Genesys Spine Lumbar Plate System

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System Contents:

- Non-Sterile Implants: Do Not Re-Use

- Non-Sterile Instruments - Reusable

Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product. Use universal precautions when handling contaminated or biohazardous components.

DESCRIPTION:
The Genesys Spine Lumbar Plate System will be offered in various device configurations based on surgical approach and patient anatomy, and will consist of a Genesys Spine Lumbar Plate and Screws that are inserted into the anterior or lateral surface of adjacent lumbar vertebrae.

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.

INDICATIONS:
The Genesys Spine Lumbar Plate system is indicated for use via the lateral or anterolateral surgical approach in the treatment of the thoracolumbar (T1-L5) spine and for use as an anteriorly placed supplemental fixation device for the lumbosacral spine (L1-S1), below the bifurcation of the vascular structures. The Genesys Spine Lumbar Plate system is indicated for use in the temporary stabilization of the anterior spine during the development of solid spinal fusions in patients with degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma including fractures, tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudo-arthrosis, spondyloysis, spondylolisthesis, stenosis and/or failed previous fusion. The system is intended to be used in skeletally mature patients in conjunction with traditional fixation and is not intended for load bearing applications.

CONTRAINDICATIONS:
The Genesys Spine Lumbar Plate System is not designed or sold for any use except as indicated.
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 expedited physiological performance, such as impinging on vital structures.
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 Lumbar 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. Use with components from any other system or company.

MATERIALS:
Implant components are manufactured of ASTM F136 implant quality titanium alloy and nickel-titanium (ASTM F2063-12). 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 Lumbar Plate System components with components from any other system or company. As with other orthopaedic implants, none of the Genesys Spine Lumbar Plate System components should be reused or re-implanted under any circumstances.

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

CLEANING of INSTRUMENTS:
Instruments should be handled and used by personnel familiar with their use, assembly, and disassembly

1. Thoroughly 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. Disassembly and reassembly is to be performed by hand - no special tools or instruments are required. For the **GBP102/GBP104 Screw Drivers** unscrew and remove the inner shaft. After cleaning and sterilization the inner shaft should be reinserted into the driver.
3. Manual cleaning is recommended using a neutral pH detergent prepared in accordance with the manufacturer's 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

TREATMENT	TIME (MM:SS)	CLEANING SOLUTION
Enzymatic Pre-Soak while brushing	20:00	Enzol (or equivalent)
Enzymatic Wash in Ultrasonic Cleaner	10:00	Enzol (or equivalent)
Rinse & Brush	04:00	Deionized water

4. Automated cleaning should be performed after manual removal of debris. Avoid excessively acidic or alkaline solutions and clean as follows:

Table 2. Automated Cleaning Procedure

TREATMENT	TIME (MM:SS)	TEMPERATURE	CLEANING SOLUTION
Enzymatic Wash	08:00	60°C ± 4°C	Steris® Prolystica® Enzymatic Presoak
Wash	04:00	Warm Tap Water	Steris® Prolystica® Ultra-Concentrate Neutral Detergent
Rinse	02:00	70°C ± 4°C	N/A
Dry	15:00	80°C ± 4°C	N/A

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 Lumbar 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 moist heat sterilization cycle, which is expected to result in a SAL of 10^{-6}, will be validated for use with Genesys Spine Lumbar Plate System (implants and instruments) prior to marketing in accordance with applicable standards, including ANSI/AAMI ST79:

Method:	Steam
Cycle:	Pre-Vacuum
Temperature:	270^0F (132^0C)
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 templates 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. To avoid the risk of vascular injury, the plate MUST be placed caudal to the bifurcation of the great vessels.
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. MIXING METALS CAN CAUSE CORROSION. Plates, screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
6. 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 Lumbar 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 LUMBAR PLATE SYSTEM INSTRUMENT. REPAIRS SHOULD ONLY BE ACCOMPLISHED BY THE MANUFACTURER. The Genesys Spine Lumbar 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 Lumbar Plate System is used.
6. MAGNETIC RESONANCE (MR) ENVIRONMENT. The Genesys Spine Lumbar Plate has not been evaluated for safety and compatibility in the MR environment. The Genesys Spine Lumbar Plate has not been tested for heating or migration in the MR environment.
7. 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 due to 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 Lumbar 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.
12. Hemorrhage of blood vessels.
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.

Catalog # IFU-011 Rev C per ECN 15-080 Genesys Spine 2015

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