Capture™ Facet Screw System

DESCRIPTION
The Spineology Facet Screw System is designed to stabilize the facet joint as an aid to fusion in the lumbar spine. These facet screws are cannulated for ease of placement and have a cancellous thread form. They are available partially or fully threaded. The screws have a major diameter of 5.25mm and are available in multiple lengths. All screws are made of titanium alloy per ASTM F136.

Instruments are provided to facilitate proper introduction and placement of the screws.

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INTENDED USE / INDICATIONS FOR USE
The Spineology Facet System is intended to stabilize the spine as an aid to fusion by transfacet fixation.

The device is indicated for posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels: Spondylolisthesis, Pseudarthrosis or failed previous fusions which are symptomatic; Degenerative Disc Disease (DDD) as defined by back pain of discogenic origin with degeneration of disc confirmed by history and radiographic studies and/or degenerative disease of the facets with instability.

CONTRAINDICATIONS
Contraindications include, but are not limited to, the following conditions:

- Sepsis, local or systemic
- Osteomyelitis at the surgical site
- Absence or destruction of any portion of the facet joint, or procedures which will require removal of any portion of the facet joint
- Known or suspected sensitivity to implant materials
- Significant metabolic bone disease (e.g. osteoporosis or osteomalacia) to a degree that posterior spinal instrumentation is contraindicated
- Any medical condition that would preclude the patient from having surgery or would impede the benefit of implant surgery

PRECAUTIONS
- The success of any spinal fusion is dependent upon many factors that include, but are not limited to, the health and metabolism of the patient. Medical conditions or disease states that alter a patient’s normal metabolism may interfere with bone healing.
- Any fusion that relies on a metal construct for stabilization during the bone healing phase presupposes that bony fusion will ultimately occur. If the bone does not heal and a non-union develops, the metal construct will eventually fail. The Spineology Facet Screw System relies upon load-sharing with an anterior interbody construct to aid in successful fusion.
- This device is intended for bilateral placement, with or without bone graft.
- It is important to choose the correct implant size. Surgeons should be fully trained and familiar with use of the instruments and proper placement of the facet screw implant.
- Pedicle screw systems, not facet screws, should be considered when there is degenerative disease of the facet joints with instability.
- As with any percutaneous spinal procedure, good imaging and interpretation of the images are critical to safety. Physicians should be experienced in interpreting biplanar fluoroscopic images of the thoracolumbar spine and experienced in image-guided instrument placement.
- Safety and effectiveness have not been established in patients with the following conditions: greater than grade 2 spondylolisthesis, two or more levels to be fused, morbid obesity (BMI >40), pregnancy.
- Patients who are taking medications that may interfere with bone or soft tissue healing (e.g. long-term steroid use) may not be suitable candidates as these medications may interfere with bone growth and graft incorporation.
- As with any permanent implant, a perioperative antibiotic protocol is recommended.
- Metallic implants can corrode, loosen, migrate, cause pain, bend or fracture even after a fusion has occurred.
- An implant should never be reused.

ADVERSE EFFECTS / SURGICAL RISKS
POSSIBLE ADVERSE EFFECTS OR RISKS INCLUDE, BUT ARE NOT LIMITED TO, THE FOLLOWING, WHICH MAY REQUIRE ADDITIONAL SURGERY:
- Infection of soft tissue and/or bone (osteomyelitis); fever
- Implant loosening
- Bending or breakage of the device
- Incomplete relief of symptoms
- Incomplete fusion, delayed union or non-union
- Fracture of the pedicle or bone of the facet joint
- Soft tissue injury
- Edema
- Skin irritation, wound dehiscence
- Dural injury, with or without CSF leakage
- Neurologic injury, transient or permanent
- Pain and loss of function
- Hemorrhage, hematoma
- Device migration
- Death

MRI WARNING
The Spineology Facet Screw has not been evaluated for safety and compatibility in the MR environment. The Spineology Facet Screw has not been tested for heating or migration in the MR environment.

IMPLANT HANDLING
Exercise care in handling implants. Protect the implants from contact with objects that may damage the surface. Inspect each implant prior to use and do not use if any damage is suspected.

PACKAGING
Sterile product packaging should be inspected for continuity. Packages for each of the sterile components should be intact upon receipt. Do not use sterile product if the packaging has been damaged or the shelf life has been exceeded. Devices must be handled properly to maintain sterility. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Spineology.
- Note that implants are provided sterile for single use only.
- Do not re-sterilize implants.

DEVICE RETRIEVAL
Contact Spineology to discuss Revision / Retrieval.

INSTRUMENTS
Surgical instruments must be handled with care. Improper handling may result in damage and may impair proper functioning of the device. Instruments that exhibit signs of damage or deterioration, including discoloration or corrosion, must be replaced. Ensure that all components of the system are available for use prior to surgery. Instruments must be sterilized before use and are to be cleaned and re-sterilized immediately after use.
- Note that these instruments are non-sterile
- Spineology recommends using an FDA-cleared wrap for sterilization

All instruments must be cleaned and sterilized by the hospital before use as described below.

CLEANING AND DECONTAMINATION
Cleaning and decontamination of surgical instruments are required before introduction into the sterile field. Following use, disassemble devices as instructed for cleaning. Preventing drying will facilitate later cleaning.
- Soak in enzymatic detergent (mixed per manufacturer’s recommendations) for one (1) minute or longer.
- Use a soft brush for manual cleaning and a soft bottle brush to clean tubes. Pay special attention to inner diameters and crevices during cleaning. Ultrasonic cleaning is acceptable.
- Rinse each part thoroughly under running water for one (1) minute or longer.

STERILIZATION
Instrument trays are provided for storing and sterilizing the instruments. Instrument trays do not provide a sterile barrier. Trays must be used with a sterilization wrap. Sterilization can be performed on wrapped trays with the following cycle parameters:

<table>
<thead>
<tr>
<th>Method</th>
<th>Exposure Time</th>
<th>Cycle</th>
<th>Temperature</th>
<th>Drying Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>4 Minutes</td>
<td>Pre-Vacuum</td>
<td>270°F (132°C)</td>
<td>Minimum 30 Minutes</td>
</tr>
</tbody>
</table>

Deviations from the recommended methods of cleaning and decontamination are not advised. It is the sole responsibility of the user to qualify such deviations.

FURTHER INFORMATION OR PRODUCT COMPLAINTS
Contact Spineology at:
Spineology Inc.
7800 3rd Street N, Suite 600
Saint Paul, MN 55128-5455
Phone: 1.651.256.8500
Fax: 1.651.256.8505

Please contact your local Spineology representative for a complete surgical technique manual or further cleaning instructions.

Manufactured by:
Spineology Inc.
7800 3rd Street N, Suite 600
Saint Paul, MN 55128-5455
1.888.377.4633

Do not reuse

Sterilized by ethylene oxide