Hermosa System

Rx Only Caution: Federal Law restricts this device to sale by or on the order of physician

Manufacturer:
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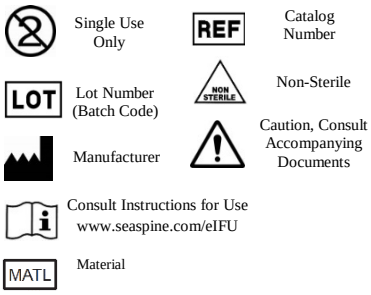

DESCRIPTION

Hermosa is a SeaSpine instrument system used to harvest morsellized autogenous bone. The system includes the harvesting device and additional components that aid in the harvesting process. Per user preference, the harvester may be used with or without a guidewire by selecting either the cannulated or non-cannulated cutting tip, respectively. The selected tip is attached to the handle and secured using the tip tightening tool. If desired, the punch may be used to puncture the cortical shell. As the harvester is advanced into the harvesting site, bone is collected in the hollow handle shaft. The plunger is used to expel harvested bone from the device.

INDICATIONS FOR USE

An orthopedic manual surgical instrument intended for use in harvesting and morselizing autogenous bone.

WARNINGS AND PRECAUTIONS

- Use of the Hermosa System should be performed only by experienced surgeons with specific training in the use of this system as this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Sterilize prior to use.

CLEANING AND DECONTAMINATION

All instruments that have been previously taken into a sterile surgical field must be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into the sterile surgical field. The following recommendations are for the manual cleaning and decontamination of implants and surgical instruments. These recommendations are considered guidelines with the ultimate responsibility for verifying adequate cleaning remaining with the user. Automated cleaning systems differ between hospitals and therefore must be qualified by the hospital.

Manual Cleaning Procedure

1	Remove all gross visible soil with a damp gauze pad or wipe.
2	Prepare an enzymatic cleaning solution (such as Prolystica® 2X Enzymatic) per manufacturer's instructions.
3	Immerse the instruments in the cleaning solution and actuate all features so the enzymatic cleaner contacts all mated surfaces and soak for 15 minutes.
4	Transfer the instruments to fresh cleaning solution (such as Prolystica® 2X Enzymatic). Thoroughly scrub all instruments with a soft bristle cleaning brush while immersed in the enzymatic cleaning solution. Be sure that thorough scrubbing also includes any lumens with an appropriate size brush. Actuate device to allow access to hard to reach areas.
5	Thoroughly rinse all instruments with warm running water and dry with a clean cloth and/or allow to air dry.

Automated Cleaning Procedure

1	Remove all gross visible soil with a damp gauze pad or wipe. Special attention will be required to examine products with tight crevices, voids, and lumens. Lumens may require pre-cleaning with dampened soft bristle brushes and tight crevices, voids, lumens should be flushed with a syringe.
2	Prepare an enzymatic cleaning solution (such as Prolystica® 2X) per manufacturer's instructions. Immerse the instruments in the cleaning solution and actuate all features so the enzymatic cleaner contacts all mated surfaces and soak for 15 minutes.
3	Transfer items to a washer and run a cycle with the parameters listed in the following steps.
4	PRE-WASH: Cold tap water [*2 minutes*].
5	ENZYME WASH: Enzyme wash using cleaner (such as Prolystica® 2X Enzymatic) per manufacturer's recommendations, hot tap water [*4 minutes*].
6	DETERGENT WASH: Detergent wash using detergent (such as Prolystica® 2X Alkaline) per manufacturer's recommendations, hot tap water (66°C/150°F) [*2 minutes*].
7	RINSE 1: Rinse, hot tap water [*2 minutes*].
8	RINSE 2: Purified water rinse (66°C/150°F) [*15 seconds*].
9	DRYING: Hot air dry (82°C/180°F) [*12 minutes*].
10	Remove items from the washer and remove any residual moisture with a lint free clean cloth.

STERILIZATION

The instrumentation in the Hermosa System are to be sterilized by the hospital prior to surgery.

Double wrap trays using FDA-cleared sterilization wraps (2 wraps). The recommended sterilization cycle will provide a Sterility Assurance Level of (SAL 10^{-6}). Following AAMI ST79 guidelines, the validated sterilization cycle for a fully loaded tray is:

Method	Steam
Cycle	Pre-vacuum
Temperature and Exposure Time	270°F (132°C) for 8 minutes
Drying Time	30 minutes

PACKAGING

All packages should be sealed and intact upon receipt. If the package or product is damaged, the product should not be used and should be returned. The product must be handled, stored, and opened in such a way that it is protected from inadvertent damage or contamination. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for damage before use.

SURGICAL TECHNIQUE

This package insert is designed to assist in using the product and is not intended to provide information on surgical technique. Contact a SeaSpine Representative, customerservice@seaspine.com or +1-760-727-8399 for a Surgical Technique Guide.

IMPLANT SELECTION

Verify that all parts and necessary instruments are present prior to surgery, including sizes larger and smaller than those that are expected for use. The construct should be assembled prior to surgery.

PREOPERATIVE WARNINGS

- All non-sterile parts should be cleaned and sterilized before use. Additional sterile components should be available in case of unexpected need.
- Devices should be inspected for damage prior to implantation.
- Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

INTRAOPERATIVE WARNINGS

- Consult Surgical Technique Guide for system specific intraoperative warnings, precautions and recommendations.
- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological function.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- Bone graft must be placed in the area to be fused and the graft must be in contact with viable bone.
- Implants and components should not be bent, reshaped, contoured or otherwise modified.

POSTOPERATIVE WARNINGS

- Surgeons should advise patients regarding the risks of surgery and the importance of post-operative compliance.
- The patient should be advised to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation.
- Patients should be advised of the potential for pain and/ or morbidity at the site where autogenous bone was harvested.

COMPLAINTS

Immediately notify SeaSpine or a SeaSpine representative by phone, fax or email regarding complaints, malfunctions or adverse events associated with this product. When possible, retain the product involved in the complaint and return to SeaSpine as instructed by SeaSpine Customer Service.

PRODUCT INFORMATION DISCLOSURE

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