NEXXT MATRIXX®

Corpectomy

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

NEXXT MATRIXX Technology®

3D Printed Porous Titanium

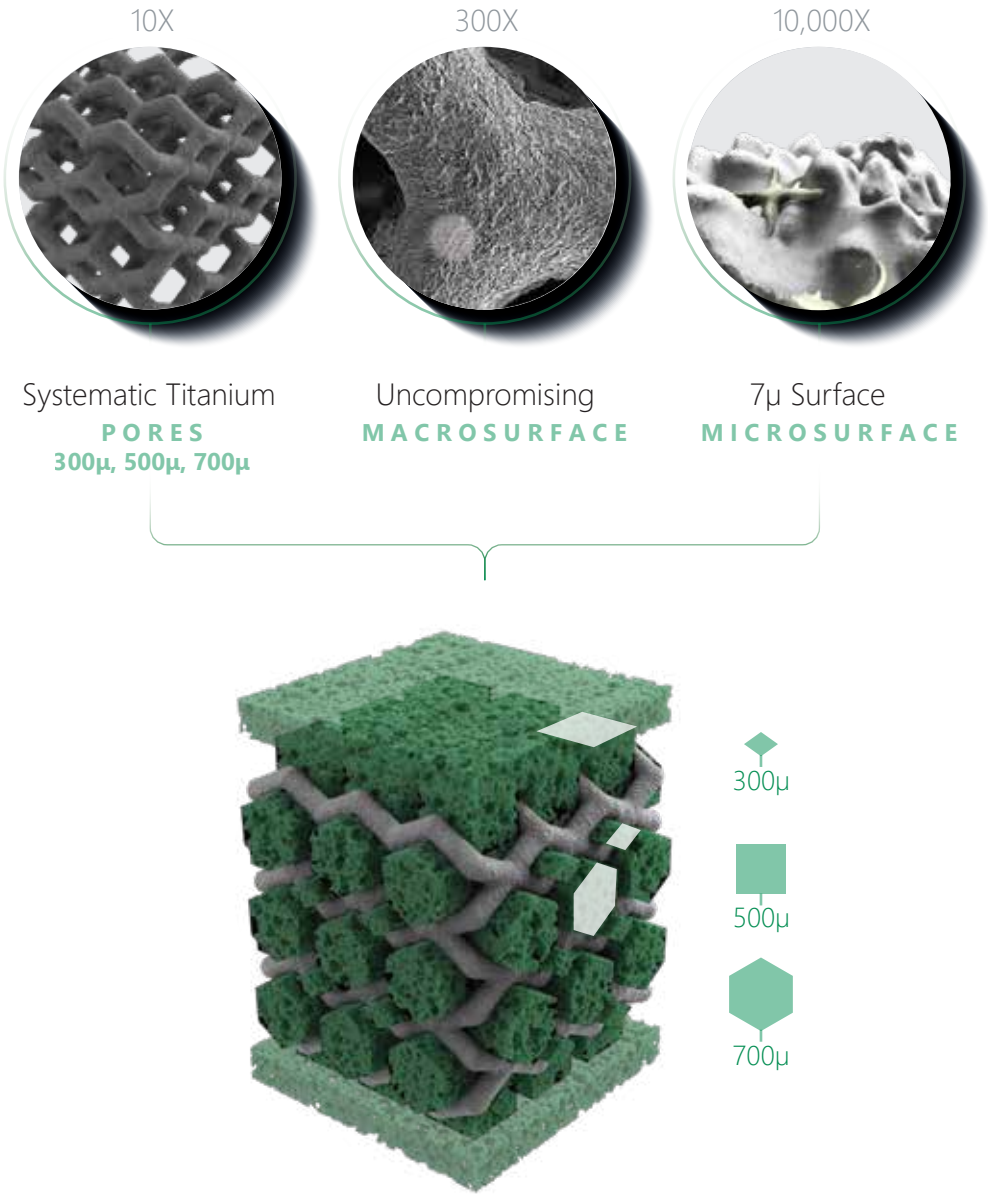


Image above used to illustrate available area for bony ingrowth.

System Features

NEXXT MATRIXX® | Corpectomy

NEXXT MATRIXX® 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 NEXXT MATRIXX® open devices incorporate a large vertical cavity which can be packed with bone graft material. These 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 NEXXT MATRIXX® implants are manufactured from Titanium Alloy (Ti6Al4V) as described by ASTM F3001.

Interbody

• 3D printed porous titanium alloy (Ti-6Al-4V ELI per ASTM F3001) integrated with NEXXT MATRIXX® technology.

• Roughened surface and aggressive inferior/superior teeth provide initial stabilization.

• 12x14mm Footprint
• 14x16mm Footprint

• Lordosis: 0° & 6°

• Heights:
11-50mm

*See page 13 for standard/available by request part numbers

Surgical Technique Steps

Step 1 - Patient Positioning
Following adequate general anesthesia, the patient is placed in a prone (thoracolumbar) or supine (cervical) position on a radiolucent spine table. Particular attention is applied to the positioning of the head and extremities to lessen the risk of ocular and nerve compression.

NOTE:
Due to potential risk of neural injury in the cervical spine, use of fluoroscopy and/or neuromonitoring during cervical procedures is recommended.

Step 2 - Exposure, Corpectomy, and Endplate Preparation
Access the operative site and retract soft tissues using preferred instruments. Perform a partial or complete corpectomy at the indicated level(s). Remove disc material and decorticate the end plates. A Rasp may be used to prepare the end plates if desired.

NOTES:
• Adequate preparation of the superior and inferior surfaces is critical in facilitating vascular supply to promote fusion.

• Incorrect preparation of the endplates may increase the risk factor for subsidence or vertebral body fracture, careful attention should be given to endplate preparation prior to insertion of the device.

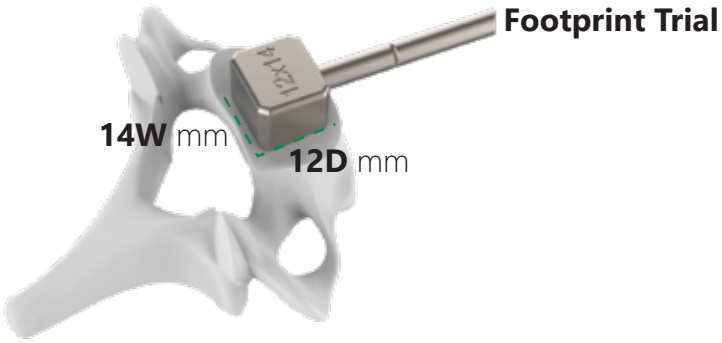
Surgical Technique Steps (Continued)

Step 3 - Implant Size Selection

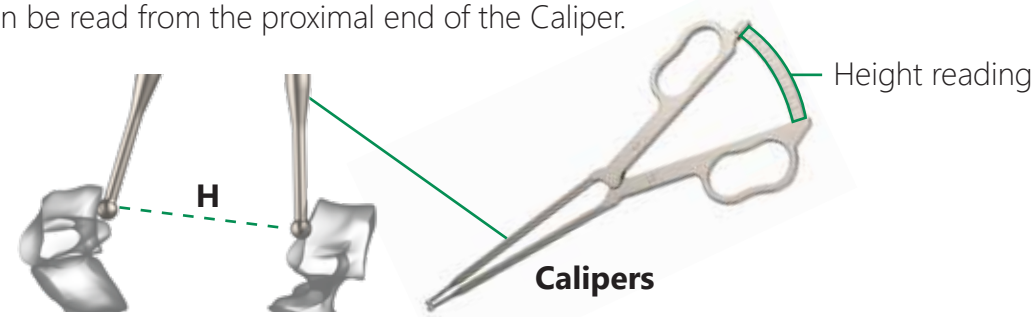
A distraction device may be used at the partial corpectomy site to facilitate restoration of the anterior column height.

1. Use a Footprint Trial to determine the width and depth of the disc space.

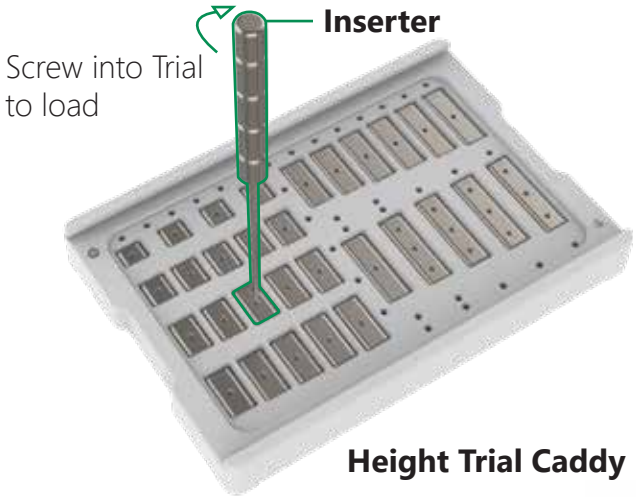
Trial Sizes:
- 12Dx14W mm
- 14Dx16W mm



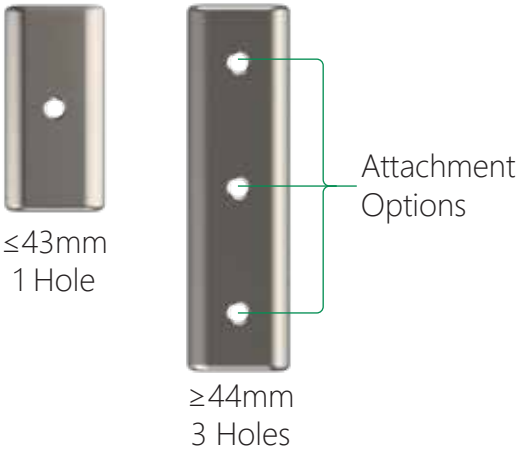
2. Determine the approximate height of the corpectomy site with the Caliper. Insert the Caliper into the site and gently squeeze the handles until the Caliper tips contact the inferior/superior endplates. The resulting height can be read from the proximal end of the Caliper.



3. Select the initial Height Trial from the Height Trial Caddy based on the Caliper reading.



Height Trial Caddy



NOTE:
Height Trials: 12Dx14Wx6° footprint
H 10-29mm in 1mm increments
H 30-50mm in 2mm increments

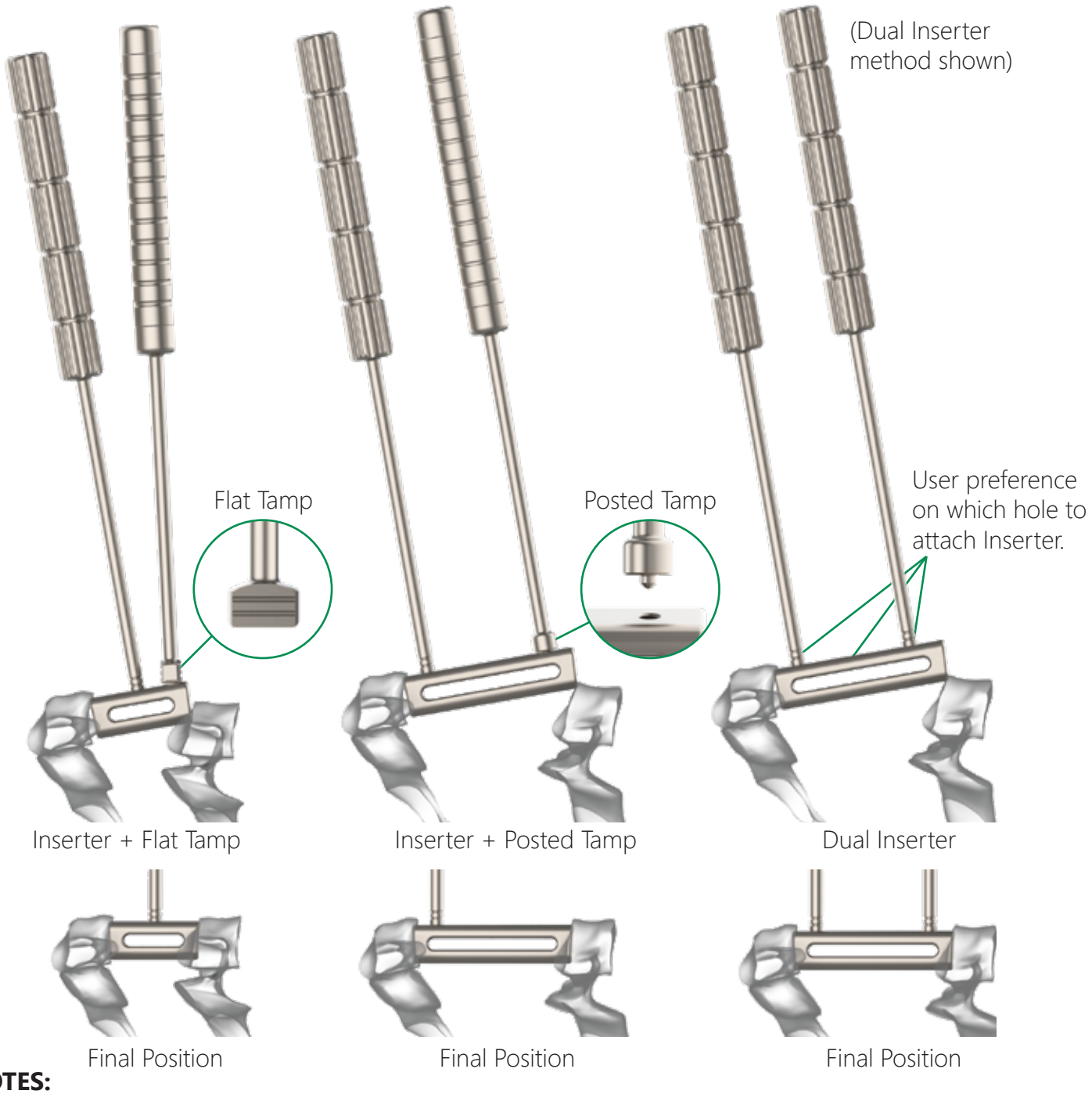
Height Trial and **Inserter**

Surgical Technique Steps (Continued)

4. Insert the Height Trial into the corpectomy site.

5. Tamp into place if desired with the Flat or Posted Tamp.

Approach Options:



NOTES:

- 10 & 11mm tall (height) Implants are indicated for use *only* in the lumbar spine.
- Posted Tamp should only be used to tamp at/on the Inserter hole(s).

Surgical Technique Steps (Continued)

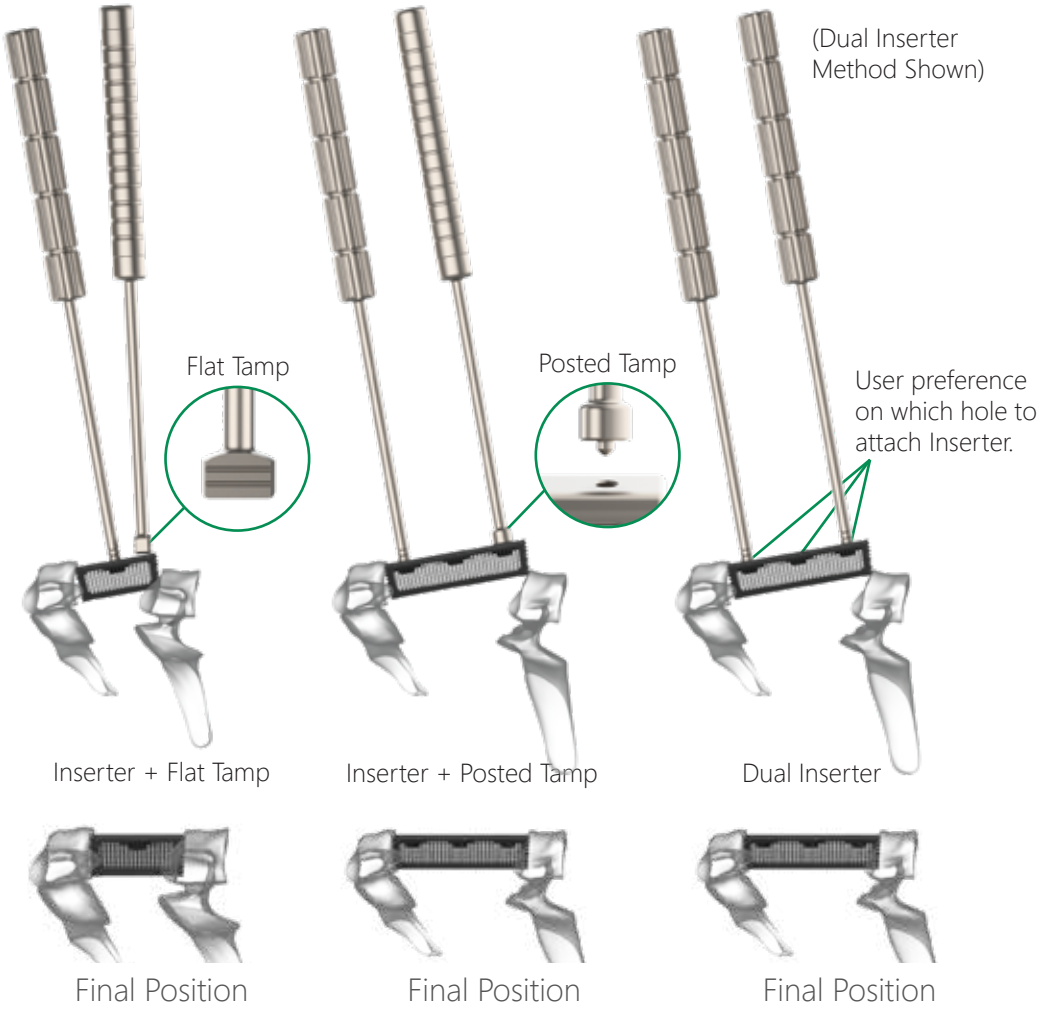
Step 4 - Implant Preparation and Insertion

Open the sterile packaging of the device that was determined during trialing. There is no need to undersize or oversize the device.

1. Attach the Inserter to the Implant and pack the center cavity of the Implant with autograft and/or allograft comprised of cancellous and or corticocancellous bone graft.
2. Insert the Implant into the intervertebral disc space.
3. Tamp into place if desired with the Flat or Posted Tamp.

Approach Options:

Mallet the top of Inserter(s) and Tamp



NOTES:

- 10 & 11mm tall (height) Implants are indicated for use *only* in the lumbar spine.
- Use caution when tightening the Implant to the Inserter to avoid stripping threads or overtightening where detachment of device from instrument becomes difficult.
- All Nexxt Matrixx® Corpectomy devices have superior/inferior teeth to help resist implant migration and expulsion while providing a high degree of initial stability.
- Implants are symmetrical down the Medial/Lateral midline.

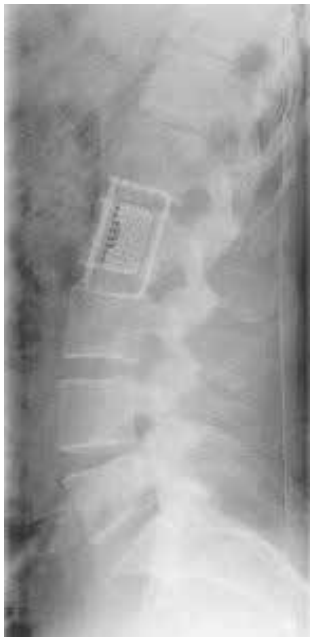
Surgical Technique Steps (Continued)

Step 4 - Implant Preparation and Insertion (Continued)

• The use of fluoroscopic imaging is recommended during any or all of the implantation steps to ensure proper positioning.

• Rotate the Inserter handle in a counterclockwise direction to release the Implant from the inserter.

• If the Implant requires further adjustment, use either the Flat or Posted Tamp to carefully manipulate the Implant into desired position.



Surgical Technique Steps (Continued)

Step 5 - Supplemental Fixation

• When used in the cervical spine at one or two levels, the NEXXT MATRIXX® Corpectomy is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine such as the Nexxt Spine Struxxure® Anterior Cervical Plate System. When used at more than two levels, supplemental fixation should include posterior fixation which is cleared by the FDA for use in the cervical spine such as the Saxxony® Posterior Cervical Thoracic System.

• When used in the thoracolumbar spine, the NEXXT MATRIXX® Corpectomy is intended to be used with supplemental fixation cleared by the FDA for use in the thoracolumbar spine such as the Nexxt Spine Inertia® Pedicle Screw System, Inertia® MIS System, or Facet Fixx® Screw System.

Step 6 - Device Removal

• Either the Inserter or Universal Removal Instrument may be used for device removal by attaching to the device via a clockwise rotation of the instrument to the implant threads.

• Be careful to avoid pushing the implant posteriorly. Once the implant is firmly attached, remove the implant from the disc space. Vertebral bone overgrowth or osteophytes may be removed to facilitate device retrieval.

Indications for Use

GENERAL DESCRIPTION

NEXXT MATRIXX® 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 NEXXT MATRIXX® open devices incorporate a large vertical cavity which can be packed with bone graft material. The inferior/ superior aspects of the NEXXT 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 NEXXT MATRIXX® implants are manufactured from Titanium Alloy (Ti6Al4V) as described by ASTM F3001.

INDICATIONS

The NEXXT MATRIXX® corpectomy devices are indicated for use in the cervical spine (C2-T1) and thoracolumbar spine (T1-L5) in skeletally mature patients to replace a diseased, collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders. The NEXXT MATRIXX® corpectomy devices are 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, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion. The NEXXT MATRIXX® corpectomy devices are intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion and with FDA-cleared supplemental internal fixation.

CONTRAINDICATIONS

NEXXT MATRIXX® 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. NEXXT MATRIXX® 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. NEXXT 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. NEXXT MATRIXX® 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.

NEXXT MATRIXX® Corpectomy Implant Part Numbers

Standard P/N	Description
12 x 14 Foot Print 0° Implants	
53-1214-16-0-SP	12Dx14Wx16H 0°
53-1214-18-0-SP	12Dx14Wx18H 0°
53-1214-20-0-SP	12Dx14Wx20H 0°
53-1214-22-0-SP	12Dx14Wx22H 0°
53-1214-24-0-SP	12Dx14Wx24H 0°
53-1214-26-0-SP	12Dx14Wx26H 0°
53-1214-28-0-SP	12Dx14Wx28H 0°
53-1214-30-0-SP	12Dx14Wx30H 0°
53-1214-32-0-SP	12Dx14Wx32H 0°
53-1214-34-0-SP	12Dx14Wx34H 0°
53-1214-36-0-SP	12Dx14Wx36H 0°
53-1214-38-0-SP	12Dx14Wx38H 0°
53-1214-40-0-SP	12Dx14Wx40H 0°
12 x 14 Foot Print 6° Implants	
53-1214-11-6-SP	12Dx14Wx11H 6°
53-1214-12-6-SP	12Dx14Wx12H 6°
53-1214-13-6-SP	12Dx14Wx13H 6°
53-1214-14-6-SP	12Dx14Wx14H 6°
53-1214-15-6-SP	12Dx14Wx15H 6°
53-1214-16-6-SP	12Dx14Wx16H 6°
53-1214-17-6-SP	12Dx14Wx17H 6°
53-1214-18-6-SP	12Dx14Wx18H 6°
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53-1214-24-6-SP	12Dx14Wx24H 6°
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53-1214-29-6-SP	12Dx14Wx29H 6°
53-1214-30-6-SP	12Dx14Wx30H 6°
53-1214-32-6-SP	12Dx14Wx32H 6°
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53-1214-36-6-SP	12Dx14Wx36H 6°
53-1214-38-6-SP	12Dx14Wx38H 6°
53-1214-40-6-SP	12Dx14Wx40H 6°
53-1214-42-6-SP	12Dx14Wx42H 6°
53-1214-44-6-SP	12Dx14Wx44H 6°
53-1214-46-6-SP	12Dx14Wx46H 6°
53-1214-48-6-SP	12Dx14Wx48H 6°
53-1214-50-6-SP	12Dx14Wx50H 6°

Standard P/N	Description
14 x 16 Foot Print 0° Implants	
53-1416-16-0-SP	14Dx16Wx16H 0°
53-1416-18-0-SP	14Dx16Wx18H 0°
53-1416-20-0-SP	14Dx16Wx20H 0°
53-1416-22-0-SP	14Dx16Wx22H 0°
53-1416-24-0-SP	14Dx16Wx24H 0°
53-1416-26-0-SP	14Dx16Wx26H 0°
53-1416-28-0-SP	14Dx16Wx28H 0°
53-1416-30-0-SP	14Dx16Wx30H 0°
53-1416-32-0-SP	14Dx16Wx32H 0°
53-1416-34-0-SP	14Dx16Wx34H 0°
53-1416-36-0-SP	14Dx16Wx36H 0°
53-1416-38-0-SP	14Dx16Wx38H 0°
53-1416-40-0-SP	14Dx16Wx40H 0°
14 x 16 Foot Print 6° Implants	
53-1416-11-6-SP	14Dx16Wx11H 6°
53-1416-12-6-SP	14Dx16Wx12H 6°
53-1416-13-6-SP	14Dx16Wx13H 6°
53-1416-14-6-SP	14Dx16Wx14H 6°
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53-1416-44-6-SP	14Dx16Wx44H 6°
53-1416-46-6-SP	14Dx16Wx46H 6°
53-1416-48-6-SP	14Dx16Wx48H 6°
53-1416-50-6-SP	14Dx16Wx50H 6°

Additional sizes available upon request.

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