

DI136A-EN (Rev G)	RENEGADE™ RADIOLUCENT SPACER	
05/2025  GLOBUS MEDICAL  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 RENEGADE™ 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 Baulkham Hills NSW 2153, Australia  0297 	

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

ENGLISH

OUTSIDE THE UNITED STATES ONLY

IMPORTANT INFORMATION ON THE RENEGADE™ RADIOLUCENT SPACER

DESCRIPTION

The RENEGADE™ Radiolucent Spacer is a unitary device that fits between spinous processes of the lumbar spine. RENEGADE™ is designed to help decompress a spinal segment and limit extension. The implants are available in various sizes to fit the anatomical needs of a variety of patients. RENEGADE™ implants are manufactured from PEEK radiolucent polymer and titanium alloy and/or tantalum as specified in F2026, F136, F1295 and F560.

INDICATIONS

The RENEGADE™ Radiolucent Spacer is indicated for treatment of patient suffering from lumbar spinal stenosis (LSS). 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. RENEGADE™ may be implanted in the lumbar spine (L1-S1). Interspinous spacers help distract and keep the foramen open by blocking extension to relieve symptoms.

WARNINGS

Possible adverse effects which may occur include, but are not limited to: failed fusion or pseudarthrosis leading to implant breakage; allergic reaction to implant materials including metallosis, staining, tumor formation and/or autoimmune disease; infection; device fracture or failure; device migration or loosening; decrease in bone density; loss of spinal mobility or function; inability to perform activities of daily living; fracture of any spinal bone including the pedicles, spinous process, pars interarticularis, vertebral body, or sacrum; change in spinal curvature or disc height; herniated nucleus pulposus, disc degeneration or disruption; graft donor site complications including pain, fracture and wound healing problems; tissue damage, pain, discomfort, or abnormal sensations due to the presence of the device or implantation surgery; scar formation causing neurologic compromise or pain; injury to nerves including loss or decrease of neurologic function, paralysis, dural tears, development of radiculopathy, numbness or tingling; cauda equine syndrome; injury to vessels, hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, or other types of cardiovascular system compromise; injury to organs including urinary retention, loss of bladder control, or other types of urologic system compromise; gastrointestinal system compromise; reproductive system compromise including sterility, sexual dysfunction; development of respiratory problems including pulmonary embolism; venous thrombosis, lung embolism and cardiac arrest; and death. Additional surgery may be necessary to correct some of these effects.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

PRECAUTIONS

Implantation of these devices should be performed only by experienced spinal surgeons with specific training in the use of the system due to a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implants.

Surgical implants must never be reused. An explanted implant must never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurologic functions. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery. To insert a cannulated screw, a guide wire may be used, followed by a sharp tap. Ensure that the guide wire, if used, is not inserted too deep, becomes bent, and/or breaks. Also ensure that the guide wire does not advance during tapping or screw insertion. Remove the guide wire and confirm that it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.

Correct handling of the implant is extremely important. Contouring of metal implants should be avoided where possible. If contouring is necessary, or allowed by design, the surgeon should avoid sharp bends, reverse bends, or bending the device at a screw hole. The operating surgeon should avoid any notching or scratching of the device when contouring it. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must have the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management.

Correct selection of the implant is extremely important. The potential for success on fracture fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can minimize risks, size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load-bearing. A higher risk of device loosening, bending, or breaking exists with fractures involving severe comminution, displacement or other difficult fracture management situations.

CONTRAINDICATIONS

The contraindications include, but are not limited to: Active infectious process or significant risk of infection (immunocompromise); local inflammation, fever, or leukocytosis, morbid obesity; pregnancy; mental illness; distorted anatomy caused by congenital abnormalities; any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities; rapid joint disease, bone absorption osteopenia, and/or osteoporosis; suspected or documented material allergy or intolerance; any case where metals must be mixed from different components; any case where the implant components selected for use would be too large or too small to achieve a successful result; any case where fracture healing is not required; any patient in which implant utilization would interfere with anatomical structures or expected physiological performance; any patient unwilling to follow post-operative instructions; any case not described in the indications.

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

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 a 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 are designed 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 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
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.