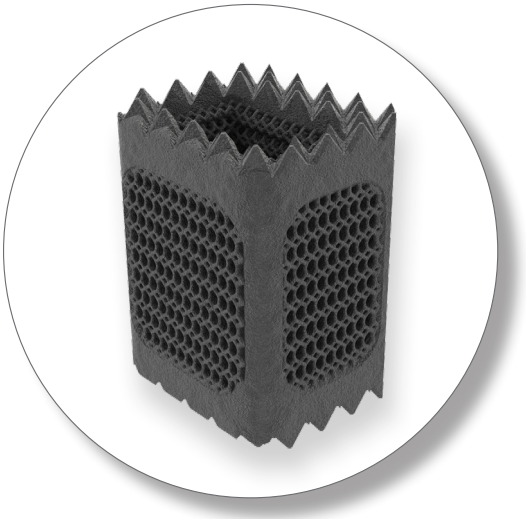
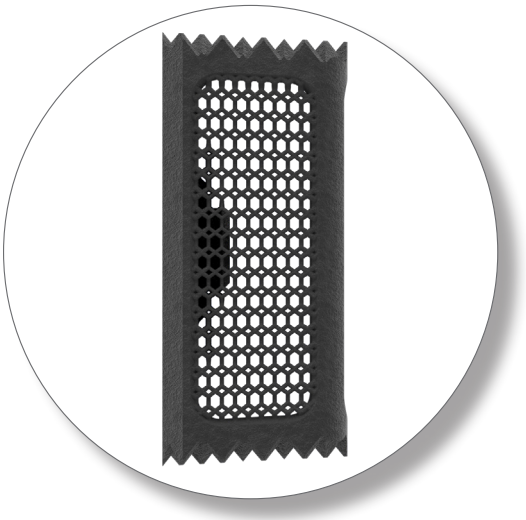
NEXXT Spine

GROW WITH US

Surgical Technique
NEXXT MATRIXX® Corpectomy





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71-041, Rev B

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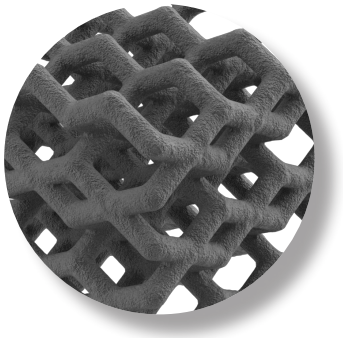
CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

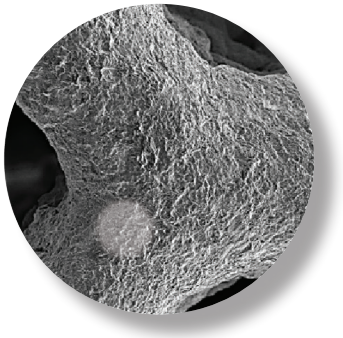
DISCLAIMER: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information 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



Systematic Titanium
PORES

300X



Uncompromising
MACROSURFACE

10,000X

7µm Surface
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]

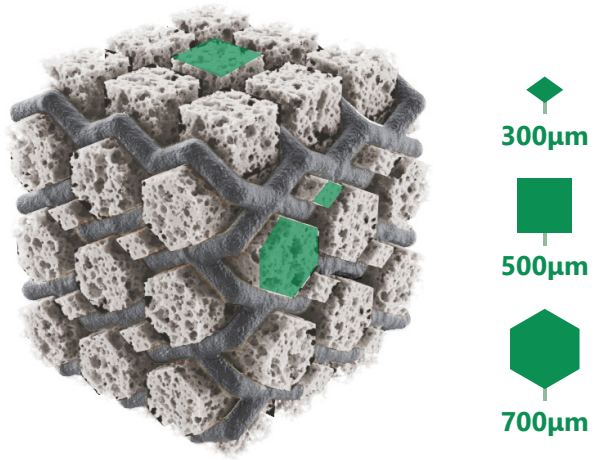


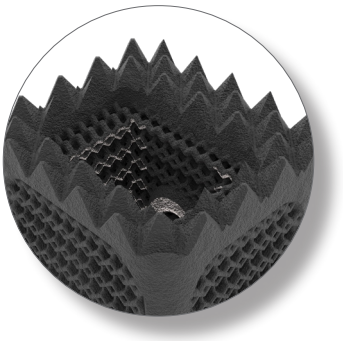
Image represents potential volume for bony in-growth

Studies referenced for the foundational design of NEXXT MATRIXX®

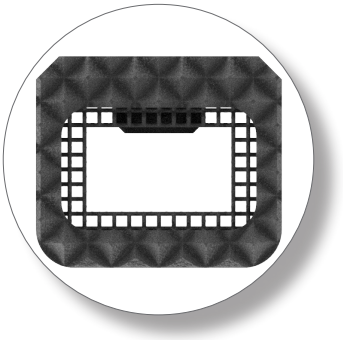
1. Karageorgiou V, Kaplan D. Porosity of 3D biomaterial scaffolds and osteogenesis. Biomaterials. 2005;26(27):5474–91.
2. Olivares-Navarrete R, Hyzy SL, Slosar PJ et al. Implant materials generate different peri-implant inflammatory factors: poly-ether-ether-ketone promotes fibrosis and microtextured 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 Wilmowsky 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 Features

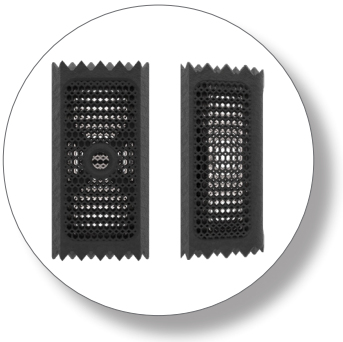
IMPLANTS



Aggressive teeth for secure placement

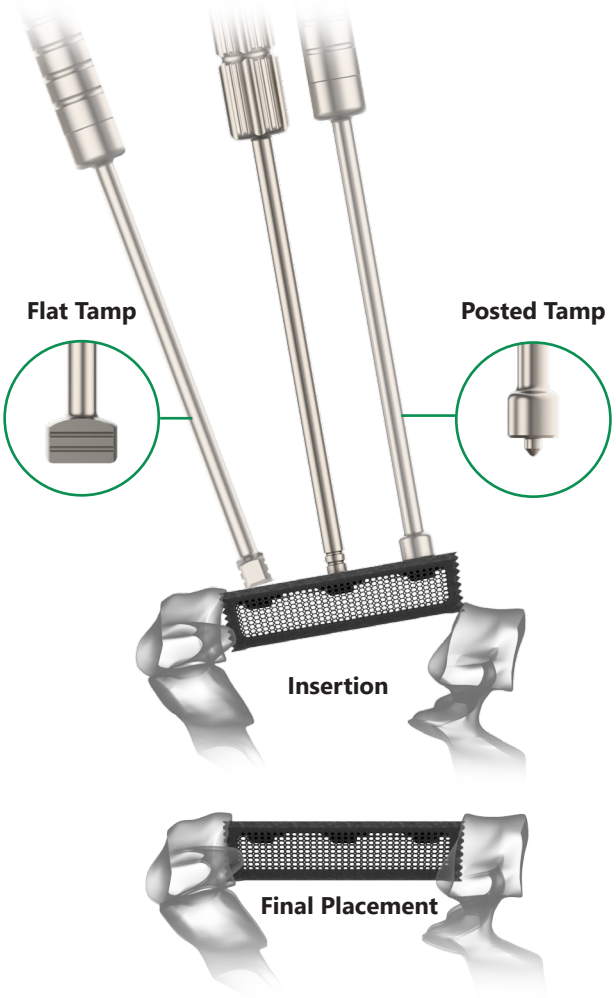


Entire implant graft support



Complete A/P + lateral visualization

INSTRUMENTATION



IMPLANT OFFERING

Accommodation of anatomy

12D x 14Wmm 0˚
12Dx14Wx16-40Hmm 0˚ 2mm increments

12D x 14Wmm 6˚
12Dx14Wx11-30Hmm 6˚ 1mm increments
12Dx14Wx32-50Hmm 6˚ 2mm increments

14D x 16Wmm 0˚
14Dx16Wx16-40Hmm 0˚ 2mm increments

14D x 16Wmm 6˚
14Dx16Wx11-30Hmm 6˚ 1mm increments
14Dx16Wx32-50Hmm 6˚ 2mm increments

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.

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.

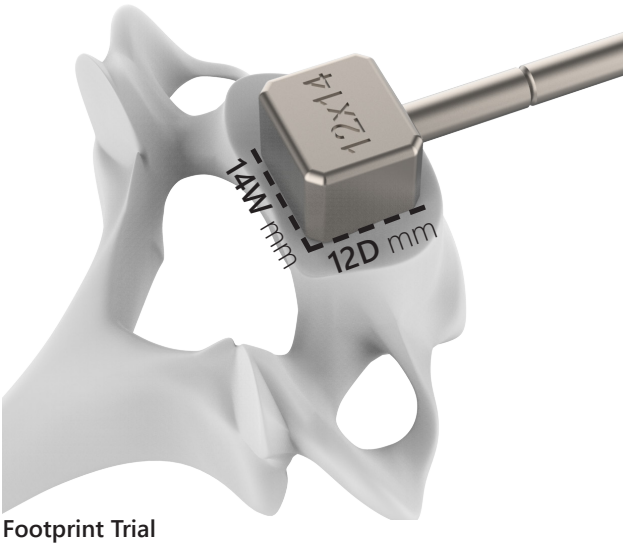
3. Implant Size Selection

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:

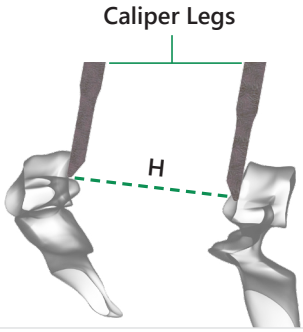
   - 12Dx14W mm
   - 14Dx16W mm

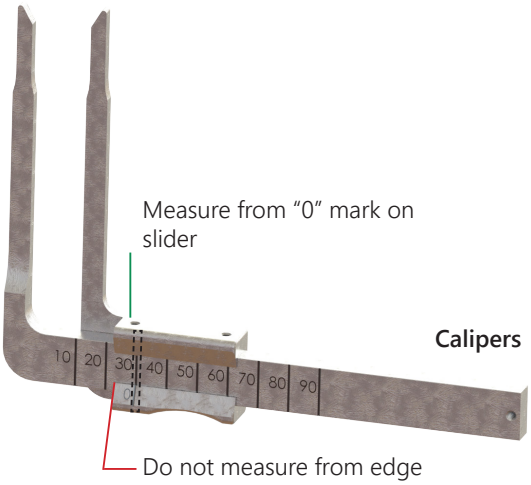


Footprint Trial

2. Determine the approximate height of the corpectomy site with the Caliper. Insert the Caliper into the site and gently separate Caliper legs until the legs contact the inferior/superior endplates. The resulting height can be read on the Caliper.

   NOTE: Measurement is read where the zero ("0") mark on the slider is aligned with the ruled markings on the Caliper.

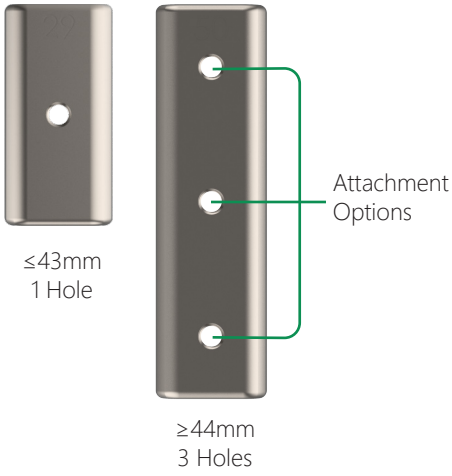


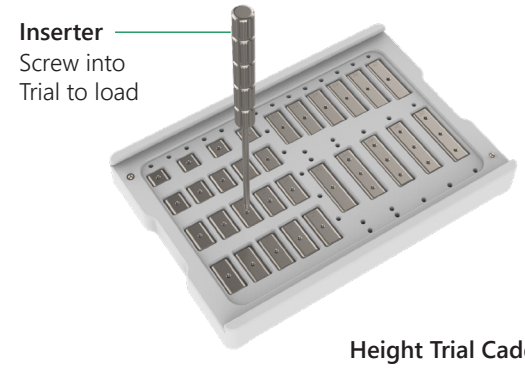


3. Implant Size Selection (continued)

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

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





Height Trial Caddy

4. Insert the Height Trial into the corpectomy site.

NOTE:
- 10 & 11mm tall (height) implants are indicated for use *only* in the lumbar spine.

Height Trial and **Inserter**

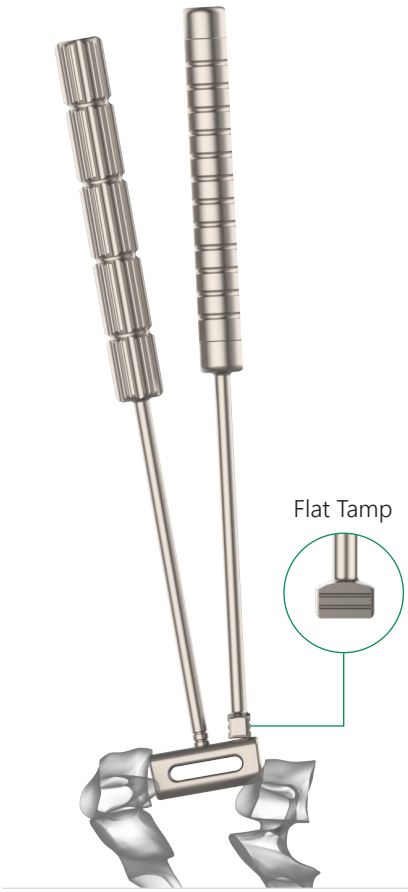
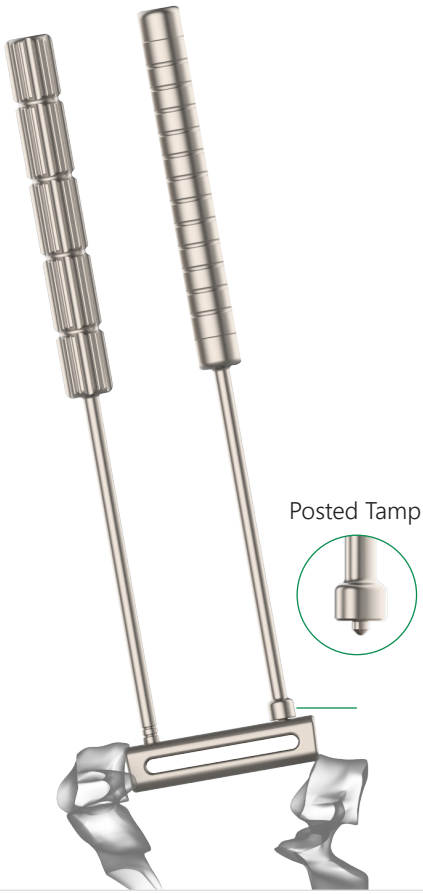
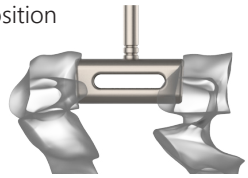
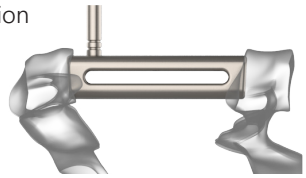
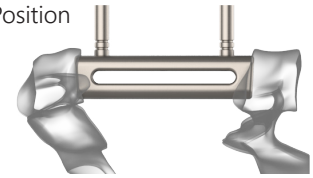
3. Implant Size Selection (continued)

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

NOTE:
Posted Tamp should *only* be used to tamp at/on the Inserter hole(s).

Approach Options

Mallet the top of Inserter(s) and Tamp

Inserter + Flat Tamp	Inserter + Posted Tamp	Dual Inserter
		
Final Position	Final Position	Final Position
		

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.

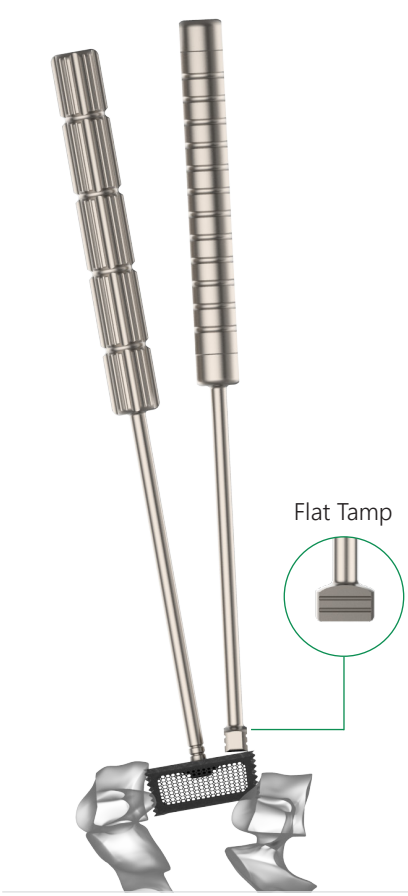
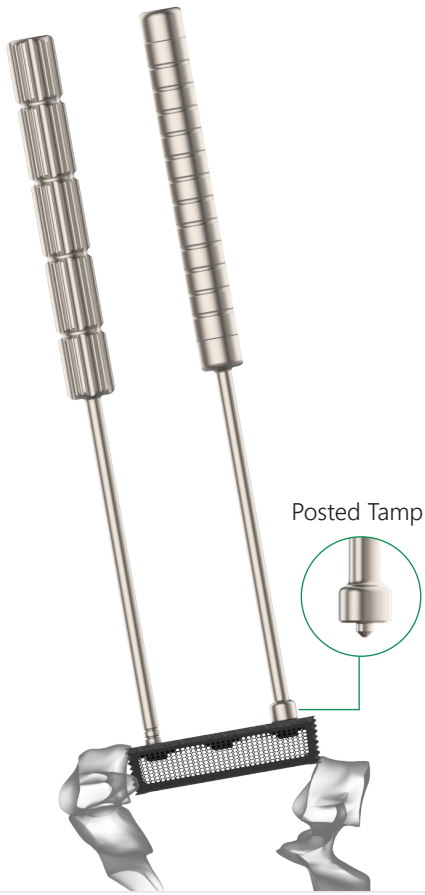
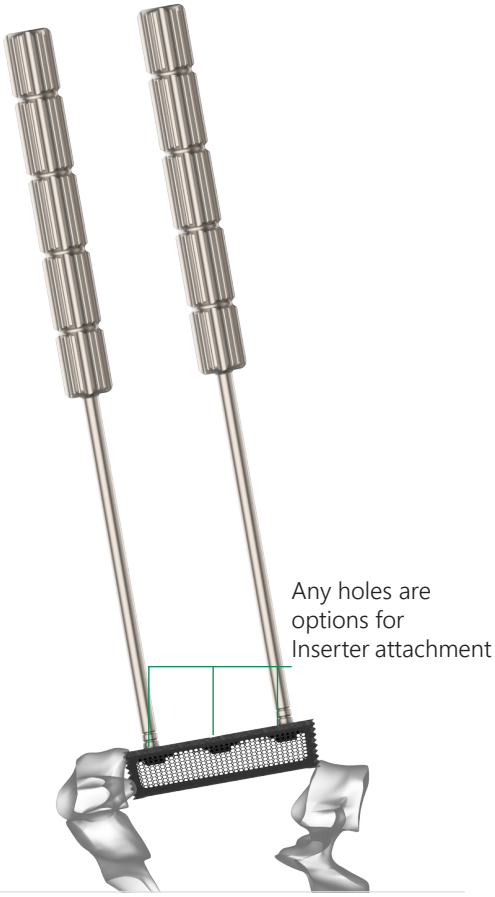
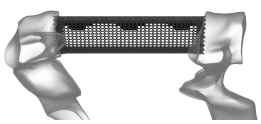
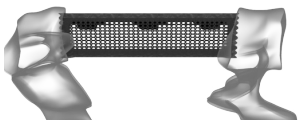
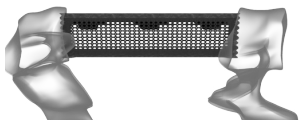
1. Attach the Inserter to the Implant and pack the center cavity of the Implant with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.
2. Insert the Implant into the intervertebral disc space.
3. Tamp into place (if desired) with the Flat or Posted Tamp.

NOTES:

- Use caution when tightening the Implant to the Inserter to avoid stripping threads or overtightening to minimize difficulty of detachment of device from instrument.
- Implants are symmetrical down the Medial/ Lateral midline.

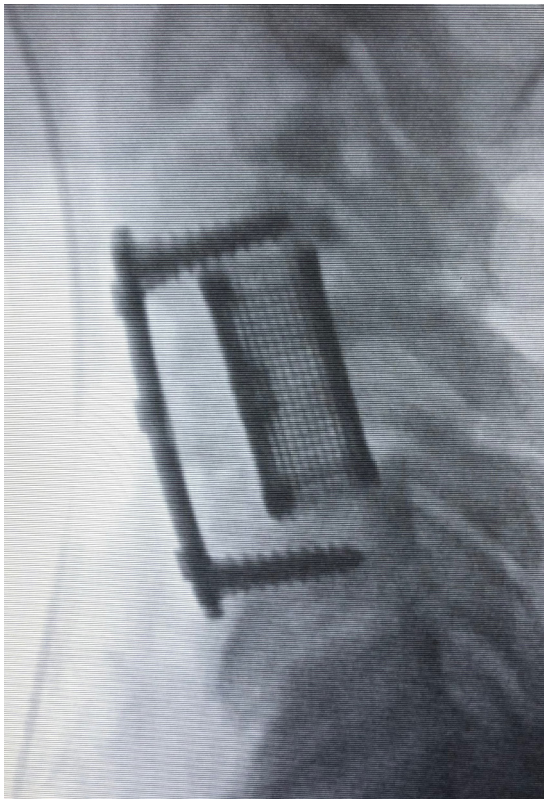
Approach Options

Mallet the top of Inserter(s) and Tamp

Inserter + Flat Tamp	Inserter + Posted Tamp	Dual Inserter
		
Flat Tamp	Posted Tamp	Any holes are options for Inserter attachment
Final Position	Final Position	Final Position
		

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.

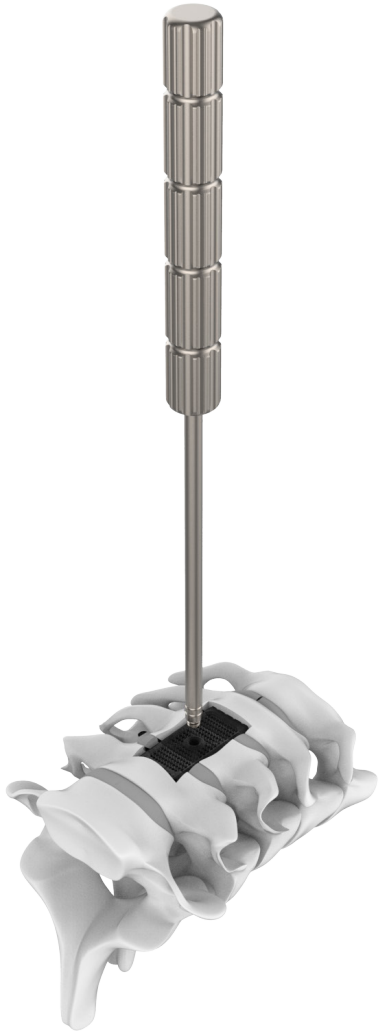


5. Supplemental Fixation

- 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.

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.



NEXXT MATRIXX® Corpectomy Implant Part Numbers

Standard P/N	Description
12x14mm Footprint 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°
12x14mm Footprint 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°
53-1214-19-6-SP	12Dx14Wx19H 6°
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53-1214-21-6-SP	12Dx14Wx21H 6°
53-1214-22-6-SP	12Dx14Wx22H 6°
53-1214-23-6-SP	12Dx14Wx23H 6°
53-1214-24-6-SP	12Dx14Wx24H 6°
53-1214-25-6-SP	12Dx14Wx25H 6°
53-1214-26-6-SP	12Dx14Wx26H 6°
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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
14x16mm Footprint 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°
12x14mm Footprint 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°
53-1416-15-6-SP	14Dx16Wx15H 6°
53-1416-16-6-SP	14Dx16Wx16H 6°
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53-1416-40-6-SP	14Dx16Wx40H 6°
53-1416-42-6-SP	14Dx16Wx42H 6°
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°

***All combinations of footprints (12x14, 14x16, 16x18) and lordosis (0° & 6°) and heights (10-70mm) available**

NEXXT MATRIXX® Corpectomy Instrument Part Numbers

Standard P/N	Description
I50-01-01	Cervical Inserter
I52-RU-05	Cervical Universal Rasp
I53-310	Corpectomy Neuro-Calipers
I53-100	Corpectomy Tamp
150-40-01	Matrixx, Cervical, Tamp
I50-50-01	Universal Removal Tool
I53-400	Corpectomy Graft Packing Tool
I53-410	Corpectomy Graft Packing Block
I53-TR24	Corpectomy Trial 12x14
I53-TR46	Corpectomy Trial, 14x16
I53-TR68	Corpectomy Trial, 16x18*

Standard P/N	Description
Modular Corpectomy Trials	
I53-T2411	12Dx14Wx11H, 6°
I53-T2412	12Dx14Wx12H, 6°
I53-T2413	12Dx14Wx13H, 6°
I53-T2414	12Dx14Wx14H, 6°
I53-T2415	12Dx14Wx15H, 6°
I53-T2416	12Dx14Wx16H, 6°
I53-T2417	12Dx14Wx17H, 6°
I53-T2418	12Dx14Wx18H, 6°
I53-T2419	12Dx14Wx19H, 6°
I53-T2420	12Dx14Wx20H, 6°
I53-T2421	12Dx14Wx21H, 6°
I53-T2422	12Dx14Wx22H, 6°
I53-T2423	12Dx14Wx23H, 6°
I53-T2424	12Dx14Wx24H, 6°
I53-T2425	12Dx14Wx25H, 6°
I53-T2426	12Dx14Wx26H, 6°
I53-T2427	12Dx14Wx27H, 6°
I53-T2428	12Dx14Wx28H, 6°
I53-T2429	12Dx14Wx29H, 6°
I53-T2430	12Dx14Wx30H, 6°
I53-T2431	12Dx14Wx31H, 6°*
I53-T2432	12Dx14Wx32H, 6°
I53-T2433	12Dx14Wx33H, 6°*
I53-T2434	12Dx14Wx34H, 6°
I53-T2435	12Dx14Wx35H, 6°*
I53-T2436	12Dx14Wx36H, 6°
I53-T2437	12Dx14Wx37H, 6°*
I53-T2438	12Dx14Wx38H, 6°
I53-T2439	12Dx14Wx39H, 6°*
I53-T2440	12Dx14Wx40H, 6°
I53-T2441	12Dx14Wx41H, 6°*
I53-T2442	12Dx14Wx42H, 6°
I53-T2443	12Dx14Wx43H, 6°*
I53-T2444	12Dx14Wx44H, 6°
I53-T2445	12Dx14Wx45H, 6°*
I53-T2446	12Dx14Wx46H, 6°
I53-T2447	12Dx14Wx47H, 6°*
I53-T2448	12Dx14Wx48H, 6°
I53-T2449	12Dx14Wx49H, 6°*
I53-T2450	12Dx14Wx50H, 6°
I53-T2451:70	12Dx14Wx51H 70mm, 6°*
I53-TP2411:70	12Dx14Wx11H 70mm, 0°*

*Made to order

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.

GROW WITH US

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