WishBone Medical Memory Staple System

Instructions for Use
WishBone Medical Memory Staple System

Manufactured for:

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Caution: Federal law restricts this device to sale by or on the order of a physician.	
5.4.2	• Single-use
REF 5.1.6	• Catalog number
LOT 5.1.5	• Lot number
5.4.3	• Caution: See instructions for use
75°F (23°C) 5.3.6	• Upper Temperature Limit (Chill per storage instructions)
STERILE EO 5.2.3	• Sterile – ethylene oxide
5.1.4	• Use by date

Symbols: ISO 15223-1:2016

CONTENTS
The package contains one Memory Staple for the express purpose of fracture managment, deformity correction, or arthrodesis.

DESCRIPTION
The WishBone Medical Memory Staple gives the surgeon a means of bone fixation and helps in the management of fracture and reconstructive surgery; It is not intended to replace normal body structures. The WishBone Medical Memory Staple is manufactured from Nitinol, a memory metal. Patient body heat causes the legs of the staple to bend toward each other resulting in compression.

IMPLANT MATERIAL SPECIFICATIONS
Implants are made from Nitinol.

MRI SAFETY INFORMATION
These devices have not been evaluated for safety and compatibility in the MRI environment. The system has not been tested for heating, migration, or image artifact in the MRI environment. The safety of these devices in the MRI environment is unknown. Scanning a patient who has this device may result in patient injury.

INDICATIONS
Indications for use include hand and foot bone fragment and osteotomy fixation and joint arthrodesis of the hand and foot bones.

CONTRAINDICATIONS
- 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.

ADVERSE EFFECTS
Possible reactions may include but are not limited to:
- Allergic reactions to metal (titanium or nickel)
- Delayed or non-union of bone
- Delayed healing
- Staples may break
- Staples may be extruded or back out of surgical site
- Contact surgeon if a change in performance or pain level is noticed.

SURGICAL TECHNIQUES
Surgical techniques are available describing the uses of this system. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use. Surgical techniques can be found on the WishBone Medical website (www.wishbonemedical.com/IFU).

STERILE:
Sterilized with ethylene oxide gas. Caution: For one procedure only. Do not re-sterilize. Do not use if package is open or damaged. This is a single use device. Re-use of this device can result in the transfer of materials not limited to bone, tissue, blood or infectious disease. This device is provided sterile and re-sterilization of the device has not been validated.

INSPECTION:
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.

WARNINGS
Please note that re-using a single-use device which has contacted human blood or tissue constitutes reprocessing & that reprocessing can only be performed by an authorized third-party reprocessor who has received 510(k) clearance for such. This does not include chilling to reset the temperature of the staple.
- 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. The safety of the device in the MR environment is unknown. Scanning patients who have these devices may result in patient injury

CARE & CAUTION
- Prior to use, thoroughly read these instructions. Each surgeon must consider the particular needs of each patient and create a surgical plan that uses the appropriate implant(s) for that patient. 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 24°C (75° F) or less. Staples that have exceeded 24°C (75° F) 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 24°C (75° F).
- The staples are a single use device.
- Do not autoclave staples.

INSTRUCTIONS FOR USE
1. Appropriately dissect and expose the entire site releasing all ligamentous and soft tissue structures as needed.
2. For joint arthrodesis, remove the articular surfaces with the power equipment of choice
3. Coaptate both bone segments, assuring congruity, and temporarily fixate with either K-wires or a compression clamp.
4. Select the appropriate staple by using the template overlay on the corresponding x-ray or intra-operatively using one of the provided drill guides. Choose the appropriate width and staple leg length. (Note: Choose the staple leg which extends closest to the plantar cortex.)
5. Using the adjustable drill guide, select the correct width on the engraving window and drill a perpendicular hole using the appropriate staple drill size.
6. Insert the anchor pin for stability and drill a perpendicular hole on the proximal side of the adjustable drill guide.
7. Insert the Memory Staple using the appropriate staple clamp and push flush to the dorsal cortex with the appropriate staple punch.
8. Staple compression will occur by body temperature however compression time may be hastened by irrigating the staple with saline 36.5°C to 37.5°C (98°F to 100°F). Mean closing time at 37°C is 2.57 seconds with a range of 1-4 seconds.
9. Remove temporary K-wires and or the compression clamp.
10. Complete the surgical procedure using established surgical techniques.

Caution Upper Temperature Limit
Chill per IFU / Shipper Labeling

STORAGE / PROCESSING INSTRUCTIONS
The Memory Staple is designed to close at body temperature 37°C (98.6° F). However, the closing process begins at 24-25°C (75-77° F).

Temperature indicator is located uderneath the container lid. One or more red dots mean that the staples have been exposed to a temperature of 24°C (75° F) or greater and needs to be reset (see below).

To reset (Chill): Place the staple in freezer for two hours at -20°C (-4°F). Temperature indicator shall be disregarded as the indicator is no longer functional.

To store: Store the staple below 24°C (75° F), provided that the temperature indicator is not red upon receipt.

To handle: It is best to always handle the staple with the hemostat provided during the surgery to prevent premature warming of the staple. The closing process of the staple can be accelerated in-vivo by flushing the staple with warm saline after implantation.

To Return Inventory: It is not necessary to refreeze the parts and the freezer packs for returning. Please return all of the container (coolers) and freezer packs to WishBone Medical. Customer will be invoiced accordingly if they are not returned.

DEVICE INTENDED TO BE USED BY A TRAINED PHYSICIAN
This description alone does not provide sufficient background for direct use of WishBone Medical products. Instruction by a surgeon experienced in handling these products is highly recommended.

FOR FURTHER INFORMATION
Please contact WishBone Medical, Inc. or your authorized representative for further information about this product.

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