Memory™ Staple

Surgical Technique

Controlled compression for fusion
Cool Fusion

Precisely controlled dynamic compression for fusion.

No costly or intrusive equipment in the OR.

International clinical experience with approximately 52,000 Memory™ Staple procedures.

The Memory Staple was designed to help achieve optimum compression for fusion. Delivered to the OR in its frozen state, the Nitinol® temperature-sensitive memory metal structure reacts to the ambient temperature within the OR as well as the temperature of the patient when it is inserted. The oval strap section opens and the arms close, drawing the bone fragments or joint together in a controlled and predictable process. This “cool” process requires no additional equipment in the OR, no electrical energy is used and heat is not applied to the surrounding bone. With approximately 52,000 international procedures completed, experience with the Memory Staple is extensive and the simple techniques for implantation are well established.
Symmetric and asymmetric Memory Staple

Indications for the 12 mm Memory Staple
Osteotomies of the first phalanx of the foot

Strong in Form and Function

Symmetric and asymmetric Memory Staple

Indications for the 20 mm Memory Staple
Arthrodesis of the first metatarsal phalangeal joint
Memory 12 Surgical Technique

Osteotomies of the first phalanx of the foot.

Prior to Surgery

Implants must be kept for at least 2 hours before implantation at a maximum temperature of 0°F (-18°C) and made available at the last minute, just before implantation.

Step 1:
Make osteotomy cuts
A. Closing wedge osteotomy to correct Hallux Valgus Interphalangeus.

A standard medial based closing wedge osteotomy is performed. The proximal cut is performed first, leaving the lateral cortex intact. When the distal cut is made, the osteotomy is closed with a greenstick maneuver (Figure 1).

B. For derotation of the proximal phalanx.

The osteotomy is made completely through the shaft of the phalanx. This is done either in isolation if no valgus deformity is present or after a closing wedge osteotomy if no valgus correction is desired (Figure 2).

Step 2:
Place a temporary axial pin

A temporary axial pin prevents displacement of the fragments when the staple is introduced. The axial wire should remain just under the dorsal cortex to allow the placement of a staple (Figure 3).

It is important to maintain dorsal and medial bony contact to allow the osteotomy to heal.
Step 3:  
**Position drill guide**  
The osteotomy should be positioned between the two arms of the drill guide.  
The distal arm of the drill guide should rest on the medial side of the proximal phalanx.  
This stage is essential because it ensures the oval part of the staple is correctly applied to the diaphyseal region of the proximal phalanx (Figure 4).

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Figure 4

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Step 4:  
**Insert proximal guide wire**  
With the drill guide in proper position, insert the proximal guide wire to penetrate both the medial and lateral cortices (Figure 5).  
Remove the drill guide.
Step 5:
Position the cannulated drill bit

The cannulated drill bit is placed over the guide wire that is already inserted, making it possible to drill the two cortices and prepare for the insertion of the proximal leg of the staple. Leave the cannulated drill bit in position and remove the guide wire (Figure 6).

Figure 6

Step 6:
Position the drill guide and drill distally with a non-cannulated drill bit

The drill guide is put back onto the cannulated drill bit, and then the distal hole is drilled using the solid drill bit. Because of the contour of the proximal phalanx, it is advisable to insure that the solid drill bit is parallel to the cannulated drill bit (Figure 7).

Figure 7
Step 7: 
Select the staple size

Using standard technique, the depth gauge allows the determination of the length of each arm of the staple. In order to ensure good bicortical purchase, the surgeon should select a staple arm length 1 mm longer than the reading (Figure 8).

Step 8: 
Verify the hole orientation

The staple trial is put into position in order to verify the proper orientation of the drill holes. The surgeon has the final opportunity to verify that the toe is in proper position (Figure 9).
Step 9: Remove staple from sterile package

The staple to be used is taken out of the freezer immediately before insertion and removed from its support using the gripping forceps. The surgeon must take care to flatten the eye of the staple and to ensure that the legs are parallel (Figure 10). Implants must be kept for at least 2 hours before implantation at a maximum temperature of 0°F (-18°C) and made available at the last minute, just before implantation.

Step 10: Insert the staple

The staple is placed in position and then impacted using the Memory arthrodesis impactor (Figure 11). Remove the temporary axial pin.

Recommendations for use

- The legs of the staple should not be opened wider than 90 degrees because this modifies the mechanical and dynamic properties of the nickel-titanium alloy.

- Do not touch the staple if it has started to close. The warmth of one’s body will cause the staple to close faster. If the staple closes prematurely, discard it. Do not refreeze the staple.

Postoperative protocol

- The surgeon should use his or her standard postoperative protocol for this type of osteotomy.
Memory 20 Surgical Technique

Arthrodesis of the first metatarsal phalangeal joint.

Prior to Surgery

Implants must be kept for at least 2 hours before implantation at a maximum temperature of 0°F (-18°C) and made available at the last minute, just before implantation.

Step 1:
Prepare the metatarsophalangeal joint for fusion

A direct approach to the metatarsophalangeal joint is made. Perform metatarsal head and base of proximal phalanx preparation in the usual fashion, ensuring cancellous bone is exposed on both surfaces (Figure 1).

Step 2:
Insert temporary pin fixation

• Put the toe in desired position for fusion.
• Insert temporary fixation.

Perform a double pin fixation of the joint. These should be inserted from a dorsomedial position of the construct to avoid collision when the staple is inserted.

One pin is inserted in a distal lateral direction from the metatarsal neck. The second pin is inserted in the base of the proximal phalanx in a proximal lateral direction. This stabilizes the metatarsophalangeal joint while the staples are inserted (Figure 2).
Step 3: Verify position of the toe

The position of the toe is verified by placing a platform against the plantar surface of the foot to simulate the floor (Figure 3).

In the sagittal plane, the pulp of the toe should be elevated no more than 4-5 mm from the supporting platform. When the interphalangeal joint is plantar flexed, the pulp should easily contact the supporting surface.

The toe should be positioned in a neutral rotation (nail plate parallel to the floor) and parallel to the second toe.

Step 4: Positioning the drill guide

The drill guide, used for insertion of the medial staple, is put into position ensuring that it is centered over the arthrodesis (Figure 4).

Drill the proximal hole first, penetrating both cortices. The drill bit is left in place and the distal hole is drilled.
Step 5: Select the staple size

Using standard technique, the depth gauge allows determination of the length of the staple to be used. In order to ensure good bicortical purchase, the surgeon should select a staple length 1 mm longer than the reading (Figure 5).

Step 6: Verify the hole orientation

The staple trial is put into position in order to verify the proper orientation of the drill holes. The surgeon has the final opportunity to verify that the toe is in proper position (Figure 6).

Step 7: Remove the first temporary fixation pin

Remove one pin to allow the staple to achieve compression when inserted.

Step 8: Remove the staple

The staple to be used is taken out of the freezer immediately before insertion and removed from its support using the gripping forceps. The surgeon must take care to flatten the eye of the staple and to ensure that the legs are parallel (Figure 7).

Implants must be kept for at least 2 hours before implantation at a maximum temperature of 0°F (-18°C) and made available at the last minute, just before implantation.
Step 9:
Insert the staple

The staple is placed in position and then impacted using the impactor. Remove the second pin (Figure 8).

Step 10:
Position the second staple

Using the same procedure, the second staple is put into position at the dorsal surface near the lateral margins of the first metatarsal and the first proximal phalanx. It is positioned slightly proximal to the medial staple (Figure 9).

Recommendations for use

• Prior to insertion, the legs of the staple should not be opened wider than 90 degrees because this modifies the mechanical and dynamic properties of the nickel-titanium alloy.

• Do not touch the staple if it has started to close. The warmth of one’s body will cause the staple to close faster. If the staple closes prematurely, discard it. Do not refreeze the staple.

Postoperative protocol

• The surgeon should use his or her standard postoperative protocol for this type of arthrodesis.
Ordering Information - 12 mm Memory Staple

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12 mm interaxis distance

Ordering Information - 20 mm Memory Staple

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20 mm interaxis distance
Essential Product Information: Memory 12, Memory 20 staples

IMPORTANT
This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

INDICATIONS
Memory 12 and Memory 20 staples are implants intended for fixation of the foot. Memory 12 staples are indicated for osteotomies of the first phalanx of the foot. Memory 20 staples are indicated for arthrodesis of the first metatarsal phalangeal joint. The patient's anatomy and skeleton must be capable of receiving the selected implant.

CONTRAINDICATIONS
Fixation may be contraindicated where the patient is overweight, where there is infection, poor bone stock, severe deformity, drug abuse, overactivity, tumor, mental incapacity, muscle, nerve or vascular disease and allergy to nickel.

WARNINGS AND PRECAUTIONS
Staples should never be re-implanted. Even if the material appears to be in good condition, microscopic imperfections may have appeared which may cause implant failure. The following conditions tend to have an adverse effect on the fixation of the staples; excessive patient weight, high levels of patient activity, likelihood of falls, poor bone stock, metabolic disorders, history of infections, significant deformations damaging the fixation or the correct insertion, tumors of the supporting bone structures, allergic reactions to nickel and tissue reactions.

Implants must be kept for at least 2 hours before implantation at a maximum temperature of 0°F (-18°C) and made available at the last minute, just before implantation.

ADVERSE EVENTS
The following are the most frequent adverse events in fixation: changes in the position of the staple, infection, loosening of the implant, cardiovascular disorders (including venous thrombosis, pulmonary embolism and myocardial infarction), hematoma and/or late wound healing, pneumonia and/or atelectasis.

Further Reading

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