INDICATIONS FOR USE

The Aesculap S4 Cervical Spinal and Occiput Systems are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniovertebral junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Aesculap S4 Cervical Spinal and Occiput Systems are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Aesculap S4 Lumbar System may be connected to the Aesculap S4 Cervical Spinal and Occiput Systems using connectors and rods.

The safety and effectiveness of pedicle screw spinal systems in general have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability of the thoracic, lumbar, and sacral spine to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis 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.

PRECAUTION

The S4 Cervical Occipital Plating System has not been evaluated for safety and compatibility in the MR environment. The S4 Cervical Occipital Plating System has not been tested for heating or migration in the MR environment.

DEVICE DESCRIPTION

The S4 Cervical Spinal System is designed to stabilize and promote fusion. The S4 Cervical Spinal System consists of plates, setscrews, bone screws, rods, transverse rod connectors, lateral offset connectors, 3.5mm rods in various lengths, pre-bent 3.5mm rods, thin and thick lamina hooks, and 3.5 and 4.0 polyaxial screws of various lengths. The occipital plate is fixed to the occiput with bone screws and the transition by locking near the base. This mechanism consists of a rod receptacle, holding insert, and set screw which are free to slide ±5mm in the medial/lateral direction and rotate (±10°) along the receptacle flange. The rod loads from the top and is fixed into and locked into place. The end of the construct is stabilized with polyaxial screws to the upper thoracic spine, as required. The S4 occipital plate assemblies are offered in two different sizes (large and small) which each have two different shapes (five holes and four holes). The S4 Occiput Access Plates are offered in two sizes (large and small), and contain four angulated screw holes. These plates are anodized blue. The S4 Occiput Access screws are anodized blue and bronze for the regular and rescue screws, respectively. These plates are designed to allow for contouring intraoperatively by the surgeon as required. The unicortical bone screws are 4.5mm and 5.5mm in diameter and are available in multiple lengths.

MATERIAL

S4 cervical implants are manufactured from forged titanium alloy Ti6Al4V according to ASTM F136 or ISO 5832-3 and pure titanium according to ASTM F67 or ISO5832-2. The specialized instruments are made primarily of surgical grade stainless steel (ISO 7153).

HOW SUPPLIED

S4 Cervical implants and instruments are provided non-sterile and must be cleaned and sterilized prior to use according to the procedures outlined in this document.

CONTRAINDICATIONS

Contraindications include, but are not limited to:
- Presence of fever, infection or inflammation (systemic or localized);
- Morbid obesity;
- Pregnancy;
- Mental illness or drug abuse;
- Severe osteopetrosis (or any medical or surgical condition) which would preclude potential benefits of implants;
- Suspected or documented metal allergy or intolerance;
- 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.

WARNINGs AND POTENTIAL RISKS

The S4 Cervical spinal implants are designed for single patient use only and must never be reused. As with all other orthopedic implants, the S4 Cervical components should never be re-implemented under any circumstances.

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.

The S4C Occiput Access plates should only be used with the S4C Occiput Access screws. Failure to do so may increase propensity for implant loosening.

The S4 Cervical implants can become loose or break if subjected to increased loading. Factors such as the patient’s weight, activity level and adherence to weight-bearing or load-bearing instructions can affect the implant’s longevity. Damage to the weight-bearing bone structures caused by infection can give rise to loosening of the components and/or fracture of the bone.

These warnings do not include all adverse effects which could occur with surgery, but are important considerations specific to metallic devices. The risks associated with orthopedic surgery, general surgery and the use of general anesthesia should be explained to the patient prior to surgery. See the PRECAUTIONS and POSSIBLE ADVERSE EFFECTS sections for additional warnings.

PRECAUTIONS

Intraoperative 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. Preoperative planning and patient anatomy should be considered when selecting implant diameter and length.

Use of cross sectional imaging (i.e., CT and/or MRI) for posterior cervical screw placement is recommended due to the unique risks in the cervical spine. The use of planar radiographs alone may not provide the necessary imaging to mitigate the risk of improper screw placement. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

Under no circumstances should damaged components or surgically excised components be used. Implants that have already been in contact with body fluids or body tissues must not be re-sterilized.

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.

Correct selection of the implant is extremely important. The morbidity as well as patient weight height, occupation and/or degree of physical activity should be considered.

Proper implant handling before and during the operative procedure is critical. Handle the implant components properly. Ensure packaging integrity. Do not allow the implants surfaces to be damaged.

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

POSSIBLE ADVERSE EFFECTS

Pre-operatively, the patient should be made aware of the possible adverse effects of orthopedic surgery. Additional surgery may be necessary to correct some of these anticipated events including, but not limited to:
- Early or late loosening, disassembly and/or breakage of any or all implants;
- Metal sensitivity to a foreign body (implant material allergic reaction), including metallosis, staining, tumor formation, auto-immune disease and/or scarring;
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown, penetration, pain, irritation and/or wound complications;
- Tissue damage resulting from improper placement of implants or instruments;
- Infection;
- Joint dislocation;
- Nerve or vascular damage due to surgical trauma, including loss of neurological function, neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, appearance of radiculopathy, and paralysis (complete or incomplete);
- Bone loss due to resorption or stress shielding, decrease in bone density or bone fracture at the operative site;
- Pain, discomfort or wound healing complications at the surgical site;
- Hemorrhage, hematoma, seroma, damage to blood vessels, embolism, stroke, excessive bleeding, wound necrosis and/or dehiscence;
- Misalignment of anatomical structures, including loss of proper spinal alignment, and/or loss of height;
- Gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium;
- Decreased joint mobility and flexibility,
Bone graft resorption/pseudoarthrosis; and
Death.

DIRECTIONS FOR USE
To implant the S4 Cervical implants, use only the specialized S4 Cervical instrumentation. Do not use implants or instruments from any other system or manufacturer.

The S4 Cervical implants and S4 Cervical instruments are provided non-sterile and must be cleaned and sterilized prior to use according to the procedures outlined in this document. All S4 Cervical device system components should be carefully inspected to ensure proper working condition. Critical areas, including joint surfaces, should be checked for wear, damage or irregularities. Damaged or broken S4 Cervical devices must not be used or processed and should be returned to Aesculap Implant Systems for evaluation.

Before using the S4 Cervical Spinal System for the first time, the surgeon should be thoroughly familiar with the S4 Cervical Surgical Technique Manual as well as the functionality and assembly of the various components. Pre-operative planning by the surgeon should determine the type of implant required and an adequate supply of the implant sizes should be available prior to surgery, including larger and smaller sizes than those expected to be used.

For complete instructions regarding the proper use and application of all S4 Cervical implants and instruments, please refer to the S4 Cervical Surgical Technique Manual (available at no charge upon request).

CARE AND HANDLING
S4 Cervical Spinal implants and S4 Cervical Spinal instruments are provided non-sterile and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be sterilized according to the standard hospital procedure. Refer to the STERILIZATION section for recommended parameters.

Instruments
Before being used for the first time and each use thereafter, the procedures outlined below should be followed 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. The decontamination process should begin immediately after completion of the surgical procedure.

2. Rinse
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.

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 the disinfection process. 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 is essential every time instruments are processed. Use a non-silicone, water-soluble lubricant prior to sterilization such as Aesculap’s Instrument Oil, JG598. Special attention should be given to boxlocks and moveable parts (joints). 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 ratcheted instruments in the first ratchet position to avoid temperature-induced stress cracks in the joints.

STERILIZATION
Warning: Aesculap Implant Systems does not recommend the S4 instruments be sterilized by Flash, EO or Chemical sterilization. Sterilization may be accomplished by steam autoclave in a standard prevacuum cycle. To achieve a sterility assurance level of 10-6, Aesculap Implant Systems recommends the following parameters:

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Temperature</th>
<th>Full Cycle Time</th>
<th>Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Vacuum</td>
<td>270°F-275°F</td>
<td>4 minutes</td>
<td>20 minutes</td>
</tr>
<tr>
<td>Pre-Vacuum</td>
<td>132°C-135°C</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Aesculap Implant Systems has validated the above sterilization cycles and has 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 S4 Cervical instruments 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 proving to be defective will be replaced or repaired, at Aesculap Implant Systems 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 S4Cervical instruments by parties other than Aesculap Implant Systems will void the above warranty.

If your S4 Cervical implants require repair or maintenance, return the instruments to the Aesculap Instrument Repair (A.I.R.) box or other study box with adequate packaging material to protect the instruments. Send the packaged instruments to: Aesculap Implant Systems 615 Lambert Pointe Dr. Hazlewood, MO 63047
Attn: Aesculap Technical Services (or call the Repair Hotline at 800-214-3392)

Note: 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
For further information regarding the S4 Cervical Spinal System or a copy of the S4 Cervical Surgical Technique Manual, please contact Aesculap Implant Systems or your local Aesculap Implant Systems Orthopaedic Distributor.

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Phone: 866-229-3002
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