



NEXXT MATRIXX® Stand Alone Cervical – TL System

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This booklet is designed to assist in using the NEXXT MATRIXX® Stand Alone Cervical – TL System. It is not a reference for surgical techniques.
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DEVICE DESCRIPTION

NEXXT MATRIXX® is a collection of additively manufactured implants. The Stand Alone Cervical-TL System includes additively manufactured spacers and traditionally machined fixation screw implants. The spacer and screw components are available in an assortment of dimensional combinations to accommodate the individual anatomic and clinical circumstances of each patient. The basic shape of the spacer is a structural column to provide surgical stabilization of the spine. Each device comprises an external structural frame having a roughened surface (~7µm). The intervening geometric lattices have 300-700µm pores. The inferior/superior aspects of the spacer incorporates a vertical cavity which can be packed with bone graft material. Each interbody is preassembled with a turn lock mechanism which secures the screw to the spacer component. NEXXT MATRIXX® Stand Alone Cervical - TL System spacers and fixation screws are manufactured from Ti-6Al-4V ELI titanium alloy per ASTM F3001 and F136, respectively.

INDICATIONS

The NEXXT MATRIXX® Stand Alone Cervical - TL System is a stand-alone anterior cervical interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (C2-T1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). These patients should have received at least six weeks of non-operative treatment prior to treatment with the device. The NEXXT MATRIXX® Stand Alone Cervical - TL System is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and implanted via an open, anterior approach. The NEXXT MATRIXX® Stand Alone Cervical - TL System is intended to be used with the bone screw fixation provided and requires no additional fixation.

CONTRAINDICATIONS

The Stand Alone Cervical - TL 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, morbid 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. Any condition not described in the Indications for Use.
4. Prior fusion at the level(s) to be treated.

WARNINGS AND PRECAUTIONS

1. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.
2. The NEXXT MATRIXX® Stand Alone Cervical – TL System devices should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Prior to use, surgeons should be trained in the surgical procedures recommended for use of these devices.
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 NEXXT MATRIXX® Stand Alone Cervical -TL 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 NEXXT MATRIXX® Stand Alone Cervical – TL 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 NEXXT MATRIXX® Stand Alone Cervical – TL 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 using established hospital methods before sterilization and introduction into a sterile surgical field. Refer to the Nexxt Spine Reprocessing Instructions for Reusable Instruments document available at Nexxtspine.com/Resources/Indications-For-Use/ or by calling 317-436-7801 for the detailed cleaning instructions.

STERILIZATION

The NEXXT MATRXXX® Stand Alone Cervical – TL System implants are supplied STERILE. All sterile products are supplied in protective sterile barrier packaging. Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize or autoclave sterile implants.

The instruments are supplied NON-STERILE and must be 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 a 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 NEXXT MATRXXX® Stand Alone Cervical – TL 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 NEXXT MATRXXX® Stand Alone Cervical – TL System Surgical Techniques 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 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.
2. Only patients that meet the criteria described in the indications should be selected.
3. Correct selection of the implant is extremely important. An adequate inventory of sizes should be available at the time of surgery.
4. Patient conditions and/or predispositions such as those mentioned in the Contraindications, Precautions and Warnings should be avoided.
5. The surgeon should be familiar with the use and handling of all components and instruments of the system prior to surgery.
6. 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 arthodesse selected vertebrae. Adequate exposure, bony preparation, and grafting are essential to this result.
2. The placement of NEXXT MATRXXX® Stand Alone Cervical – TL 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.

MANUFACTURED BY:

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SYMBOL DESCRIPTIONS



Model Number



Lot Number



Sterilized Using Irradiation



Use By Date

Rx Only

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



Consult Instructions for Use



Do Not Reuse



Manufacturer