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InstaFill™ GRAFT DELIVERY SYSTEM

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GLOBUS
M E D I C A L

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IMPORTANT INFORMATION ON THE InstaFill™ GRAFT DELIVERY SYSTEM

WITHIN THE UNITED STATES ONLY

ENGLISH

IMPORTANT INFORMATION ON InstaFill™ GRAFT DELIVERY SYSTEM

DESCRIPTION

The InstaFill™ Graft Delivery System is intended to be used for the delivery of allograft, autograft, and synthetic bone graft material to an orthopedic surgical site. The system allows delivery of graft materials that are provided in prefilled cartridges, or from empty cartridges that are filled with the desired graft material by the user.

The system consists of a reusable delivery device with an advancement rod and rod stop. Reusable graft loading instruments include a bone funnel, bone funnel pusher, and a luer lock adapter.

Single-use components include an optional conical tip and graft cartridges. The cartridges are provided empty for filling with graft material, or prefilled with graft material, including demineralized bone matrix (DBM) or SIGNIFY® Bioactive Gel. Refer to the corresponding product inserts for more information on DBM or SIGNIFY®.

INDICATIONS

The InstaFill™ Graft Delivery System is intended to be used for the delivery of allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.

CONTRAINDICATIONS

The InstaFill™ Graft Delivery System is not designed for any use except as indicated. The physician should be familiar with any contraindications of the bone graft material being delivered. Contraindications specific to the delivery system include, but are not limited to, allergies to nickel, biocompatible polymer materials or polypropylene.

PRECAUTIONS

These devices can only be used by physicians who are familiar with the surgical technique. Extreme care must be taken when the instruments are used near vital organs, nerves, or vessels.

ADVERSE EFFECTS

For a complete list of potential adverse effects, please refer to the package insert of the specific bone graft material being used. Possible adverse effects associated with this device include, but are not limited to:

- Infection
- Allergic reaction
- Neurological injury, pain, injury to soft tissues, vessels, visceral organs or joints

PACKAGING

These instruments may be supplied pre-packaged and sterile or nonsterile. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. All components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical.

Instruments provided nonsterile are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments and instrument trays and cases must be cleaned, as described in the CLEANING section below.

HANDLING

All instruments, instrument trays, and cases should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion (i.e. rust, pitting), discoloration, excessive scratches, notches, debris, residue, flaking, wear, cracks, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. Instruments may be reassembled following sterilization. The products should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments and instrument trays and cases after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.

4. Prepare Enzo® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzo® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

The InstaFill™ Cartridges (empty and prefilled) are supplied sterile only. The Delivery Device is provided nonsterile only. Single-use cartridges are not intended to be re-sterilized. All other instruments may be available sterile or nonsterile.

Sterile instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10⁻⁶. Sterile products are packaged in heat sealed, double Tyvek pouches. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile devices meet pyrogen limit specifications.

Nonsterile instruments have been validated to ensure a SAL of 10⁻⁶. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:














- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in² total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 minutes	30 minutes
Steam	Pre-vacuum	134°C (273°F)	3 minutes	30 minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

SYMBOL TRANSLATION			
	CATALOGUE NUMBER		STERILIZED BY IRRADIATION
	LOT NUMBER		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
	MEDICAL DEVICE		DO NOT RESTERILIZE
	DO NOT USE IF PACKAGE IS DAMAGED		CONSULT INSTRUCTIONS FOR USE
	QUANTITY		