UNITE® FOOT & ANKLE

Medline UNITE® Autograft Harvester

Instructions for Use
Attention Operating Surgeon

Device Description
The Medline UNITE® Autograft Harvester facilitates harvest of morselized autogenous cancellous graft from various sites of the body through a small skin incision.

Indications
The Medline UNITE® Autograft Harvester is intended to obtain morselized autogenous bone from common harvesting sites including the calcaneus, distal tibia, and proximal tibia.

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
- Bone resorption or over-production
- Metal sensitivity or histological or allergic reaction resulting from instrument material
- Infection or painful, swollen or inflamed surgical site
- Migration of particle wear debris possibly resulting in bodily response
- Pain, discomfort, or abnormal sensations due to surgical trauma
- 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.
- Known or suspect material allergies.
- Comorbidities, 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 instrument, the method of application, and the recommended surgical technique and indications for this type of device.

Intra-Operative Precautions
- The surgeon must select the size harvester that best meets the patient's surgical needs.
- **The Autograft Harvester is single use only; do not reuse.** The instrument may suddenly fail as a result of previous stresses.
- The Autograft Harvester shall be inspected for wear or damage prior to use.

Post-Operative Precautions
The patient should be warned of the limitations of surgery and the need to protect the surgical site until healing has occurred. The postoperative care instructions provided by the surgeon should be strictly followed to avoid adverse stresses applied to the surgical site. Failure to follow postoperative care instructions can cause treatment failure.

Recommendations Regarding Device Fragments
1. Things to consider and discuss with the patient include; the material composition of the instrument 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 instrument fragment should take into consideration the potential risk to the patient of a second surgical procedure.
3. If the instrument is damaged, retain the instrument to assist the manufacturer's investigation of the event.

MR Safety Information
The Medline UNITE® Autograft Harvester 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® Autograft Harvester 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. A machine wash and manual cleaning method is provided and has been developed and tested consistent with ISO 17664 and ANSI/AAMI TIR 30. 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 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 using the minimum effective concentration (i.e. 1/8 oz. per gallon).
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 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 (for example, 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
Wash1	10:00	Warm Tap Water (50 °C)	Enzymatic cleaner*
Wash2	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 Cleaning, 1/8 oz. per gallon (min. effective concentration)
†Medline Industries, LP used the following during the validation of these instructions - STERIS® Prolystica® 2X Concentrate 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. Rinse under cool running tap water to remove visual soil.
2. Prepare enzymatic detergent per manufacturer's recommendation using luke warm tap water.
3. Allow the device to soak in the prepared enzymatic detergent for one (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 three (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. Prepare neutral detergent per manufacturer's recommendation using warm tap water.
9. Allow the device to soak in the prepared neutral detergent for three (3) minutes.
10. Using a soft bristled brush, thoroughly brush the device to remove soil.
11. Run a stylet through the lumens a minimum of three (3) times to remove soil.
12. Using a syringe, aggressively flush the lumens with the prepared neutral detergent.
13. Remove the device from the detergent and rinse in running RO/DI water to remove detergent residuals.
14. Prepare enzymatic detergent per manufacturer's recommendation in a sonication unit.
15. Allow the device to sonicate for ten (10) minutes.
16. Remove the device from the sonicator and thoroughly rinse under running critical water.
17. Using a syringe, aggressively flush the lumens.
18. Dry the device with a disposable, lint-free cloth.
19. Visually inspect the device for cleanliness.
20. If device is still visibly soiled, repeat 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.

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 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	Minimum 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.**

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