DI146A-EN (Rev D)	RETRIEVE® UNIVERSAL BONE GRAFT HARVESTING SYSTEM
05/2025	**IMPORTANT INFORMATION ON THE RETRIEVE® UNIVERSAL BONE GRAFT HARVESTING SYSTEM**

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For symbols glossary, please refer to www.globusmedical.com/eIFU

ENGLISH

WITHIN THE UNITED STATES ONLY

IMPORTANT INFORMATION ON THE RETRIEVE® UNIVERSAL BONE GRAFT HARVESTING SYSTEM

DESCRIPTION

The RETRIEVE® Universal Bone Graft Harvesting System is comprised of the RETRIEVE® Bone Graft Harvest Set and the RETRIEVE® Bone Marrow Aspiration Kit. The Bone Graft Harvest Set includes instruments for harvesting autogenous bone from the iliac crest. The instruments include guide wires, cutting tips, graft remover, and various other instruments. The Bone Marrow Aspiration Kit includes instruments for aspirating bone marrow or blood from the iliac crest. The kit includes needle(s), syringes, and mixing components.

INDICATIONS

The RETRIEVE® Bone Graft Harvest Set is used to harvesting autogenous bone from the iliac crest. The harvested bone graft can then be used for a variety of uses, including filling spinal interbody fusion devices and supporting posterolateral fusion.

The RETRIEVE® Bone Marrow Aspiration Kit is intended for aspiration of bone marrow, autologous blood, plasma or other blood components. The harvested bone marrow aspirate or blood can then be used for a variety of uses, including filling spinal interbody fusion devices and supporting posterolateral fusion. The bone marrow aspirate or autologous blood may be combined with bone graft or bone void fillers.

WARNINGS AND PRECAUTIONS

- This device is designed to be used by a physician.
- These instructions are not meant to define or suggest any medical or surgical technique. The individual practitioner is responsible for the proper procedure and technique to be used with this device.
- Possible allergic reactions should be considered.
- Check if the sterile inner package is unopened and damaged. In case of damaged inner package, do not use the product.
- Check the expiration date on sterile packaging.
- Store in a cool and dry place, protect from light.
- Use of the device is restricted only to physicians.
- Sterility and integrity are guaranteed only if observed with the prescribed conditions.
- Each sterile unit is intended for single patient use only.
- Do not use the product if the package has been damaged.
- All components should be properly and safely discarded after use.
- DO NOT RE-STERILIZE ANY STERILE PACKED COMPONENTS, INCLUDING THE KIT OR DISPOSABLES WITHIN THE KIT.
- Universal precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated instrumentation. Caution should be exercised when handling devices with sharp points or cutting edges.
- Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.
- Do not place heavy instruments on top of delicate devices.
- During the manual cleaning procedures do not use metal brushes or scouring pads. These materials will damage the surface and finish of instruments. Soft bristled, nylon brushes and pipe cleaners should be used.
- Do not use high acidic (pH<4) or high alkaline (pH>10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures.
- Do not allow contaminated instruments to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluid, bone and tissue debris, saline, or disinfectant to dry on used instrumentation.
- Follow the instructions and warnings issued by the suppliers of any cleaning and disinfection agents and equipment used.
- Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, bromine, bromide, iodine or iodide are corrosive and should not be used. Instruments should not be placed or soaked in Ringers Solution.
- Mineral oil or silicone lubricants should not be used because they: 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) are difficult to remove.

SURGICAL GUIDELINES

These instructions are intended as guidelines for the use of the RETRIEVE® Universal Bone Graft Harvesting System as part of established surgical techniques. They are not intended to replace or change standard surgical procedures. Proper surgical procedures and techniques are the responsibility of the medical professional.

RETRIEVE® BONE GRAFT HARVEST SET

1. After suitable anesthesia is achieved, place the patient in the ventral supine position.
2. Using sterile technique, prepare the skin with antiseptic and drape.
3. After locating the iliac crest, palpate the anterior crest. Prepare the surgical site and create an incision.
4. Insert the guide wire into the posterior or anterior iliac crest.
5. Insert the driver over the guide wire and into the iliac crest.
6. Impact the driver into the crest and rotate to obtain the bone graft.
7. Remove the guide wire and remove the bone plug from the driver.
8. The bone graft can be applied directly to the surgical site.

RETRIEVE® BONE MARROW ASPIRATION KIT

1. After suitable anesthesia is achieved, place the patient in the ventral supine position.
2. Using sterile technique, prepare the skin with antiseptic and drape.
3. After locating the iliac crest, palpate the anterior crest. Prepare the surgical site and create an incision.
4. Remove the plastic guard from the aspiration needle.
5. Advance the needle with steady pressure and a slight twisting motion to the center of the anterior or posterior iliac prominence.
6. Advance needle using forward pressure through the cortex until all aspiration holes are engaged in the bone.
7. Remove the trocar needle and attach the syringe to the luer fitting on the aspiration needle.
8. Apply suction by withdrawing the syringe plunger. Remove the syringe with the harvested marrow.
9. Repeat until an appropriate amount of marrow is obtained.
10. The bone marrow aspirate can be applied directly to the surgical site or to the graft material.
11. The same procedure may be used to aspirate blood or other blood products.

PACKAGING

These instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and 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. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

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

HANDLING

All instruments 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, discoloration, pitting, 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. All handles must be detached. Instruments may be reassembled following sterilization. The instruments 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 of instruments 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 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 Enzol® (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 Enzol® (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

These 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 a heat sealed, double foil pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged.

Nonsterile instruments have been validated to ensure an 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 in^2 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

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 (U.S.A.) Law Restricts this Device to Sale by or on the order of a Physician.