Cleaning Procedure

All instruments should be thoroughly cleaned prior to use, and as soon as possible after use. Do not allow blood and debris to dry on instruments. If cleaning must be delayed, place instruments in a covered container and allow them to soak in appropriate detergent or enzymatic solution to delay drying.

Manual Cleaning Procedure

1. Place instruments in the open position in a clean pan.
2. Prepare enzymatic detergent solution per manufacturer's instructions.[1] Allow devices to be fully submerged in the detergent.
3. Allow devices to soak for at least 2 minutes or until blood and/or organic matter is reduced.
4. After soaking, remove devices and rinse thoroughly with water, not exceeding a temperature of 45°C, to remove cleaning solution for at least 1 minute, or in accordance to manufacturer's instructions.
5. Use mild detergent solution per manufacturer's instructions to manually clean the devices.[2] Using a soft bristle brush, thoroughly clean the devices while immersed in the cleaning solution. Thoroughly clean all cracks, openings, cannulas, slots and crevices. Avoid using harsh materials that can scratch or damage the instrument surface.
6. Rinse the devices thoroughly with water, not exceeding a temperature of 45°C, to remove cleaning solution for at least 1 minute, or in accordance to manufacturer's instructions.
7. Pat the devices dry with a clean towel. Devices with cracks, openings, cannulas, slots and crevices should be blown out with compressed air to reduce potential corrosion.
8. Visually inspect each device for evidence of organic matter or deterioration of device functionality. If any organic matter is detected, repeat cleaning process. If functional deterioration is found, replace instrument.

Note: 1. Cleaning was validated using Enzol® at 1 oz per 1 gallon of tap water.
2. Cleaning was validated using Manu-Klenz® at ½ oz per 1 gallon of DI water.

Ultrasonic Cleaning Procedure

1. Ultrasonic cleaners can be used per the ultrasonic unit's manufacturer guidelines.
2. Instruments should be rinsed thoroughly with water, not exceeding a temperature of 45°C, after ultrasonic cleaning.
3. Visually inspect each device for evidence of organic matter or deterioration of device functionality. If any organic matter is detected, repeat cleaning process. If functional deterioration is found, replace instrument.

Lubrication

Lubricate all hinged instruments which may have "metal to metal" contact/action. A non-silicone, water-soluble surgical lubricant is recommended. Do not use industrial oils or lubricants.

1. Immediately after cleaning, instruments should be immersed in the open position in the lubricant for 30 seconds, or in accordance with lubricant manufacturer's recommendations.
2. Remove the devices and thoroughly rinse under running tap water for 1 minute, or in accordance with lubricant manufacturer's recommendations, until lubricant is removed from device.
3. Pat the instruments dry with a clean towel. Compressed air can be utilized to remove all water in the hinged areas of the instruments.

INTEGRA®

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INTEGRA®

MemoFix® Super Elastic Nitinol Staple System

Instructions for Use

Description

The Integra® MemoFix® staple is a one-piece single-use nickel titanium alloy bone fixation device intended to be permanently implanted. The device is indicated for the fixation of osteotomies and joint arthrodesis of the hands and feet. The implant consists of two legs connected by a bridge and is offered in multiple combinations of bridge widths and leg lengths to accommodate various anatomies. The system also includes instruments (Drills, Temporary Pins, Sizer / Drill Guide, Staple Spreader, Tamp) to facilitate the placement of the implants.

Material

The implants are constructed from implant grade nickel titanium alloy (Nitinol) per ASTM F2063-05. The instrumentation is made from titanium and stainless steel.

Clinical Indications

The MemoFix staple is indicated for fixation and arthrodesis of the associated bones and joints of the hands and feet.

The MemoFix staples are intended for single use only.

Contraindications

Use of the MemoFix staple is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients with inadequate bone stock; in patients with certain metabolic diseases; in patients with high levels of activity; in patients who are not able to comply with postoperative treatment protocols. The MemoFix staple contains nickel and should not be used in patients where sensitivity to nickel or other metal is suspected. If material sensitivity is suspected, appropriate tests should be performed prior to implantation.

Possible Adverse Effects

The following are specific adverse effects which should be understood by the surgeon and explained to the patient. These do not include all adverse effects which can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. Infection.
2. Pain, discomfort or abnormal sensations due to the presence of the implant.
3. Metal sensitivity or allergic reaction to a foreign body.
4. Migration of the implant: loosening of the implant.
5. Delayed wound healing or deep wound infection resulting in possible removal of the implant.
6. Fracture of the implant due to non-compliance to postoperative regimen, improper implant selection, or non-union.

Warnings

1. Reoperation to remove or replace the implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
2. Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
3. Instruments, guide pins, and implants are to be treated as sharps.
4. The MemoFix staple has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or migration in the MR environment.

Maintaining Device Effectiveness

1. The surgeon should have specific training, experience, and thorough familiarity with the use of orthopedic staple implants and similar devices.
2. The implants are not intended to endure excessive abnormal functional stresses.
3. All MemoFix staples and instruments may be required for each surgery. Failure to use dedicated, unique Integra instruments and implants for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require reoperation and removal.
4. Carefully inspect the implants prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments which are faulty, damaged or suspect should not be used. They should be replaced or sent to Integra for disposition and repair.
5. Integra recommends the use of Integra products in a sterile environment.

Instructions for Use

1. Prepare the bone for the corresponding fixation or fusion required to achieve the desired correction. Using the sizer/drill guide, select the desired staple bridge length by adjusting the handles until the right handle tip is locked into place directly above the marked number indicating the bridge length. Place the barbed ends of the sizer/drill guide against the bone and verify that the selected bridge length is appropriate for the patient anatomy.
2. The staple spreaders, drills and pins are color coded to correspond with the various staple sizes. Select the appropriate color instruments for the corresponding staple size that is being utilized.

   Once the staple size has been determined, select the corresponding drill for the staple and drill one side of the fixation or fusion site. Remove the drill and place a temporary anchoring pin through the drill guide and into the bone. Drill the second hole on the other side of the fixation or fusion site. (**Note:** Optional drill stops can be used on one or both sides if precise drilling depth is desired). Remove the drill and temporary pin.
3. Load the staple into the staple spreader and secure the staple by squeezing the handles until the staple legs are engaged. Continue to slowly squeeze the handles until the staple legs are parallel. To maintain the desired distraction of the staple, turn the knob on the locking bar until it touches the handle. This will accurately maintain the staple shape during placement without the need to continue squeezing the handles of the spreader. Place the distracted staple into the predrilled holes and press the staple in until the staple spreader is almost flush with the bone.
4. Disengage the staple spreader from the staple by lifting the locking bar from the slot on the handle while gently squeezing the handles so they do not snap closed. Carefully remove the tips of the jaws from underneath the staple bridge.
5. Using the tamp, push the staple into the bone until the underside of the bridge is flush with the top surface of the bone. Additional tamping on each of the staple bridge corners can further reduce the profile of the final staple position. Use of a mallet is optional.
6. Verify the placement of the staple is correct. Verification can be confirmed by utilizing a mini C-arm (or equivalent) in multiple axes. If additional compression or stabilization is desired, multiple staples can be used by repeating Steps 1-5. The incision can be closed with the suture material of choice. Postoperative care is according to surgeon preference and should follow protocol for fixation/ fusions of a similar nature.

   Removal: If it becomes necessary to remove a staple, the removal tool can be utilized to lift the staple bridge to a position allowing the staple spreader to be engaged. Once the staple spreader is engaged, the handles can be squeezed to distract the legs sufficiently to remove the staple.

Caution:

- **Federal (USA) law restricts this device to sale by or on the order of a physician.**
- **Do not attempt a surgical procedure with faulty, damaged or suspect Integra instruments or implants. Inspect all components preoperatively to assure utility.**

Sterility

The MemoFix staples and instruments are packaged non-sterile and must be sterilized prior to surgical use.

Sterility Type: Pre-Vacuum Steam Sterilization
Exposure Temp: 270°F (132°C)
Exposure Time: 4 minutes
Dry Time: 20-30 minutes
Configuration: Wrapped
Sterility Type: Gravity Steam Sterilization
Exposure Temp: 270°F (132°C)
Exposure Time: 15 minutes
Dry Time: 15-30 minutes
Configuration: Wrapped