SOLAR™ INTERBODY FUSION SYSTEM

Instructions For Use

DESCRIPTION:

The Solar™ System is a lumbar interbody fusion device for anterior lumbar fusion procedures. The Solar™ system includes various widths, depths, and heights. The Solar™ device is comprised of a single component that is additively manufactured. The superior and inferior endplates feature a porous surface to mitigate subsidence and expulsion. The standalone (Solar-S™), anterolateral (Solar-A™), and monolithic (Solar-M™) configurations feature an anterior face with threaded holes and slots to rigidly connect to an instrument for surgical insertion. Superior and inferior faces feature a central aperture to constrain bone graft. The Solar™ spacers are additively manufactured from Puri-Ti™ unalloyed titanium. The DeGen Medical Solar-S™ and Solar-A™ incorporate integrated fixation in the form of screws manufactured from Titanium-6AL-4V ELI Alloy per ASTM F136. The Solar-S™ Lumbar Interbody Spacer must be used with three (3) integrated screws and the spacer must have ≤20° of lordosis to be considered for standalone use.

INDICATIONS:

Solar-S™ (Standalone, With Integrated Fixation) and Solar-A™ (Non-Standalone, With Integrated Fixation)

The Solar-S™ (Standalone) and Solar-A™ (Non-Standalone) are lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. Solar-S™ and Solar-A™ ALIF Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

- Solar-S™ Used With Screws:

  When used with three (3) screws, interbody devices with a lordotic angle ≤ 20° can be used as standalone interbody fusion devices at 1 or 2 contiguous levels.

  Hyperlodotic interbody devices (>20° lordosis) used with screws, must always be used with supplemental fixation, and may be used at 1 or 2 levels.

- Solar-A™:

  These devices are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

Solar-M™ ALIF Spacers (Without Integrated Fixation)

Solar-M™ ALIF Spacers are lumbar interbody fusion devices indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. Solar-M™ ALIF Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

- Active or suspected local or systemic infection
- Obesity: An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself
- Fractures and tumors with loss of anterior support
- Pregnancy
- Osteoporosis
- Systemic or metabolic bone conditions
- Mental illness
- Disease conditions that 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
- Foreign body sensitivity
- Patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during healing and may be at higher risk for implant failure
- Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count, or marked left shift in the WBC differential count.

PRECAUTIONS:

- The implantation of spinal fusion devices should be performed only by experienced surgeons with specific training in the use of such devices. This is a technically demanding procedure presenting a risk of serious injury to the patient.
- Patient Selection: In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
  1. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant.
  2. 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 implant.
  3. Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.
  4. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
  5. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Size Selection: The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant.
- Implant Failure: Implants can break when subjected to increased loading associated with delayed union or non-union. Internal fixation appliances are load-sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of implants.
- Do not reuse surgical implants: An explanted spinal fusion device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.

WARNINGS:

- Potential risks identified with the use of this device system, which may require additional surgery, include:
  - Device component fracture
  - Loss of fixation
  - Non-union
  - Fracture of the vertebra
  - Neurological injury
  - Vascular or visceral injury
- Prior to use, read all package insert instructions and precautions. Proper device selection should be made for the individual anatomical needs.
- Magnetic Resonance (MR) Safety: The DeGen Medical Solar™ Interbody Fusion System has not been evaluated for safety and compatibility in the MR environment. The system has not been tested for heating or migration in the MR environment.
- Notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage. Proper placement must take into consideration of anatomy of the patient in and around the surgical site to avoid potential damage.
- Correct handling of implants is important: Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
- Removing of implant after healing: Metallic implants can possibly increase the risk of infection, loosen, fracture, corrode, migrate, 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.
- The DeGen Medical Solar-S™ must be used with additional anterior and/or posterior fixation which have been cleared by FDA for use in lumbosacral spine to augment stability unless the lordosis of the implant is ≤20° and it is fixated with three (3) integrated screws.
- The DeGen Medical Solar-A™ and Solar-M™ Interbody Fusion System must be used with additional anterior and/or posterior fixation which have been cleared by FDA for use in lumbosacral spine to augment stability.
- Instructions to the Patient: Postoperative care and the patient's 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 follow the postoperative care regimen as instructed by his or her physician.
- Report any serious incident that has occurred in relation to this device to the manufacturer and the authority having jurisdiction in the user's locale.

POSSIBLE ADVERSE EFFECTS:

- Infection, early or late; Pain, discomfort, or abnormal sensations due to the presence of the device; Nerve damage due to surgical trauma or presence of the device; Nonunion, delayed union; Bending or fracture of implant; Loosening of the implant; Metal sensitivity or allergic reaction to a foreign body; Decrease in bone density due to stress shielding; Fracture of bony structures; Neurological difficulties including bowel and/or bladder dysfunction, sexual dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness and paresthesia; Vascular damage could result in catastrophic or fatal bleeding; Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period; Bursitis; Reflex sympathetic dystrophy; Spinal cord impingement or damage, dural tear or leak; Degenerative changes or instability in segments adjacent to fused vertebral levels; Paralysis; Death.

CLEANING:

- Unless just removed from an unopened package, all instruments and implants may be disassembled (if applicable) and cleaned before sterilization.
- Cleaning Precautions: Avoid excessively acidic or alkaline solutions. Do not exceed two hours soaking in any solution. Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.

A. PRE-CLEANING:

- Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. Remove gross contaminants with a steady stream of lukewarm/cool water (below 110º F/43º C). Disassemble the devices where possible to expose all surfaces and clean separately.

B. MANUAL CLEANING:

- Immerse the devices in solution of tap water and enzymatic cleaner. Follow manufacturers' directions regarding concentration, temperature, and contact time. Use a syringe to ensure that solution reaches all parts of cannulations and close mating surfaces where necessary. Ensure that air is not trapped within features of the device when immersing in the solution.
- After soaking is completed use nylon brushes to clean the devices thoroughly paying particular attention to features where soil may be shielded from the brushing. Use a firm bristle brush for cleaning bone-cutting features such as drill tips, reamer flutes, teeth of broaches, etc. Use a bottle brush of appropriate diameter for cannulations. Ensure that the brush passes the whole length of each cannulation at least three times.
- If a device may not be disassembled, or has a long cannula, use an ultrasonic bath and process at the frequency, temperature, contact time, and concentration recommended by the enzymatic agent manufacturer. Immerse the device completely in solution of tap water and enzymatic agent and activate the ultrasonic bath.
- Remove the instruments from the cleaning solution and transfer to a purified water bath and soak for 1 minute.
- Thoroughly rinse with purified water for a minimum of 1 minute paying attention to flush lumens, blind holes and difficult to reach areas.
- Carefully inspect each device to ensure that all visible contamination has been removed and thoroughly clean. If contamination is noted repeat the cleaning process.

C. AUTOMATED CLEANING (OPTIONAL):

- Automated is in addition to manual cleaning [step B.] and automated cleaning does not replace manual cleaning.
- If automated cleaning equipment is used, ensure the washer meets approved efficacy (Validated according to ISO 15883).
- Load the medical devices into the washer. Ensure cannulations and blind holes are not horizontal. Articulating devices should be in the open position. Connect cannulations to the rinsing ports of the washer where possible. Make sure all instruments stay in place and do not touch or overlap each other.
- Operate the washer-disinfector cycle.
- Carefully inspect each device to ensure that all visible contamination has been removed and thoroughly clean. If contamination is noted repeat the cleaning process.

D. DRYING:

- Place on drying rack and allow to air dry until no water remains. Drying may be expedited by use of lint free cloth or clean compressed air.

INSPECTION:

- Inspect all devices before sterilization or storage to ensure the complete removal of soil from surfaces, lumens, holes and movable parts.
- If damage or biological residue is observed, the implant or instrument must be discarded. Return damaged items to DeGen Medical.
- Do not use if damage or wear is noted that may compromise the proper function of the instrument or instrument case. Contact customer service or your DeGen Medical representative for a replacement.
- If corrosion is noted, do not use and contact customer service or your DeGen Medical representative for a replacement.

STERILIZATION:

All implants are provided sterile in a sterile package. Do not use implants unless marked sterile and clearly labeled as such in an unopened sterile package. All instruments used in surgery must be sterilized prior to use. Remove all packaging materials prior to sterilization. All instruments should be cleaned and sterilized prior to surgery. Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled within the instrument tray(s). Instruments should be positioned to allow the steam to come into contact with all surfaces. Do not stack trays during sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be wrapped in an FDA cleared sterilization wrap and steam sterilized.

The following is the recommended sterilization cycle:

Method:	Steam
Cycle:	Pre-Vacuum
Temperature:	270º F (132º C)
Exposure Time:	4 minutes
Drying Time:	55 minutes

WARRANTY:

The DeGen Medical products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties are hereby disclaimed.

CAUTION:

Federal law (USA) restricts this device to sale, distribution and use by or on the order of a physician.

INFORMATION:

To view Surgical Technique Guide or for further information, please contact customer service via phone or mail at:

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