This package insert covers the Savannah® Spinal System and Manual Surgical Instruments that are used for the implantation of this system. Specific sections for implants and instrumentation highlight important user information for only those devices.

GENERAL INFORMATION

Implants
Spinal Elements’ Savannah® Spinal System is comprised of a variety of pedicle screws, mono-axial and poly-axial screw heads, connecting rods, set screws, and transverse crossmembers, called the Savannah-Link. System components are available in a multitude of sizes and configurations. A variety of constructs may be assembled to suit the individual pathology and anatomy of the patient. All implant components are made from titanium alloy (Ti-6Al-4V) conforming to ASTM F 136 or ASTM F1472 and are provided non-sterile for single-use.

Spinal Elements’ instruments are manufactured from various stainless steels, titanium, aluminums, and polymers. All materials used have a history of use in such instruments. All implants are intended for single patient use only and should not be reused (used in additional patients) under any circumstances. Reuse may result in serious injury or death. Components from this system should not be used in conjunction with components from other systems.

INDICATIONS

The Savannah-T® is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or stabilization of spinal segments as an adjunct to fusion in the presence of the following conditions:

- kyphosis; spinal tumor; and/or failed previous fusion
- osteoporosis involving the spine
- active infection at the site of surgery
- any abnormality present which affects the normal process of healing
- neurological impairment and/or severe spondylolisthesis (grades 3 and 4)
- any abnormality present which affects the normal process of healing
- infection.

CONTRAINDICATIONS

Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.

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SAVANNAH® SPINAL SYSTEM AND INSTRUMENTATION

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- infection.

CONTRAINDICATIONS

Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.

2. Insufficient quality or quantity of bone which would inhibit rigid device fixation.
3. Previous history of infection.
4. Excessive local inflammation.
5. Open wounds.
6. Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
7. Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
8. Patients having inadequate tissue coverage of the operative site.
10. A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure of the device.
11. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to the implantation.
12. Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.

WARNINGS

Implants and instruments are provided non-sterile. Instruments must be cleaned and sterilized before use. Implants may be reprocessed prior to use and must be sterilized before use. Valid sterilization protocols are listed in the STERILIZATION section of this insert. Implants that have come in direct contact with a patient or bio-contaminants should be disposed of.

Some instruments may be sharp, depending on their intended use. Care should be taken in handling such instruments to avoid injury to the user or patient.

The safety and effectiveness of pedicle screw 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, dislocations, sclerosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). In addition, when used as a pedicle screw fixation system, the Savannah-T® device is intended for use in spinal segments for which the bone quality and/or nerve paralysis are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion due to the development of cardiovascular system compromise.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.

MAGNETIC RESONANCE ENVIRONMENT

The Savannah® Spinal System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POSSIBLE ADVERSE EVENTS

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Loss of fixation (implant migration).
4. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, tissue reaction from the implant, staining, tumor formation, and/or autoimmune disease.
5. Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
6. Pain, discomfort, or abnormal sensations due to the device itself.
7. Pressure on the skin from components where inadequate tissue coverage exists over the implant, with the potential for extrusion through the skin, seroma or wound dehiscence.
8. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
9. Infection or delayed infection or wound healing.
10. Dural tears, persistent CSF leakage, fistula requiring surgical repair, meningitis.
11. Loss of neurological function including paralysis (partial or complete), neurovascular compromise, radiculopathy, and/or the development or continuation of pain, paresthesia, numbness, foot-drop, spams, or sensory loss.
12. Caused by the device itself.
13. Loss of bladder control or other types of urological system compromise, gastrointestinal disorders.
14. Scarp formation possibly causing neurological compromise or compression around nerves and/or pain.
15. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
16. Soft tissue injury, vascular, or visceral injury.
17. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.

PREOPERATIVE MANAGEMENT

1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should complete understanding of the device’s indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Devices must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. All implants and instrument should be inspected for wear and tear prior to use. Devices presenting damage such as cracks, corrosion, bends etc. should not be used. Compromised devices should be segregated and not returned to Spinal Elements.
7. The type of implant to be used for the case should be determined prior to beginning the surgery.
8. All instruments and implants should be processed and sterilized prior to use.

INTRAOPERATIVE MANAGEMENT

1. Prevention should be taken in handling the implants. Damage to the implants may affect their performance.
2. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.

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7. The type of implant to be used for the case should be determined prior to beginning the surgery.
8. All instruments and implants should be processed and sterilized prior to use.
POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and complying with the patient, of the following is essential:

1. The patient should have a complete understanding of and compliance with the purpose and limitations of implant devices.
2. Postoperative patients should be instructed to limit activity as determined by their surgeon. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loading, and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight bearing or muscular activity. The risk of bending, loading, or breakage of a temporary internal fixation device is severely increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in the spinal position.
3. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions, and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or anti-estroidal or anti-convulsant medications such as aspirin during the bone graft healing process.
4. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
5. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of immobilization, the stresses cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.

6. The implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine has healed, these devices serve no further functional purpose and may be removed. While the final decision on implant removal is up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) corrosion, with localized tissue reaction or pain; (2) migration of implant portion, possibly resulting in injury; (3) risk of additional injury from postoperative trauma; (4) bending, loosening and breakage, which could make removal impractical or difficult; (5) pain, discomfort, or abnormal sensations due to the presence of the device; (6) possible increased risk of infection; (7) bone loss due to stress shielding; and (8) potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.

7. Retrieved implants should be properly disposed of and are not to be reused under any circumstance.

8. Implants should not be sterilized non-sterile and must be sterilized before use. Non-sterile implants and instruments should be autoclavable sterilized using one of the following validated cycle parameters.

9. Instructions to limit and restrict physical activities, especially loading, should be given the patient. The patient must be warned that bending, loosening, and/or breakage of a temporary internal fixation device include, but are not limited to, mechanical failure, serious injury, transmission of infectious agents and death.

10. All equipment that comes apart for cleaning and do not retain liquid. Process per the cycle below. These are minimum validated parameters:

AUTOMATED CLEANING INSTRUCTIONS

All devices must be processed manually prior to automated cleaning. Follow the instructions below for the manual and automated washing.

PRE-AUTOMATED WASHER: MANUAL CLEANING

1. Immerse and soak for a minimum of five (5) minutes in enzymatic detergent at ≤43°C.
2. Immerse in Endozime® AW Plus enzymatic detergent (or equivalent neutral pH enzymatic cleaner) according to manufacturer recommendations and clean thoroughly for at least 14 minutes at ≤43°C. Scrub all external surfaces with a soft brush, but do not apply pressure. Specimen sites must be removed. It is important to make sure that areas of concern with complex or hidden surfaces are effectively cleaned. Use a small diameter brush to clean cannulation holes. Inspect for visible soil on exposed surfaces.
3. Rinse thoroughly for 2 hours with warm demineralized water. (Purified water at ≥27°C–44°C)

AUTOMATED CLEANING

4. Transfer the instruments into the automated washer for processing. Position the parts to allow for proper drainage. Ensure the instruments stay in place and do not touch or overlap so that the design features are accessible for cleaning and do not retain liquid. Process per the cycle below. These are minimum validated parameters:

MANUAL CLEANING INSTRUCTIONS

Follow the instructions listed below for manual cleaning prior to sterilization.

1. Immerse and soak for a minimum of five (5) minutes in enzymatic detergent at ≤43°C.
2. Immerse in Endozime® AW Plus enzymatic detergent (or equivalent neutral pH enzymatic cleaner) according to manufacturer recommendations and clean thoroughly for at least 14 minutes at ≤43°C. Scrub all external surfaces with a soft brush and make sure all visible soil has been removed. It is important to make sure that areas of concern with complex or hidden surfaces are effectively cleaned. Use a small diameter brush to clean cannulation holes. Inspect for visible soil on exposed surfaces.
3. Rinse thoroughly for 2 hours with warm demineralized water. (Purified water at ≥27°C–44°C)

STERILIZATION

Implants and instruments are provided non-sterile and must be sterilized before use. Non-sterile implants and instruments should be autoclavable sterilized using one of the following validated cycle parameters.

INFORMATION

For additional information regarding any of Spinal Elements’ Patents: patent.spinalelements.com

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CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician.