UNITE
FOOT & ANKLE

MEDLINE**UNITE® FOOT PLATES AND SCREWS HALLUX, MIDFOOT, FLATFOOT AND NON-LOCKING CORTICAL**

INSTRUCTIONS FOR USE
Attention Operating Surgeon

DEVICE DESCRIPTION
The Medline UNITE® Foot 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 2.7mm and 3.5mm diameter locking and non-locking cortical screws to be used with the polyaxial locking holes and compression slots included in the plates.

INDICATIONS
Medline UNITE® Foot Plates and Screws are intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion and reconstruction of bones of the feet and toes. Specific examples include:

Arthrodesis of the first metatarsalcuneiform joint (lapidus fusion)
Arthrodesis of the first metatarsophalangeal joint (MTP) including:
- Primary MTP Fusion due to hallux ridgidus and/or hallux valgus
- Revision MTP Fusion
- Revision of failed first MTP Arthroplasty implant

Flatfoot Osteotomies:
- Lateral Column Lengthening (Evans Osteotomy)
- Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)
- Medial Displacement Calcaneal Osteotomy (MDCO)

Midfoot | Hindfoot Fusions:
- LisFranc Arthrodesis and/or Stabilization
- 1st(Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
- Intercuneiform Fusions
- Navicular-Cuneiform (NC) Fusion
- Talo-Navicular (TN) Fusion
- Calcaneo-Cuboid (CC) Fusion
- Medial Column Fusions (NC and 1st TMT)

The Medline UNITE® Locking and Non-Locking Cortical Screws are indicated for use with the Medline Foot Plates of the same base material. The Non-Locking Cortical Screws are also indicated for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

GENERAL SURGICAL CONTRAINDICATIONS
- Infection
- Physiological or psychologically inadequate patient
- Inadequate skin, bone, or neurovascular status
- Suspected or documented metal allergy or intolerance
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Patients with high level of activity.

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.
- Implant migration and/or loosening requiring revision surgery
- Bone resorption or over-production
- Metal sensitivity or histological or allergic reaction resulting from implant material
- Infection or painful, swollen or inflamed implant site
- Unexpected histological response possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in bodily response
- Embolism
- Pain, discomfort, or abnormal sensations due to the presence of an implant
- Necrosis of the bone
- Necrosis of the tissue
- Nerve damage resulting from surgical trauma.

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
- 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
- Known or suspect material allergies
- Comorbities, eg. diabetes, smoking

The patient should be warned of surgical risks and be made aware of possible adverse effects. For safe 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 loading associated with delayed union, nonunion, or incomplete healing. If excessive loading cannot be prevented, an implant should not be used.

INTRA-OPERATIVE PRECAUTIONS
- The surgeon must select the type and size implant that best meets the patient's surgical needs.
- Inspect all implants for scratching and nicking prior to use as such stress concentrations can lead to failure. Avoid flawing the implant surface during insertion to minimize the potential for failure.
- An implant shall never be reused. Previous stresses may have created imperfections, which can lead to a device failure.
- Instruments, particularly drills, reamers, and drivers shall be inspected for wear or damage prior to use.
- The Medline Foot Plates and Screws are designed specifically for use with Medline instrumentation. The use of other instrumentation is not recommended.

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.

RECOMMENDATIONS REGARDING DEVICE FRAGMENTS
1. In the event of implant fracture, carefully consider and discuss with the patient, if possible, the risk/benefit of removing the hardware versus leaving the fragment in the patient. Things to consider and discuss with the patient include; the material composition of the fragment (if known), the size and location of the fragment, and the potential mechanisms of injury if the fragment is not removed, including MRI exams
2. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure.
3. If removal is determined to be the best course of action, inspect the device imediately after removal from patient for signs of damage. If the device is damaged, retain the device to assist the manufacture's investigation of the event. Device removal should be followed by adequate postoperative care.

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 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 after 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 knobbed 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 lumens a minimum of 3 times to remove soil.
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.

Instruments should be inspected for any damage or wear prior to use. Instruments that have corrosion, pitting, and/or discoloration should not be used.

Sterilization
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.

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