SI-CURE™ Self-Harvesting™ Self-Advancing™ Autograft by Alevio® Spine

SI-Cure Sacroiliac Joint Fusion System

Product Description
The SI-Cure Sacroiliac Joint Fusion System consists of cannulated, fully threaded screws with double helix threads designed to be able to screw into pre-drilled bone. It is fabricated from medical grade titanium alloy, Ti-6Al-4V (ASTM F-136). The SI-Cure System screw comes in various sizes and lengths to accommodate patient anatomy. Optional pivoting washers are included for each screw diameter to aid in conforming to patient anatomy.

Surgical Instrument System
The SI-Cure Sacroiliac Joint Fusion System is comprised of various surgical instruments to be used to prepare the site to insert the system implants. All of the instruments are made from surgical grade materials.

Indications for Use
The SI-Cure Sacroiliac Joint Fusion System is intended for sacroiliac fusion for the following conditions:
- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

Contraindications
Contraindications for use of the SI-Cure Sacroiliac Joint Fusion System include, but are not limited to:
- Infection
- Tumor
- Severe osteoporosis
- Mental or physical impairments that limit a patient's ability to comply with necessary limitation of postoperative instructions

Warnings and Precautions
The physician should be familiar with the procedure and use of the SI-Cure Sacroiliac Joint Fusion System instruments prior to surgery.

The outcome and results obtained from this surgical procedure, as with any surgery, are highly dependent on the knowledge of surgical techniques, placement and sizes of implants used, management of the patient both pre and post operation, including the general health of the patient.

The implants used in the system are manufactured from titanium and use with implants of other metallic materials is not recommended.

The device has not been evaluated for safety in the MR environment. The device has not been tested for heating and/or migration in the MR environment.

The SI-Cure System implants are single use devices and should never be re-used.

Potential Adverse Events
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Loss of or increased in spinal mobility or function.

Care and Handling of Instruments
The SI-Cure Sacroiliac Joint Fusion System instruments are provided non-sterile and should be stored in their original packaging until cleaned and sterilized.

Single use Instruments
The guide pins used with this system are single use instruments that are to be disposed of after use.

Cleaning
Diligent execution of all steps is extremely important. Before being used for the first time and as soon as possible after each subsequent use, thoroughly clean all instruments and trays, following these steps to ensure safe handling of biologically contaminated instruments:

1. Pre-Cleaning
- Remove any packaging materials including tip protectors prior to cleaning.
- Disassemble all instruments that can be disassembled.
- Keep instruments moist and do not allow blood and/or bodily fluids to dry on instruments.
- Remove gross contaminants with a steady stream of lukewarm/cool water (below 110°F). Be sure to rinse each instrument thoroughly. Do not use saline or chlorinated solutions (bleach) for any of the cleaning processes, as these can promote corrosion.

2. Cleaning
- Hand wash using a low-sudsing, neutral pH (7-9 pH), protein dissolving detergent. Follow the detergent manufacturer's directions regarding the proper concentration, temperature and time.
- Totally immerse instruments during the cleaning process in order to prevent aerosolization. Use appropriate-sized, soft nylon brushes – Do Not Use steel wool, wire brushes, pipe cleaners or abrasive detergents.
- For cleaning cannula, lumen or hole, use a tight-fitting soft, non-metallic cleaning brush, pushing brush in and out and use a twisting motion to remove debris.
- To avoid coagulation of mucus, blood or other body fluids, do not soak instruments in hot water, alcohol, disinfectants or antiseptics. Do not exceed two hours soaking in any solution.

3. Ultrasonic Cleaning
- For ultrasonic cleaning, follow the manufacturer's specifications for suggested water level, concentration and temperature. Do not place dissimilar metal instruments in contact with each other.
- When using mechanical washers, make sure the instruments are secured in place, and do not touch or overlap.
- Rinse instruments thoroughly with tap water, deionized water or distilled water. Thoroughly rinse all internal lumens.

4. Decontamination/Disinfection
Warning: The decontamination process does not sterilize instruments. Refer to and process as outlined in the STERILIZATION section.
- Select a proper product for high-level disinfection (examples include the glutaraldehydefamily of disinfectant products). Follow the cleaning agent's recommended directions regarding the proper concentration, temperature, contact time and solution re-use.
- Do not use high acid (pH <4.0) or high alkaline (pH >10) products for disinfection, such as bleach, bi-chloride of mercury. Completely immerse instruments in disinfecting solution - force solution into all areas and cavities.
- Using a large syringe or pulsating water jet, thoroughly flush all channels and lumens with the disinfecting solution to remove debris.

5. Rinsing
Thoroughly rinse all instruments and internal lumens with distilled water for a minimum of three minutes to remove all traces of the disinfecting solution.
Use sterile water for the final rinse.

6. Drying
Instruments must be thoroughly dried to remove all residual moisture before they are stored. Use a soft, absorbent towel/cloth to dry external surfaces. Filtered compressed air or a 70% alcohol rinse can also be used to aid the drying process.

7. Testing / Preparation for Sterilization
Warning: The use of damaged instruments may increase the risk of tissue trauma, infection and length of operative procedures.
- Instruments should be visually inspected and prepared for sterilization following disinfection. If the device is determined to not be visually clean at the end of processing, the user should repeat the relevant, previous cleaning steps or alternatively, safely dispose of the device.
- Check for misalignment,burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored or damaged instruments, as well as worn instruments in which the proper function of the instrument may be compromised.

Sterilization and Packaging

Warning: Alevio does not recommend Flash or Chemical sterilization.

The implants and instruments are supplied NON-STERILE and are contained within trays that can be sterilized directly. Replenished implants are provided NON-STERILE in labelled packaging. The system is able to withstand multiple sterilizations. Do not stack trays during sterilization. Based on AAMI and current JCAHO standards, the instruments should be wrapped in an FDA cleared wrap and sterilized using a vacuum cycle, using the following guidelines:

Method	Temperature	Exposure Time	Dry Time
Steam Pre-Vacuum	270°F / 132°C	4 minutes	30 minutes

The above steam sterilization cycle has been validated through half-cycle and full-cycle tests in accordance with the ANSI/AAMI/ISO 17665-1:2006 Guidelines. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.

Storage
The implants are supplied clean and NON-STERILE. Follow the instruction in the sterilization section prior to use.

Single Use Only
Never reuse an implant. Any implant that has been twisted, bent, or implanted, then removed, even if it appears intact, must be discarded.

CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Customer Service
Additional information about the SI-Cure Sacroiliac Joint Fusion System is available from Alevio at any time, or contact your local Alevio sales representative.

ALEVIO® SPINE
Sacroiliac Joint Fusion System Moving Life Forward®

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