Regatta Lateral System –Sterile
English

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

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Single Use Only		Expiration date (YYYY-MM-DD)	
Sterilized Using Irradiation		Do Not Re-Sterilize	
Product Complies with the Requirements of Directive 93/42/EEC		Authorized Representative in the European Community	
Lot Number (Batch code)		Catalog Number	
Product Complies with the Requirements of Directive 93/42/EEC (Class I Devices Only)		Consult Instructions for Use www.seaspine.com/eIFU	
Non-Sterile		Manufacturer	
Do Not Use if Damaged		Material	

DESCRIPTION
The SeaSpine Regatta Lateral System is an intervertebral body fusion device (IBD) with large central graft windows, which are packed with autogenous bone graft and/or allogeneic bone graft, composed of cancellous and/or corticocancellous bone prior to implantation. The spacer has a bulleted insertion end for ease of implantation and 5 tantalum markers to allow easier radiological assessment of the spacer position and orientation. All spacers are manufactured from PEEK (ASTM F2026) with radiographic markers manufactured from tantalum (ASTM F560), with a one-micron thick surface of commercially pure (CP) titanium (ASTM F67) and sterile packaged. The instruments included with the system facilitate the placement and adjustment of the interbody spacers, and removal if necessary. The instruments are placed in trays and caddies for storage, protection, and organization prior to and during the steam sterilization process.

INDICATIONS FOR USE
The SeaSpine Regatta Lateral System is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD, defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies). It is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of DDD with up to Grade 1 spondylolisthesis at the involved level(s). The interior of the interbody spacer component may be packed with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or corticocancellous bone. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

The SeaSpine Regatta Lateral System is intended for use with supplemental fixation.

IMPLANT MATERIALS
The Regatta spacers are manufactured from PEEK (ASTM F2026) with radiographic markers manufactured from tantalum (ASTM F560), with a one-micron thick surface of commercially pure (CP) titanium (ASTM F67).

CONTRAINDICATIONS
Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery is a contraindication. The following conditions may reduce the chance of a successful outcome and should be taken into consideration by the surgeon. This list is not exhaustive:

- Absolute contraindications:
  - Infection in or around the operative site
  - Allergy or sensitivity to implant materials
  - Any case not described in the indication
- Relative contraindications:
  - Local inflammation
  - Morbid obesity
  - Pregnancy
  - Fever or leukocytosis
  - Prior fusion at the level(s) to be treated
  - Grossly distorted anatomy due to congenital abnormalities
  - Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis
  - Elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
  - Any case not requiring bone graft and fusion or where fracture healing is not required
  - Patients having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition
  - Unsuitable or insufficient bone support
  - Bone immaturity
  - The patient's activity level, mental condition, occupation and/or a patient unwilling to cooperate with the postoperative instructions
  - Any case where implant utilization would interfere with anatomical structures or expected physiological performance
  - Use of incompatible materials from other systems

POSSIBLE ADVERSE EVENTS
Like other spinal system implants, the following adverse events are possible. This list is not exhaustive:

- Delayed union or nonunion (pseudarthrosis)
- Bending, disassembly or fracture of implant and components
- Loosening of spinal fixation implants may occur due to inadequate initial fixation, latent infection, and/or premature loading, possibly resulting in bone erosion, migration or pain
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Dural leak requiring surgical repair.
- Cessation of growth of the fused portion of the spine.
- Subsidence of the implant into adjacent bone.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Increased biomechanical stress on adjacent levels.
- Improper surgical placement of the implant causing stress shielding of the graft or fusion mass.
- Intraoperative fissure, fracture, or perforation of the spine.
- Postoperative fracture due to trauma, defects, or poor bone stock.
- Serious complications associated with any surgery may occur. These include, but are not limited to: wound complications, infection, genitourinary disorders, gastrointestinal disorders, vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, paralysis or death.

WARNINGS AND PRECAUTIONS
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery. The safety and effectiveness of spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the spine secondary to severe spondylolisthesis, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other condition is unknown.
- The implantation of this system should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Based on the fatigue testing results, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system
- Ensure all implants, components or instruments are sterile prior surgery. The use of non-sterile devices may lead to inflammation, infection or disease.
- Implants should never be reused under any circumstances. A used implant should be discarded. While the implant may appear undamaged, it may have small defects or internal stress patterns and if implanted, could fail to perform as intended and pose safety risks to the patient. The risks include, but are not limited to, mechanical failure, breakage, difficulty with implantation, incompatibility with mating components and infection.

MRI SAFETY
The device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 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 instruments in the SeaSpine Regatta Lateral System are to be sterilized by the hospital prior to surgery. Precaution: The Regatta interbody implant is offered sterile and should not be re-sterilized.

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	270ºF (132ºC) for 4 minutes
Drying Time	30 minutes

PACKAGING

All packages containing implants 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.

Precaution: The Regatta interbody implant is offered sterile. Do not use the device if the package is opened, damaged or otherwise compromised as these conditions may render the device non-sterile and/or damaged. Do not implant the device past the expiration date. Use proper aseptic technique to transfer the contents of the sterile package to the surgical field.

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 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.

Precaution: Instructions for opening sterile packaging:

1) Peel open outer package.
2) Using aseptic technique, transfer contents to sterile field.
3) Peel open inner package and remove implant.

PREOPERATIVE WARNINGS

- Only patients that meet the criteria described in the indications should be selected.
- Patient condition and/or predispositions such as those described in the contraindications should be avoided.
- Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
- 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.
- Use great care to ensure that the implant surfaces are not scratched or notched which may reduce the functional strength of the construct.
- If the construct contains screws, prior to soft tissue closure, recheck all screws to ensure they are tightened. Failure to do so may cause loosening of the other components.

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.
- The patient should be advised that implants may bend, break or loosen despite restriction in activity.
- The patient should be advised to avoid mechanical vibrations that may loosen the device.
- The patient should be advised not to smoke or consume alcohol during recovery.

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

SeaSpine has exercised reasonable care in the selection of materials and the manufacture of these products. SeaSpine warrants to the original purchaser only that each new SeaSpine product is free from manufacturing defects in material and workmanship under normal use and service for a period of six (6) months from the date of delivery by SeaSpine to the original purchaser, but in no event beyond the expiration date stated on any product labeling. SEASPINE DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, WRITTEN OR ORAL (INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). Further, this warranty shall not apply to, and SeaSpine shall not be responsible for, any loss arising in connection with the purchase or use of any SeaSpine product that has been repaired by anyone other than an authorized SeaSpine service representative or altered in any way so as, in SeaSpine's judgment, to affect its stability or reliability, or which has been subject to misuse, negligence or accident, or which has been used otherwise than in accordance with these instructions. IN NO EVENT SHALL SEASPINE BE LIABLE FOR ANY SPECIAL, INCIDENTAL CONSEQUENTIAL, OR CONTINGENT LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM ACQUISITION OR USE OF THIS PRODUCT. SeaSpine neither assumes nor authorizes any person to assume for it any other additional liability or responsibility in connection with this product. SeaSpine intends that this device should be used only by physicians having received proper training in the use of the device.