Sierra™ - English

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

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DESCRIPTION
The SeaSpine Sierra occipito-cervico-thoracic (OCT) spinal fixation system, including polyaxial screws, rods, locking caps, occipital plates, occipital screws, lateral connectors, contoured crossbars, hooks, and components, is used to provide stabilization of the spine in order to permit the biological process of spinal fusion to occur. Accepted standard techniques of spinal fusion are an integral part of the implantation of this system. Sierra conditions should not be used with components from any other manufacturer’s spinal systems.

INDICATIONS FOR USE
The intended use of the Sierra spinal system is to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3). The indications for use are as follows:

• Degenerative disc disease (DDD) as defined by necrotic disc degeneration with loss of discogenic origin
• Degenerative of the disc confirmed by patient history and radiographic studies,
• Spondylolisthesis,
• Trauma (i.e., fracture or dislocation),
• Spinal stenosis,
• Atlantoaxial fracture with instability,
• Spinal cord injury,
• Revision of previous cervical spine surgery and/or
• Spinal tumor.

The occipital bone screws are limited to occipital fixation only.

The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

IMPLANT MATERIALS
Titanium 6Al-4V ELI or cobalt-28 chromium-6 molybdenum alloy.

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 thoracic, lumbar, or sacral implantation or 1n
• 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 device.
• 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, and other disease.
• Morbid obesity, meningitis, myocutaneous infarction, paralytic ileus.

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 pedicle screw 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, lumbar, sacral spine secondary to severe spondylolisthesis (Grades 3 and 4) of L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, subluxation, kyphosis, spinal instability, or a 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.
• This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic (T4-T12), or lumbar spine.
• Unless otherwise indicated by another system, components of another spinal system should not be used with the Sierra OCT system.
• Mechanical and clinical testing indicates that the majority of the axial or compressive load is carried in the anterior column of the spine. When posterior instrumentation is utilized for spinal stability, adequate anterior column support is necessary, either by surgical intervention or existing anatomy. Failure to maintain a stable anterior column when using posterior instrumentation may lead to overstretch of the posterior construct and implant failure.
• The product has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment and has not been tested for heating or migration in the MR environment.

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

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sterilization and reintroduction into the sterile surgical field. The following recommendations are for the manual cleaning and decontamination of implants and 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.

1. Remove packaging materials and disassemble instruments, as appropriate.
2. Submerge products in a standard hospital grade enzymatic detergent for a minimum of 1 hour. PRECAUTION: Avoid cleaning solutions containing caustic soda, caustic disinfectants, formalin, glutaraldehyde, bleach or other alkaline cleaners as these may damage some instruments and implants.
3. Clean with a soft bristle brush, lint free cloth or sponge for a minimum of 8 minutes to remove any visible soil. Special attention should be applied to hard to reach areas and tight lumens.
4. Rinse each product in a brisk stream of clean, room temperature tap water for a minimum of 2 minutes.
5. Soak again for a minimum of 30 minutes in a freshly prepared solution of the cleaning detergent.
6. Sonicate for a minimum of 30 minutes.
7. Once all visible soil has been removed, rinse immediately and thoroughly with running tap water for a minimum of 3 minutes to remove detergent residues.
8. Use de-ionized water as a final rinse.
9. Immediately dry product with a lint free towel and allow to air dry. Sterile compressed air may be used to dry product. Inspect all products prior to sterilization or storage for evidence of wear or damage.

STERILIZATION

The implants, components and instrumentation in the Sierra 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 Pre-vacuum</th>
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<tbody>
<tr>
<td>Temperature and Exposure Time</td>
<td>270°F (132°C) for 8 minutes</td>
</tr>
<tr>
<td>Drying Time</td>
<td>30 minutes</td>
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</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, custsvcspine@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.
- Cure 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.
- If the System/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.