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

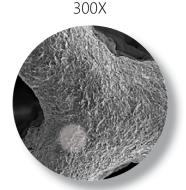
DISCLAIMER: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information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



NEXXT MATRIXX® 3D Printed Porous Titanium

10X

Interconnected Titanium **PORES**



Uncompromising **MACROSURFACE**



7µm Roughened **MICROSURFACE**

Pillars of NEXXT MATRIXX® Technology:

- 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

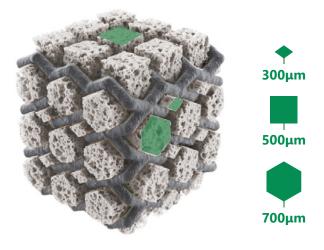


Image represents potential volume for bony in-growth

Studies referenced for the foundational design of NEXXT MATRIXX®

- Karageorgiou V, Kaplan D. Porosity of 3D biomaterial scaffolds and osteogenesis. Biomaterials. 2005;26(27):5474–91.
- 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.
- 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.
- 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
- Li JP, Habibovic P, et al.: Bone ingrowth in porous titanium implants produced by 3D fiber deposition. Biomaterials 28:2810, 2007. 5.
- Data on file at Nexxt Spine, LLC.

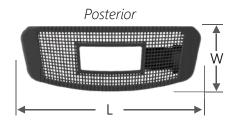
SPECIFICATIONS

Implants

Footprints

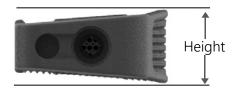
W: 18mm, 22mm, 26mm*

L: 40-60mm (5mm increments)



Heights

8 - 20mm (2mm increments)



Lordosis

0°*, 8°, 14°, and 20°*



* By Request.

Contact Info@NexxtSpine.com for full SKU offering.

PLATE INTEGRATION



Struxxure®-L Plate



Plate Insertion



Plate & Implant Mated



Construct Insertion

PRODUCT FEATURES



Anatomically matched profile

for appropriate endplate coverage and placement on apophyseal rim for stability



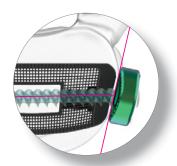
Bulleted nose design

simplifies insertion in collapsed degenerative discs without compromising apophyseal rim



Ample graft window

balanced with lattice landscape to create environment for bone growth



Anatomically driven angle

design compatible with STRUXXURE®-L for single position procedural solution





Surgical Considerations

The lateral procedure enables access to the spine and affected discs via a lateral, retroperitoneal approach. To prepare for the lateral technique, take into account the following anatomic landmarks: the iliac crest, the 12th rib, and the lateral border of the dorsal musculature.

A small, bluntly dissected incision, located in a true lateral (lateral decubitus) position, is used to place the dilators and retractor, and provides a safe working corridor and disc space access.

Retroperitoneal Access

Alternating blunt scissor and finger dissection is used to safely enter the retroperitoneal space over the effected anatomy. Once the index finger is inside the space, manual finger manipulation is used to release the peritoneum anteriorly and create a space for the access instrumentation. The initial dilator will pass through the oblique muscle layers, past the peritoneum, then down to the surface of the psoas muscle.

Transpsoas Access

The dilator is advanced throught the psoas. Direct, lateral trajectory targeting just posterior to the middle of the disc minimizes the chance of encountering a nerve and ensures that anterior vessels remain well anterior to the working corridor.

1. Patient & Table Positioning

1.1 - Approach to the Patient

Using A/P fluorocopic guidance, place the patient on a radiolucent and bendable surgical table in a direct lateral decubitus (90°) position such that the greater trochanter is slightly inferior to the table break. Following, secure the patient with tape at the following locations (Figure 1):

- Just below the iliac crest (Figure 1A).
- Over the thoracic region (Figure 1B).
- From the greater trochanter to the knee, and then secured to the table with padding placed between knees (Figure 1C).
- From the table to the knee, past the ankle, and then secured to the table (Figure 1D).

This configuration ensures that the pelvis tilts away from the ipsilateral spine, allowing access to all lumbar levels, particularly L4-L5, without interference from the iliac crest.

Using fluoroscopy to verify bony anatomy, flex the surgical table (if necessary) to increase the distance between the iliac crest and the ribs in order to gain direct access to the disc (Figure 2) and tension the skin.

NOTE:

Breaking of the table is recommended only when access to the effected disc level is blocked by anatomy such as the ribs or iliac crest. Bending of the table can increase tension on the psoas and associated neural structures (lumbar plexus).

1.2 - Approach to the Surgery

Once the patient is secured, the table should be adjusted so that the C-arm provides true A/P images when at 0° or cross table (distinct endplates and pedicles symmetrical about the spinous process), and true lateral images when at 90° (distinct endplates and superimposed pedicles) (Figure 3). The table should be adjusted when accessing each level in order to maintain this relationship. Additional steps within this procedure will require orienting of the entire C-Arm for adjacent levels to ensure proper imaging. Mark the skin to indicate the intended incision location. Approach the desired disc space level and place the Retractor. Use of intraoperative neuromonitoring is recommended to ensure patient safety. It is especially critical during approach and Retractor placement.

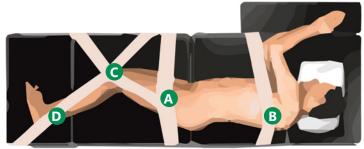


Figure 1



Figure 2



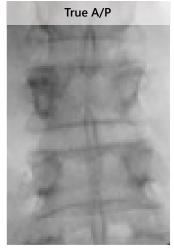


Figure 3

2. Anatomy Identification & Marking

2.1 - Anatomic Landmark and Initial Incisions

Following standard surgical protocols, the affected disc space is localized using lateral fluoroscopy (Figure 4). Use the guide wire provided in the instrument set to make longitudinal marks on the skin to:

- Define a transverse mark, in line with the middle of the disc space. Extending this transverse mark serves as a visual reference to both surgeon and C-arm operator (Figure 4A).
- Define the anterior border of the vertebral bodies (Figure 4B).
- Define the posterior border of the vertebral bodies (Figure 4C).
- Define the posterior third of the disc space (Figure 4D).

Note:

If targeting the L4/L5 disc space, the mid point of the disc space should be used as the lumbar plexus sweeps anteriorly at lower lumbar levels.

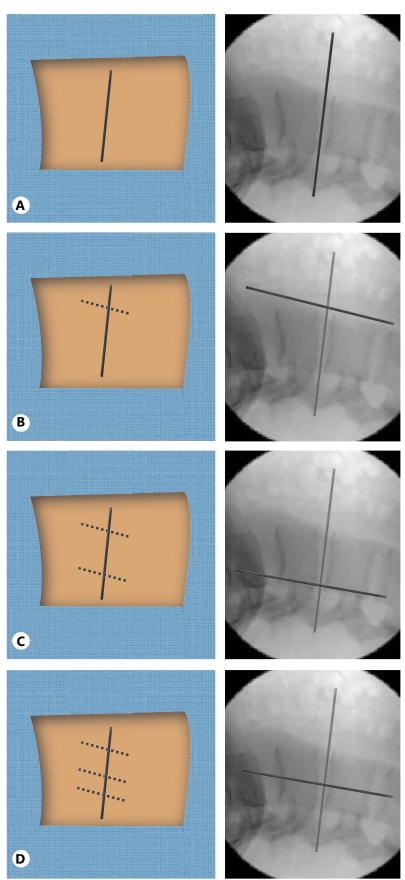


Figure 4

3. Retractor Instruction

3.1 - Retractor Insertion

A small bluntly dissected incision will be made during this procedure. The incision, located in a true lateral (lateral decubitus) position, will be used to place the dilators and retractor, and will provide a safe working corridor and disc space access.

Alternating blunt scissor and finger dissection is used to safely enter the retroperitoneal space over the effected anatomy. Once the index finger is inside the space, manual finger manipulation is used to release the peritoneum anterior and create a space through which the access instrumentation will be placed. The initial dilator will first pass through the oblique muscle layers past the peritoneum down to the surface of the psoas muscle.

Once the initial dilator is on the surface of the psoas muscle, the dilator is advanced through the psoas. Direct, lateral trajectory targeting just posterior to the middle of the disc minimizes the chance of encountering a nerve and ensures that anterior vessels remain well anterior to the working corridor. Once docked on the spine, the Dilator is affixed to the disc with a K-wire, and subsequent dilation and muscle-splitting retraction establish the safe working corridor. Approach the desired disc space level and place the Retractor. Reference document 71-045 for the XL3 Retractor System® User Guide (Figure 5). Use of neuromonitoring is recommended to ensure patient safety.

Note:

The retractor and disc preparation allows for orienting of the retractor to allow access to the disc space when bony anatomy dictates.

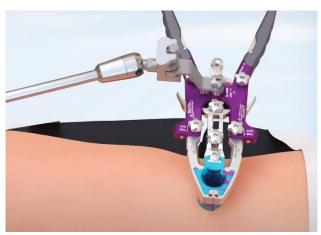


Figure 5*

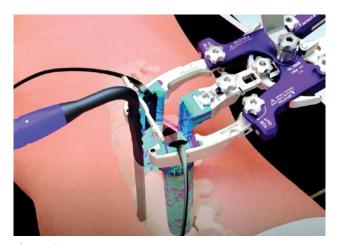


Figure 6*

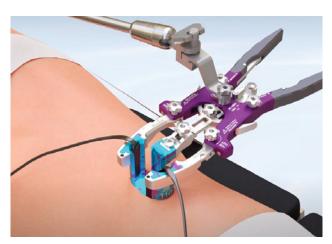


Figure 7*



4. Discectomy

4.1 - Discectomy

Create a box annulotomy (either 18mm or 22mm in A/P length, depending on the anticipated Implant size) on the lateral face of the disc (Figure 8a). Following this step, an annulotomy is created with the bayonetted blade.

Disc preparation instruments are passed along both endplates and completely through the contralateral annulus. Contralateral annulus release is important to facilitate parallel distraction of the disc space, achieve proper coronal alignment, and place a large Implant that spans the ring apophysis.

Pituitaries, Curettes, Disc Cutters, Endplate Scrapers, Rasps, and other disc preparation instruments can be used to thoroughly remove the disc and prepare the endplates for fusion (Figure 8b).

Note:

Excessive endplate preparation may compromise endplate stability and may contribute to endplate subsidence.

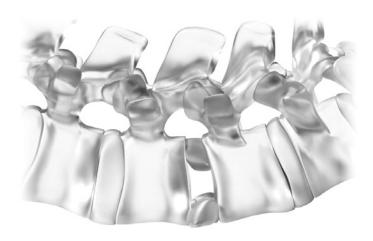


Figure 8a

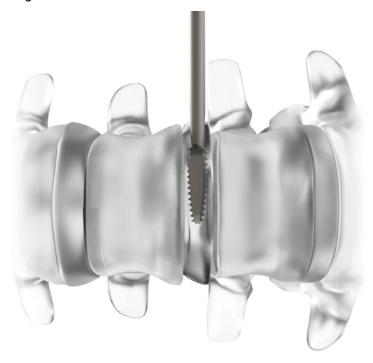


Figure 8b

5. Insertion Options

Note:

This surgical technique outlines a Standard Approach with the Straight Inserter. Anatomy or safe working corridor may require the use of the Oblique Inserter or Right/Left Angled Inserter.

5.1 - Inserter Selection

The Straight Inserter is provided for standard approach or true lateral perpendicular access.

The Oblique Inserter has a 20° angle relative to the Implant/Trial inteded for an anterior to the psoas approach. Surgeon should review and be familiar with the neurovascular anatomy when utilizing this instrument and technique.

The Left and Right Angled Inserters have a 15° angle relative to the Implant/Trial for use where orienting of the retractor due to bony anatomy dictates the trajectory and access to the effected disc space.

Note:

The Left Angled Inserter should be used when accessing the disc on the anatomic left side of the patient. The Right Angled Inserter should be used when accessing the disc on the anatomic right side of the patient.

Note:

Implant and Trial follow the same process of attachment and detachment.

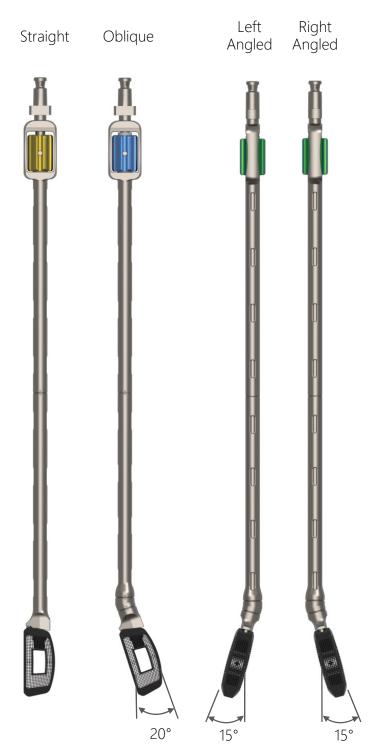


Figure 9

5. Insertion Options (Continued)

Note:

Implant and Trial follow the same process of attachment and detachment.

5.2 - Inserter & Triall/Implant Attachment

Mate the Inserter Alignment Post to the holes of the Trial/Implant (Figure 10). Turn the thumb wheel on the Inserter clockwise to tighten the Trial/Implant (Figure 11).

Note:

Verify assembly before placement in the working corridor. Instrument should seat flush with the proximal face of the Trial/Implant without toggle.

5.3 - Inserter & Trial/Implant Detachment

To disconnect the Trial/Implant, rotate the thumb wheel counterclockwise until Trial/Implant is released.



Figure 10



Figure 11

5. Insertion Options (Continued)

5.4 - Handle Attachment

T-Handle:

Pull the Hudson Connect Sleeve up (Figure 12a).

Align and connect the Hudson Connect Sleeve to the Implant Inserter (Figure 12b).

Release the Hudson Connect Sleeve (Figure 12c).



Slap Hammer:

Pull the Hudson Connect Sleeve up (Figure 13a).

Align and connect the Hudson Connect Sleeve to the Implant Inserter (Figure 13b).

Release the Hudson Connect Sleeve (Figure 13c).

Note:

A Slap Hammer Adapter is provided and allows the Slap Hammer to be connected to several instruments. The Slap Hammer Adapter is threaded into the Inline Handle and the Slap Hammer is connected to the Slap Hammer Adapter via the Hudson Connect.



5. Insertion Options (Continued)

3.2 - Cage Inserter + Trial Detachment

To disconnect the Trial/Cage, rotate the Thumb Wheel counterclockwise until the Trial/Cage is released.

Thumb Wheel Rotater

A Thumb Wheel Rotator may be used in the event that additional leverage is required to loosen the Thumb Wheel.

To use the Thumb Wheel Rotator, first remove the handle from the Inserter (Figure 5a).

Slide the Thumb Wheel Rotator over the adapter (Figure 5b) and align the two prongs over the Thumb Wheel.

Verify successful merge of the Thumb Wheel Rotator to the Inserter (Figure 5c).

Rotate the Thumb Wheel Rotator counter-clockwise to loosen while exerting slight downward pressure to allow for ratcheting (Figure 5d).



Figure 5a



Figure 5b



Figure 5c



Figure 5d

6. Trialing

6.1 - Implant Selection

Once the disc space and endplate is adequately prepared, the optimal Implant width, depth, and height can be determined by Trialing. Trial anodization colors differentiate Trials by width and lordosis. Trials are used first to determine the appropriate Implant footprint and height to be utilized.

Modular Trials can be assembled to the Implant Inserter for placement. Additional Monolithic Trials are also provided.

Note:

The height of the Trial is line-to-line with the Implant (Figure 14).

Implant length can be determined using the holes in the Trial. Holes are placed at 40, 50, and 60mm relative to the distal end of the Trial (Figure 15).

Under A/P fluoroscopy, gently impact the Trial into the disc space until centered to determine the desired implant size.

Proper A/P position is verified using true lateral fluoroscopy Figure 16). Use of incrementally taller sizes should be utilized until a tight fit is achieved. There should be no gap between the prepared site and Trial.

If satisfied with placement and fit of the Trial, surgeon can remove the Trial from the disc space. The Slap Hammer can be used, if necessary, to facilitate Trial removal.

Note:

Apply downward pressure on the Retractor when removing all instruments from the disc space to prevent migration of the blades.



Figure 14

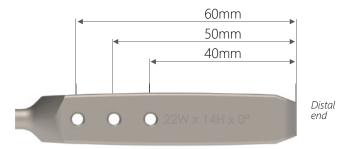


Figure 15

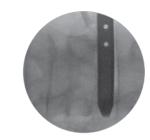




Figure 16

7. Implant Insertion

7.1 - Implant & Inserter Attachment

Pack the central graft cavity with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft prior to insertion (Figure 17).

Attach an Inline Handle Hudson Connect to proximal end of Inserter and verify security of the assembly.

7.2 - Implant Placement

Impact the Implant into the prepared disc space (Figure 18). Placement of the Implant is dictated by patient anatomy and the spinal pathology that is being treated. Generally, the Implant spans the apophyseal rim and is centered across the disc space from a medial/lateral perspective, and is near the center of the disc space from an anterior/posterior perspective.

Modular Graft Slides may be used to protect the endplates and contain graft material during Implant insertion. Assemble the Modular Handles to the Graft Slides by pulling back on the collet on the Modular Handles and slide onto the proximal mating features of the Graft Slides. Fluoroscopy should be used to verify that slides are positioned properly (Figure 19). A Tamp may be used to adjust the placement of the Implant.

7.3 - Supplemental Fixation

NEXXT SPINE® provides a full portfolio of supplemental fixation solutions such as the STRUXXURE®-L, INERTIA® Pedicle Screw System, INERTIA® Deformity Correxxion System, FACET FIXX® Transfacet System and FACET FIXX® Translaminar System.

Note:

Supplemental fixation system Indications for Use can be referenced at: www.NexxtSpine.com/Resources/Indicationsfor-use/



Figure 17

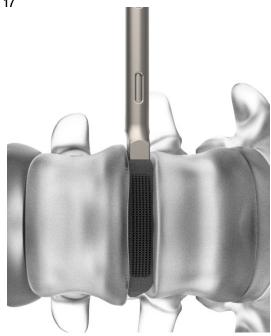


Figure 18



Figure 19



8. Removal & Closure

8.1 - Retractor Removal

Once the procedure is completed, the retractor is removed while using direct visualization to verify the absence of significant bleeding in the disc space or psoas muscle.

The skin is closed using standard surgical techniques (Figure 20).

Supplemental instrumentation is required.

8.2 - Implant Removal (As needed)

If it becomes necessary to revise the implanted Implant, access to the implantation site can be achieved in a similar fashion to the original access. Once the implanted Implant is exposed, it can be removed by reattaching the Inserter (Figure 21). If the device is difficult to remove, additional engagement or dislodging may be achieved with the Removal Tool. Separation from the inferior and superior endplate and removal of bony ongrowth should be completed so as to limit iatrogenic damage.

All supplemental instrumentation should be revised in accordance with its respective product technique guide.

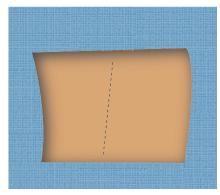


Figure 20

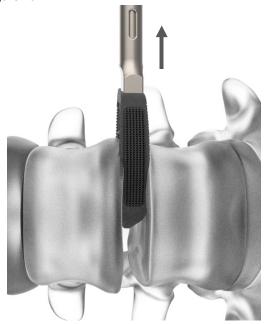


Figure 21



NEXXT MATRIXX® Lateral Implant Part Numbers - 18W

Standard P/N

Description



Standard P/N Description Lateral 18W x XXL x XXH Implants 62-1840-08-0-SP* 18Wx40Lx08H, 0° 62-1840-10-0-SP* 18Wx40Lx10H, 0° 62-1840-12-0-SP* 18Wx40Lx12H, 0° 62-1840-14-0-SP* 18Wx40Lx14H, 0° 62-1840-16-0-SP* 18Wx40Lx16H, 0° 62-1845-08-0-SP 18Wx45Lx08H, 0° 62-1845-10-0-SP 18Wx45Lx10H, 0°	
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62-1840-16-0-SP* 18Wx40Lx16H, 0° 62-1845-08-0-SP 18Wx45Lx08H, 0°))
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Stariaara 1711	Description
Lateral 18W x XXI	x XXH Implants
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62-1845-12-20-SP*	18Wx45Lx12H, 20°
62-1845-14-20-SP*	18Wx45Lx14H, 20°
62-1845-16-20-SP*	18Wx45Lx16H, 20°
62-1845-18-20-SP*	18Wx45Lx18H, 20°
62-1845-20-20-SP*	18Wx45Lx20H, 20°

Standard P/N	Description
Lateral 18W x XX	L x XXH Implants
62-1850-12-20-SP*	18Wx50Lx12H, 20°
62-1850-14-20-SP*	18Wx50Lx14H, 20°
62-1850-16-20-SP*	18Wx50Lx16H, 20°
62-1850-18-20-SP*	18Wx50Lx18H, 20°
62-1850-20-20-SP*	18Wx50Lx20H, 20°
62-1855-12-20-SP*	18Wx55Lx12H, 20°
62-1855-14-20-SP*	18Wx55Lx14H, 20°
62-1855-16-20-SP*	18Wx55Lx16H, 20°
62-1855-18-20-SP*	18Wx55Lx18H, 20°
62-1855-20-20-SP*	18Wx55Lx20H, 20°
62-1860-12-20-SP*	18Wx60Lx12H, 20°
62-1860-14-20-SP*	18Wx60Lx14H, 20°
62-1860-16-20-SP*	18Wx60Lx16H, 20°
62-1860-18-20-SP*	18Wx60Lx18H, 20°
62-1860-20-20-SP*	18Wx60Lx20H, 20°



NEXXT MATRIXX® Lateral Implant Part Numbers - 22W

Standard P/N

Description



Standard P/N	Description
Lateral 22W x XXI	x XXH Implants
62-2240-08-0-SP*	22Wx40Lx08H, 0°
62-2240-10-0-SP*	22Wx40Lx10H, 0°
62-2240-12-0-SP*	22Wx40Lx12H, 0°
62-2240-14-0-SP*	22Wx40Lx14H, 0°
62-2240-16-0-SP*	22Wx40Lx16H, 0°
62-2245-08-0-SP	22Wx45Lx08H, 0°
62-2245-10-0-SP	22Wx45Lx10H, 0°
62-2245-12-0-SP	22Wx45Lx12H, 0°
62-2245-14-0-SP*	22Wx45Lx14H, 0°
62-2245-16-0-SP*	22Wx45Lx16H, 0°
62-2250-08-0-SP	22Wx50Lx08H, 0°
62-2250-10-0-SP	22Wx50Lx10H, 0°
62-2250-12-0-SP	22Wx50Lx12H, 0°
62-2250-14-0-SP	22Wx50Lx14H, 0°
62-2250-16-0-SP*	22Wx50Lx16H, 0°
62-2255-08-0-SP	22Wx55Lx08H, 0°
62-2255-10-0-SP	22Wx55Lx10H, 0°
62-2255-12-0-SP	22Wx55Lx12H, 0°
62-2255-14-0-SP	22Wx55Lx14H, 0°
62-2255-16-0-SP*	22Wx55Lx16H, 0°
62-2260-08-0-SP	22Wx60Lx08H, 0°
62-2260-10-0-SP	22Wx60Lx10H, 0°
62-2260-12-0-SP	22Wx60Lx12H, 0°
62-2260-14-0-SP	22Wx60Lx14H, 0°
62-2260-16-0-SP*	22Wx60Lx16H, 0°
62-2240-08-8-SP*	22Wx40Lx08H, 8°
62-2240-10-8-SP*	22Wx40Lx10H, 8°
62-2240-12-8-SP*	22Wx40Lx12H, 8°
62-2240-14-8-SP*	22Wx40Lx14H, 8°
62-2240-16-8-SP*	22Wx40Lx16H, 8°
62-2245-08-8-SP	22Wx45Lx08H, 8°
62-2245-10-8-SP	22Wx45Lx10H, 8°
62-2245-12-8-SP	22Wx45Lx12H, 8°
62-2245-14-8-SP	22Wx45Lx14H, 8°
62-2245-16-8-SP*	22Wx45Lx16H, 8°
62-2250-08-8-SP	22Wx50Lx08H, 8°
62-2250-10-8-SP	22Wx50Lx10H, 8°
62-2250-12-8-SP	22Wx50Lx12H, 8°
62-2250-14-8-SP	22Wx50Lx14H, 8°
62-2250-16-8-SP*	22Wx50Lx16H, 8°

Standard 1/14	Description
Lateral 22W x XX	L x XXH Implants
62-2255-08-8-SP	22Wx55Lx08H, 8°
62-2255-10-8-SP	22Wx55Lx10H, 8°
62-2255-12-8-SP	22Wx55Lx12H, 8°
62-2255-14-8-SP	22Wx55Lx14H, 8°
62-2255-16-8-SP*	22Wx55Lx16H, 8°
62-2260-08-8-SP	22Wx60Lx08H, 8°
62-2260-10-8-SP	22Wx60Lx10H, 8°
62-2260-12-8-SP	22Wx60Lx12H, 8°
62-2260-14-8-SP*	22Wx60Lx14H, 8°
62-2260-16-8-SP*	22Wx60Lx16H, 8°
62-2240-10-14-SP*	22Wx40Lx10H, 1 4°
62-2240-12-14-SP*	22Wx40Lx12H, 1 4°
62-2240-14-14-SP*	22Wx40Lx14H, 1 4°
62-2240-16-14-SP*	22Wx40Lx16H, 1 4°
62-2245-10-14-SP	22Wx45Lx10H, 1 4°
62-2245-12-14-SP	22Wx45Lx12H, 1 4°
62-2245-14-14-SP	22Wx45Lx14H, 1 4°
62-2245-16-14-SP*	22Wx45Lx16H, 1 4°
62-2250-10-14-SP	22Wx50Lx10H, 1 4°
62-2250-12-14-SP	22Wx50Lx12H, 1 4°
62-2250-14-14-SP	22Wx50Lx14H, 1 4°
62-2250-16-14-SP	22Wx50Lx16H, 1 4°
62-2255-10-14-SP	22Wx55Lx10H, 1 4°
62-2255-12-14-SP	22Wx55Lx12H, 1 4°
62-2255-14-14-SP	22Wx55Lx14H, 1 4°
62-2255-16-14-SP	22Wx55Lx16H, 1 4°
62-2260-10-14-SP	22Wx60Lx10H, 1 4°
62-2260-12-14-SP	22Wx60Lx12H, 1 4°
62-2260-14-14-SP	22Wx60Lx14H, 1 4°
62-2260-16-14-SP	22Wx60Lx16H, 1 4°
62-2240-12-20-SP*	22Wx40Lx12H, 20°
62-2240-14-20-SP*	22Wx40Lx14H, 20°
62-2240-16-20-SP*	22Wx40Lx16H, 20°
62-2240-18-20-SP*	22Wx40Lx18H, 20°
62-2240-20-20-SP*	22Wx40Lx20H, 20°
62-2245-12-20-SP*	22Wx45Lx12H, 20°
62-2245-14-20-SP*	22Wx45Lx14H, 20°
62-2245-16-20-SP*	22Wx45Lx16H, 20°
62-2245-18-20-SP*	22Wx45Lx18H, 20°
62-2245-20-20-SP*	22Wx45Lx20H, 20°

Standard P/N	Description
Lateral 22W x XX	L x XXH Implants
62-2250-12-20-SP*	22Wx50Lx12H, 20°
62-2250-14-20-SP*	22Wx50Lx14H, 20°
62-2250-16-20-SP*	22Wx50Lx16H, 20°
62-2250-18-20-SP*	22Wx50Lx18H, 20°
62-2250-20-20-SP*	22Wx50Lx20H, 20°
62-2255-12-20-SP*	22Wx55Lx12H, 20°
62-2255-14-20-SP*	22Wx55Lx14H, 20°
62-2255-16-20-SP*	22Wx55Lx16H, 20°
62-2255-18-20-SP*	22Wx55Lx18H, 20°
62-2255-20-20-SP*	22Wx55Lx20H, 20°
62-2260-12-20-SP*	22Wx60Lx12H, 20°
62-2260-14-20-SP*	22Wx60Lx14H, 20°
62-2260-16-20-SP*	22Wx60Lx16H, 20°
62-2260-18-20-SP*	22Wx60Lx18H, 20°
62-2260-20-20-SP*	22Wx60Lx20H, 20°



NEXXT MATRIXX® Lateral Implant Part Numbers - 26W

Standard P/N

Description



Standard P/N	Description
Lateral 26W x XX	L x XXH Implants
62-2640-08-0-SP*	22Wx40Lx08H, 0°
62-2640-10-0-SP*	22Wx40Lx10H, 0°
62-2640-12-0-SP*	22Wx40Lx12H, 0°
62-2640-14-0-SP*	22Wx40Lx14H, 0°
62-2640-16-0-SP*	22Wx40Lx16H, 0°
62-2645-08-0-SP*	22Wx45Lx08H, 0°
62-2645-10-0-SP*	22Wx45Lx10H, 0°
62-2645-12-0-SP*	22Wx45Lx12H, 0°
62-2645-14-0-SP*	22Wx45Lx14H, 0°
62-2645-16-0-SP*	22Wx45Lx16H, 0°
62-2650-08-0-SP*	22Wx50Lx08H, 0°
62-2650-10-0-SP*	22Wx50Lx10H, 0°
62-2650-12-0-SP*	22Wx50Lx12H, 0°
62-2650-14-0-SP*	22Wx50Lx14H, 0°
62-2650-16-0-SP*	22Wx50Lx16H, 0°
62-2655-08-0-SP*	22Wx55Lx08H, 0°
62-2655-10-0-SP*	22Wx55Lx10H, 0°
62-2655-12-0-SP*	22Wx55Lx12H, 0°
62-2655-14-0-SP*	22Wx55Lx14H, 0°
62-2655-16-0-SP*	22Wx55Lx16H, 0°
62-2660-08-0-SP*	22Wx60Lx08H, 0°
62-2660-10-0-SP*	22Wx60Lx10H, 0°
62-2660-12-0-SP*	22Wx60Lx12H, 0°
62-2660-14-0-SP*	22Wx60Lx14H, 0°
62-2660-16-0-SP*	22Wx60Lx16H, 0°
62-2640-08-8-SP*	22Wx40Lx08H, 8°
62-2640-10-8-SP*	22Wx40Lx10H, 8°
62-2640-12-8-SP*	22Wx40Lx12H, 8°
62-2640-14-8-SP*	22Wx40Lx14H, 8°
62-2640-16-8-SP*	22Wx40Lx16H, 8°
62-2645-08-8-SP*	22Wx45Lx08H, 8°
62-2645-10-8-SP*	22Wx45Lx10H, 8°
62-2645-12-8-SP*	22Wx45Lx12H, 8°
62-2645-14-8-SP*	22Wx45Lx14H, 8°
62-2645-16-8-SP*	22Wx45Lx16H, 8°
62-2650-08-8-SP*	22Wx50Lx08H, 8°
62-2650-10-8-SP*	22Wx50Lx10H, 8°
62-2650-12-8-SP*	22Wx50Lx12H, 8°
62-2650-14-8-SP*	22Wx50Lx14H, 8°
62-2650-16-8-SP*	22Wx50Lx16H, 8°

Standard P/N	Description
Lateral 26W x XX	L x XXH Implants
62-2655-08-8-SP*	22Wx55Lx08H, 8°
62-2655-10-8-SP*	22Wx55Lx10H, 8°
62-2655-12-8-SP*	22Wx55Lx12H, 8°
62-2655-14-8-SP*	22Wx55Lx14H, 8°
62-2655-16-8-SP*	22Wx55Lx16H, 8°
62-2660-08-8-SP*	22Wx60Lx08H, 8°
62-2660-10-8-SP*	22Wx60Lx10H, 8°
62-2660-12-8-SP*	22Wx60Lx12H, 8°
62-2660-14-8-SP*	22Wx60Lx14H, 8°
62-2660-16-8-SP*	22Wx60Lx16H, 8°
62-2640-10-14-SP*	22Wx40Lx10H, 1 4°
62-2640-12-14-SP*	22Wx40Lx12H, 1 4°
62-2640-14-14-SP*	22Wx40Lx14H, 1 4°
62-2640-16-14-SP*	22Wx40Lx16H, 1 4°
62-2645-10-14-SP*	22Wx45Lx10H, 1 4°
62-2645-12-14-SP*	22Wx45Lx12H, 1 4°
62-2645-14-14-SP*	22Wx45Lx14H, 1 4°
62-2645-16-14-SP*	22Wx45Lx16H, 1 4°
62-2650-10-14-SP*	22Wx50Lx10H, 1 4°
62-2650-12-14-SP*	22Wx50Lx12H, 1 4°
62-2650-14-14-SP*	22Wx50Lx14H, 1 4°
62-2650-16-14-SP*	22Wx50Lx16H, 1 4°
62-2655-10-14-SP*	22Wx55Lx10H, 1 4°
62-2655-12-14-SP*	22Wx55Lx12H, 1 4°
62-2655-14-14-SP*	22Wx55Lx14H, 1 4°
62-2655-16-14-SP*	22Wx55Lx16H, 1 4°
62-2660-10-14-SP*	22Wx60Lx10H, 1 4°
62-2660-12-14-SP*	22Wx60Lx12H, 1 4°
62-2660-14-14-SP*	22Wx60Lx14H, 1 4°
62-2660-16-14-SP*	22Wx60Lx16H, 1 4°
62-2640-14-20-SP*	22Wx40Lx14H, 20°
62-2640-16-20-SP*	22Wx40Lx16H, 20°
62-2640-18-20-SP*	22Wx40Lx18H, 20°
62-2640-20-20-SP*	22Wx40Lx20H, 20°
62-2645-14-20-SP*	22Wx45Lx14H, 20°
62-2645-16-20-SP*	22Wx45Lx16H, 20°
62-2645-18-20-SP*	22Wx45Lx18H, 20°
62-2645-20-20-SP*	22Wx45Lx20H, 20°

Standard P/N	Description
Lateral 26W x XX	L x XXH Implants
62-2650-14-20-SP*	22Wx50Lx14H, 20°
62-2650-16-20-SP*	22Wx50Lx16H, 20°
62-2650-18-20-SP*	22Wx50Lx18H, 20°
62-2650-20-20-SP*	22Wx50Lx20H, 20°
62-2655-14-20-SP*	22Wx55Lx14H, 20°
62-2655-16-20-SP*	22Wx55Lx16H, 20°
62-2655-18-20-SP*	22Wx55Lx18H, 20°
62-2655-20-20-SP*	22Wx55Lx20H, 20°
62-2660-14-20-SP*	22Wx60Lx14H, 20°
62-2660-16-20-SP*	22Wx60Lx16H, 20°
62-2660-18-20-SP*	22Wx60Lx18H, 20°
62-2660-20-20-SP*	22Wx60Lx20H, 20°



NEXXT MATRIXX® Lateral Instruments













Standard P/N	Description
160-41-01	Slap Hammer

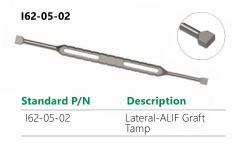


162-52-01

Standard P/N Description

162-52-01 Slap Hammer Adapter













160-05-01



Standard P/N	Description
160-05-01	Lateral Graft Loading Block



Lateral Trials

18W

162-STR-18-XX-X°



Standard P/N	Description
162-STR-18-08-8	Lateral Trial, 18Wx8H, 8°
162-STR-18-10-8	Lateral Trial, 18Wx10H, 8°
162-STR-18-12-8	Lateral Trial, 18Wx12H, 8°
162-STR-18-14-8	Lateral Trial, 18Wx14H, 8°
162-STR-18-16-8	Lateral Trial, 18Wx16H, 8°
162-STR-18-10-14	Lateral Trial, 18Wx10H, 14°
162-STR-18-12-14	Lateral Trial, 18Wx12H, 14°
162-STR-18-14-14	Lateral Trial, 18Wx14H, 14°
162-STR-18-16-14	Lateral Trial, 18Wx16H, 14°

22W

I62-STR-22-XX-X°



Standard P/N	Description
162-STR-22-08-8	Lateral Trial, 22Wx8H, 8°
162-STR-22-10-8	Lateral Trial, 22Wx10H, 8°
162-STR-22-12-8	Lateral Trial, 22Wx12H, 8°
162-STR-22-14-8	Lateral Trial, 22Wx14H, 8°
162-STR-22-16-8	Lateral Trial, 22Wx16H, 8°
162-STR-22-10-14	Lateral Trial, 22Wx10H, 14°
162-STR-22-12-14	Lateral Trial, 22Wx12H, 14°
162-STR-22-14-14	Lateral Trial, 22Wx14H, 14°
162-STR-22-16-14	Lateral Trial, 22Wx16H, 14°



Indications for Use

GENERAL DESCRIPTION

The NEXXT 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 NEXXT MATRIXX® open devices incorporate a large vertical cavity which can be packed with autograft or allograft comprised of cancellous and/or corticocancellous 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® System implants are manufactured from Titanium Alloy (Ti6Al4V) as described by ASTM F3001.

INDICATIONS

When used as a lumbar intervertebral fusion device, the NEXXT MATRIXX® 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 NEXXT MATRIXX® 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.

CONTRAINDICATIONS

NEXXT MATRIXX® System contraindications include, but are not limited to:

- 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.
- Biological factors such as smoking, use of nonsteroidal antiinflammatory 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

- Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.
- 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.
- 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.NEXXT MATRIXX® solid devices are not intended for interbody fusion as bone growth through the device has not been demonstrated.
- 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.
- 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.





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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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