Fixation Staples

IMPORTANT MEDICAL INFORMATION

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DESCRIPTION

Fixation staples are available in different styles and sizes to provide a wide range of application options to satisfy physician preference and the unique demands of each particular case. Staples are manufactured from various types of metals. The component material is provided on the outside carton label. All implantable components are designed for single use only.

INDICATIONS

1. Tendon repairs, transfers, or transplants, such as in the treatment of paralytic conditions, tendon avulsions or ruptures, in which the tendon is fixed to the bone.
2. Ligament repairs, reconstruction, or replacement in which the ligament is fixed to the bone.
3. Adjunctive internal fixation of fractures, or arthrodesis.
4. Osteotomy staples are indicated for use in internal fixation of bone following proximal tibial osteotomy.
5. The fixation of avulsed ligaments to bone such as the greater humeral tuberosity or femoral trochanter, the calcaneus, or the tibial tubercle.

CONTRAINDICATIONS

1. Pathological conditions of bone which could impart the ability to securely fix the staple.
2. Pathological changes in the soft tissue being attached to the bone which could preclude secure fixation.
3. Comminuted bone surface which could mitigate against secure staple fixation.
4. Physical conditions that would preclude adequate implant support or retard healing, such as, blood supply impairment, insufficient bone quality or quantity, previous infection.
5. Mental conditions that preclude cooperation with the rehabilitation regimen.

WARNINGS

1. Careful use of a drill jig before inserting the staples enhances accurate and precise placement. Using a twist drill or Steinman pin to prepare starting holes reduces the possibility of bending or spreading the staples during insertion. The driver-extractor locks onto the staples to facilitate insertion and removal.
2. Fractures should be reduced with as much solid bony contact as possible and the staple positioned to maintain this contact.
3. Postoperative instructions and warnings to patients are advised. The involved joint should be appropriately protected by a plaster or similar cast or orthosis until healing has occurred.
4. Periodic radiographic examination is advised for close comparison with post-op conditions until there is evidence of bony union. Removal of the staple is recommended, if not contraindicated, upon evidence of full healing.

PRECAUTIONS

1. Use extreme care in handling and storing implant components. Cutting, bending or scratching the surface of metal components can cause internal stresses which significantly reduce the strength and fatigue resistance.
2. Certain special instruments are required to perform surgeries using staples. Review of the use and handling of these instruments in important. Single use devices should not be reused due to risks of breakage, failure or patient infection.
3. The patient should be informed that the staple may eventually be removed in a subsequent surgical procedure following evidence of healing.
4. Patients should be directed to seek medical opinion before entering potentially adverse environments that could affect the performance of the implant, such as electromagnetic or magnetic fields, including a magnetic resonance environment.

ADVERSE EFFECTS

1. Loosening, bending, cracking or fracture of implant components, or loss of fixation in bone; attributed to nonunion, osteoporosis, or markedly unstable comminuted fractures.
2. Loss of anatomic position with malunion or nonunion may occur.
3. Infections, both deep and superficial, have been reported.
4. Although rare, metal sensitivity reaction and/or allergic reactions to foreign materials have been reported.
5. Painful bursa or joint pain.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

Smith & Nephew fixation staples have not been evaluated for safety and compatibility in the MR environment. Fixation staples have not been tested for heating or migration in the MR environment.

PACKAGING AND LABELING

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. If the sterile barrier has been broken, return the component to Smith & Nephew, Inc.

STERILIZATION

For components provided sterile, the sterilization method is noted on the label. Sterile implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10^{-6}. Sterile packaged components are supplied in protective sterile barrier packaging. Inspect packages for punctures or other damage prior to surgery. If the sterile barrier has been broken, return the component to Smith & Nephew, Inc.

If not specifically labeled sterile, components are supplied non-sterile and must be cleaned and sterilized prior to surgery. For non-sterile trauma implants remove all original packaging and labeling inserts prior to sterilization. It is important that adequate cleaning be carried out prior to sterilization. Please see the document, “Recommendations for decontamination and sterilization of Smith & Nephew orthopaedic devices”, which is provided with Smith & Nephew instrument sets, for further information on cleaning instructions and validated sterilization procedures.

DO NOT REUSE implant components or single use disposable instruments.

RECOMMENDED STEAM STERILIZATION CYCLE PARAMETERS

- Dynamic Air Removal (Prevacuum) Steam Cycle: 132°C (270°F) for 4 minutes or 135°C (275°F) for 3 minutes and a minimum vacuum drying time of 30 minutes.
- Gravity Displacement Steam Cycle: 132°C (270°F) for 30 minutes and a minimum vacuum drying time of 30 minutes.
- Flash Steam Cycle (Reusable instruments only): Exposure temperature: 132°C (270°F) for 10 minutes in a Gravity Displacement Cycle or 4 minutes in a Dynamic Air Removal (Prevacuum) Cycle.
- United Kingdom Steam Cycle: 134° for 3 minutes and a minimum vacuum drying time of 30 minutes. (Note: Sterilization evacuation and pulsing should be carried out in accordance with HTM 2010.)

Containment devices should be wrapped with an approved central supply wrap (CSR) or placed in an approved reusable rigid container for sterilization. All sterilization wraps may not be approved for all cycle types. Check with manufacturer for approvals.

RETRIEVAL AND ANALYSIS OF REMOVED IMPLANTS

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant from damage during handling and shipment. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent spread of bloodborne pathogens.

If the implant will be returned to Smith & Nephew, Inc. for analysis, contact Customer Service using the phone numbers outlined in the Information section.

INFORMATION

For further information, please contact Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

Manufacturing Facilities and EC Representative:

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

81034963 Rev. B 2009-12