

Memory Staple



Surgical Technique

Contents

Product

The Memory Staple is a nitinol memory-alloy staple designed to provide fast and stable fixation in a variety of procedures. The staple provides dynamic compression designed to facilitate bone healing.¹

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Indications and Contraindications

Indications for use:

1. Hand and foot bone fragment and osteotomy fixation and joint arthrodesis.
2. Fixation of soft tissue to bone.

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.
- This staple system has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment.

Adverse Effects:

- Allergic reactions to metal (titanium or nickel)
- Delayed or non-union of bone
- Delayed healing
- Staples may break
- Staples may extruded or back out of the surgical site

Contraindications:

1. Comminuted bone surface which would mitigate against staple placement.
2. Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the staple.
3. Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

Care and Caution:

- Inspect the sterile blisters used for the implants prior to use. Sterilization cannot be assured and staple should not be used if blister or seal is damaged.
- Staples should be stored at 75° F (24°C) or less. Staples that have exceeded 75° F (24°C) must be reset prior to use by placing them in a freezer at or below -4°F (-20°C) for two hours prior to use. Once they have been reset, they must be stored at or below 75 degrees.
- The staples are a single use device.
- Do not autoclave staples.

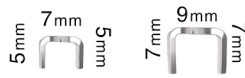
Implant Specifications

The Memory Staple is manufactured from Nitinol, a memory alloy. The staple is fully activated at 98.6°F (37°C), patient body temperature. This provides dynamic compression during the healing process.¹

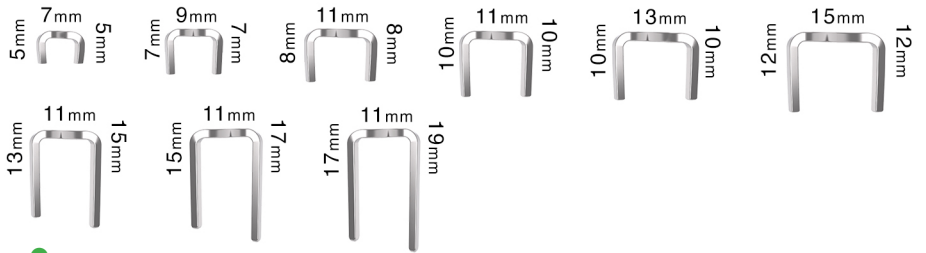
The Memory Staple is individually sterile packaged and available in 17 standard sizes. The packaging features a color coding system that coordinates staple leg size with drill diameter.

The system offers standard legs or offset legs. The standard leg staples are utilized when a flush surface exists while the offset staples offer different leg lengths to accommodate uneven bone surfaces.

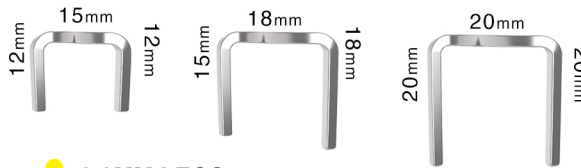
The unique S-Bend bridge of the Memory Staple ensures even compression across the fusion site, while maintaining a low profile against the bone.



● **1.2MM LEGS**



● **1.5MM LEGS**



● **2.0MM LEGS**



● **3.0MM LEGS**

Instrument Specifications

Adjustable drill guide

An adjustable drill guide is included in the instrument kit. The drill guide accommodates every staple size.

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 will also include either double-sided static drill guides or angled drill guides.



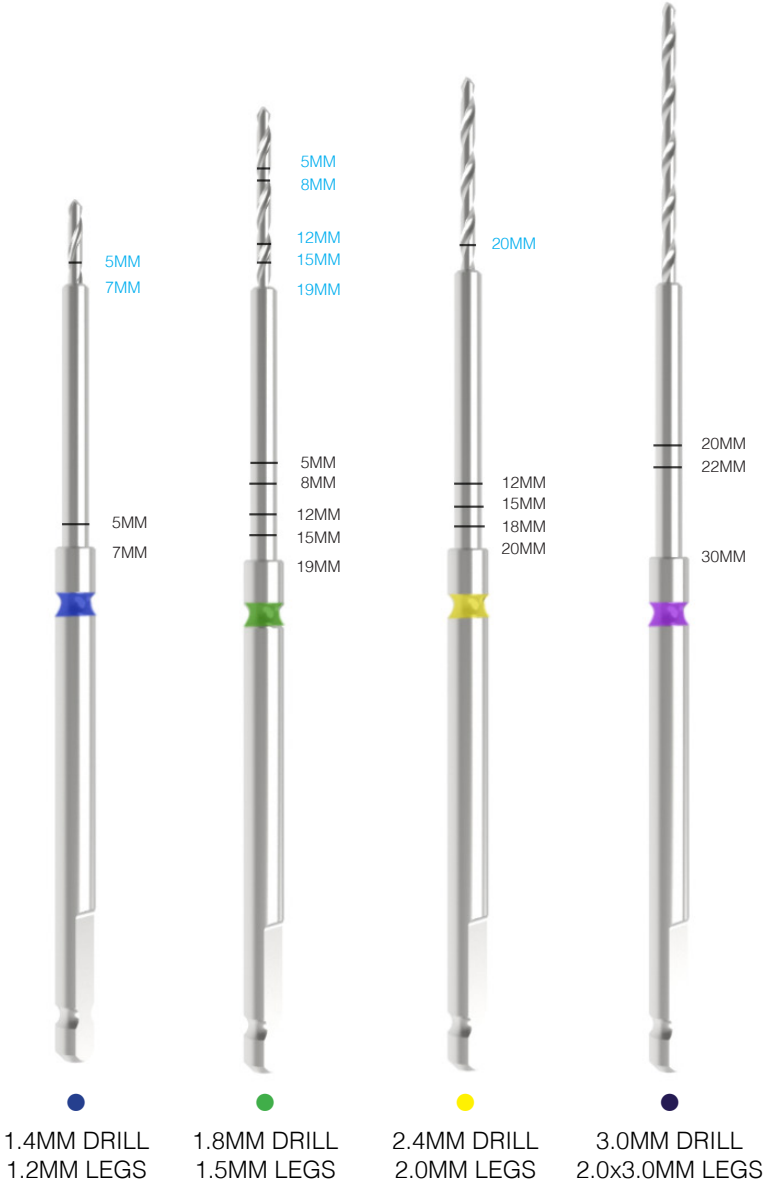
Instrument Specifications

Drill bits

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

Note:
Etched lines on the drill bit flute are only used when utilizing angled drill guides.

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

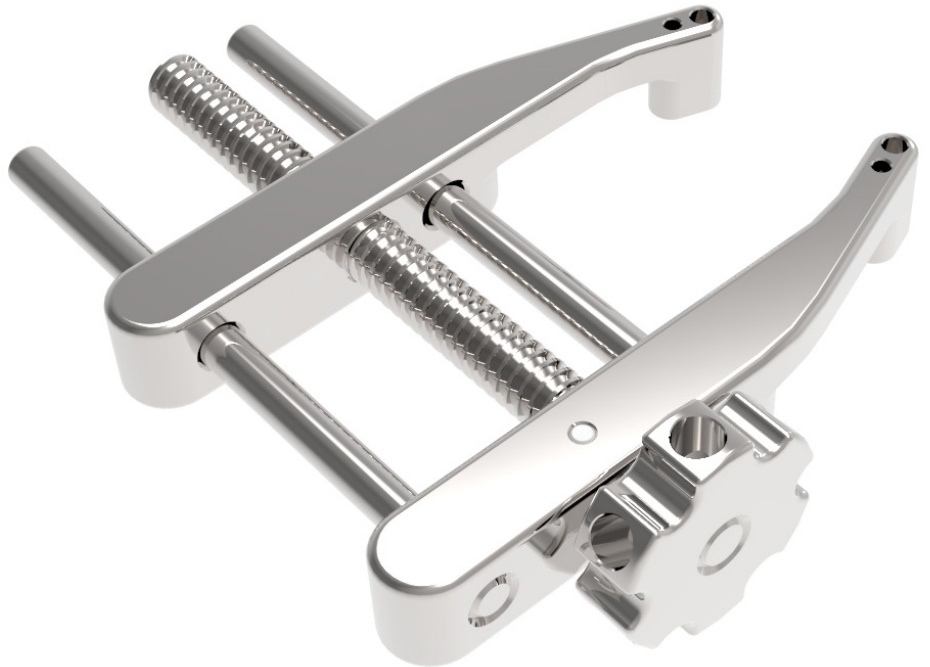


Instrument Specifications

Distraction and Compression

A distraction + compression device is available upon request.* The device allows for additional exposure and helps ensure bone to bone contact prior to staple insertion.

The device will accept either 0.045" (1.1 mm) or 0.062" (1.6 mm) k-wires.



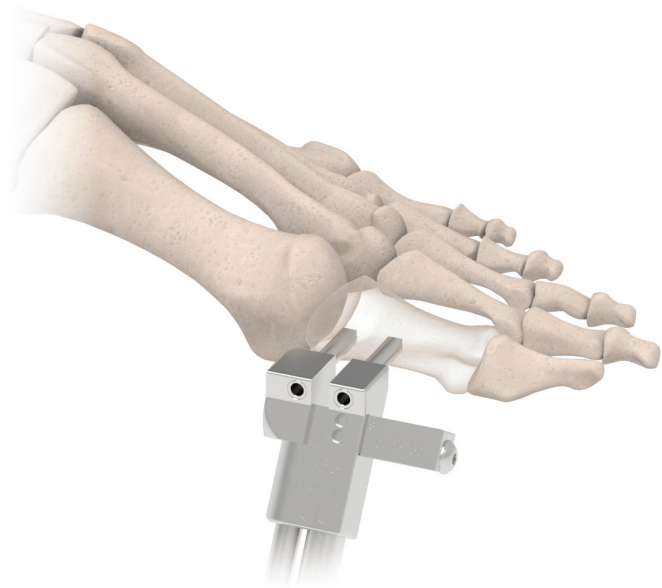
Handling Instructions

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 Memory Staple.



Surgical Technique



Step One:

Prepare the surgical site and determine optimal staple size.

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.

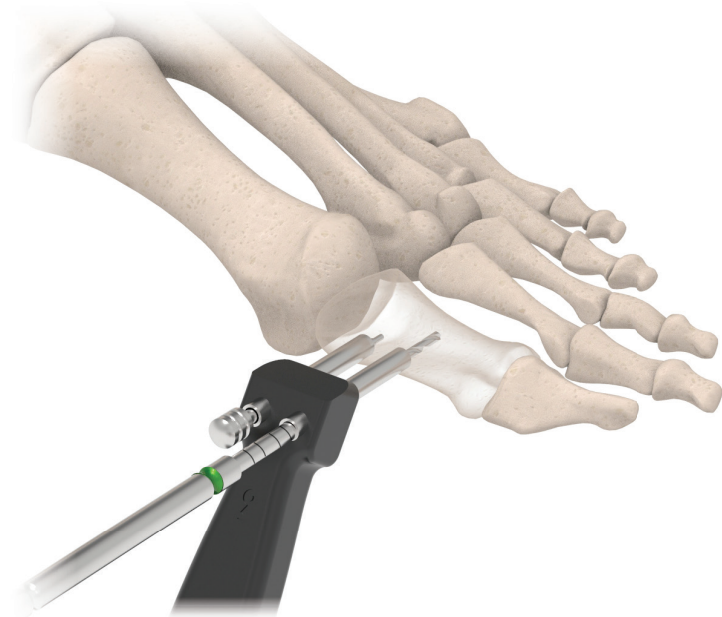
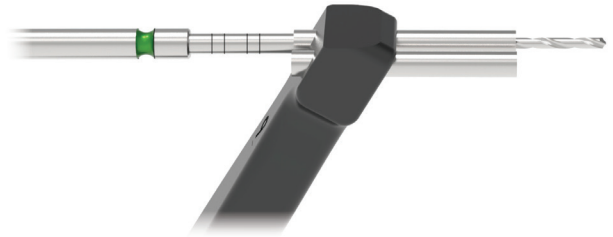


Step Two:

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

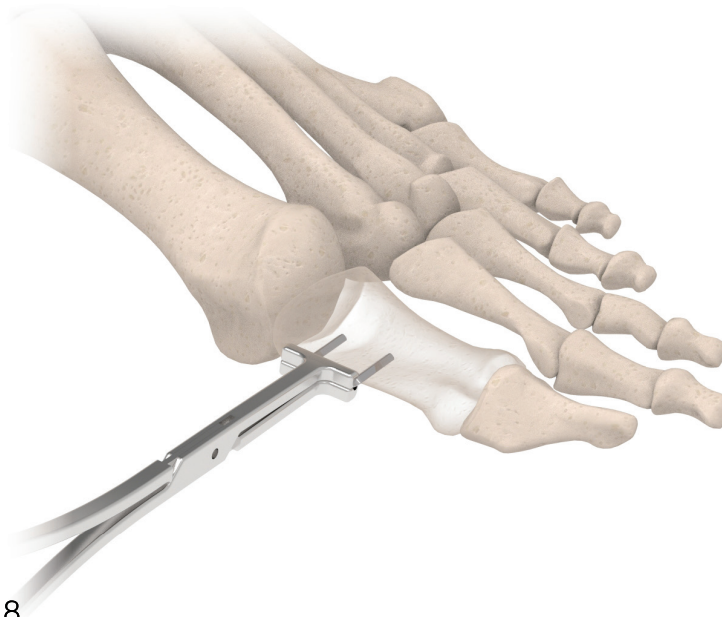
Note:

The drill bits feature etched lines that indicate drill depth. Refer to page 4 for details on the leg lengths each line corresponds to.



Step Three:

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

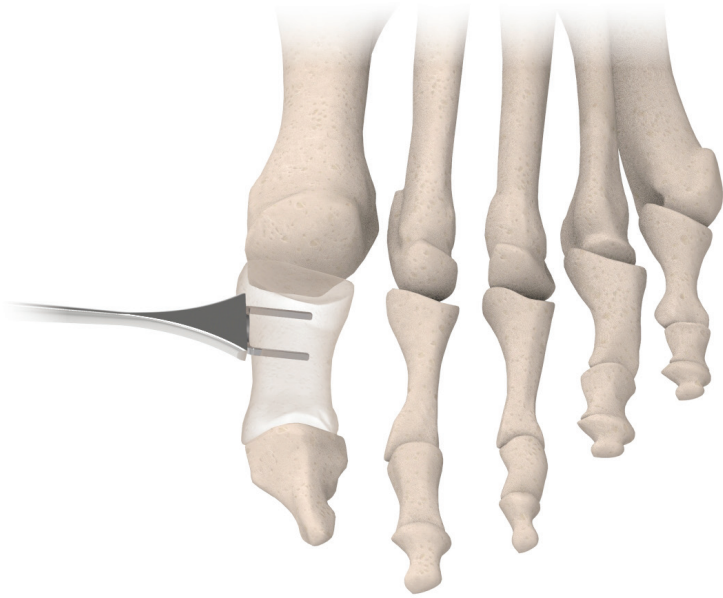


Step Four:

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

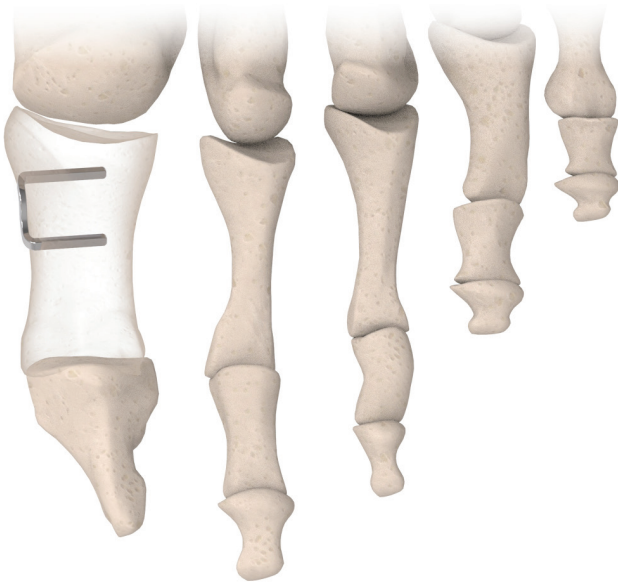
Caution

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 appropriate size staple punch to ensure the staple is fully inserted and seated against the bone.



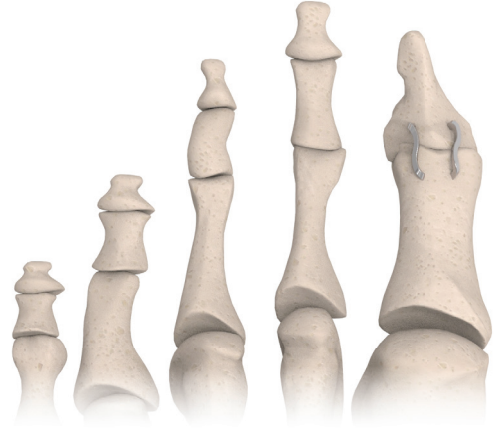
Step Six:

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).

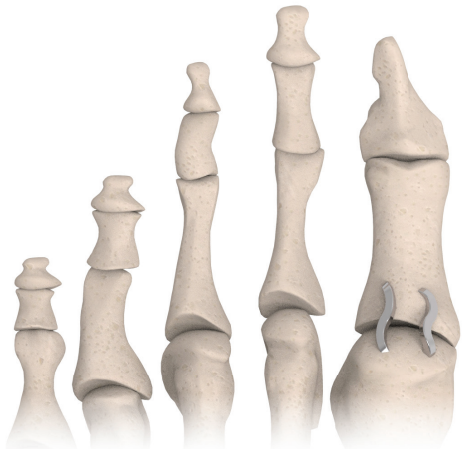
Foot & Ankle Procedures



Akin Osteotomy: 7x5, 9x7



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



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

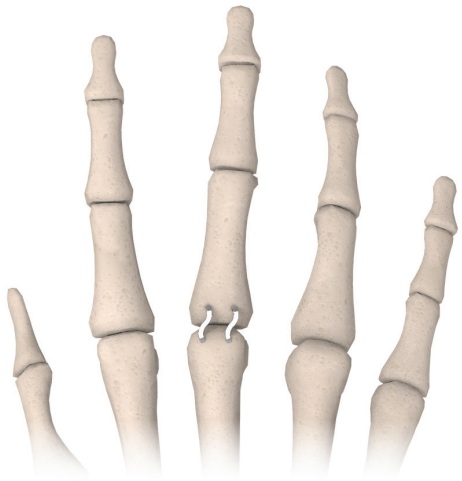


TMT Fusion (Lapidus): Dorsal- 20x20, 18x18x15
Medial -15x12

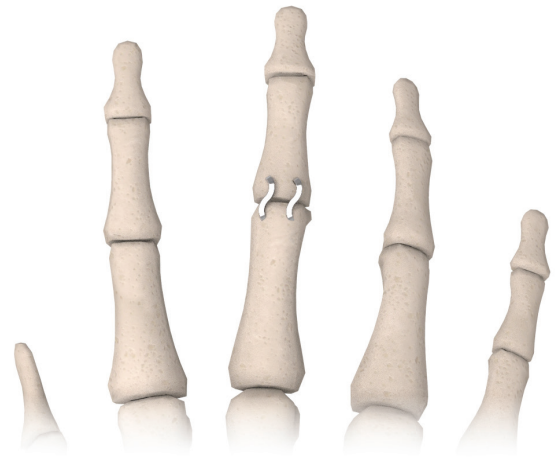
Additional Procedures

- 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

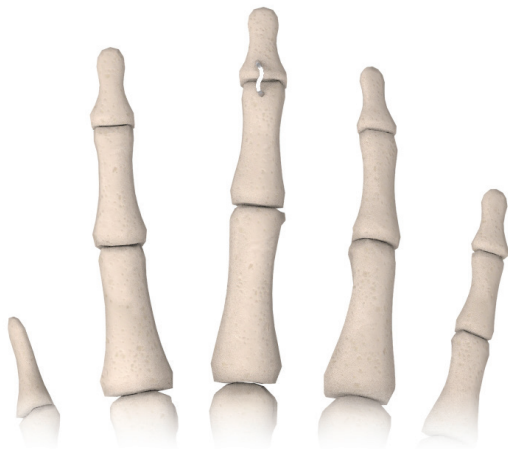
Hand & Wrist Procedures



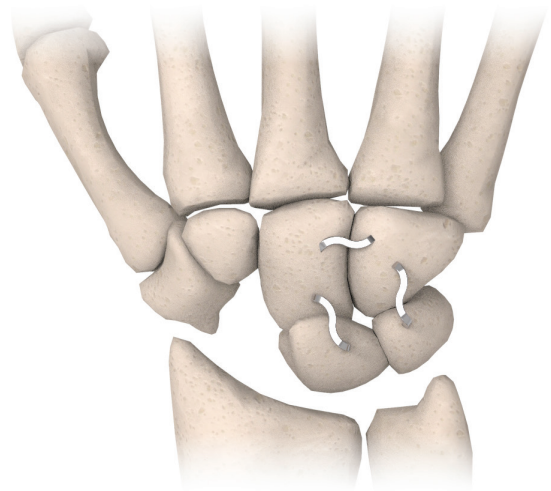
MCP Fusion: 11x8, 11x10, 13x10



PIP Fusion: 7x5, 9x7



DIP Fusion: 7x5, 9x7

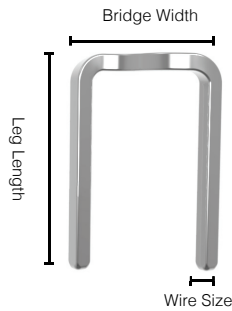


Four-corner Fusion: 11x8, 11x10, 13x10

Additional Procedures

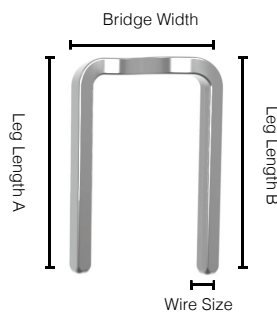
- Capitate/Scaphoid Fusion: 11x8, 11x10, 13x10
- Capitate/Lunate Fusion: 11x8, 11x10, 13x10
- CMC Thumb Fusion: 11x8, 11x10, 13x10
- Third Metacarpal/Capitate Fusion: 11x8, 11x10, 13x10
- Fifth Metacarpal/Hamate Fusion: 11x8, 11x10, 13x10

Implant Ordering



Standard Legs

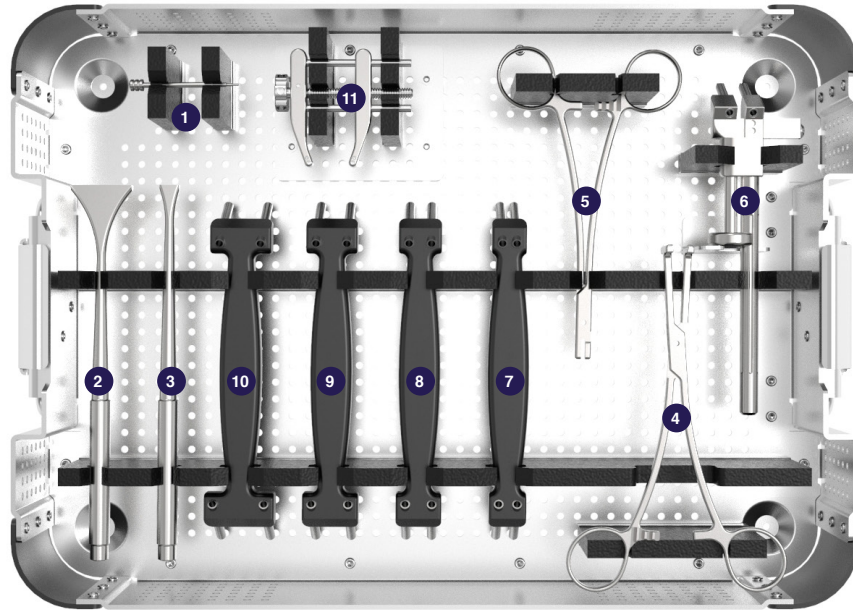
Item #	Bridge Width	Leg Length	Wire Size	Drill Ø	Color Code
17637	7mm	5mm	1.2mm	1.4mm	Blue
17628	7mm	5mm	1.5mm	1.8mm	Green
17638	9mm	7mm	1.2mm	1.4mm	Blue
17629	9mm	7mm	1.5mm	1.8mm	Green
17630	11mm	8mm	1.5mm	1.8mm	Green
17631	11mm	10mm	1.5mm	1.8mm	Green
17632	13mm	10mm	1.5mm	1.8mm	Green
17633	15mm	12mm	1.5mm	1.8mm	Green
17625	15mm	12mm	2.0mm	2.4mm	Yellow
17627	20mm	20mm	2.0mm	2.4mm	Yellow
17622	20mm	20mm	2.0x3.0mm	3.0mm	Purple
17623	25mm	22mm	2.0x3.0mm	3.0mm	Purple
17624	30mm	30mm	2.0x3.0mm	3.0mm	Purple



Offset Legs

Item #	Bridge Width	Leg Length A	Leg Length B	Wire Size	Drill Ø	Color Code
17634	11mm	15mm	13mm	1.5mm	1.8mm	Green
17635	11mm	17mm	15mm	1.5mm	1.8mm	Green
17636	11mm	19mm	17mm	1.5mm	1.8mm	Green
17626	18mm	18mm	15mm	2.0mm	2.4mm	Yellow

Instrument Ordering

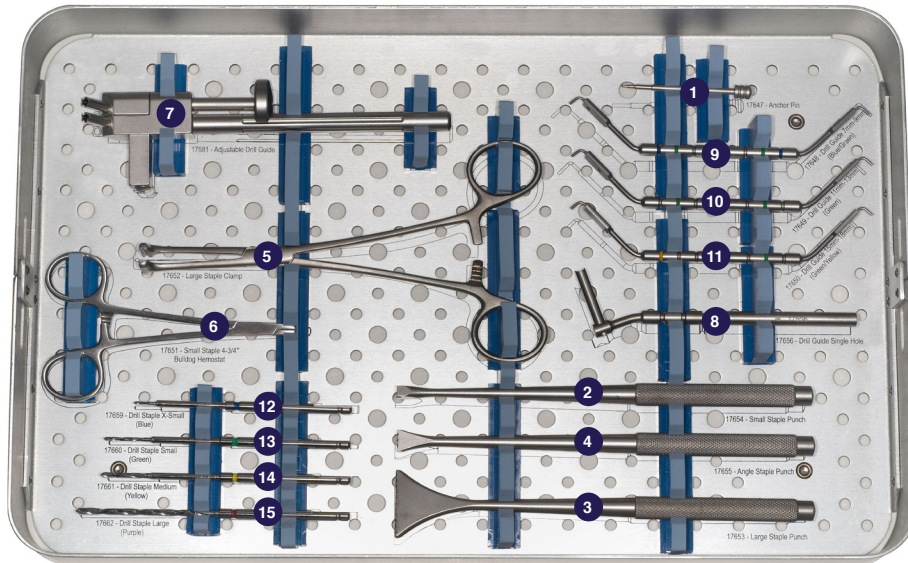


22797 - Memory Staple Gen 2

Location	Item #	Description
1	17647	Anchor pin
2	17653	Large staple punch
3	17654	Small staple punch
4	17652	Large staple clamp
5	17651	Small staple clamp
6	17681	Drill guide adjustable
7	22448	Static drill guide 7-9mm
8	22449	Static drill guide 11-13mm
9	22450	Static drill guide 15-18mm
10	22451	Static drill guide 20-25mm
11	22803	Distraction/compression device*

Note: Drill bits are not included with this instrument kit and will be sent sterile packaged.

Instrument Ordering



17707 - Memory Staple Kit

Location	Item #	Description
1	17647	Anchor pin
2	17655	Angled staple punch
3	17653	Large staple punch
4	17654	Small staple punch
5	17652	Large staple clamp
6	17651	Small staple clamp
7	17681	Drill guide adjustable
8	17656	Drill guide single hole
9	17648	Drill guide 7 - 9mm
10	17649	Drill guide 11 - 13mm
11	17650	Drill guide 15 - 18mm
12	17659	Drill bit xsm - 1.4mm
13	17660	Drill bit sm - 1.8mm
14	17661	Drill bit md - 2.4mm
15	17662	Drill bit lg - 3.0mm

Instrument Ordering



Sterile Packaged Drill Bits

Item #	Description
17750	X-Small Drill Bit - 1.4mm Sterile
17751	Small Drill Bit - 1.8mm Sterile
17752	Medium Drill Bit - 2.4mm Sterile
17753	Large Drill Bit - 3.0mm Sterile

BIOLOGICALLY ORIENTED PROSTHESES

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www.bioproimplants.com

References:

1. T.J. Chang and B.D. Overlay, "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.



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