**Genesys Spine Apache™ Interbody Fusion Device Star Cervical System IFU**

**DESCRIPTION AND INTENDED USE:**

The Genesys Spine Apache™ Interbody Fusion Device Star Cervical System will be offered in various device configurations based on surgical approach and patient anatomy, and consist of the Genesys Spine Apache™ cervical interbody fusion device, which may be implanted as a single device via an anterior approach.

The Genesys Spine implants and surgical instruments are intended for use by or on the order of a physician. The system specific Genesys Spine surgical instruments are designed to perform precise functions as referenced in the respective Genesys Spine surgical technique manuals. Such functions include but not limited to dissection, cutting, probing, clamping, gripping, handling, compressing, distracting, or inserting. The use of instruments is the responsibility of the surgeon to ascertain.

**CLEANING of INSTRUMENTS:**

1. Instruments should be handled and used by personnel familiar with their use, assembly, and disassembly. Clean all instruments prior to use, and as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying.
2. Loosen and/or disassemble instruments with removable parts. For the PEEK Inserters (GP100, GP200, GP500, GP600 & GP602): unscrew and remove the inner shaft for cleaning and sterilization.
3. Manual cleaning is recommended using a neutral pH detergent prepared in accordance with the manufacturers' instructions and utilizing a mechanical aid such as a brush. Particular attention should be taken to remove all debris from instruments with cannulations and holes.

**Table 1. Recommended Manual Cleaning Durations**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Time (MM:SS)</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enzymatic Pre-Soak while brushing</td>
<td>20:00</td>
<td>Enzol (or equivalent)</td>
</tr>
<tr>
<td>Enzymatic Wash in Ultrasonic Cleaner</td>
<td>10:00</td>
<td>Enzol (or equivalent)</td>
</tr>
<tr>
<td>Rinse &amp; Brush</td>
<td>04:00</td>
<td>Deionized water</td>
</tr>
</tbody>
</table>

**CLEANING SOLUTION:**

- Steris® Prolystica® Enzymatic Presoak
- Steris® Prolystica® Ultra-Concentrate Neutral Detergent
- Steris® Prolystica® Enzymatic Wash
- Steris® Prolystica® Neutral Detergent
- Steris® Prolystica® Warm Tap Water
- Steris® Prolystica® 70°C ± 4°C
- Steris® Prolystica® 80°C ± 4°C

**CLEANING of IMPLANTS:**

- Instruments should be handled and used by personnel familiar with their use, assembly, and disassembly. Clean all instruments prior to use, and as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying.
- Loosen and/or disassemble instruments with removable parts. For the PEEK Inserters (GP100, GP200, GP500, GP600 & GP602): unscrew and remove the inner shaft for cleaning and sterilization.
- Manual cleaning is recommended using a neutral pH detergent prepared in accordance with the manufacturers' instructions and utilizing a mechanical aid such as a brush. Particular attention should be taken to remove all debris from instruments with cannulations and holes.

**STERILIZATION:**

The Genesys Spine Apache™ Interbody Fusion Device Star Cervical System is provided non-sterile and is delivered to the customer in a surgical kit, which is comprised of implant caddies, instrument trays and instrument cases. The following moist heat sterilization cycle, which is expected to result in a SAL of 10⁻⁶, will be validated for use with Genesys Spine Apache™ Interbody Fusion Device Star Cervical System (implants and instruments) prior to marketing in accordance with applicable standards, including ANSI/AAMI ST79:

<table>
<thead>
<tr>
<th>Method</th>
<th>Steam</th>
</tr>
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<tbody>
<tr>
<td>Cycle</td>
<td>Pre-Vacuum</td>
</tr>
<tr>
<td>Temperature</td>
<td>270°F (132°C)</td>
</tr>
<tr>
<td>Exposure Time</td>
<td>4 minutes</td>
</tr>
<tr>
<td>Dry Time</td>
<td>20 minutes</td>
</tr>
<tr>
<td>Wrap</td>
<td>2 times utilizing FDA cleared wrap</td>
</tr>
</tbody>
</table>

Instruments should be positioned to allow the steam to come into contact with all surfaces. All jointed instruments should be in the open connection and should be allowed to rotate completely. All instruments should be positioned to allow the steam to come into contact with all surfaces. All jointed instruments should be in the open connection and should be allowed to rotate completely.
or unlocked position with ratchets not engaged. Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Instruments used in surgery should be re-sterilized after surgery. Implants should not be used as templates in surgery.

**POSTOPERATIVE MOBILIZATION:**
The surgeon should advise the patient to be careful not to place significant loads on the spine for the first three months after surgery. The surgeon may advise the patient to limit their activity or wear a brace. Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union. Radiographic confirmation of a mature fusion mass may be used as a guide in the lifting of these restrictions.

**WARNINGS:**
Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to spine fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
2. **PATIENT SELECTION.** In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
   a) A patient may have multiple pain generators due to advanced degeneration of the spine (e.g. intervertebral disc, facets or bony stenosis). These conditions may be present at the index level or adjacent levels. Careful review of the clinical record, including radiographic studies and applicable diagnostic tests, should be performed to make the appropriate diagnosis. Concomitant conditions may reduce the effectiveness of the surgery and this should be discussed with the patient.
   b) The patient’s weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant or subsidence.
   c) 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 or subsidence.
   d) 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.
   e) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
   f) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
   g) Implants of dissimilar metals should not be used together in or near the implant site.
   h) Components of this system should not be used with components of any other system or manufacturer.
3. **REUSE OF IMPLANTS.** The risk of reusing implants includes infection and tissue irritation. In addition, exposure to the chemicals used for cleaning can induce physical changes to the materials; the result can be sudden mechanical failure or device malfunction. Genesys Spine accepts no responsibility for a re-used implant.
4. Instruments should not be used in any capacity other than their intended use.

**PRECAUTIONS**
1. **THE IMPLANTATION OF SPINAL FIXATION 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.**
2. **PROPER SIZING OF THE IMPLANTS IS IMPORTANT.** The surgeon should use trials to determine the appropriate implant to use. The implant should be tall enough to provide segmental distraction and stability. The implant should be wide enough to maintain contact with the cortical rim of the vertebral body else the risk of subsidence may increase.
3. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted spinal fixation 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.
4. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.** The operating surgeon should avoid any notching or scratching of the device during surgery. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Visually inspect all implants for damage prior to use.
5. **ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient’s ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the body’s response to the implant and how the fusion mass is expected to develop. A patient that is non-compliant with post-operative guidance is particularly at risk during the early postoperative period.
6. **MAGNETIC RESONANCE (MR) ENVIRONMENT.** The Genesys Spine Apache™ Interbody Fusion System has not been evaluated for safety and compatibility in the MR environment. The Genesys Spine Apache™ Interbody Fusion System has not been tested for heating or migration in the MR environment.

**POSSIBLE ADVERSE EFFECTS**
1. Non-union, delayed union.
2. Bending or fracture of implant.
3. Anterior or posterior migration of the implant.
4. Allergic reaction to a foreign body.
5. Infection.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Loss of proper spinal curvature, correction height and/or reduction.
9. Vascular and/or nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
11. Death.
12. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.

**LIMITED WARRANTY:**
Genesys Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact Genesys Spine for current information.

Catalog # IFU-006 Rev F per ECN 15-080
Genesys Spine 2015