NorthStar® OCT System – English

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

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DESCRIPTION

The NorthStar® OCT System is intended for use as an aid in spine fusion. It consists of screws, hooks, rods, and connectors. These components are available in a variety of sizes to allow for a variety of configurations to better fit each individual patient's pathology.

INDICATIONS FOR USE

The NorthStar OCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, cervical spine (C1-C7) and upper thoracic spine (T1-T3):

- Traumatic spinal fractures and/or traumatic dislocations;
- Instability or deformity;
- Failed previous fusion (e.g., pseudoarthrosis);
- Tumors involving the cervical/thoracic spine;
- Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and
- Degenerative disease of the facets with instability.

The NorthStar OCT System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The NorthStar OCT System can also be linked to other SeaSpine® Screw Systems including Mariner™, NewPort™, Sierra™, Atoll™, Daytona™, Malibu™, Mariner™ MIS, Mariner Outrigger™, and Mariner Midline™ Systems with the use of transitional rods and/or transitional rod connectors.

IMPLANT MATERIALS

Titanium Alloy Ti-6Al-4V (ELI) per ASTM F136 and Cobalt Chrome Alloy Co-28Cr-6Mo per ASTM F1537.

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
  - Metabolic 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
  - Patients having inadequate tissue coverage over the operative site
  - Unsuitable or insufficient bone support
  - Skeletally immature patient
  - A patient unwilling or unable to cooperate with postoperative instructions
  - Any case where implant utilization would interfere with anatomical structures or expected physiological performance
  - Use with other devices with incompatible materials.

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, respiratory disorders; cardiovascular disorders, including myocardial infarction (heart attack) or arrythmias; neurologic injuries resulting in weakness, paralysis, numbness, tingling, or pain; vascular (blood vessel) injuries, hemorrhage (bleeding); thrombosis (blood clots) leading to deep venous thrombosis or pulmonary embolism, 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.
- 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.
- Unless otherwise specified, do not use other system components with the NorthStar OCT Spinal System components.
- This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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	Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer to a central processing unit for cleaning and sterilization. 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 Tap water for 1 minute. Then dry with a clean cloth and/or allow to air dry.
6	Visually inspect the instruments following performance of the cleaning instructions to ensure there is no visual contamination of the instruments prior to proceeding with sterilization. If possible contamination is present at visual inspection, repeat the cleaning steps. Contaminated instruments should not be used and should be returned to SeaSpine. Contact your local representative or SeaSpine directly for any additional information related to cleaning of SeaSpine surgical instruments.

Automated Cleaning Procedure

1	Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer to a central processing unit for cleaning and sterilization. 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.
11	Visually inspect the instruments following performance of the cleaning instructions to ensure there is no visual contamination of the instruments prior to proceeding with sterilization. If possible contamination is present at visual inspection, repeat the cleaning steps. Contaminated instruments should not be used and should be returned to SeaSpine. Contact your local representative or SeaSpine directly for any additional information related to cleaning of SeaSpine surgical instruments.

STERILIZATION

The implants, components and instrumentation in the NorthStar OCT System are to be sterilized by the hospital prior to surgery. **These instructions are not applicable to implants or instruments provided sterile.**

The implants and instruments can be sterilized using the provided standard open cases or Aesculap closed cases (standard or PrimeLine lid). Small baskets, trays, and other types of accessories, especially with covers or lids, not provided by SeaSpine for a specific system should not be used. Only SeaSpine standard open cases or Aesculap closed cases (standard or PrimeLine lid) are validated for use with SeaSpine products.

The Aesculap closed cases are for sterilization purposes only and should not to be used to transport implants or instruments.

For information regarding closed cases, please refer to appropriate Instructions for Use provided by the closed case manufacturer.

For standard open cases, trays are to be double wrapped using FDA-cleared sterilization wraps (2 wraps) prior to placement in autoclave. The recommended sterilization cycle will provide a Sterility Assurance Level of (SAL 10^{-6}).

In a properly functioning and calibrated steam sterilizer, effective sterilization (per AAMI ST79 guidelines) may be achieved using the following parameters:

Method	Steam
Cycle	Pre-vacuum
Temperature	270ºF (132ºC)
Exposure Time	4 minutes
Minimum Drying Time	30 minutes

or

Method	Steam
Cycle	Gravity Displacement
Temperature	270ºF (132ºC)
Exposure Time	15 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.

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 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. The construct should be assembled prior to surgery.

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.
- Unless otherwise described in the indications, autogenous 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.
- PRECAUTION: Do not over tap or use a screw that is either too long or too large. Over tapping or using an incorrectly sized screw/bolt may cause nerve damage, hemorrhage, or the other possible adverse. If screws/bolts are being inserted into spinal pedicles, use largest screw/bolt diameter that will fit into each pedicle.
- To assure maximum stability, two or more system cross-connectors on two bilaterally placed, continuous rods should be used whenever possible.
- 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.