Shoreline® 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)
STERILE R	Sterilized Using Irradiation		Do Not Re-Sterilize
CE 2797	Conformitè Europëenne Mark (CE Mark)	REF	Catalog Number
LOT	Lot Number (Batch Code)		Consult Instructions for Use www.seaspine.com/eIFU
CE	Conformitè Europëenne Mark (CE Mark) (Class I Devices Only)		Manufacturer
NON STERILE	Non-Sterile	MATL	Material
	Do Not Use if Damaged		Date of Manufacture
MD	Medical Device		

DESCRIPTION

Shoreline ACS -Anterior Cervical Standalone
The Shoreline ACS (Anterior Cervical Standalone) is a NanoMetalene® titanium bonded device, providing no profile and ultra-low profile cervical spinal fixation. Shoreline ACS is offered in a variety of footprints and heights to accommodate variations in patient anatomy and is generally box-shaped with a central canal for receiving autogenous and/or allogeneic bone graft material.

The Low-Profile Interbody, the No-Profile Interbody, the Low-Profile Plate, and the No-Profile Anterior Plate must be used with their matching component and are not intended to be used with other anterior plating systems or interbody devices. Each No-Profile or Low-Profile construct must be used with the maximum number of screws allowed by the plate interface.

Shoreline Cervical Interbody RT System
The Shoreline Cervical Interbody RT System spacer is a NanoMetalene® titanium bonded device offered in a variety of footprints and heights to accommodate variations in patient anatomy. The spacer is box-shaped and available with or without graft docking tabs, and a central canal for receiving autogenous and/or allogeneic bone graft material. The Shoreline Cervical Interbody RT System spacer is to be used with supplemental fixation, such as an anterior plate or as a standalone construct to be used with the Shoreline ACS bone screws, plate, and locking cover.

INDICATIONS FOR USE

Shoreline ACS -Anterior Cervical Standalone
The Shoreline ACS device is a stand-alone device indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease of the cervical spine at a single level (C2-T1). The Shoreline ACS implants are to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and /or corticocancellous bone and implanted via an anterior approach. The cervical device is to be used in patients who have had at least six (6) weeks of non-operative treatment.

The cervical device is to be used with Shoreline bone screw fixation and the Shoreline locking cover.

Shoreline Cervical Interbody RT System
The Shoreline Cervical Interbody RT System are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for one or two contiguous levels, depending on the system. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical and/or corticocancellous bone.

When used as a standalone system, the Shoreline Cervical Interbody RT System is intended to be used as an adjunct to spinal fusion procedures at a single level (C2-T1) and must be used with the Shoreline ACS bone screw fixation and locking cover.

When used with supplemental fixation, such as anterior cervical plates, the Shoreline Cervical Interbody Spacer Shoreline Cervical Interbody RT System is intended to be used as an adjunct to spinal fusion procedures at one or two levels of the cervical spine (C3-C7).

IMPLANT MATERIALS

Polyetheretherketone polymer (PEEK) per ASTM F-2026. Commercially Pure Titanium per ASTM F67. Tantalum per ASTM F-560.

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
- Pressure on skin where inadequate tissue coverage exists over the implant, with potential extrusion through the skin.
- 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 sterilized 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.
- 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 thoracic and lumbar spine secondary to 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.
- To achieve the best results, unless otherwise specifically described in another SeaSpine document, do not use Shoreline ACS System components in conjunction with components from any other system or manufacturer.

MRI SAFETY

This 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 this device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CLEANING AND DECONTAMINATION

All instruments and implants 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 a minimum of 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 for a minimum of 2 minutes.
5	ENZYME WASH: Enzyme wash using cleaner (such as Prolystica® 2X Enzymatic) per manufacturer's recommendations, hot tap water for a minimum of 4 minutes.
6	DETERGENT WASH: Detergent wash using detergent (such as Prolystica® 2X Alkaline) per manufacturer's recommendations, hot tap water (minimum temp of 66°C/150°F) for a minimum of 2 minutes.
7	RINSE 1: Rinse, hot tap water for a minimum of 2 minutes.
8	RINSE 2: Purified water rinse (minimum temp of 66°C/150°F) for a minimum of 15 seconds.
9	DRYING: Hot air dry (minimum temp of 82°C/180°F) for a minimum of 12 minutes.
10	Remove items from the washer and remove any residual moisture with a lint free clean cloth.

STERILIZATION

The components and instrumentation in the Shoreline ACS System are to be sterilized by the hospital prior to surgery.

Precaution: The Shoreline ACS System interbody implant is offered sterile and should not be 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	270°F (132°C)
Exposure Time	4 minutes
Minimum 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 Shoreline ACS System interbody implants are 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 +1-760-727-8399 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. The construct should be assembled prior to surgery.

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

This warranty ("Warranty") applies to the Products (defined below) purchased on or following the date set forth above. SeaSpine provides this Warranty only to the entity that purchases the Product directly from SeaSpine, (the "Purchaser").

"Products" means the following products of SeaSpine Orthopedics Corporation or its affiliates including SeaSpine Sales LLC, IsoTis OrthoBiologics, Inc., and SeaSpine, Inc. (collectively referred to herein as "SeaSpine"):

i. Medical devices or accessories used to perform actions during surgery, but not intended to be implanted in the patient, provided in non-sterile condition and sterilized by the end-user prior to use ("Instruments");

ii. Medical devices intended for implantation provided in non-sterile condition and sterilized by the end-user prior to use ("Non-Sterile Implants"); and

iii. Medical devices or biologics intended for implantation delivered in sterile condition ("Sterile Implants").

1. Warranty.

Instruments. SeaSpine warrants to the Purchaser only that the Instrument is free from manufacturing defects in material and workmanship under normal use and service (i) with respect to new Instruments, for a period of two (2) years commencing on the date of delivery by SeaSpine to the Purchaser, and (ii) with respect to used Instruments, for a period of one (1) year commencing on the date of delivery by SeaSpine to the Purchaser.

Non-Sterile Implants. SeaSpine warrants to the Purchaser only that the Non-Sterile Implant is free from manufacturing defects in material and workmanship under normal use and service for a period of commencing on the date of delivery by SeaSpine to the Purchaser and ending one hundred eighty (180) days after the date of such delivery.

Sterile Products. SeaSpine warrants to the Purchaser only that the Sterile Product is free from manufacturing defects in material and workmanship under normal use and service for a period commencing on the date of delivery by SeaSpine to the Purchaser and ending on the earlier of (i) one hundred eighty (180) after such delivery date, or (ii) the expiration date stated on the Product's labeling.

2. Warranty Conditions.

This Warranty shall not apply (i) if the Product is not used or stored in accordance with the Product's instructions for use supplied by SeaSpine and/or included in the product packaging, (ii) to any 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 (iii) to any Product which has been subject to misuse, negligence or accident.

If the Purchaser seeks to invoke the terms of the Warranty, the Purchaser must notify the SeaSpine customer service department at the address set forth in the product labeling, which can be found at www.seaspine.com, of the covered defect during the warranty period, and the Product must be returned as directed by SeaSpine. The defective Product should be returned promptly, properly packaged and postage prepaid. Loss or damage in return shipment to SeaSpine shall be at sender's risk.

SEASPINE'S SOLE RESPONSIBILITY AND LIABILITY UNDER THIS WARRANTY SHALL BE, AT SEASPINE'S SOLE DISCRETION, REPAIR OR REPLACEMENT OF THE DEFECTIVE PRODUCT, OR REFUND OR CREDIT OF THE PRICE PAID FOR THE DEFECTIVE PRODUCT, SUBJECT TO THE TERMS OF THIS WARRANTY AND APPLICABLE AGREEMENTS. SEASPINE DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION OR WARRANTY OF QUALITY. No warranty or guarantee may be created by any act or statement nor may this warranty be modified in any way, except as a result of a writing signed by an officer of SeaSpine. These limitations on the creation or modification of this warranty may not be waived or modified orally or by any conduct.

3. Liability Limitations.

TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAWS, IN NO EVENT, REGARDLESS OF THE FAILURE OF THE SOLE AND EXCLUSIVE REMEDY SET FORTH HEREIN, SHALL SEASPINE BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF ANY SEASPINE PRODUCT.