The StabiLink® MIS Spinal Fixation System is an interlaminar/spinous process fixation device intended to provide temporary stabilization of the thoracic, lumbar, or sacral spine while avoiding bony fusion to take place. As well as all orthopedic surgical procedures, detailed preparative planning is essential for a successful outcome. The surgeon must be fully aware of the risks and complications inherent to this type of surgery. Only those individuals with specialized training and experience in spinal surgery should attempt use of the implants.

Materials

The StabiLink® implants are made of titanium alloy, Ti-6Al-4V ELI per ASTM F138.

Indications for Use

The StabiLink® MIS Spinal Fixation System is a posterior, non-fusion spinal fixation device intended for use in spinal procedures designed to achieve fixation of interlaminar/spinous process plates, dedicated surgical instruments, and sterilization cases. The components are used to build a construct to provide stabilization of spinal segments in the thoracic, lumbar and sacral spine to support fusion. It is essential to use the implants with their specifically designed instruments. After a solid fusion occurs, the system serves no functional purpose and should be removed. Removal is indicated because the implants are not intended to provide support for susceptible developmental activities. However, any decision to remove the device must be made by the physician and the patient, taking into consideration the patient's general condition and the potential risk to the patient of a second surgical procedure.

Device Description

The StabiLink® MIS Spinal Fixation System is a posterior attachment spinal fixation device intended for use in spine procedures designed to achieve fixation of interlaminar/spinous process plates, dedicated surgical instruments, and sterilization cases. The components are used to build a construct to provide stabilization of spinal segments in the thoracic, lumbar and sacral spine to support fusion. It is essential to use the implants with their specifically designed instruments. After a solid fusion occurs, the system serves no functional purpose and should be removed. Removal is indicated because the implants are not intended to provide support for susceptible developmental activities. However, any decision to remove the device must be made by the physician and the patient, taking into consideration the patient's general condition and the potential risk to the patient of a second surgical procedure.

Contraindications

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall condition and the potential benefit of surgery. Any of the following conditions may be contraindications to surgery:

- Any abnormality present which affects the normal process of bone remodeling or which may, in the surgeon's opinion, lead to severe osteoporosis affecting the bone, spine absorption, osteopenia, acute infection at the site of the bone, certain metabolic disorders affecting osteogenesis.
- Morbid Obesity
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Open Wounds
- Pregnancy
- Any other medical or surgical condition which would preclude the benefit potential of spinal surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood count (WBC), or a marked left shift in the WBC differential count.
- Any case requiring the mixing of components from other manufacturers’ systems.
- Any case requiring the mixing of stainless steel with titanium, or stainless steel with cobalt chrome implant components.
- Fever or leukocytosis considered to constitute a dysfunction or deterioration in the characteristics of the implant.
- Previous history of infection.
- Any patient which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any patient unable to follow postoperative instructions.
- Inadequate tissue coverage over the operative site.

Possible Complications

Proper selection of the type of implant may reduce the complications significantly. Other general complications associated with any spinal surgical procedure may be encountered.

- Early or late implant bending, breakage, failure, loosening or movement.
- Bone and/or spinous process fracture
- Allergic reaction to implant material
- Infection
- Any patient which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any patient unable to follow postoperative instructions.
- Inadequate tissue coverage over the operative site.

Warnings

The safety and effectiveness of spinal fusion systems have been established in many instances, but the surgeon must be cautious with regard to the indication of instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, or sacral spine which generally are the result of spondylolisthesis of the L5-S1 vertebra, degenerative spondylolisthesis; tumor; trauma (i.e., fracture, degenerative disc disease (DDD) (defined as back pain of anatomical or diagnostic origin, by history and radiographic studies); spondylodiscitis; trauma (i.e., fracture or dislocation); tumor. It is not intended for stand-alone use.

Other general complications associated with any spinal surgical procedure may be encountered.

- Bone and/or spinous process fracture
- Allergic reaction to implant material
- Infection
- Any patient which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any patient unable to follow postoperative instructions.
- Inadequate tissue coverage over the operative site.

Surgical Guidelines

Preoperative Procedure

As a minimum, preoperative examination, the surgeon must check that no factors, especially biological and biomechanical, will affect the correct performance of the operation and postoperative service life. It is recommended that regular postoperative follow-up/examinations be undertaken to detect early signs of failure of the implants and to consider the action to be taken. Deterioration of the device after bone consolidation cannot be considered to constitute a dysfunction or deterioration in the characteristics of the implant. The implant can be removed after bony healing.

The StabiLink® device has not been tested for heating or migration in the articular region. Therefore, the Federal law (USA) restricts this device to sale by or on the order of a physician.

Directing Use

The information contained in this instructions for use is necessary but not sufficient for the use of this device. This information is not intended to replace the judgment, skill and experience of the surgeon in: careful patient selection; preparative planning; device selection; knowledge of the anatomy and pathology of the condition; the patient’s general condition; the mechanical characteristics of the implants used; training and skill in both instrumented and non-instrumented fusion procedures; and securing the patient’s cooperation in following an appropriately defined postoperative management program; and in appropriately defining postoperative follow-up examinations.

Intraoperative Procedures

At all times, extreme caution should be used around the spinal device has not been tested for heating or migration in the articular region. Therefore, the Federal law (USA) restricts this device to sale by or on the order of a physician.

Bone and/or spinous process fracture
- Allergic reaction to implant material
- Infection
- Any patient which implant utilization would interfere with anatomical structures or expected physiological performance.
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Positions the patient in the prone position on the operating table. At all times, extreme caution should be used around the spinal device has not been tested for heating or migration in the articular region. Therefore, the Federal law (USA) restricts this device to sale by or on the order of a physician.

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Positions the patient in the prone position on the operating table.
RATCHET ARM. For all implants, confirm that the tip of the tray is lamina and or spinous processes.

around the implant, in the posterolateral gutter and/or across the articular surfaces and place bone graft in the usual manner. If the supraspinous ligament was resected, bone grafting and closure.

The StabiLink® device is intended to be used with bone graft material and not for stand-alone use. If performing an interbody fusion, disc preparation and interbody spacer placement are typically performed prior to implantation of the device. If not previously performed, decontaminate the bone surfaces, prepare the fusion site for grafting and place the bone graft material in the usual manner. If the supraspinous ligament was resected, bone graft may be packed posterior to the device between the tips of the spinous processes. If fusing through the facetectomy, decorticate the bone surfaces and place bone graft in the usual manner. If desired, additional posterior bone grafting material may be placed around the implant, in the posterolateral gutter and across the interlaminar space. After the construct is implanted and bone graft completed, close the surgical site using standard techniques. If the supraspinous ligament insertion was intact, it may be sutured back to the tips of the spinous process. The fascia can be closed back to the supraspinous ligament.

Removing the StabiLink® Implant

The StabiLink® device can be removed if necessary. Use the removal handle/driver to loosen the locking set screw. The Base Tray plate and the Base should be carefully separated with a Cobb elevator or similar instrument and removed from the lamina and or spinous processes.

Postoperative Care

• The physician’s postoperative directions and warnings to the corresponding patient are important to allow for a successful surgical result. Detailed instructions on the use and limitations of the device should be given to the patient. Excessive weight bearing, early weight-bearing and excessive muscular activity are discouraged during the early postoperative rehabilitation period. The patient must be warned that such activity may result in complications, such as bending, loosening or breakage of the components. The risk of bending, loosening or breakage of an internal fixation device during postoperative rehabilitation may be increased if the patient is active; or, if the patient is debilitated, demented, or using weight supporting devices. The patient should be warned to avoid falls or sudden jolts to lessen the possibility for bending, loosening or breakage of the internal fixation device.

• To allow for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility, and instructed to limit physical activities, especially lifting, twisting and any type of sport participation. The surgeon should be advised not to smoke, utilize nicotine products or consume alcohol or nonsteroidal anti-inflammatory drugs such as ibuprofen or aspirin in the first postoperative week.

• The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body position.

• If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious complications occur. To minimize a delayed nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening or breakage of the implant.

• The patient should be fully instructed in the appropriate postoperative care. The patient’s ability and willingness to follow, as well as comprehension of the importance of following, instructions are one of the most important aspects of successful postoperative healing.

• Explanted surgical implants must never be reused.

• As a precaution, before patients with implants receive any subsequent surgery such as dental procedures, prophylactic antibiotics should be considered, especially for patients with increased risk for infection.

Packaging

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness, and all components, including instruments, to ensure there is no damage prior to use. Damaged packages should never be used and should be returned to the manufacturer.

Handling and Storage

The StabiLink® implant and instruments must be stored with care. Before use, inspect all instrumentation for proper function, possible damage, wear or nonfunction. Damaged or defective instruments should not be used. Contact the manufacturer for repair or replacement instructions.

Cleaning and Decontamination

The StabiLink® system implants and instruments are not supplied sterile. All instruments should be cleaned and sterilized before the next steps. Cleaning must be done before processing the implants and instruments for sterilization.

Caution: Cleaning solutions such as those containing formalin, glutaraldehyde, bleach, and/or other alkaline cleaners may damage some devices, particularly instruments. Such cleaning solutions should not be used. Note: Some instruments may require disassembly prior to cleaning.

Machine Cleaning (Recommended)

1. Prepare cleaning detergent
   a. Prepare an enzymatic detergent, following the manufacturer’s instructions for preparation and use.
   b. Saline solutions should NOT be used, as saline has a corrosive effect on stainless steel.
   c. The saline should have a near-neutral pH to prevent pitting and tarnishing.

2. Prepare devices for soaking
   a. To prevent injury, separate out sharp and pointed devices and handle with care.
   b. Disassemble devices with removable parts.
   c. Open hinged, toothed or threaded joints.
   d. Remove heavy or large debris using single-use, non-shedding wipes soaked in appropriate cleaning solution.

3. Clean and soak in detergent bath
   a. Immerse devices in prepared detergent bath.
   b. Allow devices to soak in detergent bath for the manufacturer’s recommended soaking time.
   c. Brush all surfaces of the devices with a cleaning brush (do not use steel brushes) while they are submerged in the detergent bath ensuring that all visible soil is removed.
   d. Whirlpool the devices to remove all debris.

4. Wash
   a. Use a pipe cleaner and syringe to clean all cannulae, lumens, crevices, grooves and hard to reach areas.
   b. Use appropriate cleaning solution under pressure to flush all cannulae, lumens, crevices, grooves and hard to reach areas.
   c. Repeatedly open/operate/bend/articulate movable joints while cleaning.

5. Rinse in sterile water
   a. Thoroughly rinse all devices with sterile purified water (i.e., RO or DI) for a minimum of 3 minutes.
   b. Thoroughly flush all cannulae, lumens and holes

6. Ultrasonic bath
   a. Prepare ultrasonic bath containing a blood-dissolving detergent, following the manufacturer’s instructions for preparation and use.
   b. Cover/seal the devices during transport from the rinse to the ultrasonic bath prevent contamination.
   c. Ultrasonic cleaning
   d. Ensure that the devices are completely submerged and do not overlap.

7. Dry
   a. Dry the devices with single-use, non-shedding absorbent wipes and/or medical compressed air (e.g., interiors of cannulae).
   b. Be sure to completely dry the devices immediately after rinsing to prevent corrosion.

8. Inspect
   a. Inspect the devices with the naked eye under normal lighting conditions to determine if all adherent visible soil (e.g., blood, protein substances and other debris) has been removed from surfaces, lumens, cannulae, crevices, serrations, threading, etc.
   b. Thoroughly flush/lavage the cannulae.

Manual Cleaning Instruction

1. Prepare cleaning detergent
   a. Prepare an enzymatic detergent, following the manufacturer’s instructions for preparation and use.
   b. Saline solutions should NOT be used, as saline has a corrosive effect on stainless steel.
   c. The detergent should have a near-neutral pH to prevent pitting and tarnishing.

2. Prepare devices for soaking
   a. To prevent injury, separate out sharp and pointed devices and handle with care.
   b. Disassemble devices with removable parts.
   c. Open hinged, toothed or threaded joints.
   d. Remove heavy or large debris using single-use, non-shedding wipes soaked in appropriate cleaning solution.

3. Clean and soak in detergent bath
   a. Immerse devices in prepared detergent bath.
   b. Allow devices to soak in detergent bath for the manufacturer’s recommended soaking time.
   c. Brush all surfaces of the devices with a cleaning brush (do not use steel brushes) while they are submerged in the detergent bath ensuring that all visible soil is removed.
   d. Whirlpool the devices to remove all debris.

4. Ultrasonic bath
   a. Prepare ultrasonic bath containing a blood-dissolving detergent, following the manufacturer’s instructions for preparation and use.
   b. Cover/seal the devices during transport from the rinse to the ultrasonic bath prevent contamination.
   c. Ultrasonic cleaning
   d. Ensure that the devices are completely submerged and do not overlap.

5. Rinse in sterile water
   a. Thoroughly rinse all devices with sterile purified water (i.e., RO or DI) for a minimum of 3 minutes.

6. Dry
   a. Dry the devices with single-use, non-shedding absorbent wipes and/or medical compressed air (e.g., interiors of cannulae).
   b. Be sure to completely dry the devices immediately after rinsing to prevent corrosion.

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   a. Inspect the devices with the naked eye under normal lighting conditions to determine if all adherent visible soil (e.g., blood, protein substances and other debris) has been removed from surfaces, lumens, cannulae, crevices, serrations, threading, etc.
   b. Thoroughly flush/lavage the cannulae.

Lubrication

The use of instrument lubricant, compatible with the method of sterilization, is recommended before sterilization of instruments. Ensure that instrument lubricant is diluted and maintained properly, according to the manufacturer’s instructions. This type of lubricant is referred to as “instrument milk” and usually applied by spraying the moving parts or by soaking the instruments in a solution. Lubricants that are too concentrated or too heavily applied will result in slippery instruments that will also be difficult to clean after sterilization. After thoroughly cleaning the instruments, proper application of lubricants to joints and torque handles will keep them moving freely and aid in protecting the surface from mineral deposits. Note that ultrasonic cleaner will not remove all lubrication; therefore this maintenance procedure should be done routinely after ultrasonic cleaning and before sterilization.

Proper and timely lubrication is an integral step in maintaining the long-life of the surgical instrument. Lubrication will prevent the friction of metal on metal and preserve the smooth function of the instrument, avoiding corrosion by friction. Furthermore, routine use of lubricating agents, on thoroughly clean instruments, will prevent hinged and other movable parts from sticking. Lubrication will aid in protecting the entire instrument surface from mineral deposits.

The StabiLink implants and instruments are supplied non-sterile. Implants and instruments must be sterilized prior to use. The recommended sterilization process is steam autoclave, using the parameters listed in the table below.

<table>
<thead>
<tr>
<th>Method</th>
<th>Temperature</th>
<th>Cycle</th>
<th>Time</th>
<th>Exposure</th>
<th>Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>132°C (270°F)</td>
<td>5 minutes</td>
<td>50 minutes</td>
<td>15 minutes</td>
<td>55 minutes</td>
</tr>
</tbody>
</table>

The recommended sterilization cycles have been validated to assure a Sterility Assurance Level (SAL) of at least 10-6. These gravity displacement and pre-vacuum sterilization cycles are not considered by the United States Food and Drug Administration (US FDA) to be standard sterilization cycles. Users should only use sterilization cycles listed on the U.S. Food and Drug Administration's Cytotoxic Avoidance and Sterilization Devices (STIL) list.

Product Complaints

Contact a salesperson or the manufacturer for repair or return. The appropriate solution is not to return the device to the manufacturer.

Southern Spine Customer Service,

Tel: 478.745.0000, Fax: 478.744.9996

Patents: www.SS-Pctcom Other USA and International Patents Pending

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