




DI111A-EN (Rev F)	RETAIN™ RADIOLUCENT SPACERS	
05/2025  GLOBUS MEDICAL, INC. Valley Forge Business Center 2560 General Armistead Avenue Audubon, PA 19403 USA Customer Service: Phone 1-866-GLOBUS1 (OR) 1-866-456-2871 Fax 1-866-GLOBUS3 (OR) 1-866-456-2873	IMPORTANT INFORMATION ON THE RETAIN™ RADIOLUCENT SPACER EC REP: AJW Technology Consulting GmbH Breite Straße 3 40213 Düsseldorf, Germany CH REP: AJW Technology Consulting GmbH Kreuzplatz 2, 8032 Zurich, Switzerland AUSTRALIA SPONSOR: GLOBUS MEDICAL AUSTRALIA PTY LIMITED, Unit 9/5-7 Inglewood Place Baukham Hills NSW 2153, Australia	 0297 

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

ENGLISH

IMPORTANT INFORMATION ON THE RETAIN™ RADIOLUCENT SPACER

DESCRIPTION (WITHIN THE UNITED STATES)

The RETAIN™ Radiolucent Spacer device is a vertebral body replacement device used to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The system is comprised of spacers of various fixed heights and shapes to fit the anatomical needs of a wide variety of patients. Each spacer has an open architecture to allow packing of grafting material. Ridges on the superior and inferior surfaces of each device help to grip the endplates of the adjacent vertebrae to resist expulsion.

The RETAIN™ Radiolucent Spacer devices are made from radiolucent polymer and titanium alloy and/or tantalum as specified in ASTM F2026, F136, F1295 and F560.

INDICATIONS (WITHIN THE UNITED STATES)

The RETAIN™ Radiolucent Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The RETAIN™ Radiolucent Spacer is intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material.

The RETAIN™ Radiolucent Spacer is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

DESCRIPTION (OUTSIDE THE UNITED STATES)

The RETAIN™ Radiolucent Spacer is a unitary device that fits between spinous processes of the lumbar spine. RETAIN™ Radiolucent Spacer is designed to help decompress a spinal segment and limit extension. RETAIN™ is available in different styles, heights and widths to help anatomically fit the device into the interspinous space. The device is manufactured from polyetheretherketone (PEEK) radiolucent polymer (per ASTM F2026) with titanium or tantalum pins (per ASTM F136, F1295, F560) for radiographic visualization.

INDICATIONS (OUTSIDE THE UNITED STATES)

The RETAIN™ Radiolucent Spacer is indicated for treatment in patients suffering from lumbar spinal stenosis at one or two levels between L1 and S1. Lumbar spinal stenosis (LSS) is a narrowing of the spinal canal, characterized by back, buttock, or leg pain producing nerve compression and ischemia, which is relieved by lying supine or flexing the spine. Interspinous spacers help distract and keep the foramen open by blocking extension to relieve symptoms.

WARNINGS

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- neurological injury, and
- vascular or visceral injury.

PRECAUTIONS

The implantation of vertebral body replacement devices should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

ATTENTION

See Warnings, Precautions and Potential Adverse Events sections of the insert entitled "Suggestions Concerning Orthopaedic Metallic Internal Fixation Devices" for a complete list of potential risks.

CONTRAINDICATIONS

1. Use of the RETAIN™ Radiolucent Spacer is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant.
3. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
4. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.

PACKAGING

These implants and 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 and implants 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 implants and instruments may be available sterile or nonsterile.

Sterile implants and 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 implants and 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 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 implants and 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.