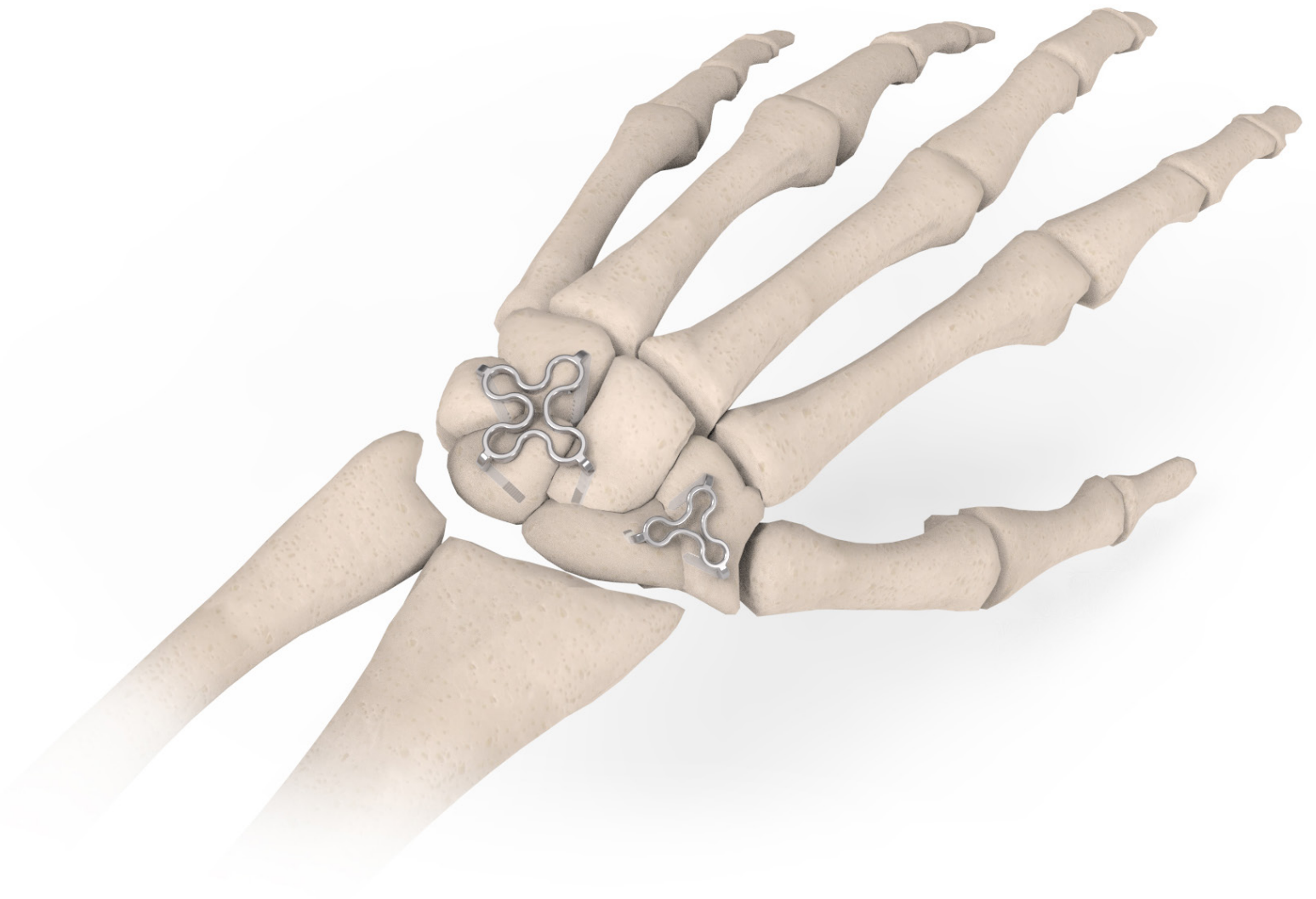


BIOLOGICALLY ORIENTED PROSTHESES

BIOPRO

Clover Staple™

Surgical Technique



Contents

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Indications & Contraindications

Indications for use:

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

Contra-indications:

1. A debilitating general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure.
2. Comminuted bone surface which would militate against staple placement.
3. Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the staple.
4. 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.
- Staples are a single use device
- Do not autoclave staples
- Exercise caution while threading the impactor tip into the handle to avoid cross-threading, as this can result in damage or the failure of the impactor tip.

Potential Complications and Adverse Effects

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

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

MR Safety Information

The Clover Staple 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. The safety of the device in the MR environment is unknown. Scanning patients who have these devices may result in patient injury.

Implant Specifications

Description

The BioPro® Clover Staple™ is a 3-leg and 4-leg nitinol memory-alloy staple specifically designed for four corner fusions and other limited wrist fusions in cases of carpal instability, Scaphoid Nonunion Advanced Collapse (SNAC) and Scapholunate Advanced Collapse (SLAC).

The Clover Staple™ was engineered to allow surgeons to use a single device and streamlined dorsal approach in intercarpal fusions, leaving the articular surfaces undisturbed. The 1mm profile and specially designed instrumentation allows the staples to sit flush preventing dorsal impingement and maximizing motion. When exposed to the activation temperature, the staple will close, creating 4-6 lbs of compressive force.* The patented clover shape allows the entire staple to compress, not just the legs, pulling all the bones towards the center of the fusion site.

Material

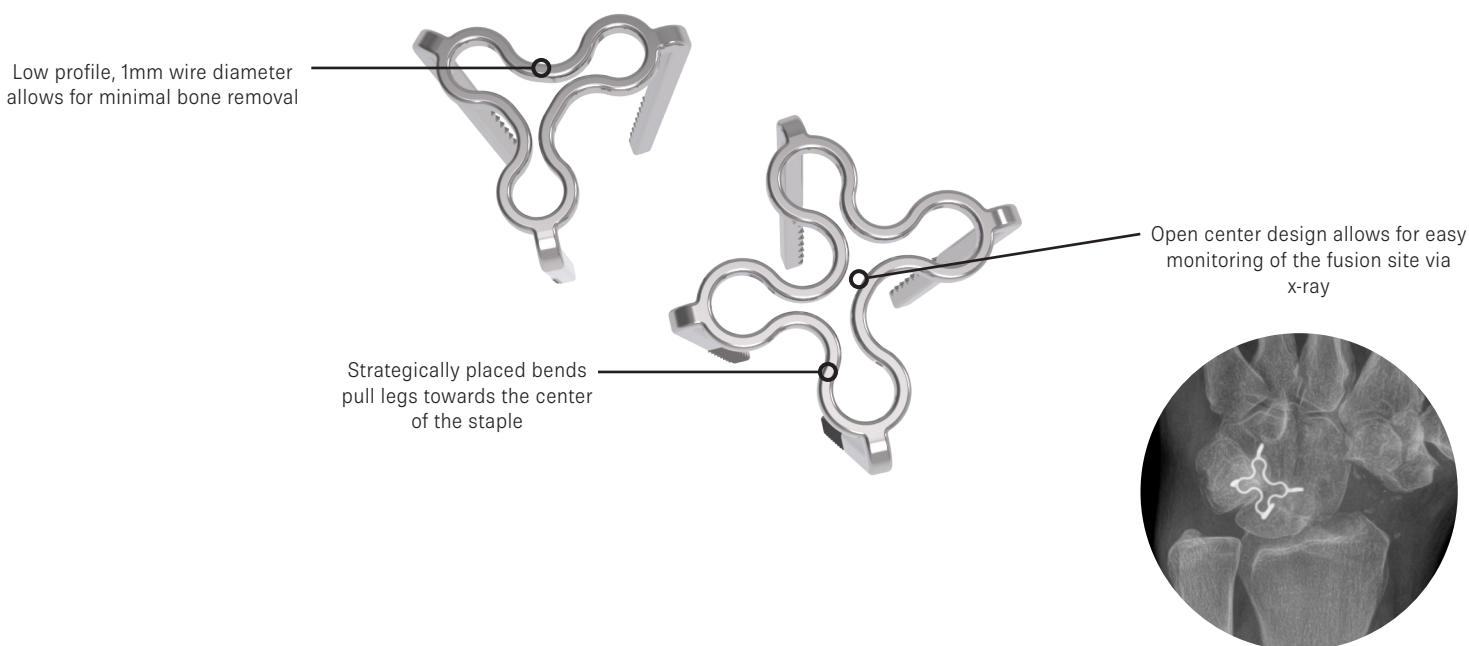
The staples are manufactured from Nitinol, a memory metal comprised of approximately 50% nickel (Ni) and 50% titanium (Ti). The alloy's unique properties allow the staple full activation at body temperature.

Sizing

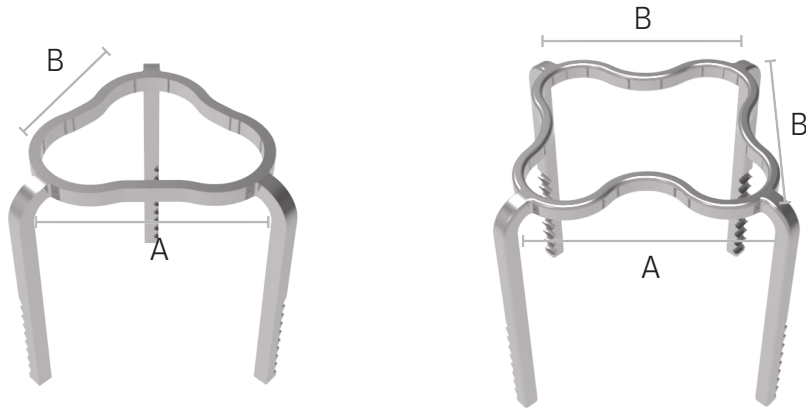
Both staples are available in three top dimensions: 10mm x 8mm, 14mm x 12mm, and 18mm x 16mm. Each staple is available in three leg lengths: 10mm, 12.5mm and 15mm.



Features



Implant Specifications



	3-LEG STAPLE	4-LEG STAPLE
Material	Nitinol	
Top Dimension (mm)	A x B	
	10 x 8	10 x 8
	14 x 12	14 x 12
	18 x 16	18 x 16
Leg Length (mm) (available for every top dimension)	10, 12.5, 15	10, 12.5, 15

Instrument Specifications

Color Coding

Instrumentation and packaging is color coded based on the staples top dimensions for quick identification. After determining the appropriate staple size, always ensure you are using the same color instrumentation for the remainder of the procedure.

Size	Color
10x8mm	Red
14x12mm	Blue
18x16mm	Green



Instrument Specifications



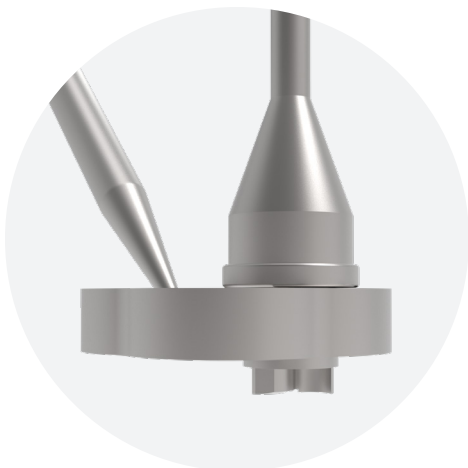
Burr Guides

The provided instrumentation includes three burr guides, one for each top dimension. Burr guides have fifteen, 0.045" (1.1mm) k-wire mounting holes for temporary fixation points, per surgeons preference.

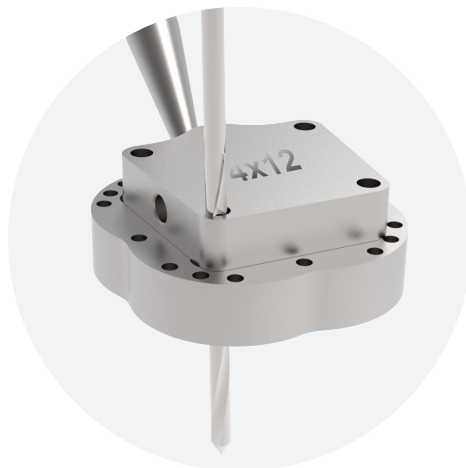
The burr guides are the primary instrument used throughout the procedure to ensure accurate bone preparation and staple placement.

Note:

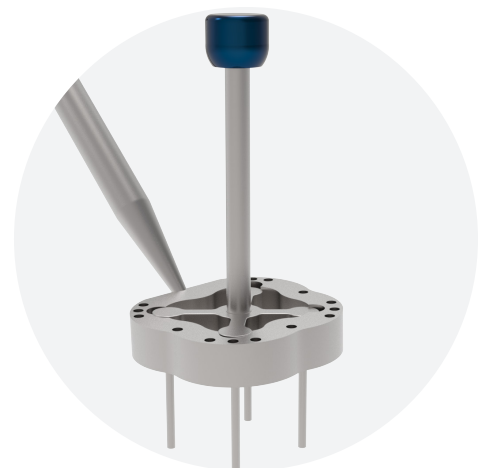
K-wires for temporary fixation are not included and must be ordered separately.



Burr cutter is inserted into the Burr Guide to plane a flush surface



Drill Guides are inserted into the Burr Guides to drill for the staple legs



Staple Pushers may be inserted through the Burr Guides to mark the drill holes

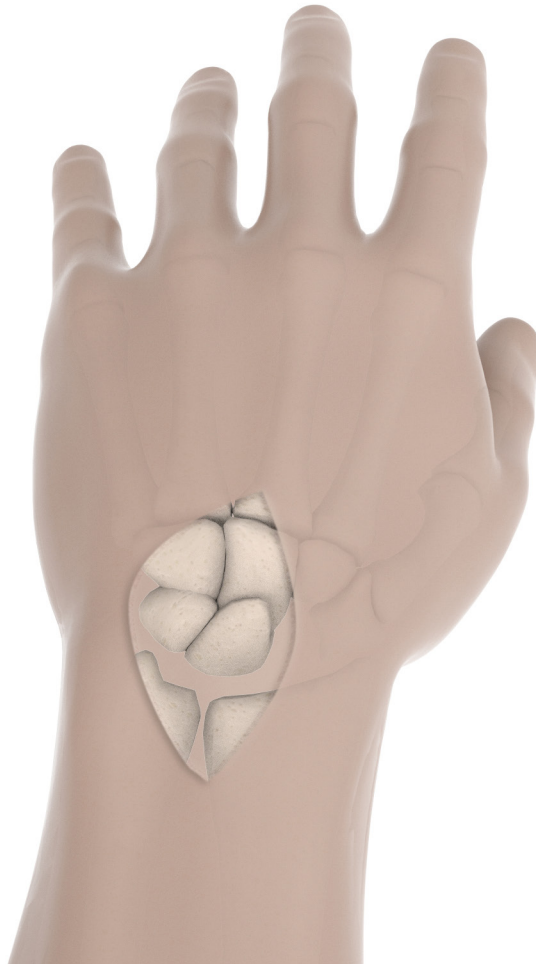
Handling Instructions

Caution

It is important to always handle the staple with the provided Staple Positioners, never by hand, as this may result in premature activation. The instrument kit includes three specially designed Staple Positioners based on the staple's top dimensions to securely handle and position the staple.



Surgical Technique



The following technique describes the use of the 4-Leg Clover Staple for a four corner fusion. This technique can be applied to use of the Clover Staple for other intercarpal fusions including the 3-Leg Clover Staple for use on STT fusions.

Step One:

Make a dorsal incision between the 3rd and 4th compartments. Expose the radial and mid carpal joint and perform scaphoidectomy, osteophytosectomy and arthrolysis.

Correct the malalignment of the first row (front and sagittal) of the carpus onto the second row.

Cartilage is removed between all bones to be fused. For optimal fusion, use a small osteotome for the cartilage and a 1 or 2mm burr to decorticate the bone.

Important Note

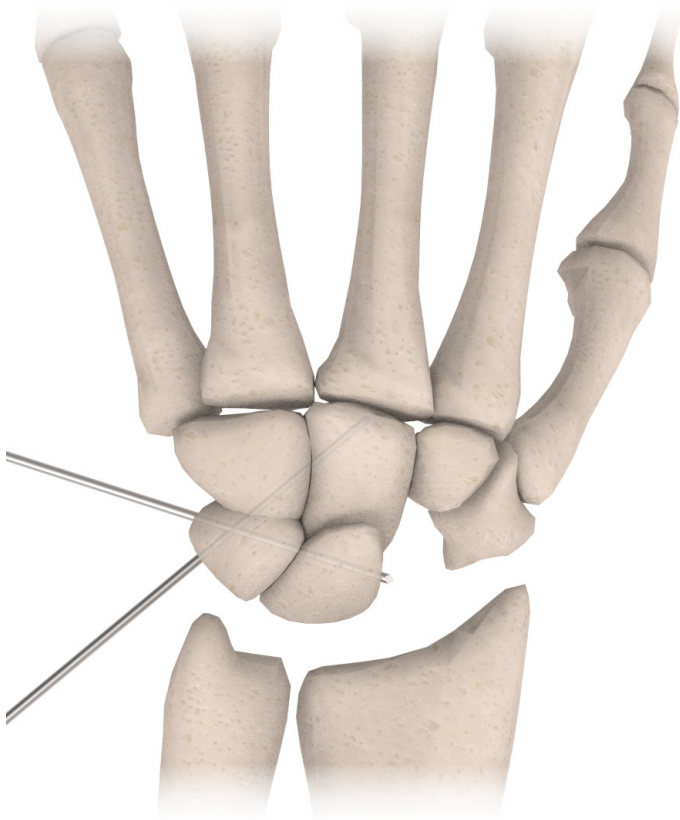
The removed bone should be denuded of cartilage and morselized to use later as bone graft.

Important Note

No fusion will succeed without adequate preparation of the joint surfaces. All cartilage must be removed and subchondral bone must be fenestrated or decorticated.

Important Note

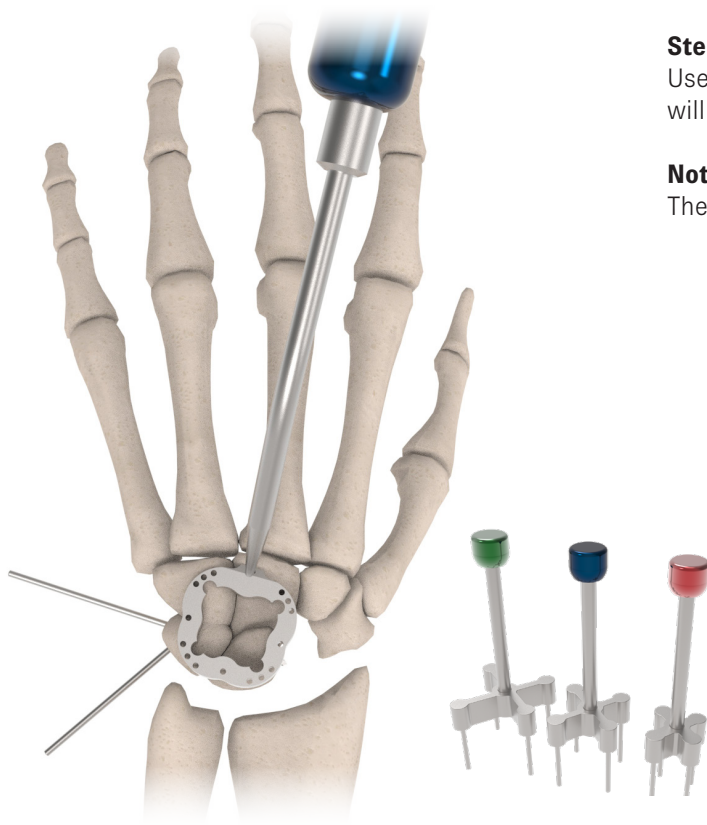
Adequate cancellous surface is important for fusion, while retaining the normal contours facilitates accurate positioning of the carpal. Thorough irrigation should remove all cartilagenous debris.



Step Two:

Reduce and pin the carpals with fluoroscopy. Mini-C-arm can be used to assure the lunate and capitate are collinear on the lateral view. Typically 0.045" K-wires provide adequate stability.

Suggested wire placement: Triquetro-Lunate, Triquetro-Hamocapitate.

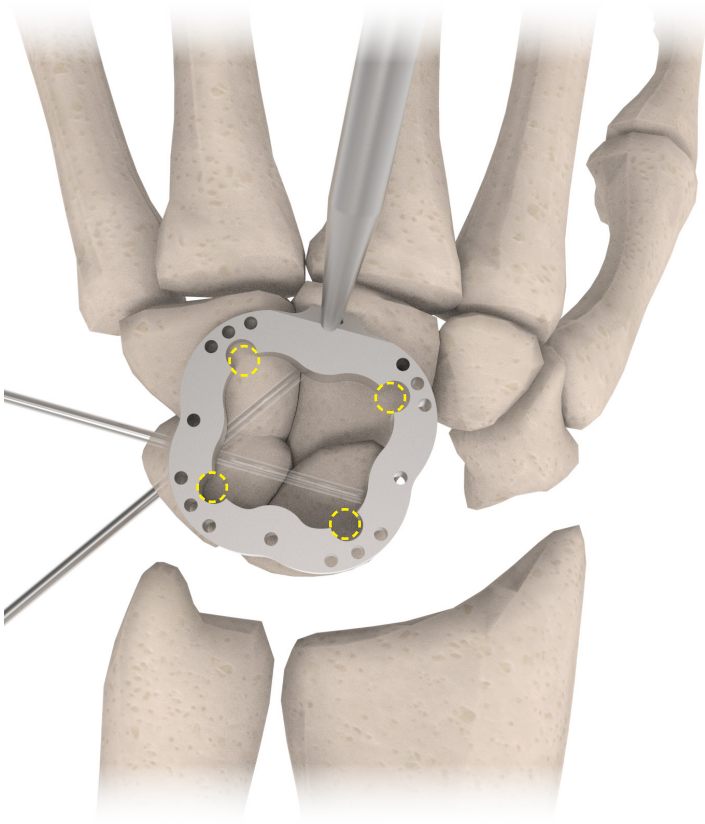


Step Three:

Use the burr guide or staple pusher to assess which size staple will obtain the best purchase in bone.

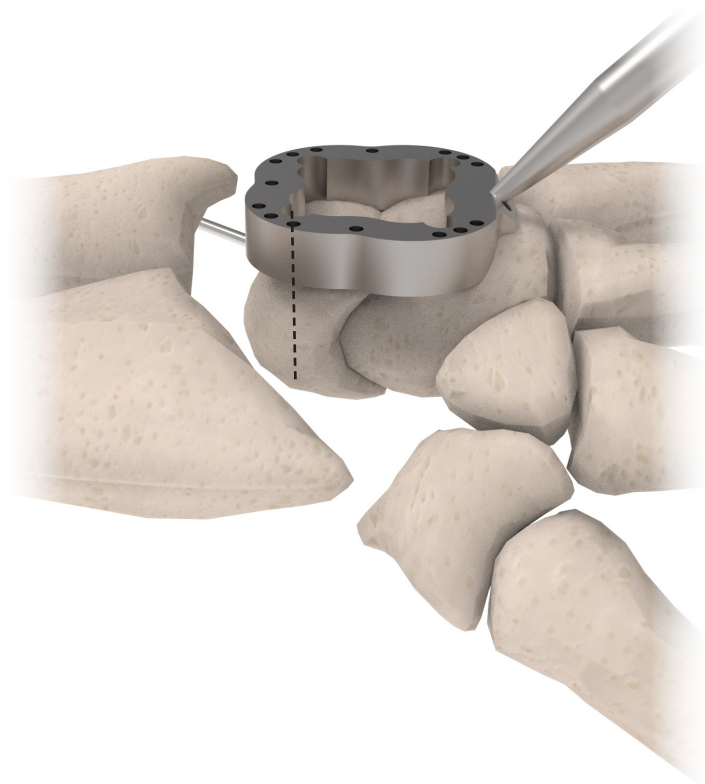
Note

The widest width of the staple is proximal to the handle.



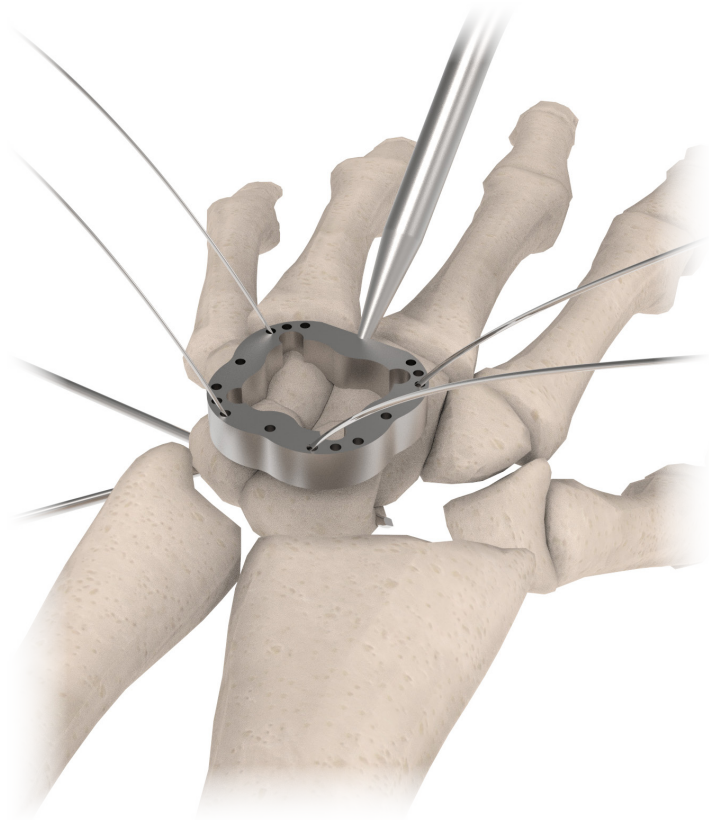
Step Four:

Position the appropriate size burr guide, ensuring it sits flush against the dorsal surface. Fluoroscopy may be used to ensure the temporary k-wires will not interfere with the staple legs.



Caution

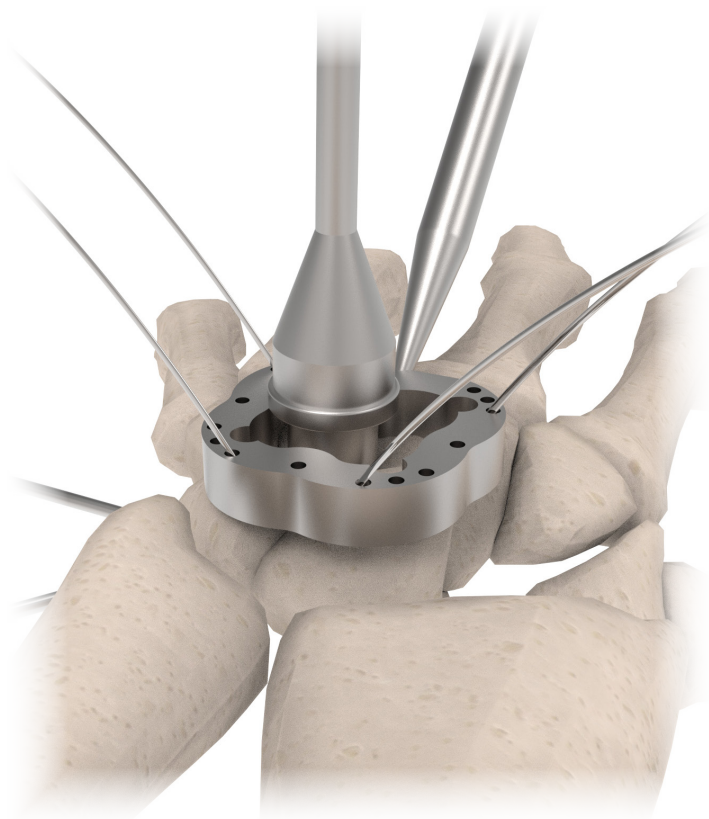
It is important to mount the burr guide as proximal as possible on the lunate to ensure proper leg placement. Due to the typical crescent shape of the lunate, mounting the guide too distal may result in a poor purchase.

**Step Five:**

Secure the burr guide in place with 0.045 (1.1mm) k-wires. A minimum of three k-wires is recommended for adequate stability.

Important Note

Slightly bend the wires outward to allow easier access to the center of the burr guide.

**Step Six:**

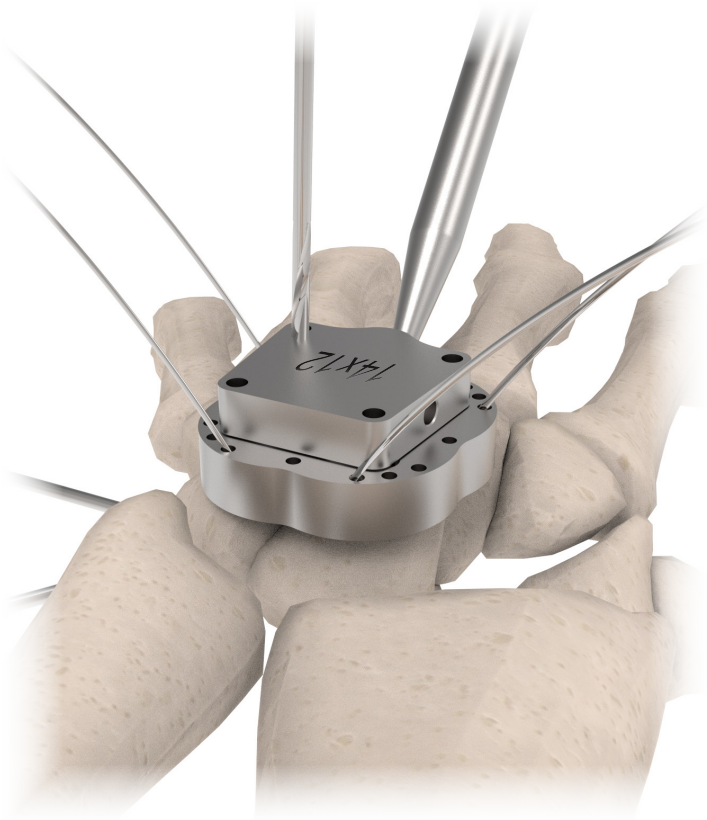
Utilizing the burr cutter in a low speed AO connection rotary hand piece, plane around the inside of the burr guide to create a recess for the Clover Staple, most importantly on the lunate. This will prevent impingement of the staple during dorsiflexion of the wrist.

Important Note

Ensure the planer bit is inserted straight so the collar rides along the planer guide. Insertion of the bit at an angle can leave bone ridges that will interfere with staple seating.

Caution

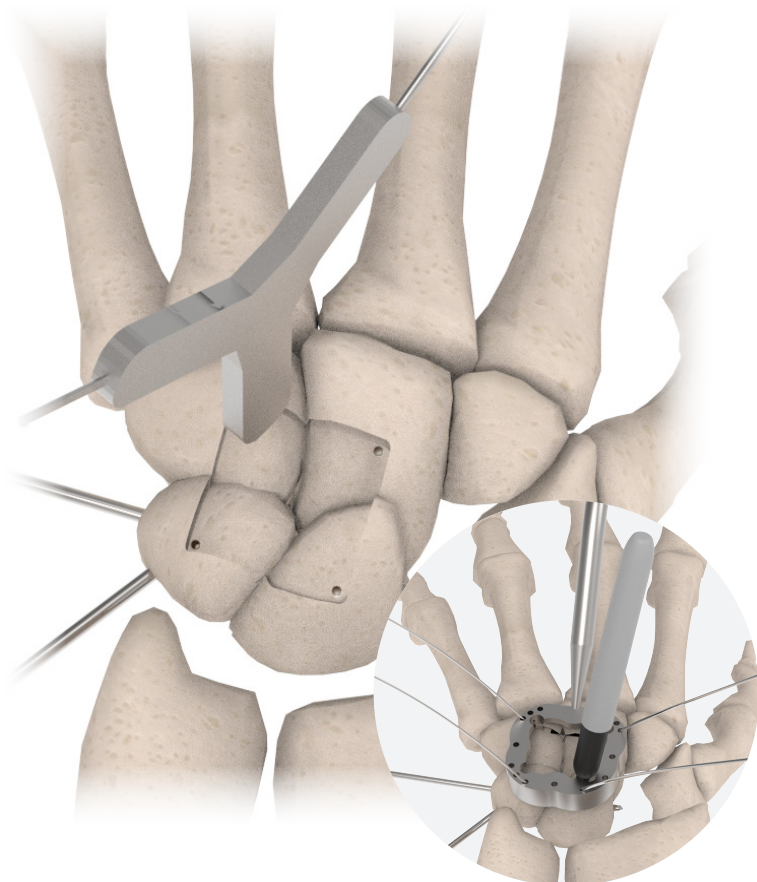
The burr cutter can be an aggressive instrument. It is advised to burr each corner of the burr guide prior to planing around the guide.

**Step Seven:**

Insert the appropriately sized drill guide into the burr guide and drill the holes for the staple legs. Drill all holes bicortically to ensure sufficient depth.

Important Note

Drill bits are not contained in the instrument kits, but are packaged sterile and provided with the sterile Clover Staple inventory. Once all holes have been drilled, remove the drill guide.

**Step Eight:**

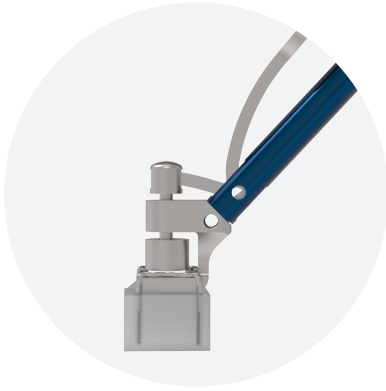
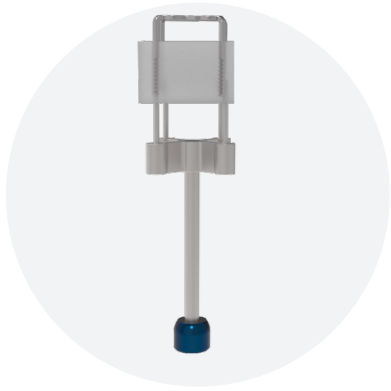
Before removing the burr guide, it is important to mark the drill holes. This can be accomplished in one of the following methods:

1. With a surgical marking pen
2. With an electro-cautery device

Once the drill holes have been appropriately marked, remove the k-wires used to mount the burr guide. Do not remove temporary fixation k-wires yet. Measure the depth of each leg hole with the depth gauge and select the longest leg length staple that will not sit bicortical.

Important Note

Ensure that the staple legs do not sit bicortical. This allows the legs to compress into the cancellous bone, ensuring the staple remains recessed within the carpals.



Step Nine:

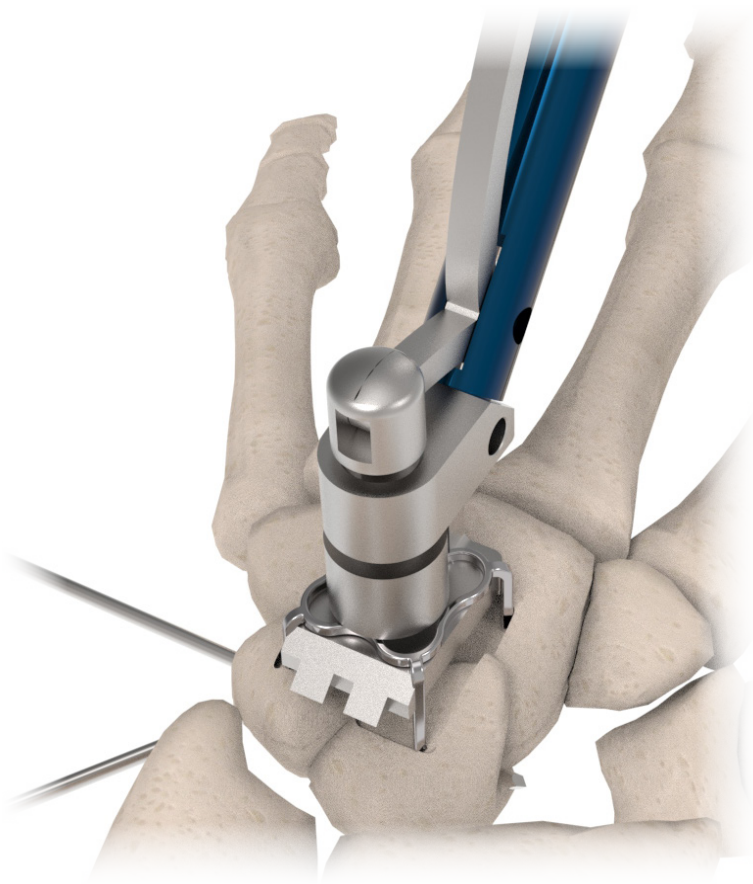
Irrigate again and then place bone graft in all interstices. Use the appropriately sized staple pusher to push the Clover Staple approximately 5mm out of its protective shipping block.

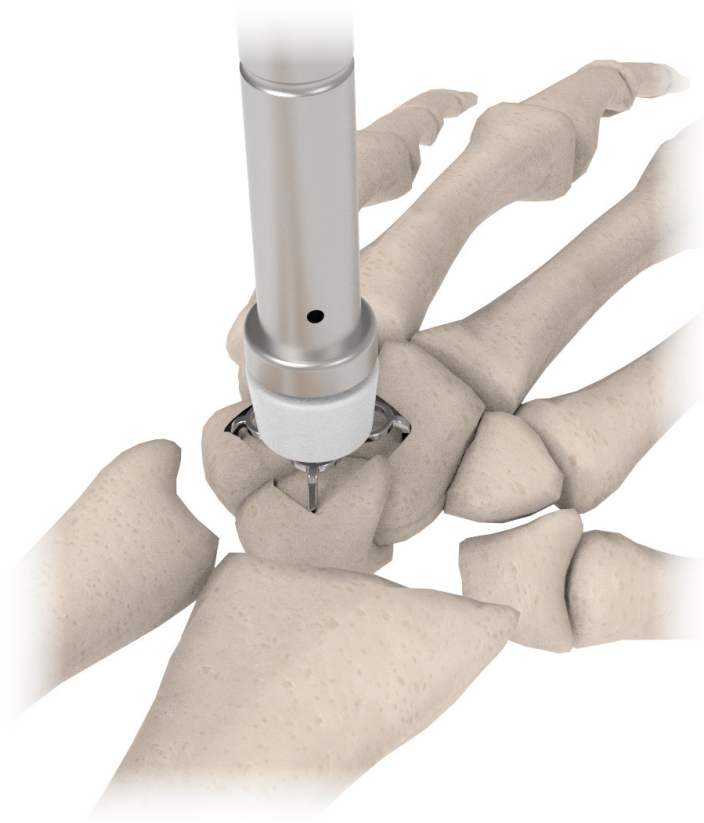
Slide the appropriately sized staple positioner between the staple and the shipping block.

Important Note

Always use the supplied Staple Positioners to handle the Clover Staple. Heat from hands can prematurely activate the staple.

Once the Clover Staple has been removed from the shipping block with the staple positioner, insert it into the drill holes as far as possible and remove the Staple Positioner.



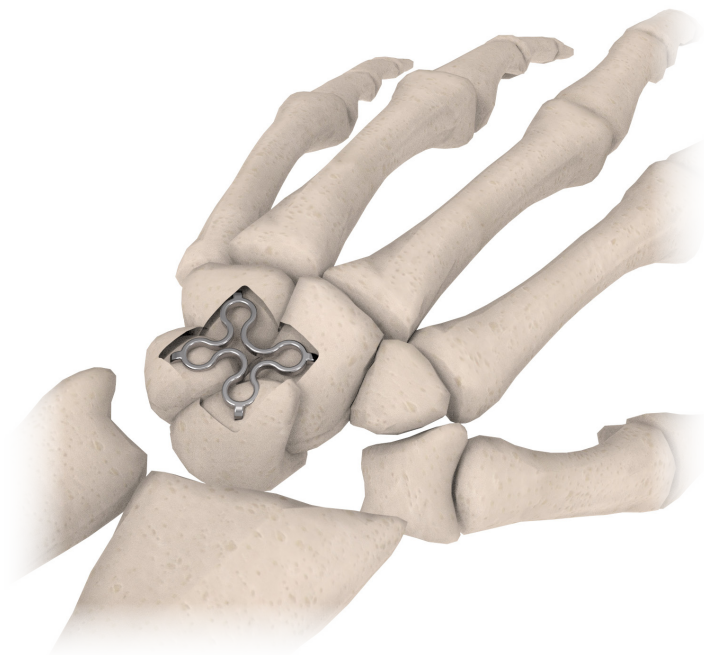


Step Ten:

Impact the staple flush with the planed surface using the impactor handle fitted with the appropriately sized impactor tip. Activate the staple with a small amount of 98° F (37°) or warmer saline and remove the provisional wires. Confirm that no debris is in the radiocarpal joint. Gently assess motion; mini-C-arm can be beneficial to provide images of the maximum stable motion provided by the implant.

Important Note

It is advised to take a lateral x-ray at this point. The Clover Staple often appears to sit proud in a lateral view. An immediate post-op x-ray will help avoid confusion in the future.



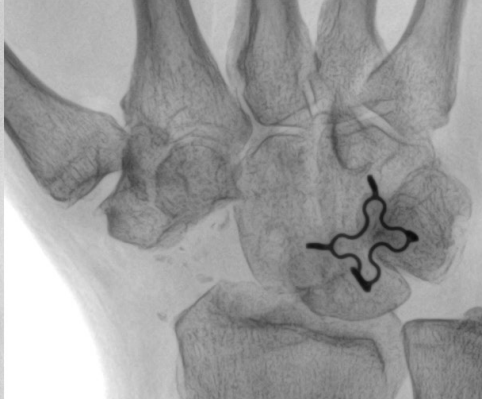
Step Eleven:

Close the joint capsule in layers using your suture of choice. The extensor tendons should have remained within their compartment unless the Extensor Pollicis Longus is intentionally left out from the chosen approach. The skin is sutured closed.

Common Applications



Radioscapholunate Fusion



Four Corner Fusion

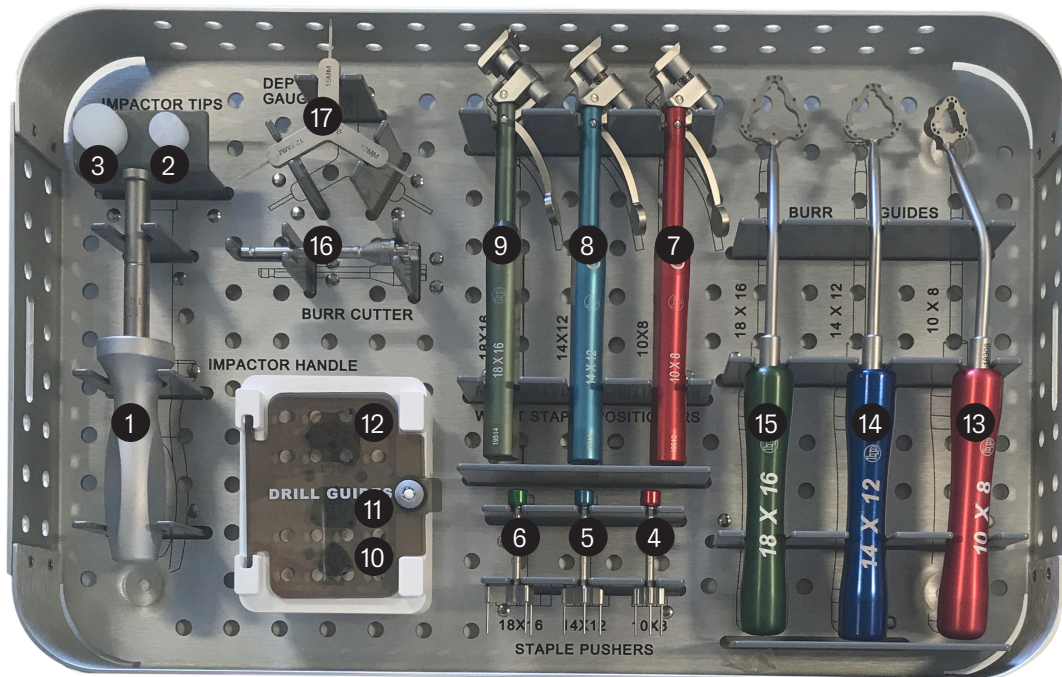


Scaphotrapeziotrapezoid Fusion

Implant Ordering

Item #	Description	Size	Leg Length
18259	4-Leg Clover Staple	10mm X 8mm	10mm
18260	4-Leg Clover Staple	10mm X 8mm	12.5mm
18261	4-Leg Clover Staple	10mm X 8mm	15mm
18062	4-Leg Clover Staple	14mm X 12mm	10mm
18063	4-Leg Clover Staple	14mm X 12mm	12.5mm
18064	4-Leg Clover Staple	14mm X 12mm	15mm
18065	4-Leg Clover Staple	18mm X 16mm	10mm
18066	4-Leg Clover Staple	18mm X 16mm	12.5mm
18067	4-Leg Clover Staple	18mm X 16mm	15mm
18262	3-Leg Clover Staple	10mm X 8mm	10mm
18263	3-Leg Clover Staple	10mm X 8mm	12.5mm
18264	3-Leg Clover Staple	10mm X 8mm	15mm
18068	3-Leg Clover Staple	14mm X 12mm	10mm
18069	3-Leg Clover Staple	14mm X 12mm	12.5mm
18070	3-Leg Clover Staple	14mm X 12mm	15mm
18071	3-Leg Clover Staple	18mm X 16mm	10mm
18072	3-Leg Clover Staple	18mm X 16mm	12.5mm
18073	3-Leg Clover Staple	18mm X 16mm	15mm
Item #	Description	Ø	Length
18960	Clover Staple Drill Bit	1.5mm	18mm

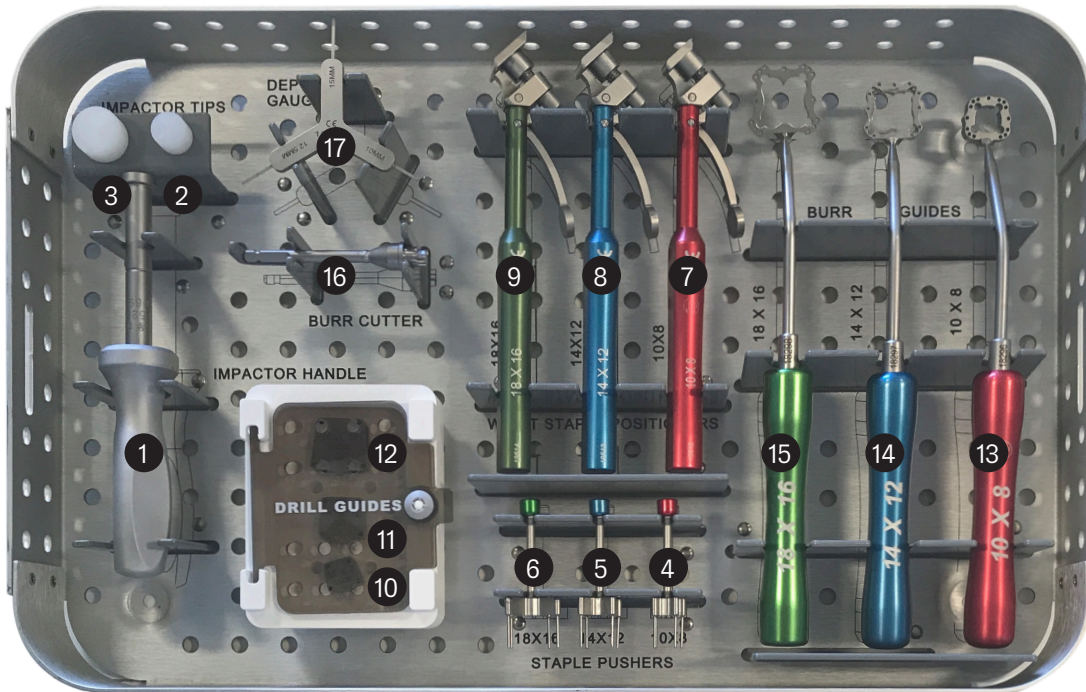
Instrument Overview



Clover Staple 3-Leg Complete Kit - 19678

Location	Item #	Description
1	15259	Impactor Handle
2	18284	Impactor Tip Sm
3	18285	Impactor Tip Lg
4	18311	Pusher 3-Leg 10x8
5	18312	Pusher 3-Leg 14x12
6	18313	Pusher 3-Leg 18x16
7	19512	Staple Positioner 10x8
8	19513	Staple Positioner 14x12
9	19514	Staple Positioner 18x16
10	18302	Drill Guide 3-Leg 10x8
11	18303	Drill Guide 3-Leg 14x12
12	18304	Drill Guide 3-Leg 18x16
13	18308	Burr Guide 3-Leg 10x8
14	18310	Burr Guide 3-Leg 14x12
15	18309	Burr Guide 3-Leg 18x16
16	18315	Burr Cutter
17	18378	Depth Gauge
	19480	Wrist Staple Instrument Tray

Instrument Overview



Clover Staple 4-Leg Complete Kit - 19543

Location	Item #	Description
1	15259	Impactor Handle
2	18284	Impactor Tip Sm
3	18285	Impactor Tip Lg
4	18299	Pusher 4-Leg 10x8
5	18300	Pusher 4-Leg 14x12
6	18301	Pusher 4-Leg 18x16
7	19512	Staple Positioner 10x8
8	19513	Staple Positioner 14x12
9	19514	Staple Positioner 18x16
10	18290	Drill Guide 4-Leg 10x8
11	18291	Drill Guide 4-Leg 14x12
12	18292	Drill Guide 4-Leg 18x16
13	18296	Burr Guide 4-Leg 10x8
14	18297	Burr Guide 4-Leg 14x12
15	18298	Burr Guide 4-Leg 18x16
16	18315	Burr Cutter
17	18378	Depth Gauge
	19480	Wrist Staple Instrument Tray

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