INTERLINK™ PEDICLE SCREW SYSTEM
Vertebral Technologies Inc.
13845 Industrial Park Blvd.
Minneapolis, MN, 55441

System Contents:
- Non-Sterile Implants – Single Use Only
- Non-Sterile Instruments - Reusable

Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.
Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product.

DEVICE DESCRIPTION:
The InterLink™ Pedicle Screw System is comprised of polyaxial pedicle screws in various diameters and lengths, spinal rods in various lengths, cross-connectors, and set screws. The InterLink™ Pedicle Screw System can be used for single or multiple level fixation. All implant components are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136.

INDICATIONS:
The InterLink™ Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients. The system is intended for posterior, pedicle fixation as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

CONTRAINdications:
1. Disease conditions which have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.
2. Active systemic infection or infection localized to the site of the proposed implantation is contraindications to implantation.
3. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the cover. Clinical indications have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.

MATERIALS:
The InterLink™ Pedicle Screw System implants are manufactured from implant grade titanium alloy (ASTM F136). Surgical instruments provided with the system are manufactured from stainless steel (ASTM F899). Do not use the InterLink™ Pedicle Screw System components with the components from any other system or company.

CLEANING OF INSTRUMENTS:
1. Within a maximum of two (2) hours after use, remove gross soil using absorbent paper wipes. Rinse with warm tap water for two (2) minutes.
2. If cleaning must be delayed, place instruments in a covered container with appropriate detergent (Enzol® Enzymatic Detergent or equivalent) to delay drying.
3. Disassemble the implant driver by following the disassembly instructions.
   a. Assembled Device shown in Figure 1.
   b. Rotate inner shaft to align flats with tube body grooves and slide out as shown in Figure 2.
   c. Remove inner shaft from tube body as shown in Figure 4.
   d. Remove inner shaft 90 degrees to align large flats with groove as shown in Figure 3.
   e. Follow Cleaning Instructions to clean tube body and inner shaft shown separated in Figure 5.
4. Pre-Treatment required for any instrument(s) heavily soiled and/or containing dried organic material in accordance with Table 1.

Table 1 Cleaning Instructions

<table>
<thead>
<tr>
<th>Step</th>
<th>Instructions</th>
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<tbody>
<tr>
<td>1. Pre-Treatment</td>
<td>Add one (1) ounce of Enzol® (or equivalent) to one (1) gallon of tap water.</td>
</tr>
<tr>
<td>2. Ultrasonic Clean</td>
<td>Rinse in warm running tap water until all traces of cleaning solution are removed.</td>
</tr>
<tr>
<td>(if required)</td>
<td>Visually inspect for any remaining soil and repeat the above steps if necessary.</td>
</tr>
<tr>
<td>3. Ultrasonic Rinse</td>
<td>To remove the detergent, thoroughly rinse each instrument with deionized water including all holes and annulations.</td>
</tr>
<tr>
<td></td>
<td>Inspect each instrument for evidence or organic matter. Repeat the sonication and rinse if needed.</td>
</tr>
<tr>
<td>4. Automated Washer</td>
<td>Place instrument(s) in an automated washer (e.g. Steris Reliance® 444 Washer/Disinfector or equivalent).</td>
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<td></td>
<td>Load instruments such that contact is avoided and articulating instruments are in the open position.</td>
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</table>

Automated Cleaning Parameters

<table>
<thead>
<tr>
<th>Step</th>
<th>Time (mm:ss)</th>
<th>Temperature (°C)</th>
<th>Cleaning Agent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enzymatic Wash</td>
<td>04:00</td>
<td>Hot Tap Water</td>
<td>Steris Prolystica 2X Concentrate (or equivalent) (1/16 oz/gal)</td>
</tr>
<tr>
<td>Wash</td>
<td>02:00</td>
<td>65.5°C</td>
<td>Steris Prolystica 2X Concentrate Alkaline Cleaner (or equivalent) (1/16 oz/gal)</td>
</tr>
<tr>
<td>Rinse</td>
<td>02:00</td>
<td>70°C</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Dry</td>
<td>15:00</td>
<td>80°C</td>
<td>Not Applicable</td>
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STERILIZATION:
The InterLink™ Pedicle Screw System components are provided in a surgical kit, which is comprised of implant caddies located within stainless steel and anodized aluminum instrument cases. All implants and instruments are supplied clean and non-sterile and must be sterilized prior to use. The following sterilization cycle has been validated and shown to result in a 10^6 Sterility Assurance Level (SAL).

Method: Steam
Cycle: Pre Vacuum
Temperature: 270°F (132°C)
Exposure Time: 4 minutes
Dry Time: 30 minutes
Wrap: 2 times utilizing FDA cleared wrap

Inspection:
1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation. Instruments with moving parts should be operated to check correct operation (medical grade lubricating oil suitable for steam sterilization can be applied as required).
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your sales representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your sales representative for a replacement.

IMPLANT DRIVER ASSEMBLY:
Assemble the implant driver by following the assembly instructions below.

1. Align large flats on inner shaft to groove on the tube body threaded end and insert Figure 6 (below).
2. With threaded end inserted, rotate inner shaft 90 degrees to align the small flats with the body tube grooves Figure 7 (above).
3. Insert inner shaft into tube body, rotate 90 degrees and push towards large end to expose 1/4” drive Figure 8 (below).
4. Assembled device ready for placement in tray Figure 9 (above).

POSTOPERATIVE MOBILIZATION:
Careful patient handling for two (2) to four (4) months post-operatively is very important while the fusion mass matures and becomes able to share load with the implant. Until X-rays confirm maturation of the fusion mass, external mobilization (such as bracing or casting) is recommended.
Instructions to the patient to reduce stress on the implant are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure. In younger patients, once the fusion mass has healed, the implants may be removed to allow the fused bone to return to a better state of load transfer. This is, as with all patient care, left to the discretion of the operating surgeon.

WARNINGS, PRECAUTIONS, AND ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES:

Following are specific warning, precaution, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

WARNINGS:

1. In the U.S.A., this product has labeling limitations.
2. THE SAFETY AND EFFECTIVENESS OF PEDICLE SCREW SPINAL SYSTEMS HAVE BEEN ESTABLISHED ONLY FOR FUSION PROCEDURES WHERE BONE GRAFT IS USED.
3. CONDITIONS WITH SIGNIFICANT MECHANICAL INSTABILITY OR DEFORMITY REQUIRING FUSION WITH INSTRUMENTATION.
4. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.
5. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH UNION OR NON-UNION.
6. MIXING METALS CAN CAUSE CORROSION.
7. PATIENT SELECTION.

POSSIBLE ADVERSE EFFECTS:

1. Loss of proper spinal curvature, correction height and/or reduction.
2. Loss of proper spinal curvature, correction height and/or reduction.
3. Vascular or/and nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
5. Dural leak.
6. Paralysis.
7. Loss of proper spinal curvature, correction height and/or reduction.
8. Loss of proper spinal curvature, correction height and/or reduction.

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LIMITED LIABILITY:
The InterLink™ Pedicle Screw System products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

For product information, questions pertaining to sales and service, or to request a surgical technique manual, please contact your local sales representative or Vertebral Technologies customer service.

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