The StabiLink® MIS Spinal Fixation System is a posterior, attachment spinal fixation system composed of interlaminar/spinous process plates, dedicated surgical instruments, and stainless steel with cobalt chrome implant components. It is 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 anatomically designed instruments. After a solid fusion occurs, the system serves no further functional purpose and should be removed. Removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. However, any decision to remove the device must be made by the physician in consultation with the patient, taking into consideration the patient’s general medical condition and the potential risk to the patient of a second surgical procedure.

**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-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for fixation to achieve supplemental fusion in the following conditions: degenerative disc disease (DDD) (defined as back pain of discogenic origin), degenerative joint disease (DJD) (defined as back pain of non-discogenic origin), spondylolisthesis; trauma with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown. A subsequent result is not always achieved in every surgical case. This fact is especially true in patients where many existing circumstances may compromise the results. Consider the extent of decompression, as well as the amount of intact bone remaining on the spinal processes. Appropriate patient selection and careful tying of the supplemental fixation for an interbody fusion system.

**Preparation of the Implant Site**

Identify the spinous processes at the level to be instrumented, using the previously described technique, the supraspinous ligament may be left intact, reflected or decorticated. Depending on the surgeon’s preferred technique, the supraspinous ligament may be left intact, reflected or decorticated. Depending on the surgeon’s preferred technique, the supraspinous ligament may be left intact, reflected or decorticated. Depending on the surgeon’s preferred technique, the supraspinous ligament may be left intact, reflected or decorticated. Depending on the surgeon’s preferred technique, the supraspinous ligament may be left intact, reflected or decorticated.
spines are fully resected in the bone, with proper opposition against the spinous processes. To ensure that the Set Screw is located over the "Tray" for locking, at a minimum, compress the Handle until it lies on or near both the Black Square [9] on the threaded ratchet arm and is located near the top of the Black Triangle [10]. Confirmation of the implant alignment can now be performed using X-ray or any other image guidance tools as necessary. Load the handle to the Torque Driver into the Insert. Ensure that the Driver shaft is engaged with the handle; this can be verified by pulling on the shaft. **CAUTION:** Do NOT use the Removal Handle for locking the loader. The Driver assembly into the Insertor sheath marked "++". The Torque Driver will guide itself into the "Lock" side of the implant and into the set screw. Tighten the set screw with the Torque Driver. This tightening process is critical, as the set screw is to be securely fixed for grafting. Please check for completeness, and all components, including instruments, to ensure there is no damage prior to use. Damaged packaged or products should never be used and should be returned to the manufacturer.

**Packaging**

Packages for each of the components should be intact upon receipt. If a label or container or 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 packaged parts or products should never be used and should be returned to the manufacturer.

**Cleaning and Disinfection**

**Clean the StabiLink® system implants and instruments are not supplied sterile. All packaging and labeling must be removed before the next steps. Cleaning must be done before processing the implants and instruments sterilization.**

**Cleaning Steps:**

a. Immerse devices in prepared detergent bath.

b. Thoroughly rinse the devices under running water for a minimum of 1 minute.

c. Dry the devices with single-use, non-shedding absorbent wipes

d. If visible soil remains, repeat the cleaning procedure.

e. Neutralize with neutral pH detergent; drain.

**Drying:**

a. 2 minutes: Prewash with cold water; drain.

b. 5 minutes: Detergent wash with hot water; drain.

c. 2 minutes: Neutralize with neutral pH detergent; drain.

d. 2 minutes: Rinse with hot water; drain.

e. Dry with hot air at a maximum of 115°C.

**Equipment Used:**

- Prewash bath
- Detergent wash bath
- Neutral pH detergent
- Autoclave

**Disinfection:**

a. Use a syringe to repeatedly apply rinsing solution under pressure to flush all cannulae, lumens, crevices, grooves, and hard to reach areas.

b. Brush the inside of hollow spaces along their entire length.

c. Rinse the devices from the soaks bath.

d. Thoroughly rinse the devices under running water for a minimum of 1 minute.

e. Thoroughly rinse, canulae, lumens and holes

**Ultrasonic bath**

- Use a ultrasonic bath
- Prepare an ultrasonic bath containing a blood-dissolving detergent, following the manufacturer’s instructions for preparation and use.
- Place the device in the ultrasonic bath for the manufacturer’s recommended soaking time.
- 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.
- If necessary, apply a syringe repeatedly applying rinsing solution under pressure to flush all cannulae, lumens, crevices, grooves, and hard to reach areas.
- Thoroughly rinse, canulae, lumens and holes.

**Cleaning and Disinfection:**

- Use a syringe to repeatedly apply rinsing solution under pressure to flush all cannulae, lumens, crevices, grooves, and hard to reach areas.
- Thoroughly rinse, canulae, lumens and holes.
- Place the device in the ultrasonic bath for the manufacturer’s recommended soaking time.
- Thoroughly rinse, canulae, lumens and holes.
- Brush the inside of hollow spaces along their entire length.
- Thoroughly rinse, canulae, lumens, crevices, grooves and hard to reach areas.
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