

BIOLOGICALLY ORIENTED PROSTHESES

BIOPRO

Memory Staple

Surgical Technique



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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) for a minimum of two hours will return staples to their 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

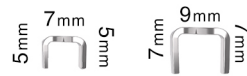
The BioPro Memory Staple is a 2-leg nitinol memory-alloy staple designed for bone fixation in the hand and foot. The unique S-Bend bridge of the Memory Staple ensures even compression across the fusion site, while maintaining a low profile against the bone.

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 where standard leg staples are utilized when a flush surface exists while the offset staples offer different leg lengths to accommodate uneven bone surfaces.

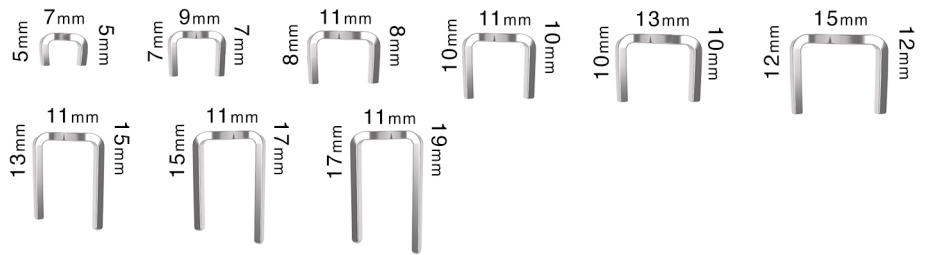
Material

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).

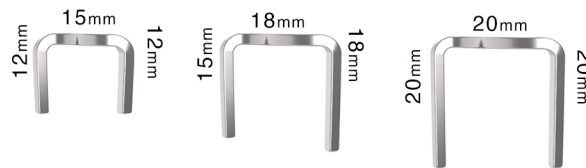
Sizing



1.2MM LEGS



1.5MM LEGS



2.0MM LEGS



3.0MM LEGS

Instrument Specifications

Adjustable drill guide

An adjustable drill guide is included in the instrument kit. The 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 will also include either double-sided static drill guides or angled drill guides.



Instrument Specifications

Drill bits

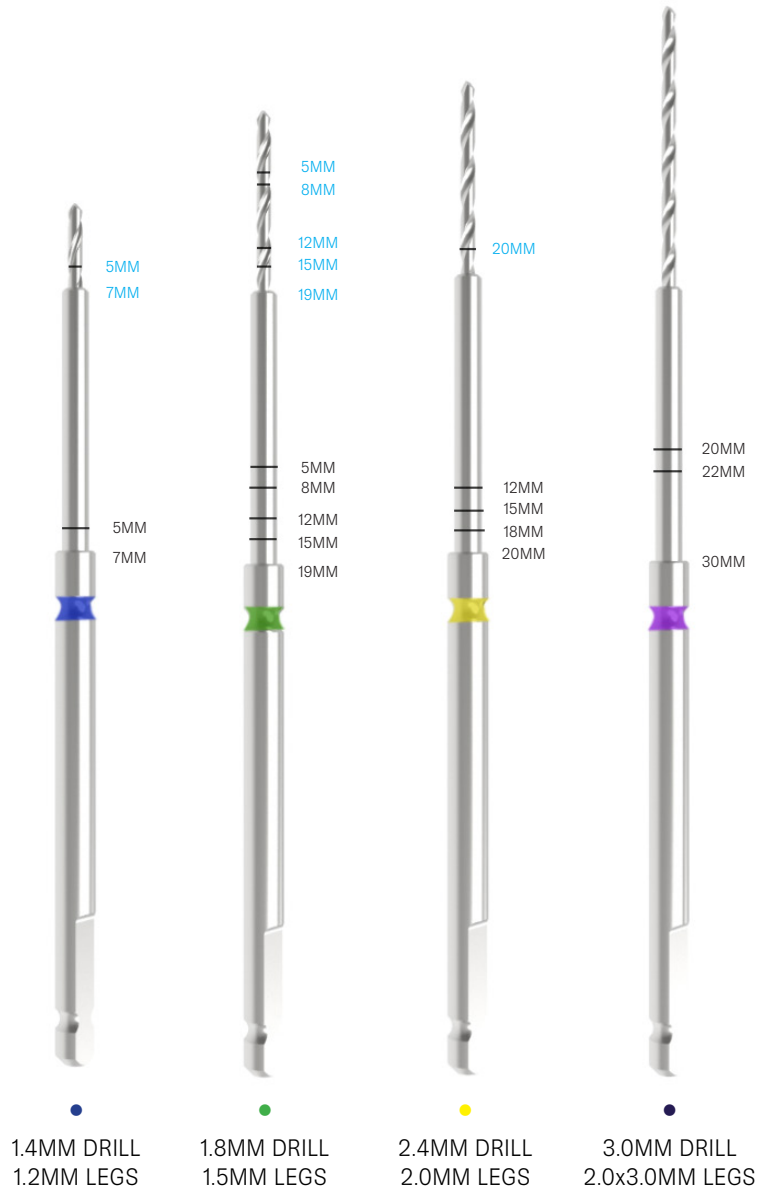
Ø1.4mm, 1.8mm, 2.4mm, and 3.0mm color coded drill bits feature etched lines that indicate drill depth, corresponding to available staple leg lengths.

Note:

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.



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 by tightly opposing bone fragments and temporarily fixating with a k-wire.

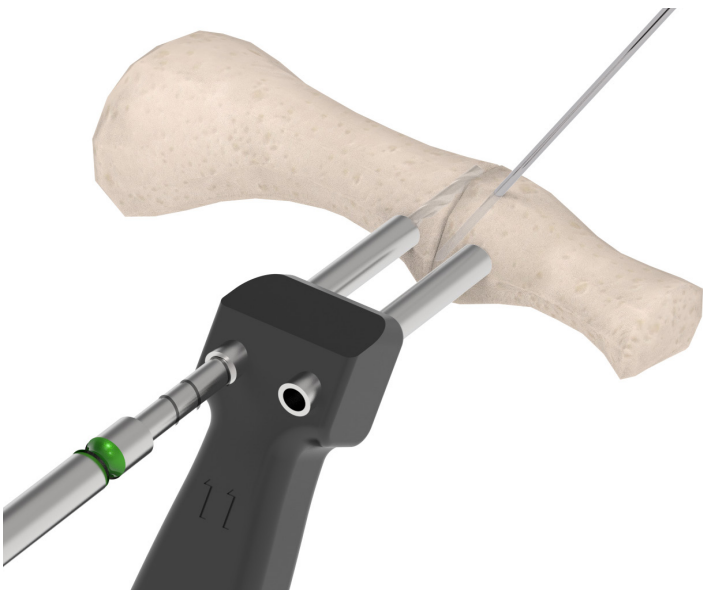


Step Two

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.

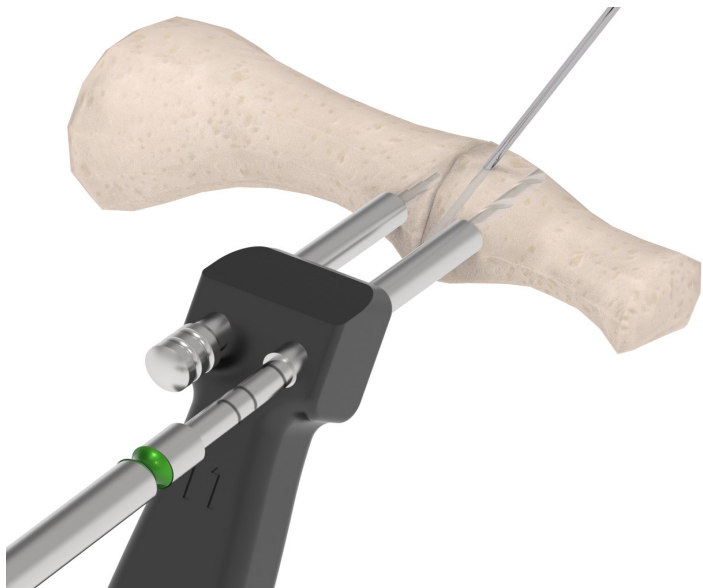


Step Three:

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

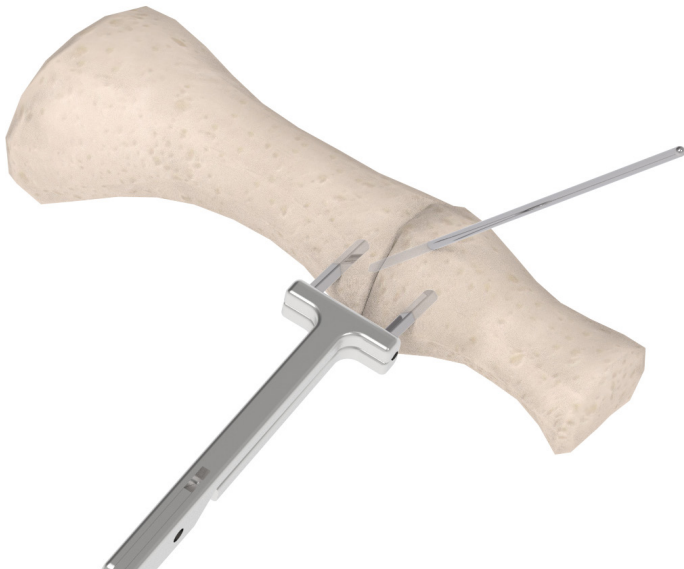
Note:

The drill bits feature etched lines that indicate drill depth. Refer to page 4 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.

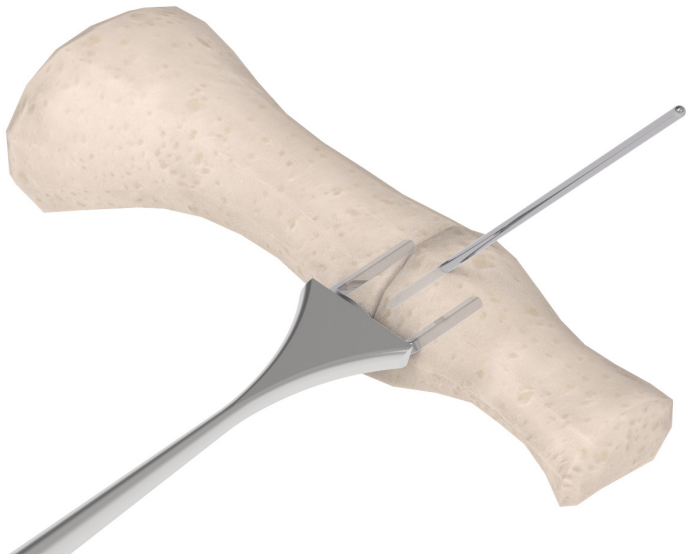


Step Four:

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.



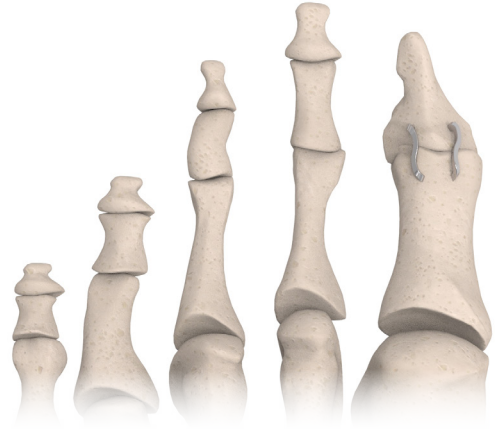
Step Six:

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).

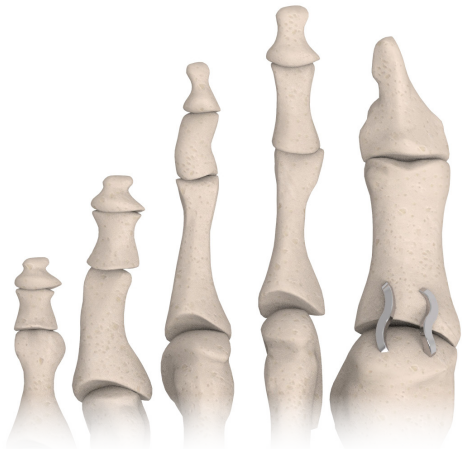
Foot & Ankle Procedures



Akin Osteotomy: 7x5, 9x7



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



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

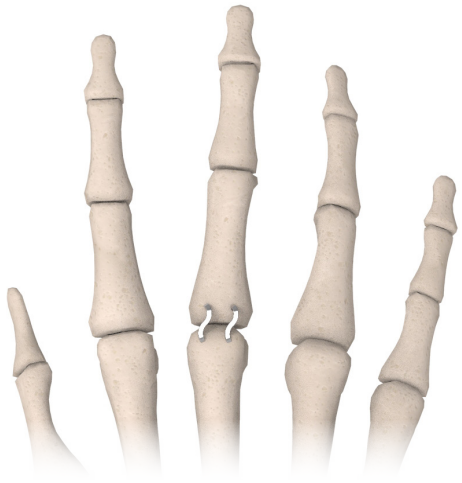


TMT Fusion (Lapidus): Dorsal- 20x20, 18x18x15
Medial- 15x12

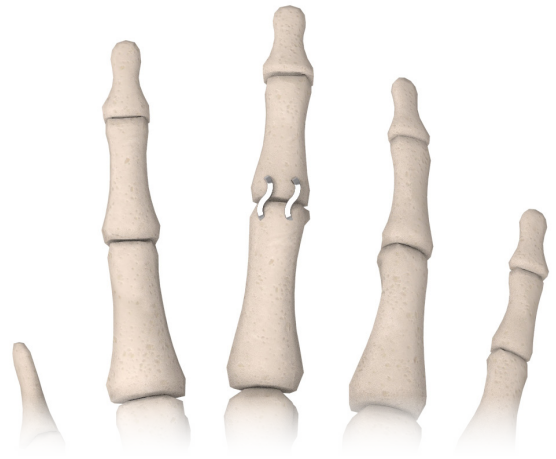
Additional Procedures

- 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

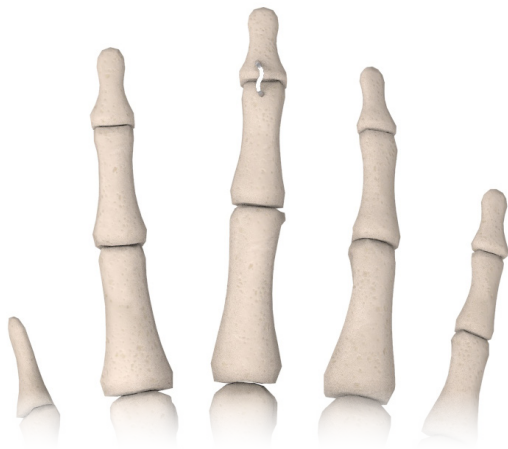
Hand & Wrist Procedures



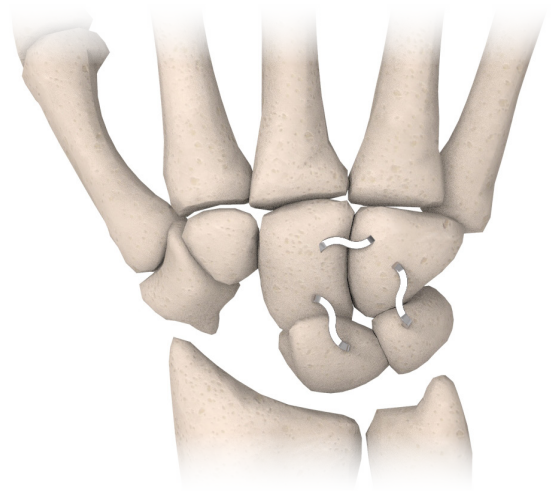
MCP Fusion: 11x8, 11x10, 13x10



PIP Fusion: 7x5, 9x7



DIP Fusion: 7x5, 9x7

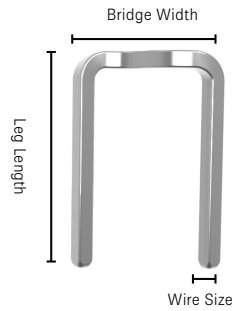


Four-corner Fusion: 11x8, 11x10, 13x10

Additional Procedures

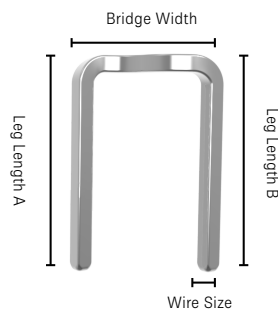
- Capitate/Scaphoid Fusion: 11x8, 11x10, 13x10
- Capitate/Lunate Fusion: 11x8, 11x10, 13x10
- CMC Thumb Fusion: 11x8, 11x10, 13x10
- Third Metacarpal/Capitate Fusion: 11x8, 11x10, 13x10
- Fifth Metacarpal/Hamate Fusion: 11x8, 11x10, 13x10

Implant Ordering



Standard Legs

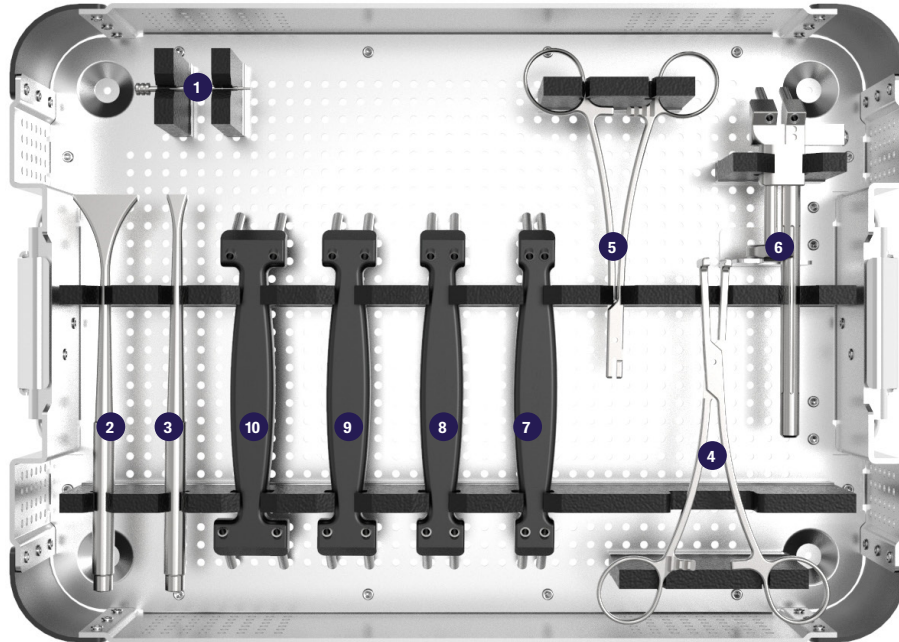
Item #	Bridge Width	Leg Length	Wire Size	Drill Ø	Color Code
17637	7mm	5mm	1.2mm	1.4mm	Blue
17628	7mm	5mm	1.5mm	1.8mm	Green
17638	9mm	7mm	1.2mm	1.4mm	Blue
17629	9mm	7mm	1.5mm	1.8mm	Green
17630	11mm	8mm	1.5mm	1.8mm	Green
17631	11mm	10mm	1.5mm	1.8mm	Green
17632	13mm	10mm	1.5mm	1.8mm	Green
17633	15mm	12mm	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

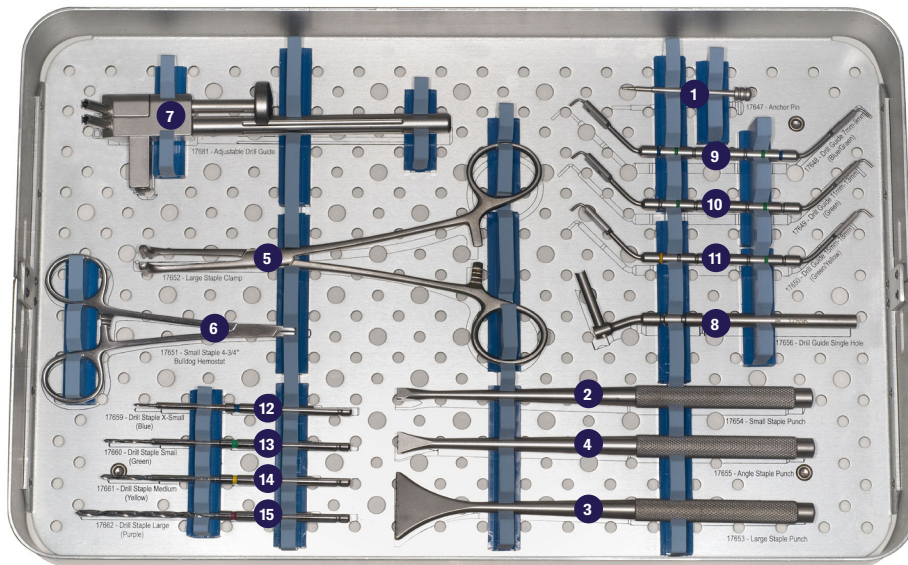


22797 - Memory Staple Gen 2

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

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

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Call us at 1-810-982-7777 to schedule a case today.

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.

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