TiLock Pedicle Screw 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.

DESCRIPTION and INTENDED USE:
The Genesys Spine TiLock Pedicle Screw System is comprised of polyaxial screws (solid and cannulated) and monoaxial screws in various lengths and diameters, lock plugs, crosslinks, tulips and rods in various lengths. The TiLock System only allows the placement of 5.5 mm titanium rods.

The TiLock cannulated polyaxial screws may be implanted via a minimally invasive technique. Manual instrumentation for implantation of the system is available for both conventional and minimally invasive procedures. The minimally invasive procedure is performed using k-wire and fluoroscopy, which allows the implanting surgeon to employ two smaller incisions rather than a longer midline incision.

The TiLock tulips are available in three (3) configurations: standard, break off and extended tab. The extended tab tulip is only assembled utilizing cannulated screws, as it is intended to facilitate screw insertion during minimally invasive procedures.

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 TiLock Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

CONTRAINDICATIONS:

1. Disease conditions which have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.
2. Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.
3. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other posterior spinal instrumentation system.
4. Any entity or condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis or osteopenia, is a relative contraindication. Other relative contraindications include obesity, pregnancy, certain degenerative disease, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, some patients may, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant. See also the WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS sections of this insert.

MATERIALS:
The TiLock System implants are manufactured from implant grade titanium (ASTM F136). Surgical instruments provided with the system are manufactured from stainless steel (ASTM F899).

The Genesys Spine TiLock Pedicle Screw 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 TiLock Pedicle Screw System components may not be used with components from any other system or manufacturer. As with other orthopedic implants, none of the TiLock Pedicle Screw 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 **GL206 Inline Rod Reducer**: Close the handle to unscrew the inner shaft for cleaning. To reassemble, close the handle, drop in the inner shaft, open the handle, & screw in the inner shaft. For the **GLC400 MIS TTS Rod Inserter**, **GLC406 MIS Rod Inserter, GLC422 MIS Offset Rod Inserter, & GLC431 MIS Angled Rod Inserter**: remove the inner shaft by unscrewing the knob from the handle. For the **GL417 MIS Rod Caliper**: remove the knob. For the **GL324 Speed Driver Handle**: remove the side handle by unscrewing the side handle from the main handle. For the **GLC425 MIS Disc Space Adjuster**: to disassemble, flip the ratchet switch to "DISTRACT" and slide the slider assembly off the rack. To reassemble, flip the ratchet switch to "COMPRESS" and slide the slider assembly on over the rack. For the **GLC450 MIS Modular Disc Space Adjuster**: to disassemble, press and hold the button on the Slide and remove the Slide from the Rack while the button is compressed. To reassemble, press and hold the button on the Slide and inserter the rack through the Slide's window. For the **GL217 Sleeved Thread-In Driver**: remove the outer sleeve by pulling the sleeve toward the tip of the instrument. During reassembly push the outer sleeve on until it snaps in place.
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 TiLock System components are provided in a surgical kit, which is comprised of stainless steel and anodized aluminum instrument cases, and plastic implant caddies with Radel lids.

All implants and instruments are supplied visually clean and non-sterile and must be sterilized prior to use. The following sterilization cycle is expected to result in a SAL of 10^{-6} and was validated prior to marketing in accordance with applicable standards:

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

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. If an unused implant entered the surgical wound it should be cleaned and re-sterilized after surgery.

POSTOPERATIVE MOBILIZATION:
Careful patient handling for two to four months 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, PRECAUTIONS, AND ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES

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.

WARNINGS:

1. IN THE U.S.A., THIS PRODUCT HAS LABELING LIMITATIONS.

2. THE SAFETY AND EFFECTIVENESS OF PEDICLE SCREW SPINAL SYSTEMS HAVE BEEN ESTABLISHED ONLY FOR SPINAL CONDITIONS WITH SIGNIFICANT MECHANICAL INSTABILITY OR DEFORMITY REQUIRING FUSION WITH INSTRUMENTATION. These conditions are significant mechanical instability secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions is unknown.

3. BENEFIT OF SPINAL FUSIONS UTILIZING ANY PEDICLE SCREW FIXATION SYSTEM HAS NOT BEEN ADEQUATELY ESTABLISHED IN PATIENTS WITH STABLE SPINES.
Potential risks identified with the use of this device system, which may require additional surgery, include:

a) Device component fracture.
b) Device component fracture.
c) Loss of fixation.
d) Non-union.
e) Fracture of the vertebra.
f) Neurological injury.
g) Vascular or visceral injury

4. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.
The potential for satisfactory fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

5. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NON-UNION. Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

6. MIXING METALS CAN CAUSE CORROSION.
There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc. which come into contact with other metal objects, must be made from like or compatible metals.

7. 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) The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.
b) 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 device.
c) A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
d) Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary relief.
e) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
f) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.

8. 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. THE IMPLANTATION OF PEDICLE SCREW SPINAL SYSTEMS SHOULD BE PERFORMED ONLY BY EXPERIENCED 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.
2. SURGEONS SHOULD HAVE KNOWLEDGE OF HOW TO TARGET PEDICLE SCREWS USING FLUOROSCOPY AND KWIRE WHEN UTILIZING A MINIMALLY INVASIVE SURGICAL TECHNIQUE.
3. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted metal implant should never be re-implanted. Even though the device appears 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. Contouring of the metal implants should only be performed with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease fatigue life and may cause failure.
5. REMOVAL OF THE IMPLANT AFTER HEALING. Metallic implants can loosen, fracture, corrode, migrate, 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 refracture. 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.
6. 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 that physical activity and full weight bearing have been implicated in bending or fracture. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weigh- supporting devices may be particularly at risk during postoperative rehabilitation.
7. MAGNETIC RESONANCE (MR) ENVIRONMENT. The TiLock System has not been evaluated for safety and compatibility in the MR environment. The TiLock System has not been tested for heating or migration in the MR environment.
8. PATIENT SELECTION. Based on fatigue testing results, when using the Genesys Spine TiLock Pedicle Screw System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.
9. Instruments should not be used in any capacity other than their intended use

POSSIBLE ADVERSE EFFECTS

1. Non-union, delayed union.
2. Bending or fracture of implant. Fraying, kinking, loosening, bending, or breaking of any or all of the cable implant components.
3. Loosening of the implant.
4. Metal sensitivity, or 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. Cable cutting through soft osteoporotic, osteogenic or cancellous bone.
10. 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. Bursitis.
12. Dural leak.
13. Paralysis.
14. Death.
15. 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 for current information.

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For product information, questions pertaining to sales and service, or to request a surgical technique manual, please contact your local sales representative or Genesys customer service.

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