ADVERSE EFFECTS

When selecting a patient for surgery, the surgeon should carefully consider the following:

PRE-OPERATIVE PRECAUTIONS

- Nerve damage resulting from surgical trauma.
- Embolism
- Implant migration and/or loosening requiring revision surgery
- Fracture of implant due to excessive activity, prolonged loading upon the device, incomplete healing. If excessive loading associated with delayed union, nonunion, or incomplete healing. A manual cleaning method is provided and has been developed and tested consistent with TIR 30 (manual). The provided sterilization recommendations have been developed and tested consistent with ANSI/AAMI ST79. An implant should never be re-sterilized after contact with human body tissues or fluids in a manner intended for single use only should never be reused. Reuse of these devices may result in, but are not limited to: decreased performance of the product, cross-infection, and contamination.

CAUTION:

Sterilization should be performed in the provided tray double-wrapped in FDA cleared sterilization wrap using the following method:

- Cycle Type
- Parameter
- Minimum Set Point
- Prevacuum
- Exposure Temperature
- 270°F (132°C)
- Exposure Time
- 4 Minutes
- Dry Time
- 40 Minutes

Do not stack trays during sterilization. Ensure that the implants and instruments are at room temperature prior to use.

STORAGE:

- Store all devices in a clean and dry environment. The devices are manufactured from non-degradable materials. When stored under the recommended conditions, the shelf life of this product is not limited.

CAUTION:

Federal Law (USA) restricts this device to sale by or on the order of a physician. For additional product information, please visit www.medline.com or contact customer service at 1-800-MEDLINE.

www.medline.com

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IFUMINI V1_RD19

MEDI Leone UNITE MINI PLATES AND SCREWS

INSTRUCTIONS FOR USE

Attention Operating Surgeon

DEVICE DESCRIPTION

The Medline UNITE® Mini Plates and Screws are manufactured from Titanium Alloy. The System includes plates offered in various styles, sizes and options; each contoured for specific anatomy and designed for specific procedures, and 2.0mm, 2.4mm and 2.7mm diameter locking and non-locking screws to be used with the polyaxial locking holes and compression slots included in the plates as well as 4.0mm cannulated screws to be used with the hook plate. The system also includes reusable instrumentation necessary to implant the plates and screws, e.g., drill guides, tissue protectors, and drill bits.

INDICATIONS

Medline UNITE® Mini Plates and Screws are intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The system can be used in both adult and pediatric patients. Examples include:

- Metatarsal or metacarpal fractures and osteotomies
- Cuboid fractures
- Navicular fractures
- Talar neck fractures
- Jones and avulsion fractures of the 5th metatarsal
- Lesser metatarsal shortening osteotomies (i.e., Weil Osteotomies)
- Phalanges fractures and osteotomies
- Growing patients with open epiphyses
- Nerve damage resulting from surgical trauma.
- Embolism
- Implant migration and/or loosening requiring revision surgery
- Fracture of implant due to excessive activity, prolonged loading upon the device, incomplete healing. If excessive loading associated with delayed union, nonunion, or incomplete healing. A manual cleaning method is provided and has been developed and tested consistent with TIR 30 (manual). The provided sterilization recommendations have been developed and tested consistent with ANSI/AAMI ST79. An implant should never be re-sterilized after contact with human body tissues or fluids in a manner intended for single use only should never be reused. Reuse of these devices may result in, but are not limited to: decreased performance of the product, cross-infection, and contamination.

TRAYS should be thoroughly cleaned and inspected prior to use. Visually inspect the tray for cleanliness. Repeat cleaning process, as necessary, until tray is visually clean. All instruments, where applicable, must be disassembled prior to cleaning.

Manual Cleaning

Do not allow excessive debris and soft tissue to dry at use before. Begin cleaning process as soon after use as possible. Additional scrubbing may be required if debris and soft tissue dry.

1. Rinse under cool running tap water to remove visual soil.
2. Prepare enzymatic detergent per manufacturer’s recommendation using lukewarm tap water.
3. Allow the device to soak in the prepared enzymatic detergent for 1 minute.
4. Using a soft bristled brush, thoroughly brush the device to remove soil.
5. Run a stylet through the lumens a minimum of 3 minutes to remove soil.
6. Using a syringe, flush the lumen with the prepared enzymatic detergent.
7. Remove the device from the detergent and rinse under cool running tap water to remove detergent residuals.
8. Using a syringe, aggressively flush the lumens.
9. Prepare neutral detergent per manufacturer’s recommendation using warm tap water.
10. Allow the device to soak in the prepared neutral detergent for 3 minutes.
11. Using a soft bristled brush, thoroughly brush the device to remove soil.
12. Run a stylet through the lumens a minimum of 3 times to remove soil.
13. Using a syringe, aggressively flush the lumens with the prepared neutral detergent.
14. Remove the device from the detergent and rinse in running RO/DI water to remove detergent residuals.
15. Prepare enzymatic detergent per manufacturer’s recommendation in a sonication unit.
16. Allow the device to sonicate for 10 minutes.
17. Remove the device from the sonicator and thoroughly rinse under running RO/DI water.
18. Using a syringe, aggressively flush the lumens.
19. Dry the device with a disposable, lint-free cloth.
20. Visually inspect the device for cleanliness.

Sterilization

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