Saxxony® Posterior Cervical Thoracic System

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This booklet is designed to assist in using the Saxxony® Posterior Cervical Thoracic System. It is not a reference for surgical techniques.

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

GENERAL DESCRIPTION

The Saxxony® Posterior Cervical Thoracic System consists of rods, pedicle screw and hook anchors, connectors and set screws. Rods are available in either straight, prebent (curved) or transition forms in a variety of lengths. Polyaxial pedicle screws are available fully threaded or having a partially smooth shaft in a variety of diameter-length combinations. Connectors include rod-rod, rod-screw and screw-screw. Set screws fasten the rod, anchors and connectors. All implant components are manufactured from titanium alloy (Ti-6AL-4V ELI) per ASTM F136; transition rods are additionally available manufactured from cobalt chromium alloy per ASTM F1537.

INDICATIONS FOR USE

The Saxxony® Posterior Cervical Thoracic System is intended to immobilize and stabilize cervical (C1 to C7) and thoracic (T1 to T3) spinal segments as an adjunct to fusion for the treatment of the following acute and chronic instabilities: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The Saxxony® Posterior Cervical Thoracic System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Saxxony® Posterior Cervical Thoracic System rods may be connected to cervicothoracic or thoracolumbar stabilization systems ranging in diameter from 3.5mm to 6.5mm, using corresponding rod to rod connectors and/or transition rods.

CONTRAINDICATIONS

The Saxxony® Posterior Cervical Thoracic System contraindications include, but are not limited to:

1. The presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, any demonstrated allergy or foreign body sensitivity to any of the implant materials, drugs/alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. Prior fusion at the level(s) to be treated.

4. Any condition not described in the Indications for Use.

WARNINGS AND PRECAUTIONS

1. The implantation of spinal fixation systems should be performed only by experienced spinal surgeons with specific training in the use of these spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant diameter and length.
2. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.
3. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the device.
4. These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.
5. The Saxxony® Posterior Cervical Thoracic System is used to augment the development of a spinal fusion by providing temporary stabilization. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant's longevity.
6. The correct handling of the implant is extremely important. Use care in handling and storage of devices. Store the devices in a clean, dry area away from radiation and extreme temperatures and corrosive environments such as moisture, air, etc.
7. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
8. Components of this system should not be used with components of any other manufacturer.
9. Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.

POTENTIAL 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: pseudarthrosis, insufficient bone stock, painful bursa, pressure necrosis, palpable components, 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; infections possible requiring removal of devices; loss of neurological function, including paralysis, spinal cord impingement or damage.

MRI SAFETY INFORMATION

The Saxxony® Posterior Cervical Thoracic 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 Saxxony® Posterior Cervical Thoracic System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CLEANING AND DECONTAMINATION

All instruments must first be cleaned before sterilization and introduction into a sterile surgical field. Refer to the Nexxt Spine ***Reprocessing Instructions for Reusable Instruments*** document available at www.NexxtSpine.com/Resources/Indications-For-Use or by calling 317-436-7801 for the detailed cleaning instructions.

STERILIZATION

The Saxxony® Posterior Cervical Thoracic System and instruments are supplied NON-STERILE and must be cleaned and sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap is recommended. The following validated steam autoclave cycle has been validated to an SAL of 10^{-6}.

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270°F (132°C)	4 minutes	30 minutes

INSTRUCTIONS FOR USE

The Saxxony® Posterior Cervical Thoracic System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Refer to Saxxony® Posterior Cervical Thoracic System Surgical Technique for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Nexxt Spine customer service by phone, 317-436-7801.

 **INSTRUCTIONS:**

PREOPERATIVE

1. Preoperative Planning - Use of cross-sectional imaging (i.e., CT and/or MRI) for posterior cervical screw placement is recommended due to the unique risks in the cervical spine. The use of planar radiographs alone may not provide the necessary imaging to mitigate the risk of improper screw placement. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.
2. Preoperative instructions to the patient are essential. The adverse effects, warnings, precautions and limitations should be understood by the surgeon and explained to the patient prior to the surgery.
3. Only patients that meet the criteria described in the indications should be selected.
4. Correct selection of the implant is extremely important. An adequate inventory of sizes should be available at the time of surgery.
5. Patient conditions and/or predispositions such as those mentioned in the Contraindications, Precautions and Warnings should be avoided.
6. The surgeon should be familiar with the use and handling of all components and instruments of the system prior to surgery.
7. Proper function of the surgical instruments and components should be verified prior to every surgical procedure. All instruments and components must be sterilized before use.

INTRAOPERATIVE

1. The primary goal of this surgery is to arthroses selected vertebrae. Adequate exposure, bony preparation, and grafting are essential to this result.
2. The placement of the Saxxony® Posterior Cervical Thoracic System devices should be checked radiographically.
3. Care should be taken when positioning the implants to avoid neurological damage. Extreme caution should be used around the spinal cord and nerve roots.

POSTOPERATIVE

1. Adequately instruct the patient on postoperative care, use and limitations and potential complications. Successful healing depends on postoperative care and the patient’s ability and willingness to follow instructions.
2. The patient must be made aware of the limitations of the implant and that physical activity and load bearing may cause premature loosening, bending or fracture of the internal fixation

device. The patient should be warned to avoid falls, sudden jolts, mechanical vibrations, and lifting, twisting motions and restrict any type of sport participation. An active, debilitated, or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation.

3. If a nonunion develops, or if the implants loosen, fracture, corrode, migrate, cause pain, or stress, the device(s) should be evaluated, revised and/or removed. Patients with evidence of these conditions should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity, revision or removal considered.
4. Periodic X-rays for at least the first year postoperatively are recommended to detect any evidence of nonunion, changes in position, loosening, bending or cracking of components.
5. Any retrieved devices must never be reused under any circumstances.

PRODUCT COMPLAINTS

The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Nexxt Spine immediately. Nexxt Spine should be notified immediately of any product malfunction 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.

SYMBOL DESCRIPTIONS

Reference number	Symbol	Title	Description of symbol per ISO 15223-1:2016 Standard (unless otherwise noted)
5.1.1		Manufactured by	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
5.1.5		Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
5.1.6		Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
5.2.7		Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
5.4.2		Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
5.4.3		Consult Instructions for use	Indicates the need for the user to consult the instructions for use.
		Prescription Only	CAUTION: Federal law restricts this device to sale by or on the order of a physician. (21 CFR Part 801.109(b)(1))

MANUFACTURED BY: Nexxt Spine, LLC
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