UNITE® FOOT & ANKLE

Medline UNITE® REFLEX® HYBRID Nitinol Implant System

Instructions for Use
Attention Operating Surgeon

Device Description
The Medline **UNITE®** REFLEX® HYBRID Nitinol Implants are manufactured from nickel titanium alloy (nitinol). The system includes implants offered in various styles, sizes, and options; each designed for specific anatomy and procedures. The implants can accommodate Ø2.7mm, Ø3.5mm, and Ø4.0mm locking and non-locking cortical screws to be used with the polyaxial locking holes and compression slots. The system also includes disposable and reusable instrumentation necessary for implantation of the REFLEX® HYBRID Nitinol Implant, e.g. drill guides, drills, locating pins, lag pins, inserter, and tamp.

Indications
The Medline **UNITE®** REFLEX® HYBRID Nitinol Implants are intended to provide fixation for fractures, fusions or osteotomies of the bones of short (tarsals) and long (metatarsals, phalanges, distal tibia and fibula) bones comprising the foot and ankle such as: First metatarsal-cuneiform arthrodesis, First metatarsophalangeal arthrodesis, Talonavicular arthrodesis, Lisfranc arthrodesis, Scarf and Chevron osteotomies. Implants are intended for single use only.
The Medline **UNITE®** Locking and Non-Locking Cortical Screws are indicated for use with the Medline **UNITE®** REFLEX® HYBRID Nitinol Implant. 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

Warnings
This device contains Nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials.

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
- Comorbidities, e.g., 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. Medline **UNITE®** REFLEX® HYBRID Nitinol Implants 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 defects can lead to device failure and/or increased corrosion susceptibility.
- Avoid flawing the implant surface during insertion to minimize the potential for failure and to minimize the risk of increased corrosion susceptibility/nickel exposure.
- An implant shall never be reused. Previous stresses may have created imperfections, which can lead to device failure.
- Instruments labeled single use, including drills, lag pins, and locating pins, shall never be reused.
- Instruments, particularly drills and lag pins, shall be inspected for wear or damage prior to use.
- The Medline **UNITE®** REFLEX® HYBRID Nitinol Implants 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 immediately after removal from patient for signs of damage. If the device is damaged, retain the device to assist the manufacturer's investigation of the event. Device removal should be followed by adequate postoperative care.

MR Safety Information
The Medline **UNITE®** REFLEX® HYBRID Nitinol Implant System has 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®** REFLEX® HYBRID Nitinol Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Cleaning, Disinfection & 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 machine wash and manual cleaning method is provided and has been developed and tested consistent with ISO 17664 and ANSI/AAMI ST98. 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. If possible, the machine procedure (Washer-Disinfector) should be used for cleaning and disinfection of instruments. The Manual Cleaning procedure should only be used if an automated procedure is not available. 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.

Machine Wash Cleaning

Pre-Cleaning
1. Remove gross soil from all device surfaces by rinsing under running cold tap water while brushing with a soft-bristled nylon brush for at one (1) minute.
2. Rinse devices under warm running tap water (<35°C) for at least one (1) minute.
3. In an ultrasonic bath, prepare a cleaning solution with cold tap water according to the manufacturer's instructions (note: Medline Industries, LP used the following during the validation of these instructions – STERIS® Prolystica® 2X Concentrate Enzymatic Pre-Soak and Cleaner, 1/8 oz. per gallon (min. effective concentration)).
4. Immerse the device in the cleaning solution and brush under the solution surface for two (2) minutes. Special attention should be paid to hard-to-reach areas, such as hinges, joints, crevices, and lumens. All movable parts must be actuated at least five (5) times. Lumens must be brushed with appropriate diameter and length bristle size for particular lumen.
5. Place the devices in the open position with all surface/lumens in contact with the cleaning solution and sonicated at a minimum of 40 +/-5 kHz for ten (10) minutes.
6. Following sonication, remove each device from the bath and rinse under cold, running tap water for at least one (1) minute. All hard-to-reach areas and lumens must be thoroughly and aggressively rinsed.
7. Proceed to Machine (Automated) cleaning.

Cleaning and Thermal Disinfection

1. Return devices to their appropriate location in the tray. The systems should not be fully assembled, and the lid should not be secured during automated cleaning. Each level of the system and tray lid must be loaded in the mechanical washer such that all design features are accessible and any design feature that will retain liquid can drain, if possible.
2. Run an automated wash cycle with fundamentally approved efficiency of the washer-disinfector (e.g., CE marking according to EN ISO 15883 or FDA approval/ clearance/ registration).
3. The minimum recommended wash cycle parameters listed below were utilized by Medline during the validation of these instructions:

Treatment	Time (mm:ss)	Temperature	Cleaning Solution
Pre-wash	03:00	Cold Tap Water	N/A
Wash 1	10:00	Warm Tap Water (50°C)	Enzymatic Cleaner*
Wash 2	02:00	Warm Tap Water (50°C)	Neutral Detergent†
Rinse	03:00	Cold Tap Water	N/A
Thermal Disinfection Rinse	05:00	Warm RO/DI Water (90°C)	N/A
Drying	06:00	90°C	N/A

**Medline Industries, LP used the following during the validation of these instructions – STERIS® Prolystica® 2X Concentrate Enzymatic Pre-Soak and Cleaner, 1/8 oz. per gallon (min. effective concentration)*

†Medline Industries, LP used the following during the validation of these instructions – STERIS Prolystica® 2X Concentra Neutral Detergent, 1/8 oz. per gallon (min. effective concentration)

4. Remove the devices from the washer-disinfector following the completion of the program and check devices for visible soil.
5. Repeat cleaning if soil is visible and re-inspect, or safely dispose of devices.

Manual Cleaning

1. Remove gross soil from all device surfaces by rinsing under running cold tap water while brushing with a soft-bristled nylon brush for one (1) minute.
2. Rinse devices under warm running tap water (<35°C) for at least one (1) minute.
3. Prepare enzymatic detergent solution with warm cold water according to the manufacturer's instructions.
4. Allow the devices to soak in the prepared enzymatic detergent for two (2) minutes.
5. While immersed in the enzymatic detergent, brush with a soft bristled brush for two (2) minutes. Special attention should be paid to hard-to-reach areas, such as hinges, joints, crevices, and lumens. All movable parts must be actuated at least five (5) times. Lumens must be brushed with appropriate diameter and length bristle sizes for particular lumen.
6. Run a stylet through the lumens a minimum of three (3) times to remove soil.
7. Using a syringe, aggressively flush the lumens with the prepared enzymatic detergent.
8. Remove the devices from the enzymatic detergent and rinse under cool running tap water to remove detergent residuals.
9. Prepare a neutral detergent solution with warm tap water according to the manufacturer's instructions.
10. Allow the devices to soak in the prepared neutral detergent for three (3) minutes.
11. While immersed in the neutral detergent, brush with a soft bristled brush for two (2) minutes. Special attention should be paid to hard-to-reach areas, such as hinges, joints, crevices, and lumens. All movable parts must be actuated at least five (5) times. Lumens must be brushed with appropriate diameter and length bristle size for the particular lumen.
12. Run a stylet through the lumens a minimum of three (3) times to remove soil.
13. Using a syringe, aggressively flush the lumens with the prepared neutral detergent.
14. Remove the devices from the detergent and rinse in running RO/DI water to remove detergent residuals.
15. Prepare enzymatic detergent solution per manufacturer's recommendation in a sonication unit.
16. Place the devices in the open position with all surface/lumens in contact with the cleaning solution and sonicate at a minimum of 40 +/-5 kHz for ten (10) minutes.
17. Remove the devices from the sonicator and thoroughly rinse each device under running critical water for at least one (1) minute. All hard-to-reach areas and lumens must be thoroughly and aggressively rinsed.
18. Dry the devices with a disposable, lint-free cloth.
19. Visually inspect the devices for cleanliness.
20. If a device is still visibly soiled, repeat the manual cleaning instructions or safely dispose of the device.

Instruments should be inspected for any damage or wear prior to use. Instruments that have corrosion, pitting, and/or discoloration should not be used. If an instrument or component is lost, damaged, or corroded, contact Medline **UNITE®** directly or your local representative.

Sterilization

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

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

Do not stack trays during sterilization.

Ensure that the implants and instruments are at room temperature prior to use.

Closed Container Sterilization

Closed container validation has been completed with OneTray Sterile Container System. Ensure that the sterilization container is in proper working order prior to sterilization. The care and handling of these containers can be found at https://onetray.com/products/onetray/

NOTE: THE STERILIZATION PARAMETERS WITHIN THE OneTray STERILE CONTAINER INSTRUCTIONS-FOR-USE DO NOT SUPERSEDE THE STERILIZATION PARAMETERS OUTLINED BELOW.

Only FDA cleared OneTray Sterile Containers are to be used. (e.g., Container M2408, OneTray Processing Kit OTK-210)

Cycle Type	Parameter	Set Point
Prevacuum	Exposure Temperature	270°F (132°C)
	Exposure Time Minutes	4
	Dry Time Minutes	20
	Wrapped	No

Do not stack trays/containers 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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