GENERAL SURGICAL CONTRAINDICATIONS

ADVERSE EFFECTS

• Patients with high level of activity.
• Possibility for conservative treatment
• Inadequate skin, bone, or neurovascular status

Arthrodesis of the first metatarsophalangeal joint (MTP) including:
• Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)

INTRA-OPERATIVE PRECAUTIONS

It is the surgeon’s responsibility to determine the best course of action for each patient. The surgeon should carefully consider the following when selecting a patient for surgery:

• More conservative treatment options
• Patient’s willingness to follow post-operative instructions
• Patient conditions that may limit their ability to recognize limitations of the device that may lead to device failure, such as senility, mental illness, or alcoholism

ADVERSE EFFECTS

• Fracture of implant due to excessive activity, prolonged loading upon the device, incomplete or inadequate healing, or excessive force exerted on the implant during insertion.

PRE-OPERATIVE PRECAUTIONS

It is the surgeon’s responsibility to determine the best course of action for each patient. The surgeon should carefully consider the following when selecting a patient for surgery:

• More conservative treatment options
• Patient’s weight, occupation, and activity level
• Patient’s expectations of the device

INTRA-OPERATIVE PRECAUTIONS

The patient should be warned of surgical risks and be made aware of possible adverse effects. For the patient and effective use the surgeon must be thoroughly familiar with this type of implant, the method of application, instrumentation, and the recommended surgical technique and indications for this type of device. Improper implantation of the device can increase the possibility of loosening or migration. No metal implants can be expected to withstand loads at the same level as healthy bone. The Medline Foot Plates and Screws have not been designed to withstand the stress of weight bearing, load bearing, or excess activity. Fracture of the implant or damage can occur when the implant is subjected to increased loads associated with delayed union, nonunion, or incomplete healing. If excessive loading cannot be prevented, an implant should not be used.

POST-OPERATIVE PRECAUTIONS

The patient should be warned of the limitations of surgery and the need to protect the implant from full weight bearing until adequate fixation and healing have occurred. The postoperative care instructions provided by the surgeon should be strictly followed to avoid adverse stresses applied to the device. Failure to follow postoperative care instructions can cause implant and/or treatment failure. Periodic follow-up, including x-rays for comparison to early post-op conditions, is recommended to monitor the position and state of the implant, the condition of the bone, and any signs of implant migration, loosening, bending, or cracking.

CONCERNING MAGNETIC RESONANCE ENVIRONMENT

The Medline UNITE® Ankle Fracture Plates and Screws have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Medline UNITE® Ankle Fracture Plates and Screws in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CLEANING & STERILIZATION

All implants and instruments are provided non-sterile in trays or individually packaged and must be adequately cleaned and sterilized prior to use or re-use. 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. Devices labeled for single use should only be never 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. Begin cleaning process as soon after use as possible. Additional scrubbing may be required if debris and soft tissue dry. Prior to cleaning, the pin distractor should be disassembled into 7 pieces by removing the 3 knobbled screws.

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 lumen a minimum of 3 times.
6. Using a syringe, aggressively flush the lumens 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

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

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Parameter</th>
<th>Minimum Set Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevacuum</td>
<td>Exposure Temperature</td>
<td>270° F (132° C)</td>
</tr>
<tr>
<td></td>
<td>Exposure Time</td>
<td>4 Minutes</td>
</tr>
<tr>
<td></td>
<td>Dry Time</td>
<td>40 Minutes</td>
</tr>
</tbody>
</table>

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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