smith&nephew

Mini-Fragment Plating System

- **VLP® Mini-Mod Small Bone Plating System**
- **EVOS® Mini Plating System**
- **VLP Mini-Mod Talus Plates**

STERILE R* NON-STERILE*

**Refer to the product labeling to determine if the product is sterile or non-sterile.*

Important Information

Fracture fixation devices are only used to aid in healing; they are not a substitute for normal intact tissue or bone. The anatomy of human bones presents limitations with respect to the size or thickness of bone screws or plates, thus the strength of implants is limited. Full load bearing prior to complete bone healing is contraindicated. With repeated stress in patients with delayed healing or nonunion, the appliance will bend, break or pull out of bone.

The component material is provided on the outside carton label. Use only components made from the same material together. Do not mix dissimilar metals at any time. Components from different manufacturers should not be mixed, except when advised by the manufacturer. All implantable components are designed for single use only. Some of the instruments are also designed for single use only as noted on the package label.

Note: A single use device (SUD) which comes into contact with human blood or tissue should not be reused, but should be returned to the manufacturer or disposed of properly.

Indications for Use

The Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System is indicated for adolescent (12–18 years) and transitional adolescent (18–21 years) subpopulations and adults, as well as patients with osteopenic bone.

The Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System is indicated for fracture fixation, arthrodesis, reconstruction, replantation or reduction of small bones and small bone fragments. This system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.

The VLP Mini-Mod Talus Plates can be used in adolescent (12–18 years) and transitional adolescent (18–21 years) subpopulations and adults, as well as patients with osteopenic bone. The VLP Mini-Mod Talus Plates are indicated for fracture fixation, reconstruction or arthrodesis of small bones, including those in the forefoot, midfoot and hindfoot.

Contraindications

- Physical conditions that would preclude adequate implant support or retard healing, such as, blood supply impairment, insufficient bone quality or quantity, previous infection, obesity, severe bow or gross distortion of the radius.
- Mental conditions that preclude cooperation with the rehabilitation regimen.

EC REP

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11/2015 81092293 Rev. 0

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⚠ Warnings

Do not use if package is damaged. Do not use if the product sterilization barrier or its packaging is compromised.

- **Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE. For single use only. Do not use after the expiration date.**
- **It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.**
- **Read these instructions completely prior to use.**
- **This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.**
- **It is extremely important to select the appropriate size and type components. Failure to use the largest possible components or improper positioning may result in loosening, bending, cracking, or fracture of the device or bone or both.**
- **Use only Ti-6Al-4V screws with Ti-6Al-4V devices. Use only stainless steel screws with stainless steel devices.**
- **Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System devices and accessory components should not be placed across growth plates in pediatric patients.**

Precautions

℞ ONLY U.S. Federal law restricts this device to sale by or on the order of a physician.

- Use extreme care handling and storing implant components. Cutting, bending or scratching the surface of metal components may cause internal stresses which may significantly reduce the strength and fatigue resistance.
- Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear and damage prior to surgery. Single use devices should not be reused due to risks of breakage, failure or patient infection.
- Continuous screening with an image intensifier (fluoroscopy) during guide wire insertion and whenever cannulated instruments are advanced over a guide wire is recommended to prevent unintended guide wire advancement and penetration into the surrounding tissues.
- Intraoperative cleaning of cannulated instruments is recommended to prevent accumulation of bone debris in the cannulation.
- If a computer assisted surgery system is used, consult the applicable software and hardware reference manuals provided by the manufacturer to ensure proper operation of this equipment.
- For computer assisted surgery systems, it is extremely important to correctly select input parameters (e.g., bony landmarks). Operators of this equipment should be familiar with the anatomy relevant to the procedure. Failure to provide proper input could cause problems such as violation of critical anatomical structures and malpositioned implants.
- Postoperative instructions to patients and appropriate nursing care are critical. Early load bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early load bearing should only be considered where there are stable fractures with good bone-to-bone contact.
- Patients should be directed to seek a 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.
- While the surgeon must make the final decision regarding implant removal, wherever possible and practical for the patient, fixation devices should be removed once their service as an aid to healing is complete.
- After use, these components may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.
- Surgical technique information is available on request.

Adverse Effects

- Loosening, bending, cracking or fracture of implant components.
- Loss of anatomic position with malunion may occur.
- Infections, both deep and superficial, have been reported with internal fixation devices.
- Vascular disorders including thrombophlebitis, pulmonary emboli, wound hematomas, and avascular necrosis may result from the surgery and concomitant use of internal fixation devices.
- Metal sensitivity reactions and/or allergic reactions to foreign materials have been reported.
- Penetration of a K-wire, screw, or peg into a joint can occur.
- Tissue reactions which include macrophage and foreign body reactions adjacent to implants can occur.

Magnetic Resonance Imaging (MRI) Safety

Smith & Nephew fracture fixation devices have not been reviewed by the FDA for safety and compatibility in the MR environment. Fracture fixation components have not been tested for heating or migration in the MR environment. Known risks of exposing implant devices to the MR environment include displacement, torque, and radio frequency induced heating. Implant devices may also create image artifacts in MR scans.

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 or is past the expiration date, return the component to Smith & Nephew, Inc. Use of damaged or expired product increases the risk of infection, which may lead to revision surgery.

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 (i.e. plates and screws), 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, "Instructions for care, maintenance, cleaning, 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. Minimum vacuum drying time:
  - Wrapped devices - 15 minutes
  - Containerized devices - 30 minutes
- Gravity Displacement Steam Cycle: 132° C (270° F). Exposure time:
  - 15 minutes for instruments not in a containment device
  - 30 minutes* for devices in a containment device

  Minimum vacuum drying time of 30 minutes.
- Immediate Use Steam Sterilization (IUSS): 132° C (270° F).

  Exposure time: dynamic air removal (prevacuum) - 4 minutes.

For Non-U.S. Customers:

- United Kingdom Steam Cycle: Prevacuum cycle. 134° C (273° F) for 3 minutes. Minimum vacuum drying time of 30 minutes.

  Note: Sterilization evacuation and pulsing should be carried out in accordance with HTM 2010.
- World Health Orgnization (WHO) Steam Cycle: 134° C (273° F). Exposure time 18 minutes and a minimum vacuum drying time of 30 minutes.

Containment devices should be wrapped with a central supply wrap (CSR) or placed in a reusable rigid container for sterilization.

Note to U.S. Customers: Sterilizers and wraps used in the sterilization process must be FDA-cleared.

*This sterilization cycle is not considered by the United States Food and Drug Administration (US FDA) to be a standard sterilization cycle. Only use sterilizers and accessories (such as sterilization wraps sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been FDA-cleared for the selected sterilization cycle specifications (time and temperature).

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.

For Further Information

For further information, contact Customer Service at 1 800 238 7538 for calls within the continental USA and +1 901 396 2121 for international calls.