DESCRIPTION
The SeaSpine Laminoplasty System consists of titanium 6Al-4V ELI alloy plates and screws that are attached to the lamina after a laminoplasty procedure. Implants are available in a range of sizes and shapes, as well as in various screw hole configurations to accommodate variations in patient anatomy. The system also includes instruments to assist with implantation and a tray for organization and storage.

INDICATIONS FOR USE
The SeaSpine Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) for laminoplasty procedures. The SeaSpine Laminoplasty System is used to hold the allograft material in place in order to prevent the allograft material from expulsions, or impinging the spinal cord.

IMPLANT MATERIALS
Titanium 6Aluminum-4Vanadium ELI

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 or trauma
    • 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 embol; 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 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 SeaSpine Laminoplasty System components in conjunction with components from any other system or manufacturer.

MRI SAFETY
The SeaSpine Laminoplasty System 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 SeaSpine Laminoplasty System 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.

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 SeaSpine Laminoplasty System components in conjunction with components from any other system or manufacturer.
Following AAMI ST79 guidelines, the validated a way that it is protected from inadvertent damage or the product should not be used and should be returned. 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. 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.

2. Transfer items to a washer and run a cycle with the parameters listed in the following steps.

3. **PRE-WASH:** Cold tap water for a minimum of 2 minutes.

4. **ENZYME WASH:** Enzyme wash using cleaner (such as Prolystica® 2X Enzymatic) per manufacturer’s recommendations, hot tap water for a minimum of 4 minutes.

5. **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.

6. **RINSE 1:** Rinse, hot tap water for a minimum of 2 minutes.

7. **RINSE 2:** Purified water rinse (minimum temp of 66°C/150°F) for a minimum of 15 seconds.

8. **DRYING:** Hot air dry (minimum temp of 82°C/180°F) for a minimum of 12 minutes.

9. Remove items from the washer and remove any residual moisture with a lint free clean cloth.

**STERILIZATION**

The components, implants, and instrumentation in the SeaSpine Laminoplasty System are to be sterilized by the hospital prior to surgery.

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:

<table>
<thead>
<tr>
<th>Method</th>
<th>Steam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle</td>
<td>Pre-vacuum</td>
</tr>
<tr>
<td>Temperature and Exposure Time</td>
<td>270°F (132°C) for 4 minutes</td>
</tr>
<tr>
<td>Drying Time</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

**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, customercare@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.
- 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 care and adherence to adverse events associated with this product. 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 screws.
- 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, adverse events, 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”); and ii. Medical devices or instruments 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 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 of one hundred eighty (180) days after 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. "SEASPIN"SE’S SOLE RESPONSIBILITY AND LIABILITY UNDER THIS WARRANTY SHALL BE, AT SEASPIN’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 is made by SeaSpine or 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.

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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.