Matrixx System

14425 Bergen Blvd, Suite B, Noblesville, IN 46060 USA
Phone: 317-436-7801 Fax: 317-245-2518
www.nexxtspine.com

This booklet is designed to assist in using the Matrixx 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 Matrixx System is a collection of additively manufactured spacers for cervical, lumbar/lumbosacral and thoracolumbar implantation. The basic shape of these implants 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 pores 300-700µm. The inferior/superior aspects of the Matrixx open devices incorporate a large vertical cavity which can be packed with bone graft material. The inferior/superior aspects of the Matrixx solid devices are closed and do not permit the packing of bone graft within the implant. The solid devices are only to be used for partial vertebral body replacement. The open and solid devices are available in an assortment of height, length, width and lordotic angulation combinations to accommodate the individual anatomic and clinical circumstances of each patient. The Matrixx System implants are manufactured from Titanium Alloy (Ti6Al4V) as described by ASTM F3001.

INDICATIONS FOR USE
When used as a cervical intervertebral fusion device, the Matrixx System open devices are indicated for use at up to two contiguous levels in the cervical spine, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation.

When used as a lumbar intervertebral fusion device, the Matrixx System open devices are indicated for use at one or two contiguous levels in the lumbar spine, from L2-S1, in skeletally mature patients who have had six months of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Additionally, the Matrixx System lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The device is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation.

When used as a vertebral body replacement device, the Matrixx System open and solid devices are indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The device is intended for use with autograft or allograft and with supplemental internal fixation.

CONTRAINDICATIONS
The Matrixx 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. 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 Matrixx 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. The Matrixx solid devices are not intended for interbody fusion as bone growth through the device has not been demonstrated.
5. These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.
6. The Matrixx System is used to augment the development of a spinal fusion by providing temporary stabilization. This device is not intended to be the sole means of spinal support – supplemental internal fixation must be used. 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.
7. 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.
8. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
9. Components of this system should not be used with components of any other system or manufacturer.
10. 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 Matrixx 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 Matrixx 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 www.NexxtSpine.com/Nexxt_Spine_Products or by calling 317-436-7801 for the detailed cleaning instructions.

STERILIZATION

The Matrixx 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 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 Matrixx 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 Matrixx 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 arthodese selected vertebrae. Adequate exposure, bony preparation, and grafting are essential to this result.
2. The placement of the Nexxt Spine Matrixx 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:

Nexxt Spine, LLC
14425 Bergen Blvd, Suite B
Noblesville, Indiana 46060
Telephone: (317) 436-7801
Fax: (317) 245-2518
www.nexxtspine.com

SYMBOL DESCRIPTIONS

REF	Model Number	**Rx Only**	Caution: Federal law restricts this device to sale by or on the order of a physician
LOT	Lot Number		Consult Instructions for Use
STERILE R	Sterilized using irradiation		Do Not Reuse
	Use By Date		Manufacturer