Senecka Spine
Seneka I and II Polyscrew Pedicle Fixation System

Senecka Spine	**SENEKA I and II Polyscrew Pedicle Fixation System**	***Please Read Carefully***

CAUTION: FEDERAL LAW (USA) RESTRICTS use of THESE DEVICES TO SALES BY OR ON THE ORDER OF A PHYSICIAN.

Description:

The Seneka I and II Polyscrew Pedicle Screw System is an implant device made from a titanium alloy TI 6Al 4V-ELI. It is to be implanted from the posterior approach. The screws are available as either solid or cannulated in diameters from 4.5-8.5 mm and in lengths from 30-120 mm. Rods are available in 5.5mm diameter either straight or pre-curved in lengths from 30-400 mm in Pure Titanium (CPTi), Ti6Al-4V Alloy and Cobalt-Chrome Alloy. The system includes set screws, polyaxial heads along with the associated instrumentation to complete the procedure and implant construct.

Indications: The Seneka I and II Polyscrew Pedicle Fixation System is intended for noncervical pedicle fixation and non-pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: 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: Contraindications include, but are not limited to:

-infection, systemic or localized

-fever or leukocytosis

-suspected or documented sensitivity or allergies to the implant materials

-presence of congenital abnormalities, vague spinal anatomy, tumors, or any other condition which prevents secure implant screw fixation and/or decreases the useful life of the device

Cautions and Precautions

CAUTIONS:

- Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium components must NOT be used together.
- Do not use components of the Pedicle Screw System with components from any other manufacturer.
- As with all orthopedic implants, none of the Pedicle Screw System components should ever be reused under any circumstances.
- Implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system.

Precautions: When used in the following conditions, the surgeon must weigh the risks versus potential benefits.

- History of Smoking
- Morbid obesity
- Mental illness
- Alcoholism or drug abuse
- Pregnancy
- Severe osteopenia
- Any condition having inadequate tissue coverage over the operative site

- Any circumstances not described under Indications for Use
- Patients unwilling or unable to follow post-operative instructions

Preoperative:

Preoperative instructions to the patient are essential.

Care should be used in the handling and storage of the implant components. The implants should not be damaged. Implants should be protected from corrosive elements during storage. The type of construct required for the surgery should be determined prior to beginning the surgery. Implants and instruments must be inspected, cleaned and sterilized prior to use in the operative field.

Intraoperative:

Breakage, slippage, misuse, or mishandling of the instruments or implant components, such as on sharp edges, may cause injury to the patient or operative personnel. The implants must be handled and contoured carefully so as to avoid damage to the surface. Before closing the soft tissues, all of the set screws should be tightened firmly according to the operative surgical technique. The tightness of all set screws must be rechecked before wound closure to ensure that no loosening occurred during tightening or manipulation of the other implants. Explanted implants must never be reused.

Post-Operative:

The patient should be instructed in the proper use of crutches, canes, external braces or any other weight bearing or assist devices that may be required, and limit those physical activities which would place excessive stresses on the implants or cause delay of the healing process. The patient should also be instructed in the proper methods to ambulate, climb stairs, get in and out of bed and perform activities of daily living, while minimizing rotational and bending stresses.

Warnings:

- 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.
- This device system is not intended to be the sole means of spinal support. Its use without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending, loosening or fracture of the implant will eventually occur. The proper selection and compliance of the patient will greatly affect the results.
- Even with the use of spinal implants, a successful result in terms of pain, function, or fusion is not always achieved in every surgical case.
- This Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. This Pedicle Screw System has not been tested for heating or migration in the MR environment.

Possible Adverse Effects:

Pre-operatively, the patient should be made aware of the following possible adverse effects of spinal implant surgery. Additional surgery may be necessary to correct some of these effects:

- Early or late loosening of the components
- Rod migration
- Disassembly, bending, loosening, and/or breakage
- Foreign body reaction to the implants including possible tumor migration
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site which may result in skin breakdown and/or wound complications
- Pressure on the skin from components where there is inadequate tissue coverage over the implant
- Loss of proper spinal curvature, correction, height, and/or reduction
- Infection
- Hemorrhage of blood vessels and/or hematomas
- Bone graft, intervertebral body and/or sacral fracture at, above, and/or below the level of surgery
- Non-union or delayed union

- Loss of neurological function (e.g., bowel or bladder dysfunction), appearance of radiculopathy, and/or development of pain
- Neurovascular compromise including paralysis or other types of serious injuries
- Gastrointestinal and/or reproductive system compromise, including sterility
- Cessation of growth of the fused portion of the spine
- Death

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.

Decontamination, Cleaning, and Sterilization:

All Pedicle Screw implants and ancillary instruments are delivered non-sterile and therefore, must be decontaminated, cleaned and sterilized prior to surgical use.

Decontamination and cleaning reduces the population of microorganisms and facilitates subsequent sterilization. Strict compliance with instructions pertaining to decontamination, cleaning, and sterilization is mandatory. These processes are validated to AAMI standards TIR 12 and TIR 30.

Pedicle Screw implants are provided clean, but not sterile. Once an implant comes in contact with any human tissue or bodily fluid, it should not be resterilized and used.

- **Decontamination and Cleaning**:

All instruments must first be thoroughly cleaned and decontaminated using the following method:

Clean instruments immediately after use to prevent drying of debris or body fluids. If cleaning must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying.

Loosen and/or disassemble instrument with removable parts.

Remove any debris with a water moistened gauze pad. Substitute a fresh pad if it becomes soiled.

Immerse the instruments and implants in a neutral pH detergent such as “Terg-A-Zyme” prepared in accordance with the manufacturer’s instructions and soak for 15 minutes.

Use a soft-bristle brush and a pipe cleaner to gently clean each instrument and implant (particular attention shall be given to cannulations, holes, and other hard-to-clean areas) until all visible soil has been removed.

After manual cleaning, rinse with deionized or purified water and dry with a lint-free cloth. Drain and wipe dry using a sterile gauze pad.

Visually inspect all instruments to assure there is no visual contamination. If any visual contamination is detected, repeat the cleaning process prior to sterilization.Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage, particularly instruments; these solutions should not be used. All products should be treated with care; improper use or handling may lead to damage and possible improper functioning of the device

Sterilization: It is imperative to steam-sterilize the kits under the following operating conditions:

Steam Sterilization, pre-vacuum, wrapped in an FDA Cleared Wrap

Minimum duration	Minimum temperature	Number of Pulses	Dry Time
4 minutes	132˚C (270˚F)	4	30 minutes
Recommended duration	Minimum Temperature		Dry Time

15 minutes	132˚C (270˚F)		30 minutes

NOTE: **Sterilization does not replace decontamination or cleaning**. **Only a clean product can be correctly sterilized.**

Only sterile implants and instruments may be used for surgery.

Useful life of instruments

Routinely inspect devices for wear and tear. If evidence of wear such as corrosion, pitting, or discoloration is observed, dispose of the instrument and obtain a new instrument from the manufacturer. If any cutting instruments become dull and do not function properly, obtain a new instrument from the manufacturer.

Surgical Technique Manual

The Seneka II and I Polyscrew Pedicle Screw System Surgical Technique is available by contacting Senecka Spine's Customer Service.

PRODUCT COMPLAINTS:

The customer or health care provider should report any dissatisfaction with the product quality, labeling, packaging or performance to Senecka Spine 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, Senecka Spine 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.

For Product Complaints or for additional product information please contact:
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Deidre Danek
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