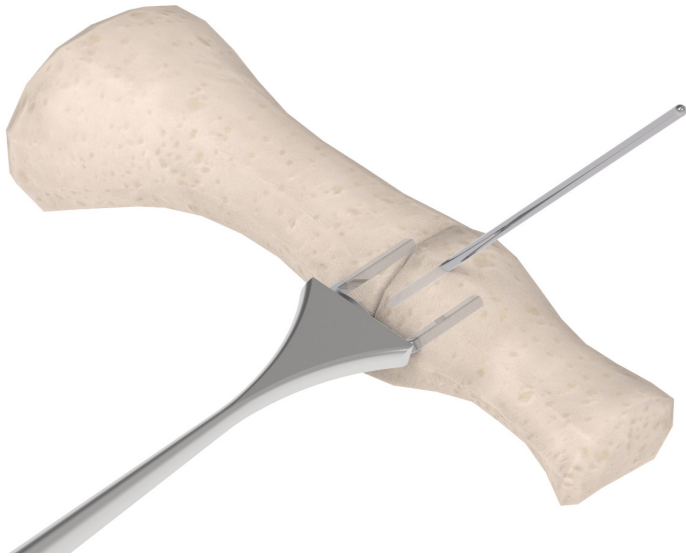
Step Four:

Utilizing a pair of the included staple clamps, remove the staple from its protective shipping block and place it into the pre-drilled holes.

Caution

It is important that the staple is always handled with staple clamps, never by hand, as this may result in premature activation.





Step Five:

Use the appropriately sized staple punch to ensure the staple is fully inserted and seated against the bone.



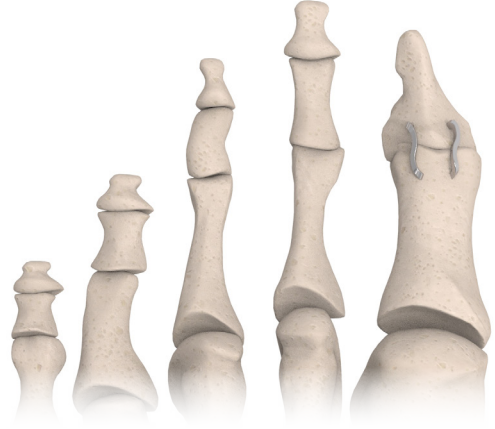
Step Six:

Remove the k-wire if one has been used in the procedure. After insertion, the staple should sit flush against the bone. Staple compression will occur at body temperature, but may be hastened by irrigation with saline 98°F (37°C) to 100°F (38°C).

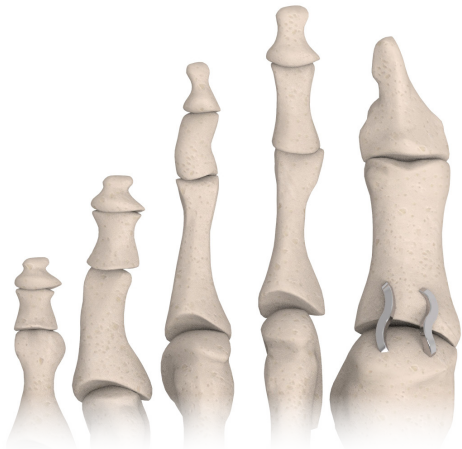
Foot & Ankle Procedures



Akin Osteotomy: 7x5, 9x7



Hallux IP Fusion: 9x7, 11x8, 11x10, 13x10



Hallux MTP Fusion: 11x8, 11x10, 13x10, 15x12

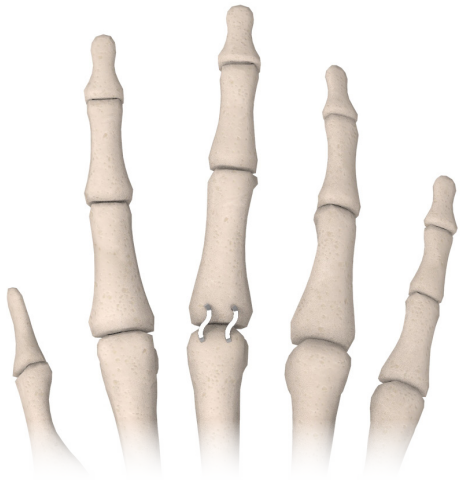


TMT Fusion (Lapidus): Dorsal- 20x20, 18x18x15
Medial- 15x12

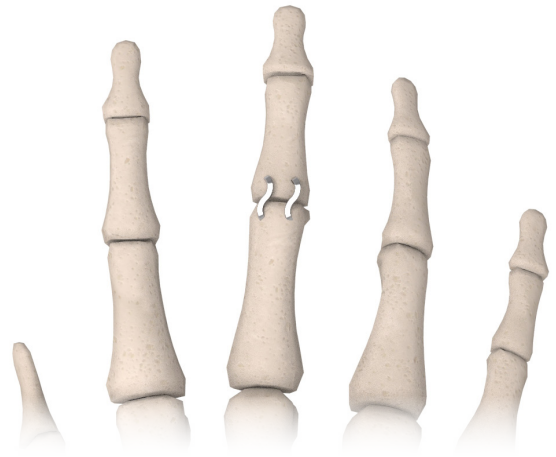
Additional Procedures

- Lesser PIPJ Fusion: 7x5, 9x7
- Distal Metatarsal Osteotomies: 11x10, 13x10, 11x15x13
- Base Wedge Osteotomies: 11x10, 13x10, 15x12, 18x18x15
- Cotton Procedure: 20x20, 18x18x15
- Talonavicular Fusion: 18x18x15, 20x20
- Calcaneal Cuboid Fusion: 15x12, 18x18x15, 20x20
- Dwyer Osteotomy: 20x20

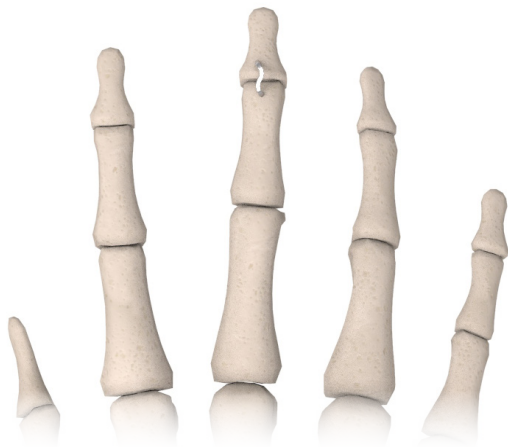
Hand & Wrist Procedures



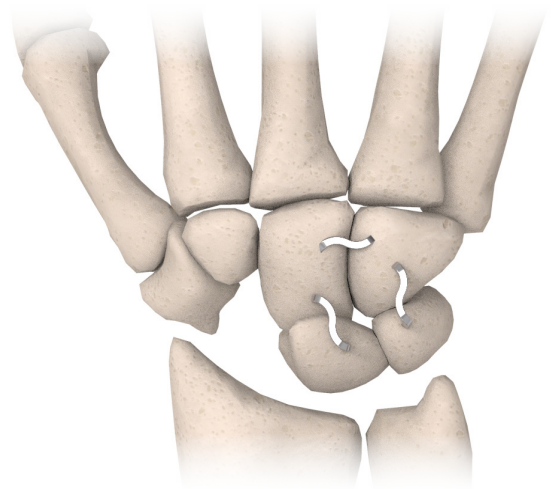
MCP Fusion: 11x8, 11x10, 13x10



PIP Fusion: 7x5, 9x7



DIP Fusion: 7x5, 9x7

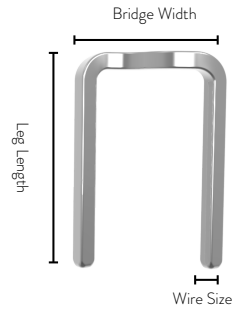


Four-corner Fusion: 11x8, 11x10, 13x10

Additional Procedures

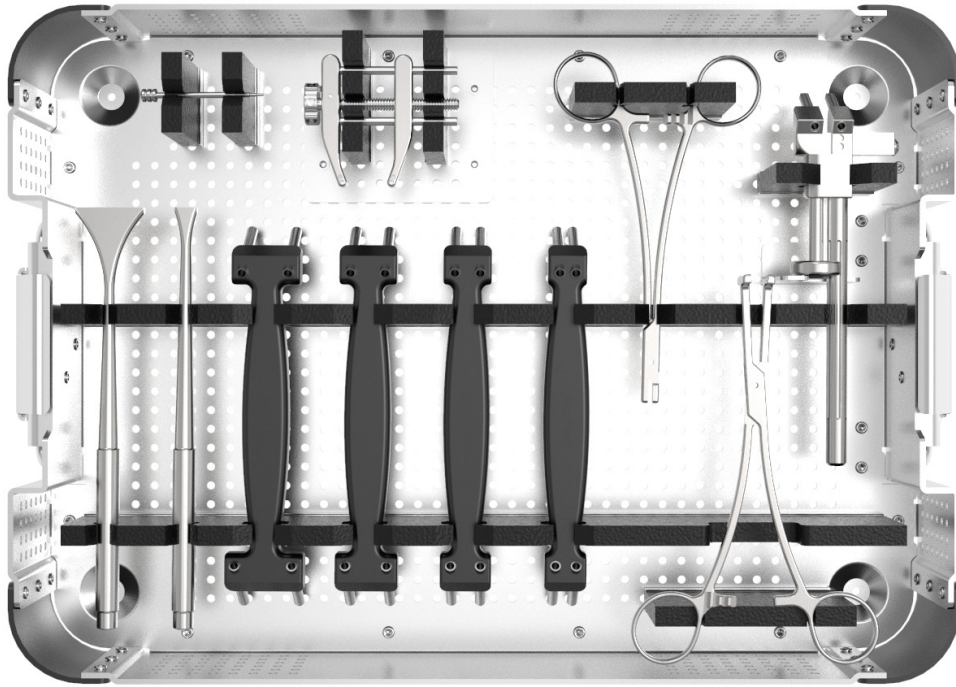
- Capitate/Scaphoid Fusion: 11x8, 11x10, 13x10
- Capitate/Lunate Fusion: 11x8, 11x10, 13x10
- CMC Thumb Fusion: 11x8, 11x10, 13x10
- Third Metacarpal/Capitate Fusion: 11x8, 11x10, 13x10
- Fifth Metacarpal/Hamate Fusion: 11x8, 11x10, 13x10

Implant Ordering



Item #	Description
ON-ST1512	Memory Staple, Nitinol, 15mm x 12mm
ON-ST1818	Memory Staple, Nitinol, 18mm x 18mm
ON-ST2020	Memory Staple, Nitinol, 20mm x 20mm
ON-ST2522	Memory Staple, Nitinol, 25mm x 22mm

Instrument Ordering



Item #	Description
ONST101	OrthoNovis Base Memory Staple Tray Gen 2
ONST102	Anchor Pin
ONST103	Large Staple Punch
ONST104	Large Staple Clamp
ONST105	Static Drill Guide 15-18mm
ONST106	Static Drill Guide 20-25mm

Instrument Ordering



Item #	Description
ON-STDR24	2.4mm Drill Staple Medium
ON-STDR30	3.0mm Drill Staple Large



References:

1. T.J. Chang and B.D. Overley, "An In Vitro Comparative Study of Screw and Nitinol Staple Compression: A Model Showing Active 'Dynamic' Compression," Presented at the American College of Foot & Ankle Surgeons 65th Annual Scientific Conference, Orlando, FL, March 2007.
- This document is intended solely for the use of healthcare professionals. A surgeon must always rely on their own professional clinical judgement when deciding whether to use a particular product when treating a particular patient. OrthoNovis does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.
 - Please contact your OrthoNovis representative if you have question about the availability of OrthoNovis products in your area.
 - This document is applicable to the United States only and not intended for distribution in the USA
 - All surgical techniques are available as PDF files at www.orthonovis.com/ifu

