InterLink™ Pedicle Screw System

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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 use of this or any other posterior spinal instrumentation system.
4. Any entity or condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis or osteopenia, is a relative contraindication. Other relative contraindications include obesity, pregnancy, certain degenerative disease, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, some patients may, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant. See also the WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS sections of this insert.

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**.

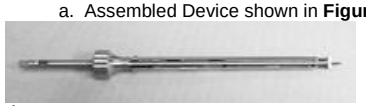

Figure 1

   b. Rotate inner shaft to align flats with tube body grooves and slide out as shown in **Figure 2**.

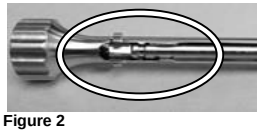

Figure 2

Figure 3

   c. Rotate inner shaft 90 degrees to align large flats with groove as shown in **Figure 3**.
   d. Remove inner shaft from tube body as shown in **Figure 4**

Figure 4

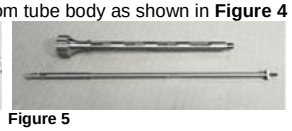

Figure 5

   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

Step	Instructions
1.Pre-Treatment	Add one (1) ounce of Enzol® (or equivalent) to one (1) gallon of tap water. Using a soft bristle brush, clean the instrument thoroughly, paying particular attention to rough surfaces and features where soil may be impacted or shielded from the cleaning process.
	Rinse in warm running tap water until all traces of cleaning solution are removed. Visually inspect for any remaining soil and repeat the above steps if necessary. Allow to dry, and then transfer to the cleaning step.
2.Ultrasonic Clean (if required)	Add one (1) ounce of Enzol (or equivalent) and one (1) gallon of warm tap water to an ultrasonic cleaner. Completely submerge instruments and sonicate for ten (10) minutes.
3.Ultrasonic Rinse	To remove the detergent, thoroughly rinse each instrument with deionized water including all holes and cannulations. Inspect each instrument for evidence or organic matter. Repeat the sonication and rinse if needed.
4.Automated Washer	Place instrument(s) in an automated washer (e.g. Steris Reliance® 444 Washer/Disinfector or equivalent). Load instruments such that contact is avoided and articulating instruments are in the open position.

Automated Cleaning Parameters

Step	Time (mm:ss)	Minimum Temp.(°C)	Cleaning Agent
Enzy-matic Wash	04:00	Hot Tap Water	Steris Prolystica 2X Concentrate (or equivalent) (1/8 oz./gal)
Wash	02:00	65.5°C	Steris Prolystica 2X Concentrate Alkaline Cleaner (or equivalent) (1/8 oz./gal)
Rinse	02:00	70°C	Not Applicable
Dry	15:00	80°C	Not Applicable

5.Inspection	Visually inspect each instrument for evidence of organic matter. Repeat the cleaning process if necessary. If instruments are wet, use a lint-free wipe to dry.

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).

Figure 6

Figure 7

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).

Figure 8

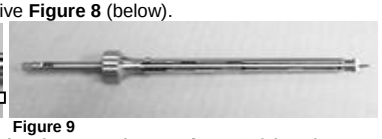

Figure 9

4. Assembled device ready for placement in tray **Figure 9** (above).

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 visually 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

Instruments should be positioned to allow the steam to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged.
Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Instruments used in surgery should be re-sterilized after surgery. Implants should not be used as templates in surgery.

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 warnings, precautions, 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 SPINAL CONDITIONS WITH SIGNIFICANT MECHANICAL INSTABILITY OR DEFORMITY REQUIRING FUSION WITH INSTRUMENTATION**. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
3. **Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines. Potential risks identified with the use of this device system, which may require additional surgery, include:**
   a) Device component fracture.
   b) Loss of fixation.
   c) Non-union.
   d) Fracture of the vertebra.
   e) Neurological injury.
   f) Vascular or visceral injury.
4. **CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.** The potential for satisfactory fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
5. **IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NON-UNION. Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue**. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
6. **MIXING METALS CAN CAUSE CORROSION.** There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc. which come into contact with other metal objects, must be made from like or compatible metals.
7. **PATIENT SELECTION.** In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
   a) The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.
   b) The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the device.
   c) A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
   d) Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary relief.
   e) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
   f) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.

PRECAUTIONS:
1. **THE IMPLANTATION OF PEDICLE SCREW SPINAL SYSTEMS SHOULD BE PERFORMED ONLY BY EXPERIENCED SURGEONS WITH SPECIFIC TRAINING IN THE USE OF THIS PEDICLE SCREW SPINAL SYSTEM BECAUSE THIS IS A TECHNICALLY DEMANDING PROCEDURE PRESENTING A RISK OF SERIOUS INJURY TO THE PATIENT**.
2. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted metal implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
3. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT**. Contouring of the metal implants should only be performed with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease fatigue life and may cause failure.
4. **REMOVAL OF THE IMPLANT AFTER HEALING.** Metallic implants can loosen, fracture, corrode, migrate, possibly increase the risk of infection, cause pain, or stress shield bone even after healing, particularly in young, active patients. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risk involved with a second surgery.
5. **ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in bending or fracture. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weight- supporting devices may be particularly at risk during postoperative rehabilitation.
6. **MAGNETIC RESONANCE (MR) ENVIRONMENT.** The InterLink™ Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment The InterLink™ Pedicle Screw System System has not been tested for heating or migration in the MR environment.
7. **PATIENT SELECTION.** Based on fatigue testing results, when using the InterLink™ Pedicle Screw System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

POSSIBLE ADVERSE EFFECTS:
1. Non-union, delayed union.
2. Bending or fracture of implant. Fraying, kinking loosening, bending or breaking of any or all of the cable implant components.
3. Loosening of the implant.
4. Metal sensitivity or allergic reaction to a foreign body.
5. Infection.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Loss of proper spinal curvature, correction height and/or reduction.
9. Cable cutting through soft osteoporotic, osteogenic, or cancellous bone.
10. Vascular and/or nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
11. Bursitis.
12. Dural leak.
13. Paralysis.
14. Death.
15. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.

LIMITED WARRANTY:
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.

If more than two (2) years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact Vertebral Technologies for current information.

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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.

MS4062 Rev A 04/20/2016 DCO2016-020