Surgical Technique

MH Memory Staple

Intra-Operative Stability

Body Temperature Activated

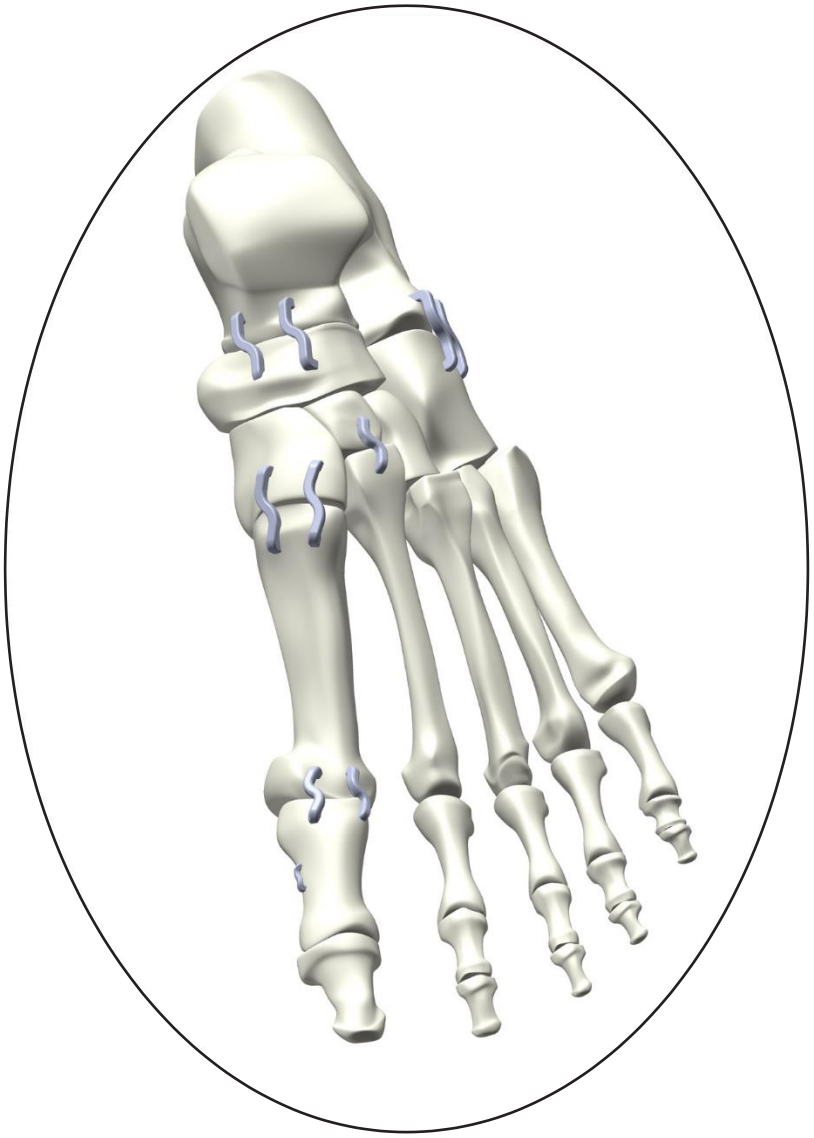
Bone Bridge Compression

Minimal Surgical Steps

Simple Instrumentation

Multiple Sizes

Sterile Packaged



maxx health

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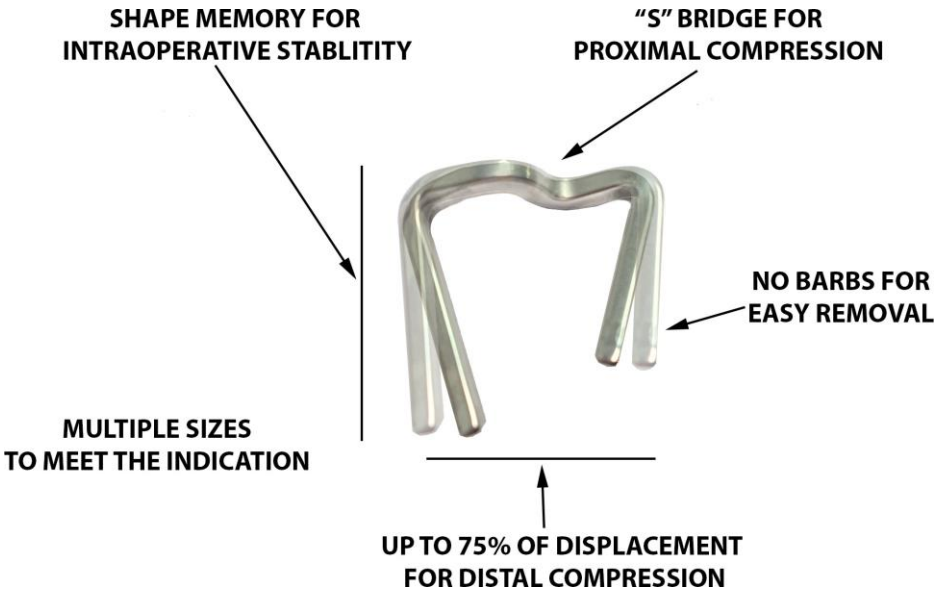
The comprehensive and versatile Maxx Health Staple was designed for ease of use and intraoperative stability. The implant offers the following advantages:

- An ideal form of fixation for arthrodesis, osteotomy, and fracture fixation.
- Manufactured from Nitinol, the Memory Staple offers continuous compression to help speed the fusion process.
- Nitinol is a shape memory alloy allowing the staple to offer active compression at the activation temperature of 98.6F (37C), patient body temperature.
- This eliminates the need for an external activation device while also offering benefits over pre-compressed staples such as uniform compression.
- The S-Bend across the bridge of the Memory Staple ensures even compression across the fusion site, while maintaining a low profile against the bone.



Indications and Contraindications

Indications

- Hand and foot bone fragment, osteotomy fixation, and joint arthrodesis.
- Fixation of soft tissue to bone such as anterior cruciate reconstruction.

Contraindications

The implant should not be used in a patient who has current, or who has a history of:

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

Important Note

- Any adjunctive procedures should be completed prior to staple implantation to avoid disrupting staple positioning.
- 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 should not be relied upon to achieve closure or reduction of the fracture line.

Care and Caution

- Inspect sterile pouches prior to use. Sterilization cannot be assured and staple should not be used if pouch or seal is damaged.
- Staples should be stored at 75ºF (24ºC) or less. Staples should be cooled to 75ºF (24ºC) prior to removing from the shipping block. Placing staples at -5ºF (-20ºC) will return staples to original position.
- The Memory Staples are a single use device.
- Do not autoclave staples.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a Physician.

Warnings and Potential Risks

The implants are designed for single patient use only and must never be reused. As with all other orthopedic implants, the components should never be re-implanted under any circumstances.

The implants can become loose or break if subjected to increased loading. Factors such as the patient's weight, activity level, and adherence to weight-bearing or load-bearing instructions can affect the implant's longevity. Damage to the weight-bearing bone structures caused by infection can give rise to loosening of the components and/or fracture of the bone.

Serious post-operative complications may occur from the implant in a patient who: lacks good general physical conditions, has severe osteoporosis, demonstrates physiological or anatomical anomalies, has immunological responses, sensitization or hypersensitivity to foreign materials, systemic or metabolic disorders.

These warnings do not include all adverse effects which could occur with surgery but are important considerations specific to metallic devices. The risks associated with orthopedic surgery, general surgery, and the use of general anesthesia should be explained to the patient prior to surgery. See the Precautions section for additional warnings.

Precautions

The implantation of Memory Staple systems should be performed only by experienced surgeons with specific training in the use of this staple system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Under no circumstances should damaged components or surgically excised components be used. Implants that have already been in contact with body fluids or body tissues must not be resterilized. The Staple Systems should never be used with dissimilar materials.

Preoperative assessment of the suitability of the patient's anatomy for accepting implants is made on the basis of X-rays, CT scans, and other radiological studies.

Only patients that meet the criteria described in the Indications for Use section should be selected. Correct selection of the implant is extremely important. The morbidity as well as patient weight, height, occupation, and/or degree of physical activity should be considered.

Proper implant handling before and during the operation is crucial. Handle the implant components properly. Ensure packaging integrity. Do not allow the implants surfaces to be damaged.
Adequately instruct the patient. The physician should inform the patient about orthopedic implant advantages and disadvantages, post-operative limitations, weight/load bearing stresses which could affect bone healing, implant limitations, and the fact that premature physical activity and full weight/load bearing stresses have been implicated in premature loosening, damage, and/or fracture of orthopedic prostheses.

Preparation and Implant Attachment

STEP 1 - Preparation

Dissect a clean approach to the desired region of the bone where the staple will be inserted.

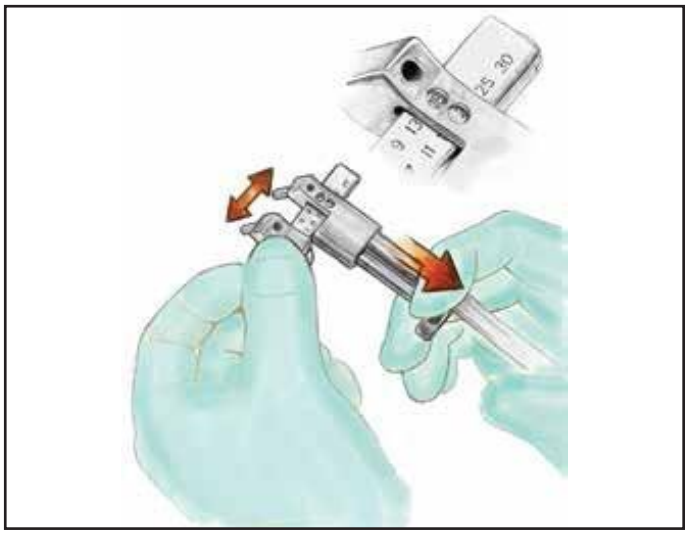


FIGURE 1

STEP 2 -Set Adjustable Drill Guide

Set the adjustable drill guide by pulling down on the set pin while sliding the guide bar until the desired staple size shows in the engraving window (Figure 1).

Select the corresponding drill diameter based on the staple size. Drill the perpendicular hole using the drill guide (Figure 2).

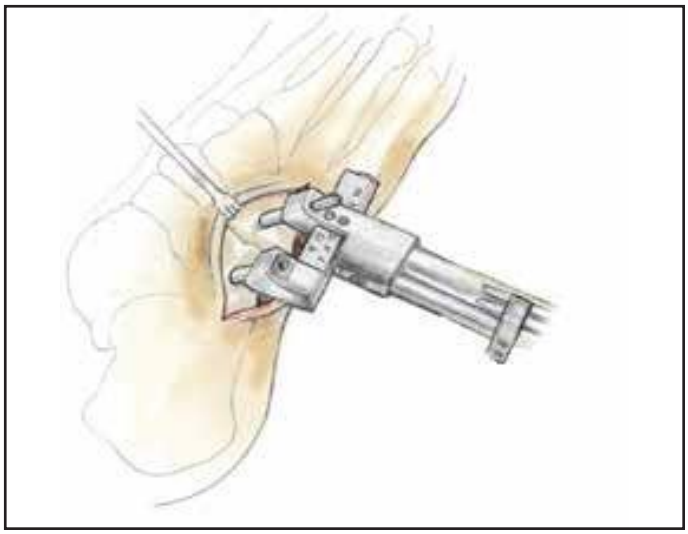


FIGURE 2

STEP 3 -Staple Handling

Always use hemostats to handle the Memory Staple taking care to not contact your gloved hand (Figure 3).

NOTE: Warmth from a hand may prematurely activate the staple.

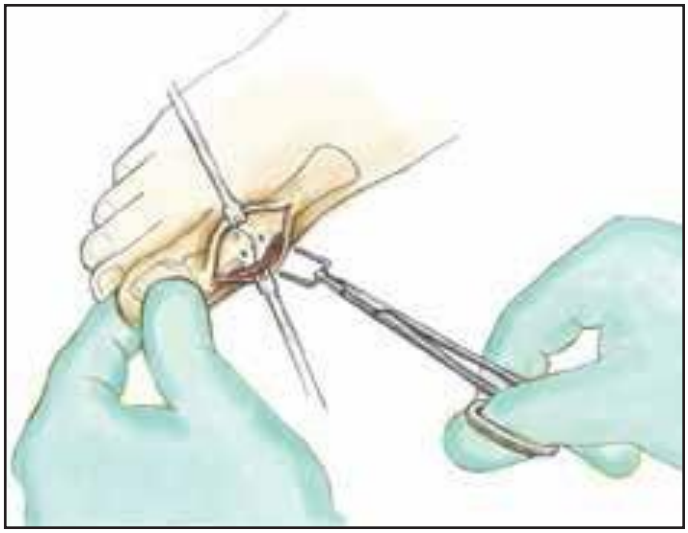


FIGURE 3

Insertion and Removal

STEP 4 - Implantation

Align the staple barbs with the pre-drilled holes and apply firm pressure to fully seat the staple (Figure 4).

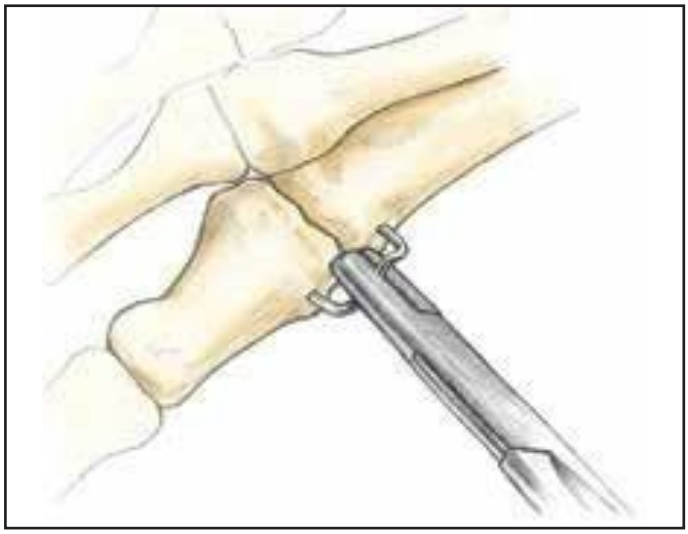


FIGURE 4

STEP 5 -Tamp (Optional)

A tamp maybe used to ensure the staple is fully inserted and seated against the bone (Figure 5).

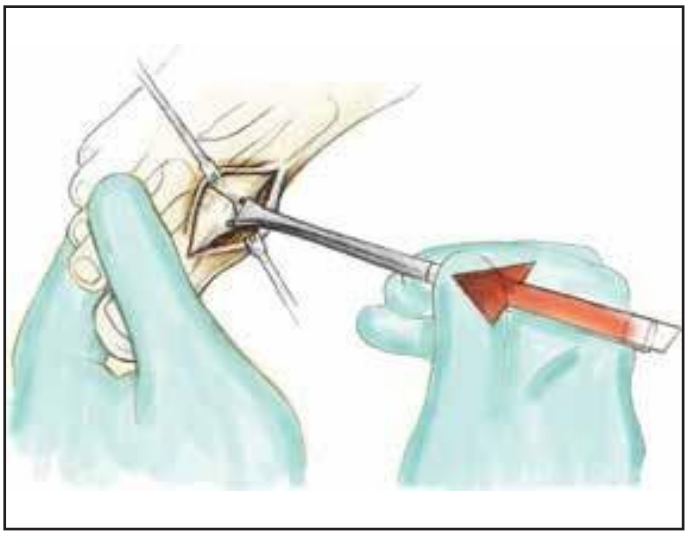


FIGURE 5

STEP 6 -Activation

After insertion, staples 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) (Figure 6).

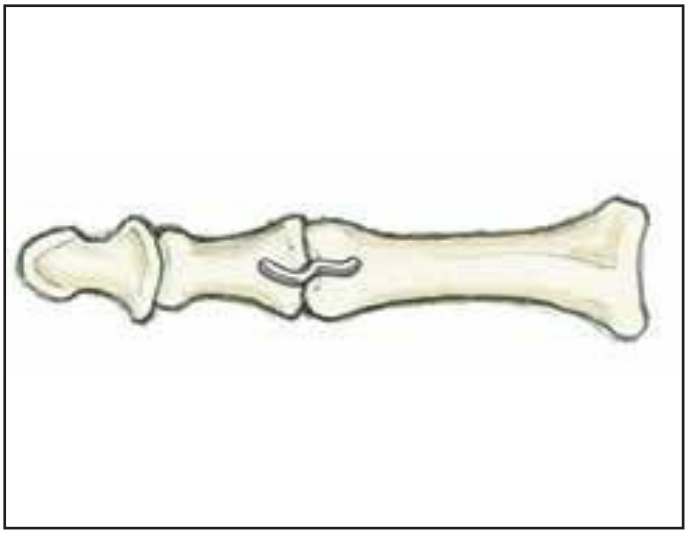
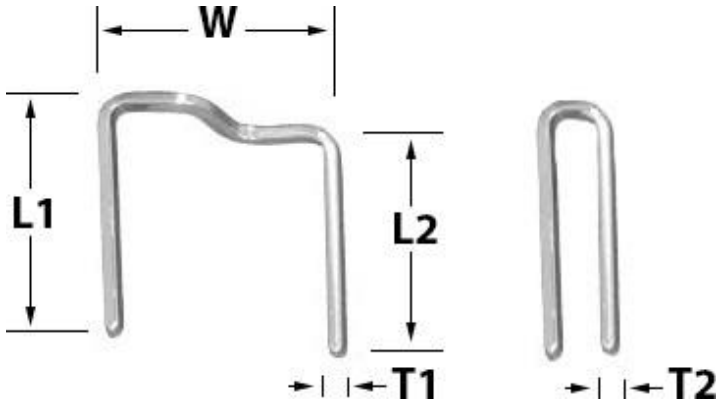
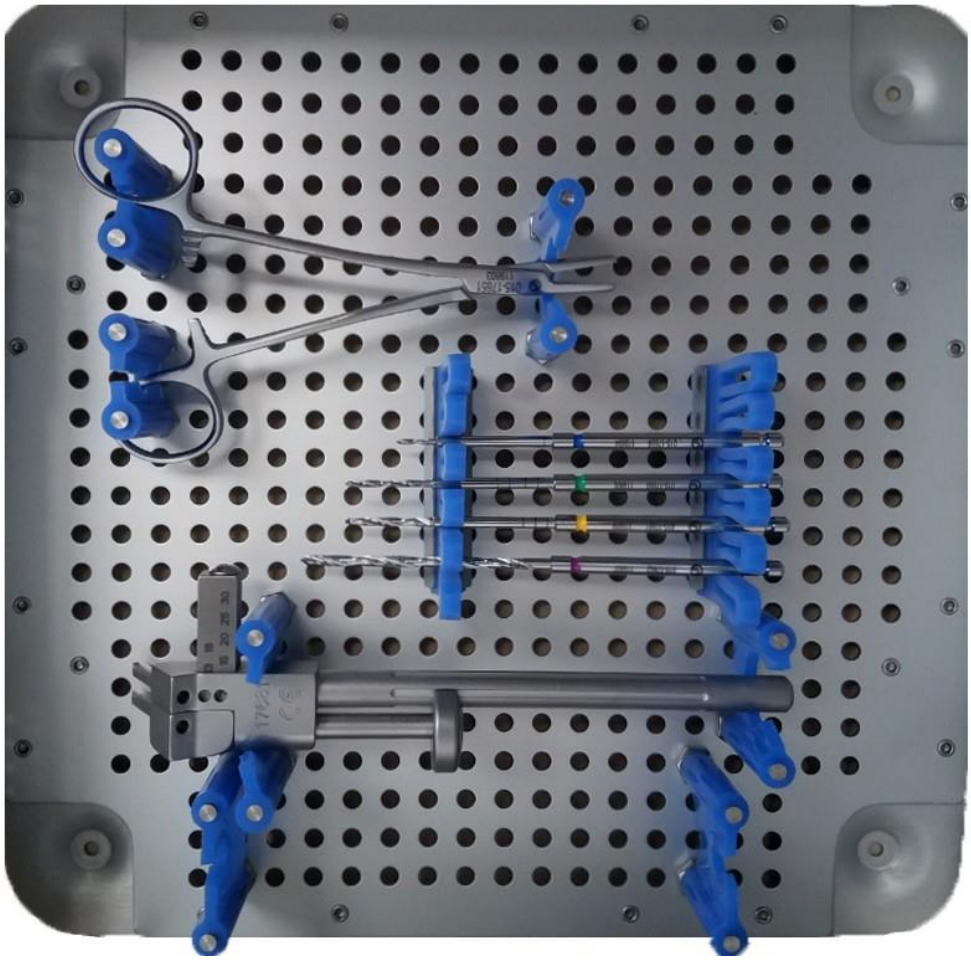


FIGURE 6



Reference #	Description: W x L1 x L2 (If Applicable) – T1 x T2
MX-120705	7 x 5 - 1.2 x 1.2mm
MX-120907	9 x 7 - 1.2 x 1.2mm
MX-150705	7 x 5 - 1.5 x 1.5mm
MX-150907	9 x 7 - 1.5 x 1.5mm
MX-151108	11 x 8 - 1.5 x 1.5mm
MX-151110	11 x 10 - 1.5 x 1.5mm
MX-151310	13 x 10 - 1.5 x 1.5mm
MX-151512	15 x 12 - 1.5 x 1.5mm
MX-151115	11 x 15 x 13 - 1.5 x 1.5mm
MX-151117	11 x 17 x 15 - 1.5 x 1.5mm
MX-151119	11 x 19 x 17 - 1.5 x 1.5mm
MX-201512	15 x 12 - 2 x 2mm
MX-201818	18 x 18 x 15 - 2 x 2mm
MX-202020	20 x 20 - 2 x 2mm
MX-302020	20 x 20 - 2 x 3mm
MX-302522	25 x 22 - 2 x 3mm
MX-303030	30 x 30 - 2 x 3mm

Instruments



Item #	Description
015-17651	Small Staple 4 ¾ Bull Dog Hemo
015-17681	Drill Guide Adjustable
015-17659	1.4mm Drill Bit (1.2mm Staple)
015-17660	1.8mm Drill Bit (1.5mm Staple)
015-17661	2.4mm Drill Bit (2.0mm Staple)
015-17662	3.0mm Drill Bit (3.0mm Staple)
015-17654	Small Staple Punch
015-000000	Memory Staple System Case

Sterilization

The Memory Staple instrumentation are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to use.

The following steam sterilization parameters are recommended:

Cycle: Pre-Vacuum
Temperature: 270°F (132°C)
Time: 4 minutes
Drying time: 30 minutes
NOTE: Allow For Cooling

Consult the Package Insert for additional cleaning and sterilization instructions.

Individuals not using the recommended method temperature and time are advised to validate any alternative methods or cycles using an approved method or standard.

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