Genesys Spine Anterior Cervical Plate System

DO NOT USE THE IMPLANTS IN THE PRESENCE OF ANY CONTRAINDICATION.

Contraindications include, but are not limited to:
1. Presence of overt infection and/or localized inflammation.
2. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
3. Suspected or documented metal allergy or intolerance.
4. Any patient having inadequate tissue coverage over the operative site.
5. Any time implant utilization would interfere with anatomical structures or expected physiological performance, such as while brushing.
6. Severe comminuted fractures such that segments may not be maintained in satisfactory proximate reduction.
7. Use in displaced, non-reduced fractures with bone loss.
8. The presence of marked bone absorption or severe metabolic bone disease that could compromise the fixation achieved.
9. Any other medical or surgical condition which would preclude the potential benefit of surgery, such as elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), fever, leukocytosis or a marked left shift in the WBC differential count.
10. The physical contact of the Genesys Spine Anterior Cervical Plate System implants with metal implant made of anything other than implant grade titanium, such as stainless steel (ASTM F138) or MP35 N, or other dissimilar metal.
11. Situations with the absence or compromise of significant stabilizing elements.
12. Use in the presence of any neural or vascular deficits or other compromising pathology, which may be further injured by device intervention.
13. See also the WARNINGS, PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS sections of this insert.

MATERIALS:
Implant components are manufactured of ASTM F136 implant quality titanium alloy and nickel-titanium (ASTM F2063-00). Specifications are controlled for optimization of metallurgical properties and corrosion resistance, and are based on the strength and rigidity requirements of the individual component. Thus to achieve the best results, do not use any of the Genesys Spine Anterior Cervical Plate System components with components from any other system or company. As with other orthopaedic implants, none of the Genesys Spine Anterior Cervical Plate System components should be reused or re-implanted under any circumstances.

Refer to the Genesys Spine Anterior Cervical Plate System Surgical Technique for instructions for implantation.

CERVICAL BONE AWL-PUNCH unscrew and remove the metal sleeve that extends to the distal end of the instrument. After cleaning and sterilization the sleeve should be reinserted into the bone awl-punch.

1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact your Genesys Spine representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Genesys Spine representative for a replacement.

Table 1. Recommended Manual Cleaning Durations

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

Table 2. Automated Cleaning Procedure

<table>
<thead>
<tr>
<th>TREATMENT</th>
<th>TIME (MM:SS)</th>
<th>TEMPERATUR E</th>
<th>CLEANING SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enzymatic Wash</td>
<td>08:00</td>
<td>60°C ± 4°C</td>
<td>Steris® Prolystica® Enzymatic Presoak</td>
</tr>
<tr>
<td>Wash</td>
<td>04:00</td>
<td>Warm Tap Water</td>
<td>Steris® Prolystica® Ultra-Concentrate Neutral Detergent</td>
</tr>
<tr>
<td>Rinse</td>
<td>02:00</td>
<td>70°C ± 4°C</td>
<td>N/A</td>
</tr>
<tr>
<td>Dry</td>
<td>15:00</td>
<td>80°C ± 4°C</td>
<td>N/A</td>
</tr>
</tbody>
</table>

INSPECTION:
The Genesys Spine instruments should be inspected after cleaning to ensure all components are secured properly. Genesys Spine instruments are supplied non-sterile and must be cleaned and sterilized per hospital protocol and according to procedures in this document. Failure to comply with these procedures could cause the instrument to fail to operate to specifications. Inappropriate use can lead to irreparable damage and cause the instrument to fail to function as specified.

1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your Genesys Spine representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Genesys Spine representative for a replacement.

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

Method: Steam
Cycle: Pre-Vacuum
Temperature: 270°F (132°C)
Exposure Time: 4 minutes
Dry Time: 20 minutes
Wrap: 2 times utilizing FDA cleared wrap

Routine monitoring per AORN recommended practices for in-hospital sterilization should be followed. Instruments should be positioned to allow the sterilant to come into contact with all surfaces. All jointed instruments should be in the open 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 surgical instruments used in surgery.

Instruments used in surgery should be in the open 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 surgical instruments used in surgery.

POSTOPERATIVE MOBILIZATION:
Careful patient handling post-operatively is very important while the fusion mass matures and becomes able to share load with the implant. Until X-rays confirm maturation of the fusion mass, external mobilization (such as bracing or casting) is recommended. Instructions to the patient to reduce stress on the implant are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure. In younger patients, once the fusion mass has healed, the implants may be removed to allow the fused bone to return to a better state of load transfer. This is, as with all patient care, left to the discretion of the operating surgeon.

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 metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. IN THE U.S.A., THIS PRODUCT HAS LABELING LIMITATIONS.
2. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
3. Compromise procedures should not be performed in the absence of posterior fixation.
4. Potential risks identified with the use of this device system, which may require additional surgery, include:
   a) Device component fracture.
   b) Loss of fixation.
   c) Non-union.
   d) Fracture of the vertebra.
   e) Neurological injury
   f) Vascular or visceral injury
5. 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.

PRECAUTIONS
1. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Do not over bend or alter any Genesys Spine Anterior Cervical Plates. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
2. VERIFY SECUREMENT TAB ENGAGEMENT. Surgeon should visually inspect the plate to verify that the tab is properly engaged (refer to the surgical technique).
3. REMOVAL OF THE IMPLANT AFTER HEALING. Metallic implants can loosen, fracture, corrode, migrate, and possibly increase the risk of infection, 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 re-fracture. 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.
4. 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 limitations of the implant and follow the post-operative care regimen as instructed by his or her physician.
5. DO NOT ALTER OR MODIFY ANY GENESYS SPINE ANTERIOR CERVICAL PLATE SYSTEM INSTRUMENT. REPAIRS SHOULD ONLY BE ACCOMPLISHED BY THE MANUFACTURER. The Genesys Spine Anterior Cervical Plate System is only a temporary implant used for the correction and stabilization of the cervical spine. A successful result is not achieved in every surgical case. Bone grafting must be part of the spinal fusion procedure in which the Genesys Spine Anterior Cervical Plate System is used.
6. The Genesys Spine Anterior Cervical Plate has not been evaluated for safety and compatibility in the MR environment. The Genesys Spine Anterior Cervical Plate has not been tested for heating or migration in the MR environment.
7. FIXATION PINS ARE INSTRUMENTS AND MUST BE REMOVED PRIOR TO COMPLETING THE PROCEDURE. The Fixation Pins are for temporary stabilization of the Anterior Cervical Plate and not for implantation.
8. Instruments should not be used in any capacity other than their intended use.

Reoperation to remove or replace implants may be required at any time for medical reasons or device failure. If corrective action is not taken, complications may occur.

These complications may include but not be limited to:
1. Device Corrosion with localized tissue reaction and pain.
2. Device migration, which may result in injury to soft tissue, visceral organs or joints.
3. Loosening or disassembly of implants resulting in additional injury.
4. Bending, loosening or breaking of the implant making removal difficult, impractical or impossible.
5. Abnormal sensations discomfort or pain.
6. Increased risk of infection.
7. Bone loss due to stress shielding.

Preoperative and operating procedures including knowledge of surgical techniques, good reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the Genesys Spine Anterior Cervical Plate System.

Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Patients with poor bone quality are also poor candidates for surgery.

POSSIBLE ADVERSE EFFECTS
Occurrence of any adverse effects may require re-operation and removal of the implant. Adverse effects may include but not be limited to:
1. Early or late loosening of the components.
2. Disassembly, fretting, loosening, bending, breakage and/or migration of any component or component portion.
3. Foreign body reaction to the implants.
4. Pressure on the skin from component parts where there is inadequate tissue coverage over the implant, causing skin irritation.
5. Early or late infection.
6. Vertebral body fracture at, above, or below the level of surgery.
7. Implants cutting through bone, especially soft osteoporotic, osteopenic, or Cancellous bone.
8. Bone forming around the implant, making removal difficult or impossible.
9. Non-union (pseudarthrosis) or bone fracture.
10. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
11. Neurovascular compromise including radiculopathy, paralysis, or other types of serious injury causing pain and disability.
13. Cessation of growth of the operated portion of the bone.

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.

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For product information, questions pertaining to sales and service, or to obtain a copy of the surgical technique manual, please contact your local sales representative or Genesys Spine customer service.

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