INDICATIONS FOR USE

The SOCON® Spinal System is a pedicle screw system for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the SOCON® Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondyloolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

PRODUCT DESCRIPTION

SOCON® Spinal System implants consist of pedicle bone screws, straight and pre-bent connecting rods, and specially-designed clamps for connecting the screws, rods and cross bars. Specialized instrumentation is designed for implantation of these devices and for the distraction, compression or reduction of the pedicle screw at the fifth lumbar-first sacral (L5-S1) vertebral joint.

The 6.0mm pedicle screws range from 35mm to 65mm in length and are available in two styles: standard mounting or longitudinal mounting, as in more narrow physiological conditions.

The universal clamp (FG601T) and the semi-open clamp (FG602T) can be used with either type of pedicle screw (standard or longitudinal). The FG602T clamp can be mounted vertically on the longitudinal screws or horizontally on the standard screws. Either clamp can be used at any point of a multisegmental construct (caudal, cranial ends or middle mount). The longitudinal mounting saves approximately 6mm of height and is helpful in the lower lumbar spine where screw ends may lie very close to each other.

The open clamps FG603T (right) and FG604T (left) have an open hook for more flexibility in fixing the rod and provide additional stabilization in multisegmental fusions. The open clamps can only be used in a horizontal orientation and in the center mounting position (not at the caudal or cranial ends).

Cross bars are also available in 4 varying lengths (50mm to 80mm - measured from midpoint hole to hole). They are applied to the rods with the use of the cross bar clamp (FT606T).

MATERIAL

All SOCON implants are manufactured from titanium alloy, Ti-A16-4V (ISO 5832/3) and the specialized instruments are made primarily of surgical grade stainless steel (ISO 7153/1).

HOW SUPPLIED

SOCON implants and instruments are provided non-sterile and should be stored in the original packaging until sterilized. Prior to use, each implant or instrument must be cleaned and sterilized according to standard hospital procedure. Refer to the STERILIZATION section for recommended parameters.

CONTRAINDICATIONS

Contraindications include, but are not limited to:
- presence of fever, infection or inflammation (systemic, spinal or localized);
- pregnancy;
- severe osteopenia (or any medical or surgical condition) which would preclude potential benefits of spinal implants;
- metal sensitivity or allergies to the implant materials;
- mixing of implant components from other manufacturers;
- any case not listed in the indications; and
- patients unwilling or unable to follow post-operative care instructions.

Note: The FG603T and FG604T (right and left open clamps) are contraindicated when used alone in mono and multisegmental fusions.

WARNINGS AND POTENTIAL RISKS

The SOCON implants are designed for single patient use only and must never be reused. As with all other orthopedic implants, the SOCON components should never be re-implanted under any circumstances.

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 degenerative spondyloolisthesis with objective evidence of neurological 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.

The mixing of different manufacturer implant components is not recommended due to metallurgical, mechanical and functional reasons. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Do not use implants or instruments from other systems or manufacturers, and do not mix stainless steel and titanium implant components.

The SOCON spinal implants can break if subjected to increased loading associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices which hold a fracture in alignment until healing occurs. If healing is delayed or does not occur, the implant could eventually break due to metal fatigue.

Factors such as the patient’s weight, activity level and adherence to weight-bearing or load-bearing instructions can also affect implant stresses and longevity. In indications where extremely high forces are expected (such as high grade spondylolisthesis and patient.

MATERIAL

®

SOCON® SPINAL SYSTEM

®

Pre-operative assessment of the suitability of the patient’s anatomy for accepting implants is made on the basis of x-rays, CT scans and other radiological studies. Only patients that meet the criteria described in the Indications for Use section should be selected.

The implantation of pedicle screw spinal systems should be performed only by experienced spinal 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.

Internal fixation implants are load-sharing devices intended to stabilize and hold an alignment in place until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

Correct selection of the implant is extremely important. The physician should inform the patient about spinal implant advantages and disadvantages, post-operative limitations, weight/load bearing stresses which could affect bone healing, implant limitations, and the fact that physical activity and full weight/load bearing stresses have been implicated in premature loosening, bending and/or fracture of internal fixation devices.

POSSIBLE ADVERSE EFFECTS

Pre-operatively, the patient should be made aware of the possible adverse effects of spinal surgery. Additional surgery may be necessary to correct some of these events including, but not limited to:
- Early or late loosening, bending, disassembly and/or breakage of any or all implants;
- Nonunion (pseudarthrosis) or delayed union;
- Metal sensitivity to a foreign body (implant material allergic reaction), including metallosis, staining, and/or scarring;
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may lead to skin breakdown, penetration, pain, irritation and/or wound complications;
- Tissue damage resulting from improper placement of implants or instruments;
- Infection;
- Dural tears;
- Nerve or vascular damage due to surgical trauma, including loss of neurological function, neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, appearance of radiculopathy, paresis (complete or incomplete) and cerebral spinal fluid leakage;
- Bone loss due to resorption or stress shielding, decrease in bone density or bone fracture at, above or below the level of surgery;

Adequately instruct the patient. The physician should inform the patient about spinal implant advantages and disadvantages, post-operative limitations, weight/load bearing stresses which could affect bone healing, implant limitations, and the fact that physical activity and full weight/load bearing stresses have been implicated in premature loosening, bending and/or fracture of internal fixation devices.

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Lubrication

Avoid using brushes, pipe cleaners or abrasive detergents. 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. 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, stopcocks and ratchets.

4. Decontamination / Disinfection

Warning: The decontamination process does not sterilize instruments. Refer to process as outlined in the STERILIZATION section.

Select a proper product for high-level disinfection (examples include the glutaraldehyde-family 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 internal lumens, stopcocks and ratchets with distilled water to remove all traces of the disinfecting solution. USE STERILE WATER ON 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. Compressed air or a 70% alcohol rinse can also be used to aid the drying process.

Before final tightening of the clamp, insert the screw under x-ray guidance so the hexagon top is flush with the clamp (Fig. 3). The border of the clamp must be on the same level as the lower border of the hexagonal screw portion.

Implant Removal

1. Loosen the nuts on the clamps by using the FG290R or FG311R wrench. Remove cross bars and clamps.

2. Unscrew the pedicle screws from the vertebral body by using the FG270R, T-Handle instrument.

CARE AND HANDLING

SOCON implants and instruments are provided non-sterile and should be stored in their original packaging until cleaned and sterilized.

SOCON implants are composed of titanium alloy (TiAl6V4, acc. to ISO 5832/3) and possess a natural oxide layer to protect the metal. Implant color depends on the oxide layer thickness; slight discolorations are possible but do not affect the quality of the implant. No coating has been applied to the implant.

Instruments

Before being used for the first time and each use thereafter, follow these steps to ensure safe handling of biologically contaminated instruments:

1. 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 110°). Be sure to rinse each instrument thoroughly. Do not use saline or chlorinated solutions.

Fully open jaws of hinged instruments for cleaning. Instruments with more than one part or piece must be disassembled in order to expose all surfaces to the cleaning process.

2. Cleaning

Hand wash using a low-sudsing, neutral pH (7-9), protein dissolving detergent. Follow the detergent manufacturer’s directions regarding the proper concentration, temperature and contact 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.

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. 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, stopcocks and ratchets.

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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. 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. 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.

Lubrication of joints is essential every time instruments are processed. Use a non-silicone, water-soluble lubricant prior to sterilization such as Aesculap Implant System’s Instrument Oil JG586. Only lubricate dry instruments and do not use mineral oil, petroleum, or silicone-based products. Reassemble instruments, as necessary, before placing into baskets or trays. Close racketed instruments in the first racket position to avoid temperature-induced stress cracks in the joints.

STERILIZATION

Warning: Aesculap Implant Systems does not recommend Flash or Chemical sterilization.

To achieve a sterility assurance level of 10^-6, Aesculap Implant Systems recommends the following parameters:

<table>
<thead>
<tr>
<th>Minimum Cycle Parameters*</th>
<th>METHOD</th>
<th>STERLICONTAINER</th>
<th>WRAPPED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam Pre-Vac</td>
<td>1270°F / 152°C</td>
<td>4 minutes</td>
<td>4 minutes</td>
</tr>
<tr>
<td>Steam Gravity</td>
<td>270°F / 132°C</td>
<td>30 minutes</td>
<td>10 minutes</td>
</tr>
<tr>
<td>250°F / 121°C</td>
<td>40 minutes</td>
<td>15 minutes</td>
<td></td>
</tr>
<tr>
<td>EO</td>
<td>125°F - 130°F / 52°C - 54°C</td>
<td>Pre-vac: 20Hg - 508mmHg (min)</td>
<td>Humidity: 40-60% RH</td>
</tr>
</tbody>
</table>

Aesculap Implant Systems has validated the above steam sterilization cycle on the data on file. 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 components in Aesculap Implant System’s SOCON system must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

WARRANTY

Every product bearing the Aesculap Implant Systems name is guaranteed to be free of defects in workmanship and materials when used properly for its intended purpose. Any Aesculap Implant Systems product delivered from Aesculap Implant Systems, Inc. proving to be defective will be replaced or repaired, at Aesculap Implant System’s discretion, at no charge to the customer.

These warranties shall not apply to conditions or defects resulting from, but not limited to: negligence, improper use, improper care and handling, improper opening techniques, unauthorized repair work, caustic or abrasive cleaners, or items modified or customized by the customer at the customer’s request.
MAINTENANCE and REPAIR

Warning: Repair of SOCON instruments by parties other than Aesculap Implant Systems will void the above warranty.

If your SOCON instruments require repair or maintenance, return the instruments in the Aesculap Implant Systems Instrument Repair (A.I.R.) box or other sturdy box with adequate packaging material to protect the instruments. Send the packaged instruments to:

Aesculap Implant Systems, Inc.
615 Lambert Pointe Dr.
Hazelwood, MO 63042

Attn: Aesculap Implant Systems Technical Services
(or call the Repair Hotline at 800-214-3392)

Instruments returned to Aesculap Implant Systems must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

CUSTOMER SERVICE

Additional information about the SOCON® Spinal System is available from Aesculap Implant Systems at any time or contact your local Aesculap Implant Systems sales representative.

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

AESCULAP
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Center Valley, PA 18034

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