ChoiceSpine™

Proliant® Posterior Pedicle Screw and Hook Fixation System

Instruction for Use

℞ only

IMPLANTS

NON STERILE

CE 2797

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USA

General Description:
The ChoiceSpine Proliant Posterior Pedicle Screw and Hook Fixation System is a top-loading spinal fixation system including screws, rods, and connectors for fixation to the thoracic, lumbar and sacral spine. Various sizes of the implants are provided. The components are manufactured from titanium alloy (Ti-6Al-4V ELI as described by ASTM F136) with rods being available in both titanium alloy and cobalt chrome alloy (Co-28Cr-6Mo, per ASTM F1537). The Proliant Posterior Pedicle Screw and Hook Fixation System components are provided clean and non-sterile. The products must be steam sterilized by the hospital prior to use.

Indications for Use:
The Proliant Posterior Pedicle Screw and Hook Fixation 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 acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine.

The Proliant Posterior Pedicle Screw and Hook Fixation System is intended for posterior, noncervical pedicle and non-pedicle fixation for the following indications: (DDD) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis including severe spondylolisthesis (Grade 3 & 4) of L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; trauma (i.e., fracture or dislocation); spinal stenosis; curvature (i.e., scoliosis, kyphosis, and/or lordosis); tumor; and failed previous fusion (pseudoarthrosis).

Contraindications:
Contraindications for the Proliant Posterior Pedicle Screw and Hook Fixation System are similar to those of other systems of similar design, and include, but are not limited to:

- Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
- Morbid obesity
- Pregnancy
- Grossly distorted anatomy (e.g., congenital abnormalities) and bone abnormalities (e.g., bone absorption, osteopenia, or osteoporosis) preventing safe screw fixation
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery
- Suspected or documented metal allergy or intolerance

Warnings and Precautions:
The Proliant Posterior Pedicle Screw and Hook Fixation System should only be implanted by experienced spinal 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. In addition, based on the fatigue test results, the surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions (e.g., smoking, occupation), which may impact the performance of the system.

MR Magnetic Resonance Environment

MR Conditional: (implants only)
Non-clinical testing has demonstrated that the Proliant Posterior Pedicle Screw and hook Fixation System is MR Conditional under a range of exemplar configurations. A patient with the devices implanted in a way substantially and effectively similar to tested configurations can be safely scanned in an MR system under the following conditions:

- System contains only rods, connectors, screws, offsets, and hooks.
- Rods are oriented primarily parallel to the axis of the bore of the magnet and screws are oriented substantially perpendicular to the axis of the bore of the magnet.
- Screws are nominal length 95mm or less.
- Rods and constructs are length 600mm or less.
- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T).
- Maximum spatial gradient field of 19 T/m (1900 G/cm).
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode)

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than or equal to 11°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends radially up to 4.2cm and 7.6cm (respectively) from the device when imaged with a gradient echo pulse sequence in a 1.5T MR system and a spin echo pulse sequence in a 3.0T MR system.

Preoperative:
A successful result is not achieved in every surgical case, especially in spinal surgery where many extenuating circumstances may compromise results. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are critical considerations in achieving a successful result.

Only patients that meet the criteria described in the indications should be selected. Patient conditions and/or predispositions such as those mentioned in the contraindications should be avoided.

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 or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.

The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.

Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins.

All components and instruments must be cleaned and sterilized prior to use. Additional sterile components should be available in case of unexpected need.

Intraoperative:
The surgeon should follow established practices and specific instructions for implantation of the system.

Contouring or bending of a screw may reduce its fatigue strength and cause failure under load. If screws are bent or damaged during insertion or adjustment, they may not be implanted and must be replaced. Rods should only be contoured with the proper contouring instruments. Incorrectly contoured rods or rods which have been repeatedly or excessively contoured should not be implanted.

Bone grafts must be placed in the area to be fused.

Some degree of corrosion occurs on all implanted metal and alloys. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.

Different manufacturers use different materials, varying tolerances and design configurations. Components of the Proliant Posterior Pedicle Screw and Hook Fixation System must not be used with components from any other system or manufacturer.

Postoperative:
The physician's post-operative directions and warnings to the patient and the corresponding patient compliance are extremely important.

Detailed instructions on the use and limitations of the device should be given to the patient.

The patient should be instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation.

Patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent restriction in body motion. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.

If a non-union develops or the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening or breakage of the device(s).

Any decision to remove the implants should take into consideration the risk to the patient of additional surgeries, as well as the difficulty of removal.

Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the Proliant Posterior Pedicle Screw and Hook Fixation System components should be reused under any circumstances.

Possible Adverse Effects:
Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems, and include, but are not limited to:

- Early or late loosening of the components
- Disassembly, bending or breakage of any or all of the components
- Foreign body (allergic) reaction to the implants
- Infection
- Non-union (pseudoarthrosis)
- Loss of neurological function
- Excessive blood loss
- Misalignment of anatomical structures or loss of spinal mobility
- Reduction in bone density due to different distribution of mechanical stresses
- Cessation of any potential growth of the operated portion of the spine
- Death

Additional surgery may be necessary to correct some of these potential adverse effects.

Intended Clinical Benefit:

- Possibility of a higher fusion rate
- To preserve decompression neural structures, which provides pain relief, and to prevent movement or motion postoperatively which can cause pain

How Supplied:

The Proliant Posterior Pedicle Screw and Hook Fixation System devices are provided clean, but non-sterile and must be sterilized prior to use. Implants are intended for single use only. Instruments can be reprocessed using the recommended cleaning instructions.

Cleaning and Decontamination:
All instruments and implants are supplied to the health care facility clean but non-sterile. Implants are single use only but need to be sterilized before each use. Additionally, all instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using methods recommended in this document or established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse. Process instruments as soon as is reasonably possible after use. It is recommended not to delay cleaning for more than 2 hours.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.

These devices are packaged in a convenience caddy/case. All devices must be removed from the case, inspected and cleaned via one of the appropriate methods below. Where applicable, instruments should be disassembled prior to cleaning and reassembled prior to sterilization. All devices must be placed back into the caddy and case prior to steam sterilization.

Recommended Cleaning:
The terms "Steris 444", "Enzol®" and "Prolystica®" are tradenames of ultrasonic equipment and detergents utilized in the recommended cleaning instructions. Any ultrasonic washer or equivalent ultrasonic detergent can be utilized when used in accordance to the manufacturer's instructions and labeling.

Automated Cleaning:

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
3. Transfer instrument(s) into a STERIS 444 washer with the following parameters. Incline the instrument(s) to assist in drainage. Motor speed: High.

Phase	Time (min)	Temperature	Detergent
Pre-Wash 1	1:00	Cold Tap Water	N/A
Enzyme Wash	1:00	Hot Tap Water	Enzol® at 1 oz per 1 gal water
Wash 1	2:00	60°C	Prolystica® 2x Conc. Neutral at 1/8 oz per 1 gal water
Rinse 1	1:00	Hot Tap Water	N/A
Drying	7:00	115°C	N/A

4. Remove instruments and inspect for soil, repeat cleaning if necessary.

Mechanical Cleaning (Ultrasonic):

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & rinse with cool tap water (< 35°C) for at least one (1) minute.
7. Prepare the ultrasonic cleaner with an Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55°C).
8. Load instrument(s) into the cleaner & sonicate for ten (10) minutes.
9. Remove instrument(s) from cleaner & thoroughly rinse using reverse osmosis/ deionized (RO/DI) water for at least one (1) minute.
10. Dry instrument(s) using a clean, soft towel & filtered, pressurized air (20 psi).
11. Visually inspect for soil. Repeat if necessary.

Manual Cleaning:

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & thoroughly rinse with reverse osmosis/ deionized (RO/DI) water for at least one (1) minute. Use a sterile syringe to aid in rinsing.
7. Dry instrument(s) using a clean, soft cloth & filtered, pressurized air (20 psi).
8. Visually inspect for soil. Repeat if necessary.

Care and Handling:

- All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.
- Refer to ASTM standard F1744-96, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information.
- Before use, instruments should be visually inspected, and function should be tested to ensure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, cracked, show excessive wear, or have other irregularities, DO NOT use.
- Lubricate instruments to protect instruments during sterilization and storage. This should be done with a water soluble, preserved lubricant after each cleaning. The lubricant should contain a chemical preservative to prevent

bacterial growth and be made with distilled water. Excess lubricant should be wiped off prior to storage and sterilization.

Inspection:
The implants should be inspected after processing, prior to sterilization. Any implant with damage, corrosion, discoloration, scratches, residue, or debris should be discarded.

Sterilization:
ChoiceSpine devices are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Implants and Instrument are recommended to be steam sterilized by the hospital using the following process parameters.

Steam Sterilizer Type: Pre-Vacuum
Temperature: 134°C
Duration: 3 minutes
Drying Time: 60 minutes

All devices are to be wrapped in two-layers of 1-ply polypropylene wrap (Kimguard KC400 or equivalent) using various wrapping techniques per ANSI/AAMI ST79.

Single Use Only:
Never reuse an implant. Any implant that has been twisted, bent, or implanted, then removed, even if it appears intact, must be discarded. These devices are provided as single use only.

Storage and Handling:
Implants should be stored in the implant sterilization case in clean, dry, well-ventilated conditions away from floors, ceilings, and outside walls. Store and transport sterile implants in such a way as to maintain sterility and functional integrity. Do not use implants if the sterilization wrap is opened, damaged or wet. Implants should remain covered until needed to avoid contamination. Only those to be implanted should be handled. Instrument and Implant disposal should follow local hospital disposal instructions, or the explanted implants may be returned to ChoiceSpine for disposal.

Limitations and Restrictions:
Repeated sterilization according to these instructions has a minimal effect on ChoiceSpine devices. Sterilization equipment varies in performance characteristics and must be validated accordingly. The sterilizing facility is responsible for the routine validation and monitoring of all equipment, materials and personnel used in their facility to ensure the desired results are achieved. These instructions have been validated as being capable of sterilizing these ChoiceSpine implants and instruments. Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

Patient Education:
It is essential to provide preoperative instructions to the patient. The patient should be made aware of the potential risks of the surgery and the implant limitations. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components.
The patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Device Retrieval Efforts:
Should it become necessary to remove any or all of the Proliant® Posterior Pedicle Screw and Hook Fixation System components, please call ChoiceSpine at the number below to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information.

Surgical Technique Manual:
The Proliant Posterior Pedicle Screw and Hook Fixation System Surgical Technique Manual is available by contacting ChoiceSpine Sales Support.

Product Complaints:
The customer or health care provider should report any dissatisfaction with the product quality, labeling, packaging or performance to ChoiceSpine immediately. Furthermore, if any of the implants "malfunction" (i.e., do not meet any of their performance specifications or otherwise do not perform as intended) and may have caused or contributed to the death or serious injury of the patient, ChoiceSpine should be notified immediately by telephone, fax or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

Some components may not be currently available. Please contact your ChoiceSpine representative for additional information. The products discussed herein may be available under different trademarks in different countries. All copyrights and pending and registered trademarks are property of ChoiceSpine. For more information on a specific product or trademark, please contact your local ChoiceSpine representative.

Product Lifetime:
The intention of the spinal implants included in this submission are to provide short-term stability while fusion occurs. The implant devices are mechanically tested in static and dynamic loading. Dynamic testing to 5,000,000 cycles is intended to represent the number of cycles experienced by a patient over a two-year period based on a moderate activity level. Within a two-years of implantation, fusion is expected to occur which would alleviate the need for the implants to withstand loading. The minimum expected fusion expectancy would be one year therefore the lifetime range of our devices is one to two years. The device is intended to remain in the patient for the lifetime of the patient if fusion occurs.

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

Information:
See choicespine.com for more information.

See choicespine.com/patents/ for patent information.

Summary of Safety & Clinical Performance and Periodic Summary Update Report can be found at https://ec.europa.eu/tools/eudamed
The Basic UDI for this system is 084099610320050FS.

For product complaints please contact:
ChoiceSpine, LLC
Quality/Regulatory Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; Fax: 865-588-4045

For additional product information please contact:
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Knoxville, TN 37919
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EC REP
Emergo Europe B.V.
Westervoortsedijk 60
6827 AT Arnhem
Netherlands

Symbol Legend:

Note: The symbol legend includes all symbols relative to ChoiceSpine portfolio. All the applicable symbols will either appear on the label or the IFU**.**

Symbol	Definition
	Do not reuse
	Caution, consult instructions for use for warnings and precautions
	Consult instructions for use
	Do not use if package is damaged
	Lot number
	Reference number
	Serial Number

STERILE R	Sterilized by irradiation
	Use by
	Manufacturer
	Date of Manufacture
Rx only	Federal law (USA) restricts this device to sale by or on the order of a physician
	Non-Sterile
	European Medical Devices
EC REP	Authorized representative in the European Community
	MR Conditional
UDI	Unique Device Identification
MD	Medical Device