# Genesys Spine Apache™ Lateral Lumbar Interbody Fusion Device System IFU

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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.

DESCRIPTION and INTENDED USE:

The Genesys Spine Apache™ Interbody Fusion System will be offered in various device configurations based on surgical approach and patient anatomy, and consist of:

1) Genesys Spine lumbar interbody fusion device(s), which may be implanted
   - as a single device via a Lateral / Posterolateral (LLIF) approach.

2) The Genesys Spine surgical instruments are designed to perform a specific function as referenced in respective Genesys Spine surgical techniques. Such functions include but not limited to dissection, cutting, probing, clamping, gripping, handling, compressing, distracting, or inserting.

3) 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 Apache™ Lateral Lumbar Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

CONTRAINDICATIONS:

1. Active systemic infection and infection localized to the site of the proposed implantation are contraindications to implantation.
2. Known sensitivity to PEEK material.
3. Severe osteoporosis is a relative contraindication because it may result in implant subsidence and loss of fixation.
4. Any condition that significantly affects the likelihood of fusion may be a relative contraindication (e.g. cancer, diabetes, osteomalacia, heavy smoker, morbid obesity) and the surgeon must evaluate the relative risks and benefits individually with each patient.
5. Other relative contraindication may include mental illness, drug abuse or alcoholism as these may cause the patient to be non-compliant with post-operative guidance (e.g. bracing and physical therapy).
6. Prior fusion at the levels to be treated.
7. Any condition not described in the indications for use.

MATERIALS:

The Genesys Spine Apache™ Interbody Fusion System implant components are made of polyether ether ketone (PEEK Optima LT1) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers (ASTM F560) to assist the surgeon with proper placement of the device.

The Genesys Spine Apache™ Interbody Fusion System is implanted using a combination of device specific and universal class I instruments manufactured from stainless steel materials that conform to ASTM F899.

The Genesys Spine Apache™ Interbody Fusion System components may not be used with components from any other system or manufacturer. As with other orthopedic implants, none of the Apache™ Interbody Fusion System implants may be reused or re-implanted under any circumstance.

CLEANING of INSTRUMENTS:

Instruments should be handled and used by personnel familiar with their use, assembly, and disassembly

1. 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)**: 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

| 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 Apache™ Interbody Fusion 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 Apache™ Interbody Fusion

System (implants and instruments) prior to marketing in accordance with applicable standards, including ANSI/AAMI ST79:

| | |
|---|---|
| Method: | Steam |
| Cycle: | Pre-Vacuum |
| Temperature: | 270$^0$F (132$^0$C) |
| Exposure Time: | 4 minutes |
| Dry Time: | 20 minutes |
| Wrap: | 2 times utilizing FDA cleared wrap |

Instruments should be positioned to allow the steam 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:

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 spinal 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.
3. 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.
4. 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
5. 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.
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.
7. IMPLANTATION OF THE LATERAL LUMBAR IBFD MAY NOT BE SUITABLE IN ALL PATIENTS. Patient anatomy may preclude suitable access at the L5-S1 level. Proper patient screening is to be performed prior to performing any surgical operation.

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.
10. Paralysis.
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.

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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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EC REP

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