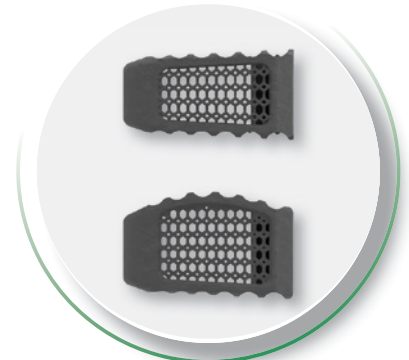
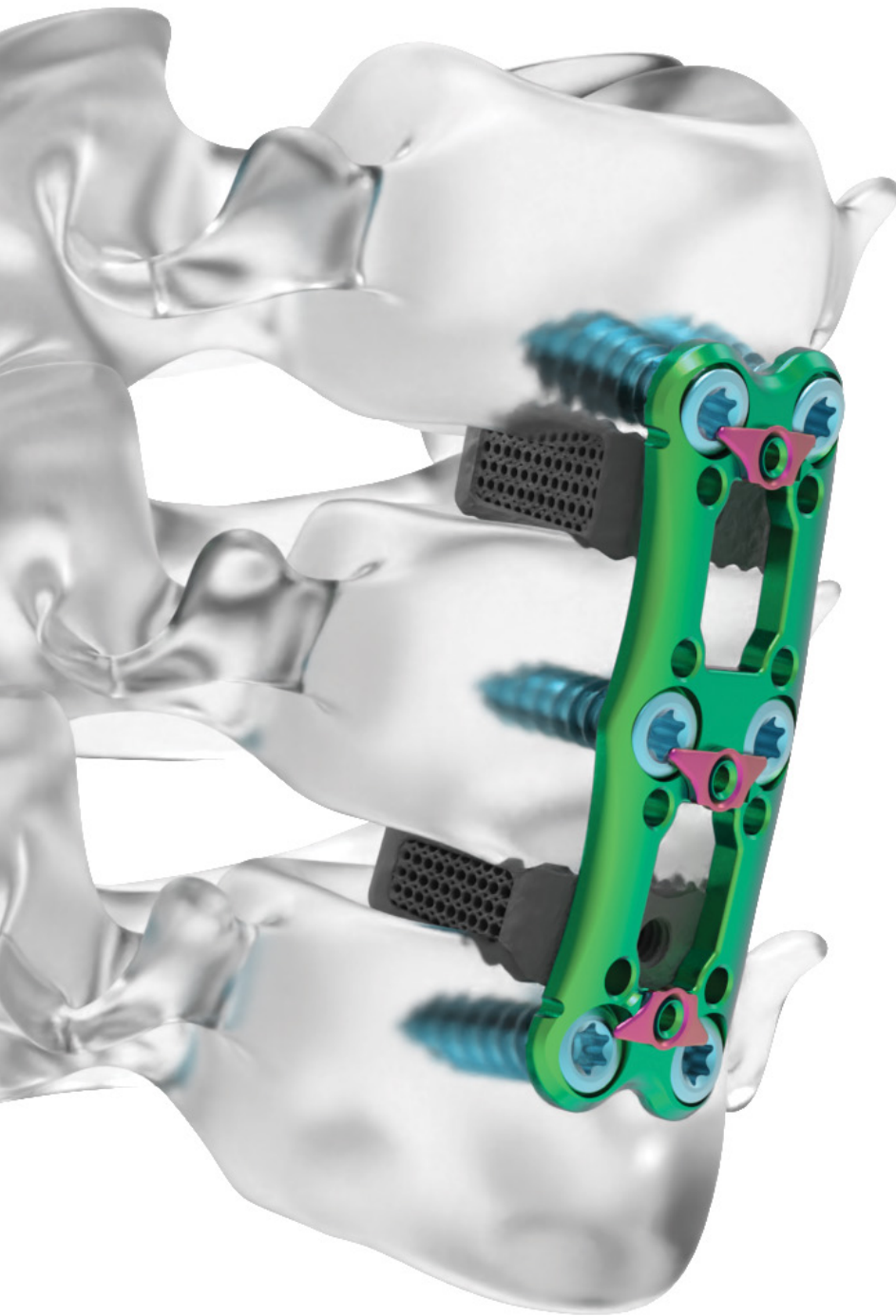
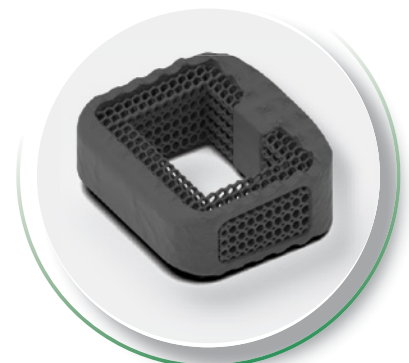




ANATOMICAL
DESIGN



NEXXT MATRIXX®
CONVEXX™



NEXXT MATRIXX®
CERVICAL

NEXXT MATRIXX®
CERVICAL



Nexxt Spine, LLC
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(317) 436-7801
Info@NexxtSpine.com

70-040, Rev D



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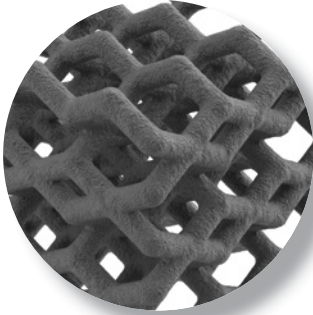
Indications For Use _____ 13

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

DISCLAIMER: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

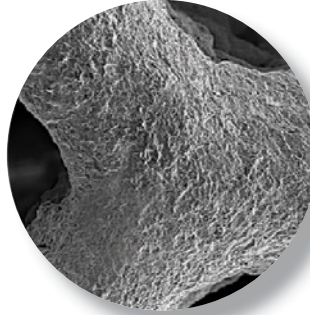


10X



Interconnected Titanium
PORES

300X



Uncompromising
MACROSURFACE

10,000X



7µm Roughened
MICROSURFACE

Pillars of NEXXT MATRIXX® Technology:

1. Varied pore array of 300, 500, and 700µm designed to support vascularization and osteogenesis.^{1,4,5}
2. 7µm surface roughness designed to increase osteoblast differentiation, production of angiogenic factors, and surface osteointegration.^{2,3,6}
3. 75% porous, open titanium architecture developed for greater surface area and nutrient exchange, leading to increased volume for potential bony in-growth.^{4,5,6}
4. Modulus of elasticity engineered to be comparable to PEEK devices leading to a more physiological product.⁶
5. 700µm A/P and lateral lattice geometry designed to provide robust radiographic imaging unimpeded by reducing overall titanium material and device density.⁶

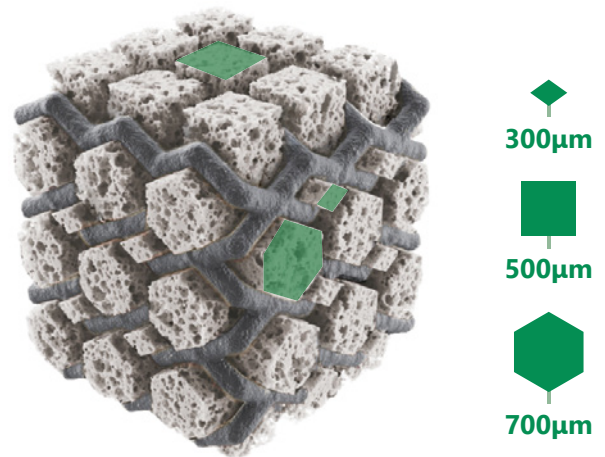


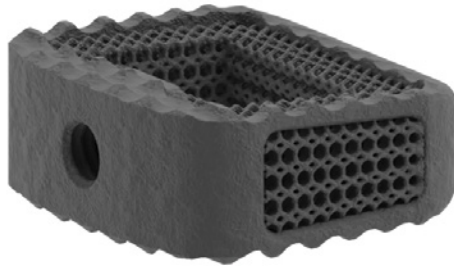
Image represents potential volume for bony in-growth

Studies referenced for the foundational design of NEXXT MATRIXX®

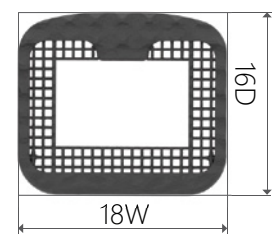
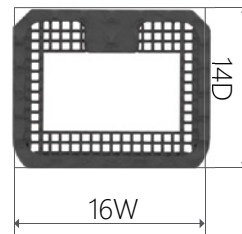
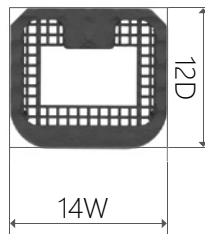
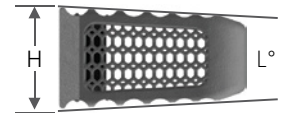
1. Karageorgiou V, Kaplan D. Porosity of 3D biomaterial scaffolds and osteogenesis. *Biomaterials*. 2005;26(27):5474–91.
2. Olivares-Navarrete R, Hyzy SL, Slosar PJ et al. Implant materials generate different peri-implant inflammatory factors: poly-ether-ether-ketone promotes fibrosis and microtextured titanium promotes osteogenic factors. *Spine*. 2015;40(6):399–404.
3. Olivares-Navarrete R, Hyzy SL, Gittens RA, et al. Rough titanium alloys regulate osteoblast production of angiogenic factors. *Spine J*. 2013;13(11):1563–70.
4. Ponader S, von Wilmsowky C, Widenmayer M, et al. In vivo performance of selective electron beam-melted ti-6al-4v structures. *J Biomed Mater Res A* 2010;92A:56–62
5. Li JP, Habibovic P, et al.: Bone ingrowth in porous titanium implants produced by 3D fiber deposition. *Biomaterials* 28:2810, 2007.
6. Data on file at Nexxt Spine, LLC.

**SYSTEM SPECIFICATIONS***

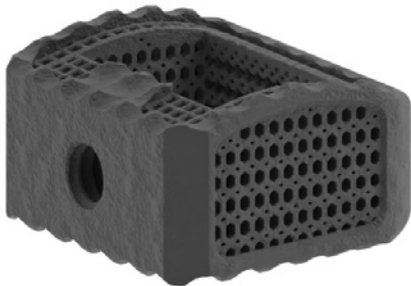
Cervical Implants



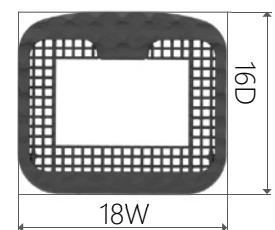
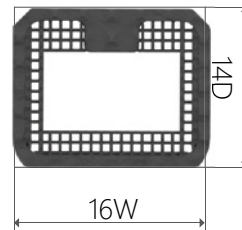
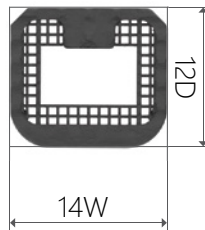
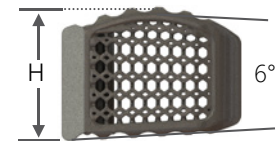
DxW (mm)	Heights (mm)	Lordosis
12 x 14	5-10, 11-18	0°, 6°, 10°
14 x 16	5-10, 11-18	0°, 6°, 10°
16 x 18	5-10, 11-18	0°, 6°, 10°



Convexx™ Cervical Implants



DxW (mm)	Heights (mm)	Lordosis
12 x 14	5-10, 11-12	6°
14 x 16	5-10, 11-12	6°
16 x 18	5-10, 11-12	6°

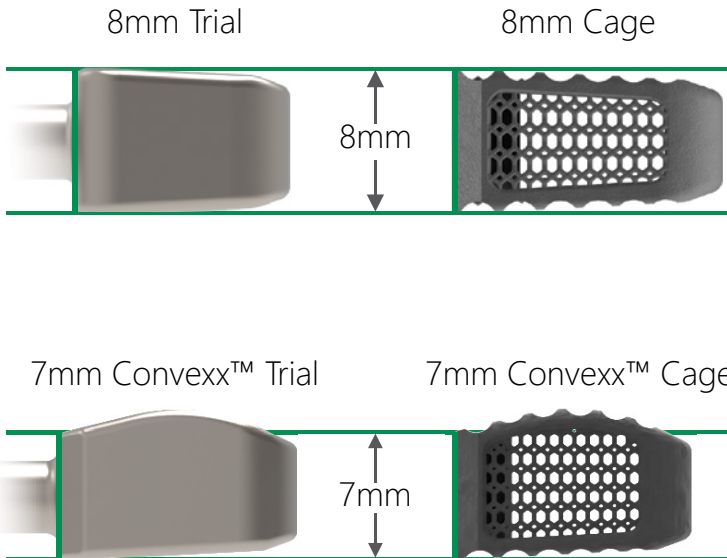


*Some footprints only available [By Request](#).
Contact Info@NexxtSpine.com for full SKU offering.



SYSTEM SPECIFICATIONS*

Trials



Trials are color-coded according to height.



Rasp

- 12x14x5mm universal Rasp included in set
- Rasp height includes cutting teeth
- Not recommended for use on Convexx™ cages





This surgical technique demonstrates and illustrates the instrumentation for both the NEXXT MATRIXX Cervical and Convex interbody systems. The NEXXT MATRIXX Cervical cage and instrumentation are shown for clarity.

1. Patient Positioning

Following adequate general anesthesia, the patient is placed in the supine position with the head in slight extension (Fig. 1). The mandible is tilted out of the surgical field. The posterior cervical spine is supported to establish and maintain normal lordosis.



Figure 1

2. Exposure of Operative Levels

Access the operative site and retract the tissues using preferred instruments. Retract the muscles, trachea, esophagus and carotid artery to clearly see the vertebral bodies and discs. Insert a marker into the disc(s) and confirm the correct operative level(s) using a lateral radiograph (Fig. 2).

NOTE:

NEXXT MATRIXX® Cervical Interbodies are indicated for use at up to two contiguous levels in the cervical spine from C2-T1.



Figure 2

3. Discectomy

Perform a complete discectomy using preferred surgical instruments. Pituitaries, curettes, and rongeurs may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament and endplates. A high-speed burr may be used for removal of posterior osteophytes to achieve neural decompression (Fig. 3). The posterior longitudinal ligament may be removed to access and remove any disc material that may be pressing on the neural elements.

NOTE:

Adequate preparation of the endplates is critical in facilitating vascular supply to promote fusion. Pre-operative and intraoperative fluoroscopic evaluation should be utilized for both NEXXT MATRIXX® Cervical or Convex interbody devices.

WARNING:

Excessive removal of subchondral bone during endplate preparation may weaken the bone, resulting in subsidence and/or segmental instability.



Figure 3



4. Endplate Preparation

Rasps can be used sequentially, in 1mm increments, to remove the superficial layer on the endplates (Fig. 4). This will aid in creating bleeding bone to promote spinal fusion. Appropriate endplate preparation will optimize surface contact with the selected interbody.

NOTE: It is not recommended to utilize the Rasp with the MATRIXX® CONVEXX™ device. Minimal manipulation of the endplate and retention of the natural morphology is important to maintain apposition of the device and the endplate.

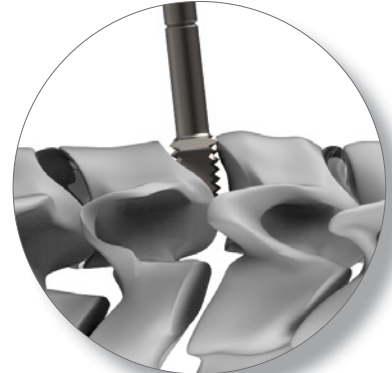
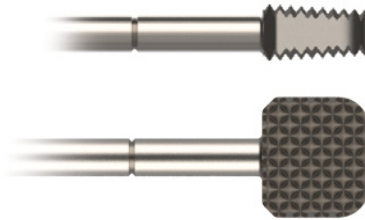


Figure 4

5. Implant Size Selection

Selection of the Trial depends on the height, width, and depth of the intervertebral space. Based on pre-operative imaging and surgical technique, select a Trial of appropriate height (Fig. 5).

Each Trial is color coded to differentiate height and should be used incrementally to determine the appropriate dimensions of the interbody required (Fig. 6).

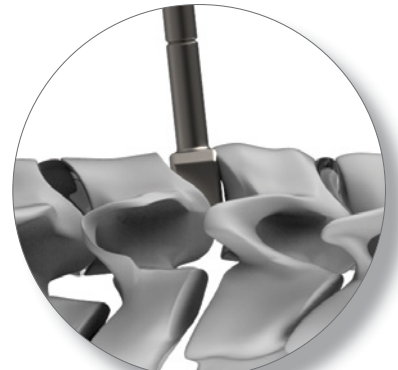
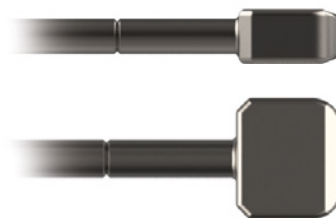


Figure 5

NOTE:

- Rasp and Trial sizes (W x D x H) are a line-to-line match to the corresponding interbody.
- Standard Angulation (Lordosis) of Rasps, Trials and corresponding interbodies is 6°
 - Parallel (0° lordosis) and 10° geometries are optional for standard NEXXT MATRIXX® Cervical interbodies.
 - Only the 6° Convexx™ trials should be utilized for the optional NEXXT MATRIXX Convexx™ interbodies.
- All labeled heights are measured from the area representing the highest point on the anterior wall of the implant.



Figure 6



6. Implant Preparation and Insertion

Open the sterile packaging of the Interbody (height and footprint) that was determined with the Trial. There is no need to undersize or oversize the Implant.

Attach the Interbody to the Inserter by aligning the male/female thread components while rotating the instrument handle clockwise. Confirm the Implant is securely attached but **DO NOT** overtighten (Fig. 7).

If desired, a modular sleeve with a 2mm Safety Stop can be attached to the shaft of the Inserter prior to loading the implant. The Safety Stop will contact the anterior edge of the vertebral body when the Interbody is inserted 2mm beyond the anterior edge of the vertebral body.

Adjust the position of the Safety Stop on the modular Inserter sleeve if utilized. Safety stop should be positioned in the cephalad orientation.

Pack the center cavity of the Implant with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft (Fig. 8).

Gently insert the Implant into the intervertebral disc space. It is important to ensure the Implant is seated in the midline of the disc space and slightly recessed (approximately 2mm). If necessary, controlled and light tamping with a mallet can be used to help advance the implant to the desired position within the intervertebral disc space.

NOTE:

Use caution when tightening the Implant to the Inserter to avoid stripping threads or overtightening where detachment of implant from instrument becomes difficult.

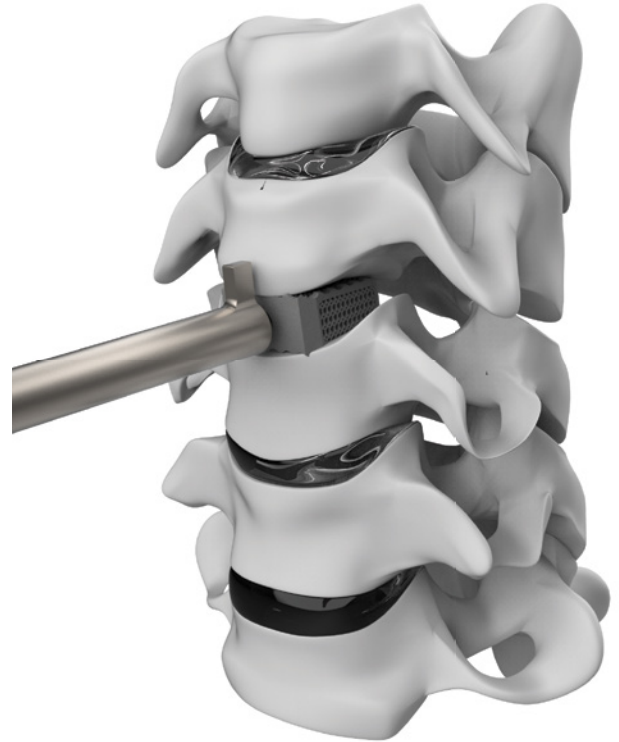


Figure 7

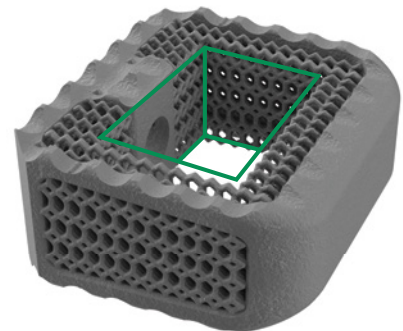


Figure 8



6. Implant Preparation and Insertion (continued)

The use of fluoroscopy is recommended during any or all of the implantation steps to ensure proper positioning (Fig. 9).

Rotate the Inserter handle in a counterclockwise direction to release the implant from the Inserter.

If the implant requires further adjustment, use the Cervial Tamp to carefully manipulate the implant into desired position.

Complete the procedure by following the surgical technique for the specific device to be used as supplemental fixation, such as the Nexxt Spine Struxxure® Anterior Cervical Plate System.

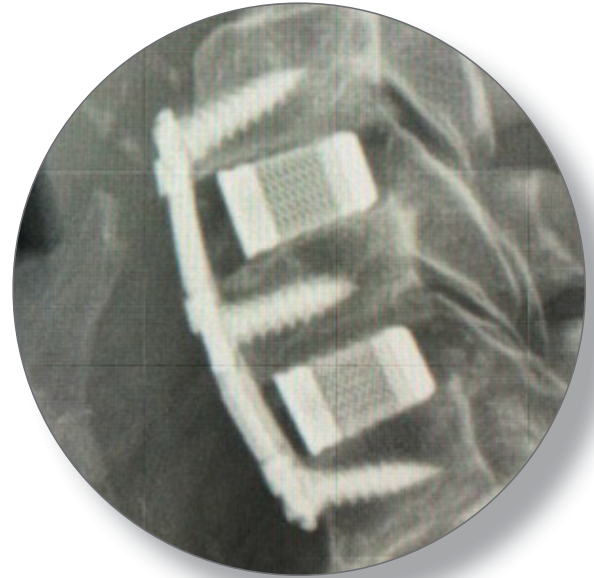


Figure 9

7. Implant Removal

Either the Inserter or Universal Removal Instrument may be used for Implant removal by attachment via clockwise rotation to the implant threads (Fig. 10). 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 implant retrieval.

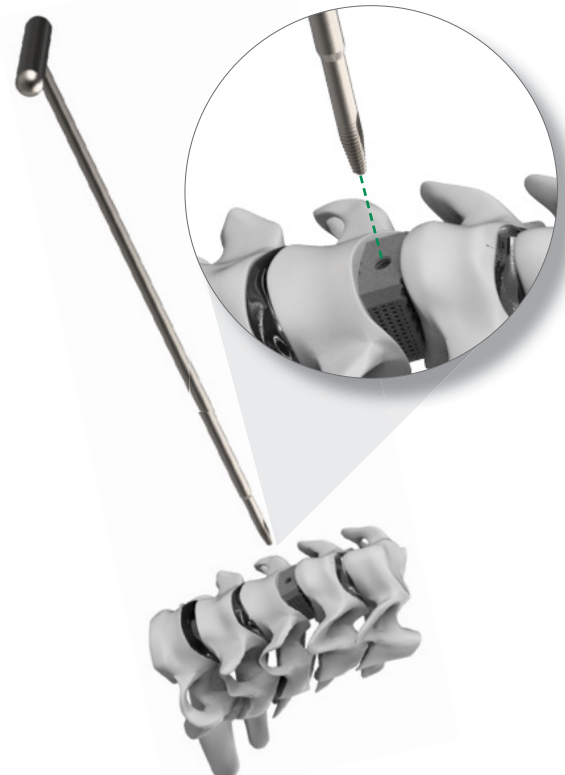
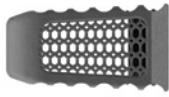


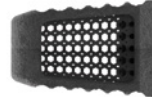
Figure 10



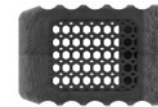
NEXXT MATRIXX® Cervical Implant Part Numbers



Standard P/N	Description
6° Lordotic Implant Set	
50M-1214-05-SP	12Dx14Wx5H, 6°
50M-1214-06-SP	12Dx14Wx6H, 6°
50M-1214-07-SP	12Dx14Wx7H, 6°
50M-1214-08-SP	12Dx14Wx8H, 6°
50M-1214-09-SP	12Dx14Wx9H, 6°
50M-1214-10-SP	12Dx14Wx10H, 6°
50M-1214-11-SP*	12Dx14Wx11H, 6°
50M-1214-12-SP*	12Dx14Wx12H, 6°
50M-1416-05-SP	14Wx16Wx5H, 6°
50M-1416-06-SP	14Wx16Wx6H, 6°
50M-1416-07-SP	14Wx16Wx7H, 6°
50M-1416-08-SP	14Wx16Wx8H, 6°
50M-1416-09-SP	14Wx16Wx9H, 6°
50M-1416-10-SP	14Wx16Wx10H, 6°
50M-1416-11-SP*	14Wx16Wx11H, 6°
50M-1416-12-SP*	14Wx16Wx12H, 6°
50M-1618-05-SP*	16Wx18Wx5H, 6°
50M-1618-06-SP*	16Wx18Wx6H, 6°
50M-1618-07-SP*	16Wx18Wx7H, 6°
50M-1618-08-SP*	16Wx18Wx8H, 6°
50M-1618-09-SP*	16Wx18Wx9H, 6°
50M-1618-10-SP*	16Wx18Wx10H, 6°
50M-1618-11-SP*	16Wx18Wx11H, 6°
50M-1618-12-SP*	16Wx18Wx12H, 6°



Standard P/N	Description
10° Lordotic Implant Set*	
50M-1214-10-06-SP	12Dx14Wx6H, 10°
50M-1214-10-07-SP	12Dx14Wx7H, 10°
50M-1214-10-08-SP	12Dx14Wx8H, 10°
50M-1214-10-09-SP	12Dx14Wx9H, 10°
50M-1214-10-10-SP	12Dx14Wx10H, 10°
50M-1214-10-11-SP*	12Dx14Wx11H, 10°
50M-1214-10-12-SP*	12Dx14Wx12H, 10°
50M-1416-10-06-SP*	14Wx16Wx6H, 10°
50M-1416-10-07-SP*	14Wx16Wx7H, 10°
50M-1416-10-08-SP*	14Wx16Wx8H, 10°
50M-1416-10-09-SP*	14Wx16Wx9H, 10°
50M-1416-10-10-SP*	14Wx16Wx10H, 10°
50M-1416-10-11-SP*	14Wx16Wx11H, 10°
50M-1416-10-12-SP*	14Wx16Wx12H, 10°
50M-1618-10-06-SP*	16Wx18Wx6H, 10°
50M-1618-10-07-SP*	16Wx18Wx7H, 10°
50M-1618-10-08-SP*	16Wx18Wx8H, 10°
50M-1618-10-09-SP*	16Wx18Wx9H, 10°
50M-1618-10-10-SP*	16Wx18Wx10H, 10°
50M-1618-10-11-SP*	16Wx18Wx11H, 10°
50M-1618-10-12-SP*	16Wx18Wx12H, 10°



Standard P/N	Description
Parallel Implant Set*	
50M-1214P-05-SP	12Dx14Wx5H
50M-1214P-06-SP	12Dx14Wx6H
50M-1214P-07-SP	12Dx14Wx7H
50M-1214P-08-SP	12Dx14Wx8H
50M-1214P-09-SP	12Dx14Wx9H
50M-1214P-10-SP	12Dx14Wx10H
50M-1214P-11-SP*	12Dx14Wx11H
50M-1214P-12-SP*	12Dx14Wx12H
50M-1214P-13-SP*	12Dx14Wx13H
50M-1214P-14-SP*	12Dx14Wx14H
50M-1214P-15-SP*	12Dx14Wx15H
50M-1214P-16-SP*	12Dx14Wx16H
50M-1214P-17-SP*	12Dx14Wx17H
50M-1214P-18-SP*	12Dx14Wx18H
50M-1416P-05-SP	14Wx16Wx5H
50M-1416P-06-SP	14Wx16Wx6H
50M-1416P-07-SP	14Wx16Wx7H
50M-1416P-08-SP	14Wx16Wx8H
50M-1416P-09-SP	14Wx16Wx9H
50M-1416P-10-SP	14Wx16Wx10H
50M-1416P-11-SP*	14Wx16Wx11H
50M-1416P-12-SP*	14Wx16Wx12H
50M-1416P-13-SP*	14Wx16Wx13H
50M-1416P-14-SP*	14Wx16Wx14H
50M-1416P-15-SP*	14Wx16Wx15H
50M-1416P-16-SP*	14Wx16Wx16H
50M-1416P-17-SP*	14Wx16Wx17H
50M-1416P-18-SP*	14Wx16Wx18H



Standard P/N	Description
6° Lordotic Convex™ Implants*	
50A-1214-05-SP	12Dx14Wx05H, 6°
50A-1214-06-SP	12Dx14Wx06H, 6°
50A-1214-07-SP	12Dx14Wx07H, 6°
50A-1214-08-SP	12Dx14Wx08H, 6°
50A-1214-09-SP	12Dx14Wx09H, 6°
50A-1214-10-SP	12Dx14Wx10H, 6°
50A-1214-11-SP*	12Dx14Wx11H, 6°
50A-1214-12-SP*	12Dx14Wx12H, 6°

Standard P/N	Description
6° Lordotic Convex™ Implants*	
50A-1416-05-SP	14Dx16Wx05H, 6°
50A-1416-06-SP	14Dx16Wx06H, 6°
50A-1416-07-SP	14Dx16Wx07H, 6°
50A-1416-08-SP	14Dx16Wx08H, 6°
50A-1416-09-SP	14Dx16Wx09H, 6°
50A-1416-10-SP	14Dx16Wx10H, 6°
50A-1416-11-SP*	14Dx16Wx11H, 6°
50A-1416-12-SP*	12Dx14Wx12H, 6°

Standard P/N	Description
6° Lordotic Convex™ Implants*	
50A-1618-05-SP*	16Dx18Wx05H, 6°
50A-1618-06-SP*	16Dx18Wx06H, 6°
50A-1618-07-SP*	16Dx18Wx07H, 6°
50A-1618-08-SP*	16Dx18Wx08H, 6°
50A-1618-09-SP*	16Dx18Wx09H, 6°
50A-1618-10-SP*	16Dx18Wx10H, 6°
50A-1618-11-SP*	12Dx14Wx11H, 6°
50A-1618-12-SP*	12Dx14Wx12H, 6°

*By Request, contact Info@NexxtSpine.com for full SKU offering.

Green rows indicate Standard Order within implant set.

**NEXXT MATRIXX® Cervical Instruments****Cervical Inserter**

Standard P/N	Description
I50-01-01	Cervical Inserter
I35-31-01*	Cervical Inserter Sleeve

Universal Remover

Standard P/N	Description
I35-50-01S	Universal Remover, Short
I35-50-01*	Universal Remover

Universal Rasp

Standard P/N	Description
I52-RUS-05	Cervical Universal Rasp

Cervical Tamp

Standard P/N	Description
I50-40-01	Matrixx Cervical Tamp

Standard Trials

Standard P/N	Description
I50-TR24-XX-NS	(12x14) x 05-10Hmm Trial
I50-TR46-XX-NS	(14x16) x 05-10Hmm Trial
I50-TR24-XX-NS*	(12x14) x 11-18Hmm Trial
I50-TR46-XX-NS*	(14x16) x 11-18Hmm Trial

Convexx™ Trials

Standard P/N	Description
I50A-TR24-XX*	(12x14) x 05-12Hmm Trial
I50A-TR46-XX*	(14x16) x 05-12Hmm Trial
I50A-TR68-XX*	(16x18) x 05-12Hmm Trial

*By Request, contact Info@NexxtSpine.com for full SKU offering.

Green rows indicate Standard Order.



NEXXT MATRIXX®

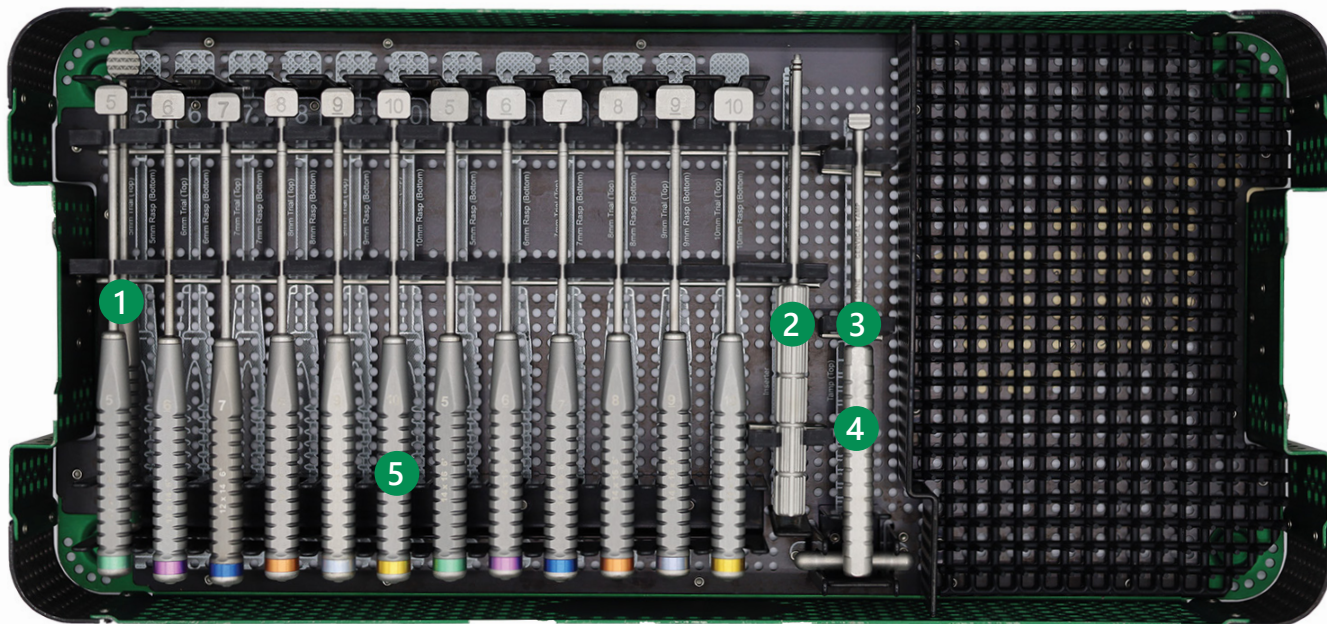
3D Printed Porous Titanium

MATRIXX® CERVICAL

Total Implant Lattice Integration

12

NEXXT MATRIXX® Standard Cervical Instrument Tray Layout



- | | |
|----------------------------------|--|
| 1 Universal Rasp (BOTTOM) | 4 Universal Remover (BOTTOM) |
| 2 Cervical Inserter | 5 Chosen Set of Cervical Trials |
| 3 Cervical Tamp | |



Indications for Use

GENERAL DESCRIPTION

NEXXT MATRIXX® is a collection of additively manufactured spacers for cervical 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 open 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

When used as a cervical intervertebral fusion device, the NEXXT 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 cortico-cancellous bone graft and with supplemental 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, 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. These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.
5. 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.
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 system or 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.



NEXXT MATRIXX®

3D Printed Porous Titanium

MATRIXX® CERVICAL

Total Implant Lattice Integration

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Additional Cervical Products



SAXXONY®
Cervical Pedicle Screw System



NEXXT MATRIXX®
SA Cervical



NEXXT MATRIXX®
Corpectomy



STRUXXURE®
Anterior Cervical Plates



NEXXT
Spine



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For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit NexxtSpine.com for additional product information.

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