

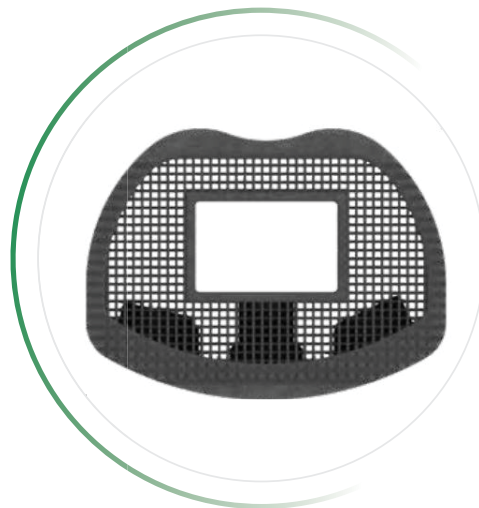
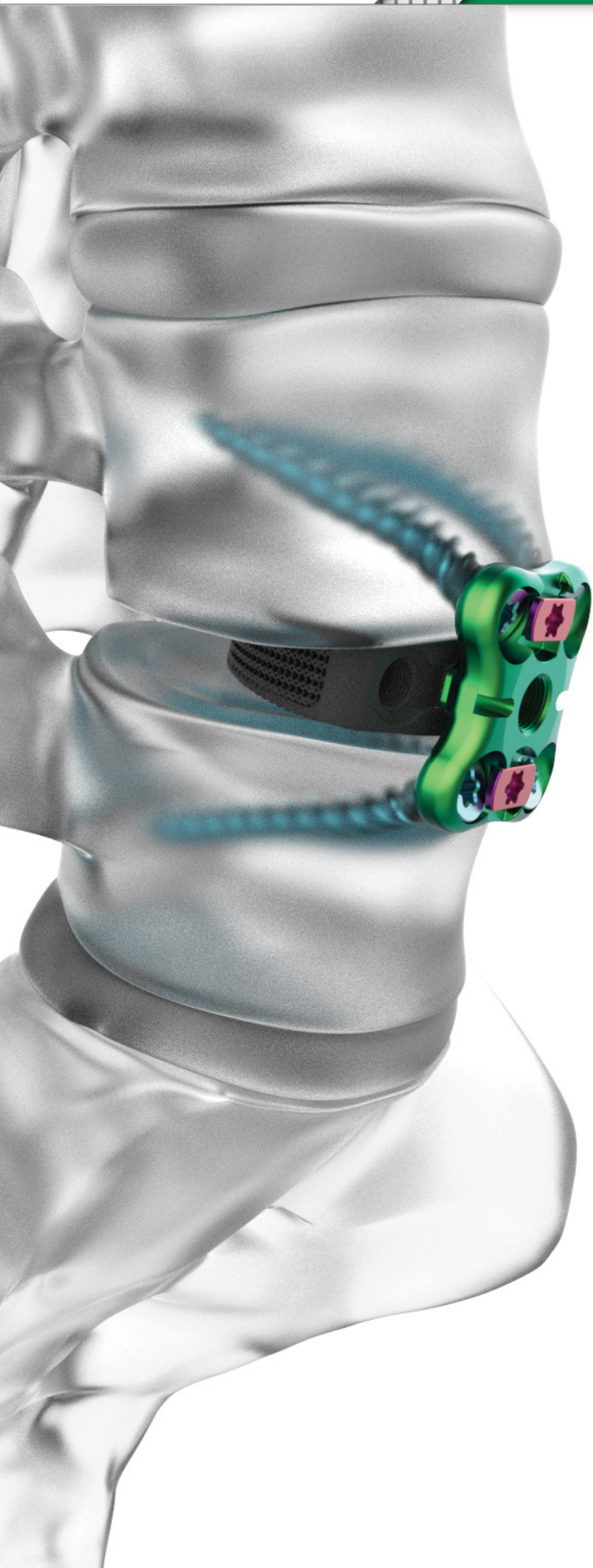




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CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

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® Technology

NEXXT MATRIXX® is a collection of additively manufactured spacers for cervical, lumbar/lumbosacral and thoracolumbar implantation. Each device comprises an external structural frame with a roughened surface, and is shaped as a structural column to provide surgical stabilization of the spine.

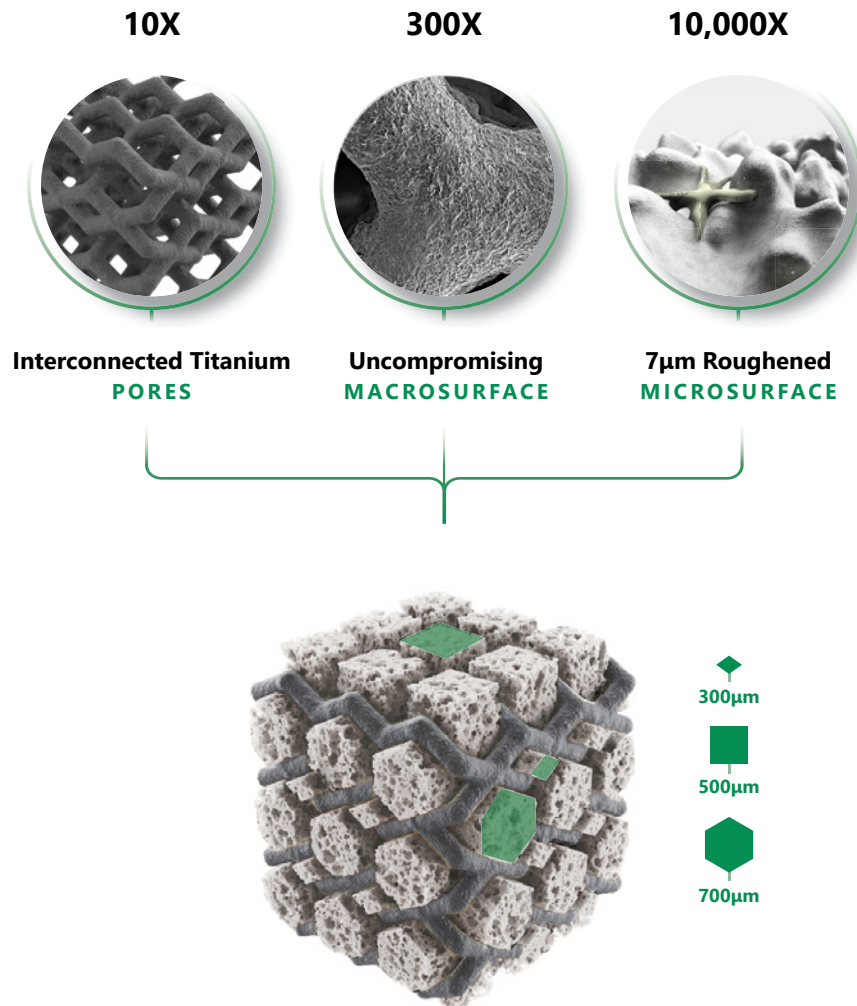


Image represents potential boney ingrowth

TI PORES

- NEXXT MATRIXX® exhibits three pore sizes of 300, 500, and 700µm.
- Minimized titanium material resulting in a 75% open porous architecture.

MATERIAL

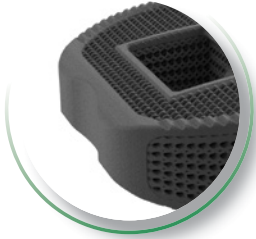
- NEXXT MATRIXX® implants are manufactured from Titanium Alloy (Ti-6Al-4V) as described by ASTM F3001.

SURFACE

- Nexxt Spine has developed a proprietary, residue-free, micro-roughening process that creates a highly cohesive 7µm roughened topography.
- Due to the micro-roughened porous structure of the NEXXT MATRIXX® titanium, the implants exhibit up to 4X more surface area for bone apposition and potential bony integration than conventional spinal implants.



PRODUCT FEATURES



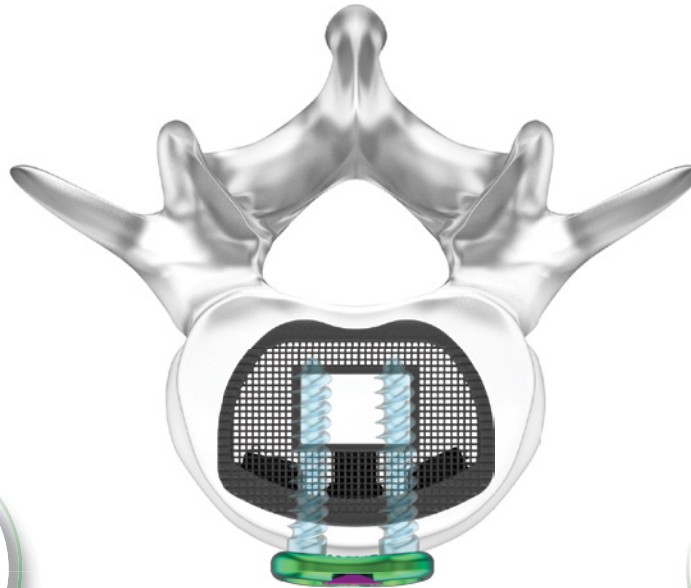
Bulleted nose design

simplifies insertion in collapsed degenerative discs without compromising the apophyseal rim



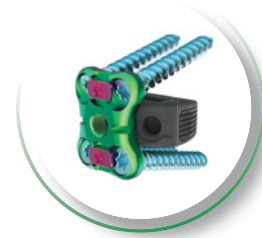
Anatomically matched profile

for appropriate endplate coverage and placement on apophyseal rim for stability



Ample graft window

balanced with lattice landscape to promote bone growth



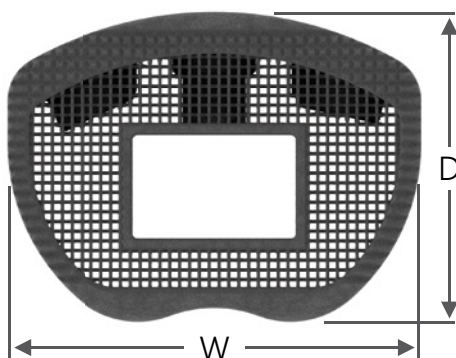
Self-tapping Screws

designed with tip-to-head thread pattern for cancellous and cortical bone fixation

SPECIFICATIONS

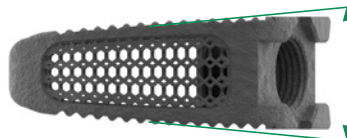
Footprints (mm)

24Dx32W / 27Dx36W



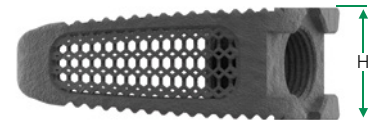
Lordoses

8°, 14°, 20°



Heights

10, 12, 14, 16, 18, and 20mm*



Insertion Angle

0°, 12°, 25°



*By Request

Contact Info@NexxtSpine.com for full SKU offering.



1. Patient Positioning + Surgical Preparation

1.1 - Patient Positioning

Perform the customary approach for an ALIF as determined by surgeon preference (Figure 1.1).

NOTE:

While cleared for use at L5-S1, the anatomic position of the iliac crest or left femoral artery can make an oblique approach challenging at the L5-S1 level.

1.2 - Confirm Disc Location with Fluoroscopy

A disc marker may be inserted into the affected disc and a radiographic image taken to confirm the appropriate level.

1.3 - Retractor Insertion

Using fluoroscopy, identify the middle of the disc space. 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.

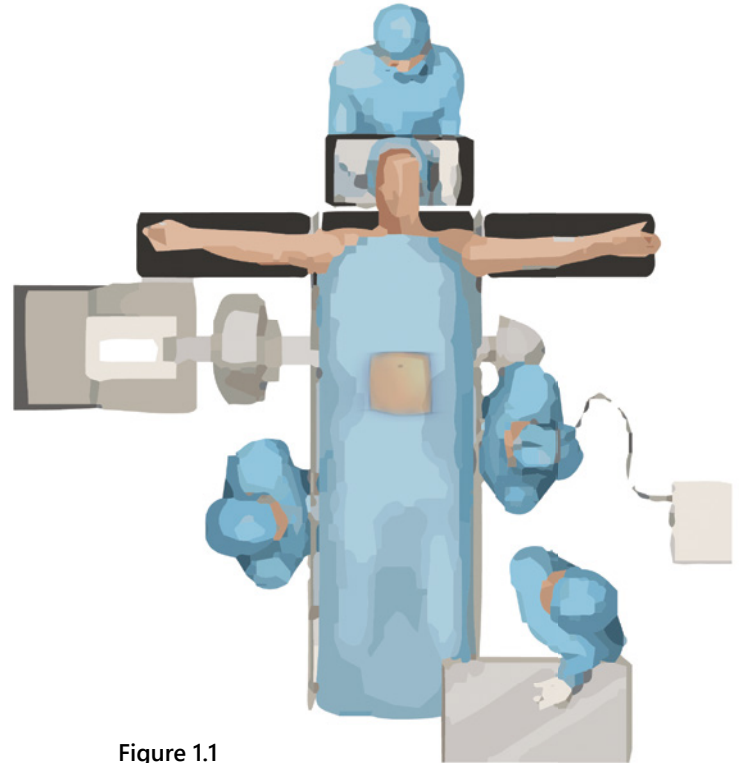


Figure 1.1



2. Midline Verification + Disc Removal

2.1 - Midline Verification

Position the Annulotomy Template (32 or 36mm wide) on the disc space and insert the Centering Pin (23mm deep) in the midline (Figure 2.1).

Note:

Utilize A/P fluoroscopy to verify midline and lateral fluoroscopy to verify depth.

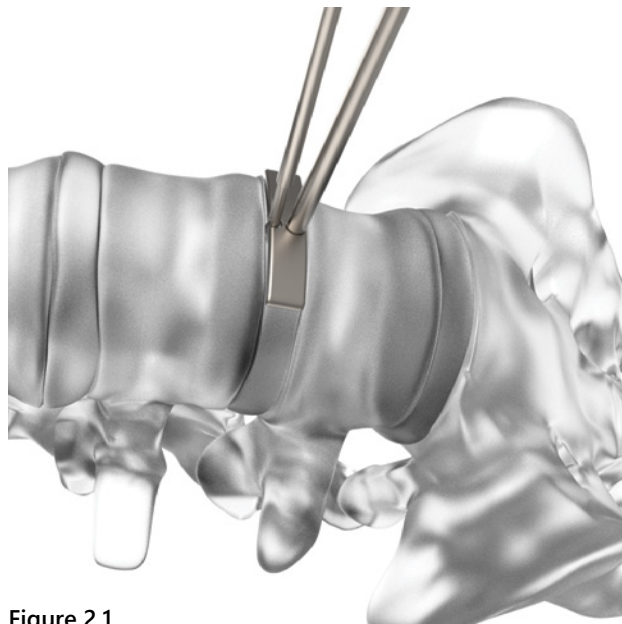


Figure 2.1

2.2 - Disc Removal

Use an annulotomy knife to make incisions in the annulus along the lateral edges of the Annulotomy Template. (Figure 2.2).

Note:

The width of the Annulotomy Template matches the width of the Trial/Cage.

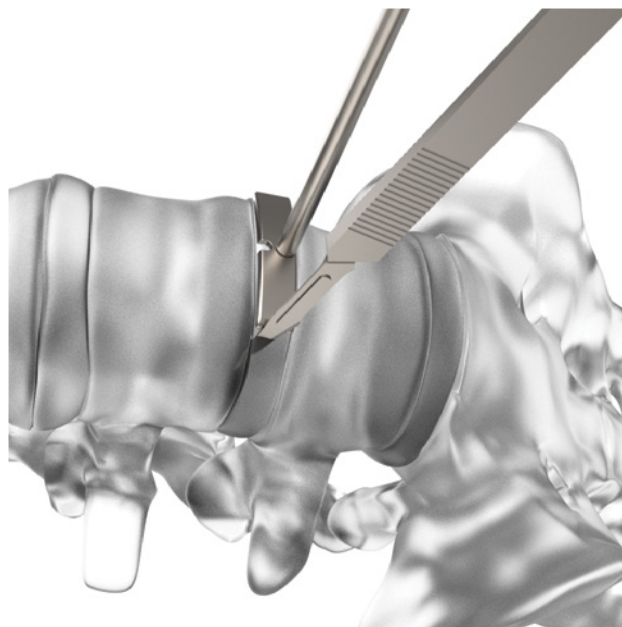


Figure 2.2



3. Cage Inserter Instruction

3.1 - Cage Inserter + Trial Attachment

Align the Cage Inserter to the Trial/Cage. Use the Mate Alignment Post on the Cage Inserter to assist in alignment. (Figure 3.1). Trials may be loaded to the Cage Inserter in both orientations.

Turn the Thumb Wheel on the Cage Inserter clockwise to tighten to the Trial/Cage (Figure 3.2).

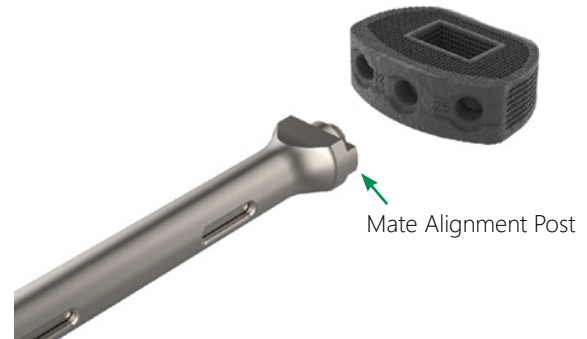


Figure 3.1



Figure 3.2

3.2 - Cage Inserter + Trial Detachment

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

Thumb Wheel Rotator

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 3.3).

Slide the Thumb Wheel Rotator over the adapter (Figure 3.4) and align the two prongs over the Thumb Wheel.

Verify successful merging of the Thumb Wheel Rotator to the Inserter (Figure 3.5).

Rotate the Thumb Wheel Rotator counter-clockwise to loosen while exerting slight downward pressure to allow for ratcheting (Figure 3.6).



Figure 3.3

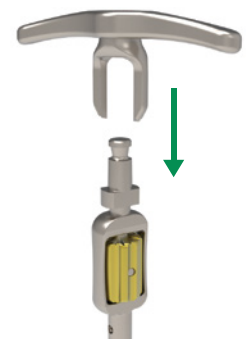


Figure 3.4



Figure 3.5



Figure 3.6



4. Handle Instruction

4.1 - Cage Inserter + T-Handle Attachment

Pull the Hudson Connect Sleeve up (Figure 4.1).

Align and connect the Hudson Connect Sleeve to the Cage Inserter (Figure 4.2).

Release the Hudson Connect Sleeve (Figure 4.3).

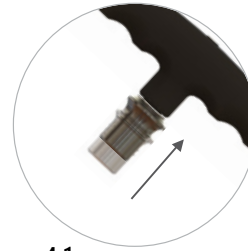


Figure 4.1



Figure 4.2

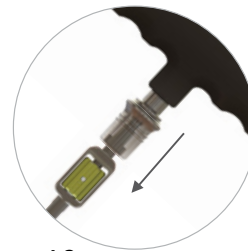


Figure 4.3



4.2 - Cage Inserter + Slap Hammer Attachment

Pull the Hudson Connect Sleeve up (Figure 4.4).

Align and connect the Hudson Connect Sleeve to the Cage Inserter (Figure 4.5).

Release the Hudson Connect Sleeve (Figure 4.6).

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.

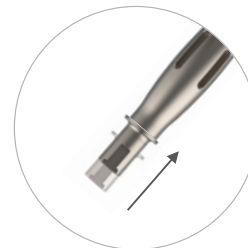


Figure 4.4



Figure 4.5

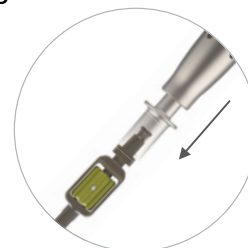


Figure 4.6





5. Trialing

5.1 Trialing: Cage Selection

Once the disc space and endplates are adequately prepared, the optimal Cage footprint and height can be determined by Trialing. Anodization colors differentiate Trials by lordosis.

Note:

The height of the Trial is line-to-line with the Cage (Figure 5.1).



Figure 5.1

Attach the Trial to the Cage Insertor or Trial Insertor.

Cage Insertor

Attach a T-Handle Hudson Connect to the proximal end of the Cage Insertor and verify the security of the assembly (Figure 5.2). Center the Trial in the vertebral cavity.

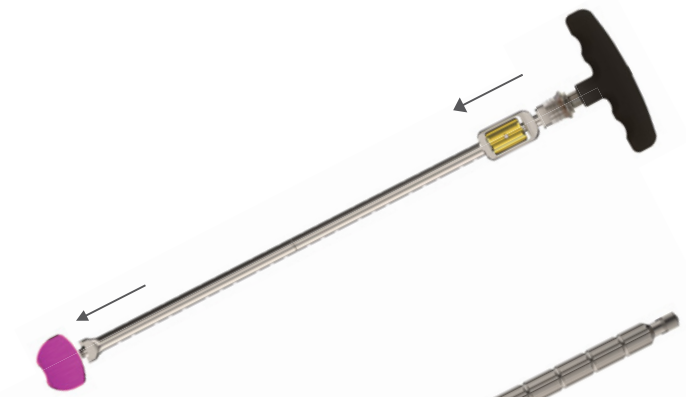


Figure 5.2

Trial Insertor

Thread Trial inserter into desired hole on the anterior face of the trial body until bottomed out (Figure 5.3).



Figure 5.3

To determine the appropriate Cage size, gently impact the Trial into the disc space until it is centered under medial/lateral fluoroscopy (Figure 5.4). Use incrementally taller sizes until a tight fit is achieved; there should be no gap between the prepared site and the Trial.

Once the optimal placement and fit of the Trial is determined, the Trial can be removed from the disc space. The Slap Hammer can be used, if necessary, to facilitate Trial removal.

Note:

Trials can be loaded directly from the Caddy.



Figure 5.4



6. Cage Insertion

6.1 - Cage + Cage Inserter Attachment

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

If anatomy necessitates an oblique Cage insertion, the Cage may be loaded from 12° or 25°. Cephalad/Caudal symmetry allows for left or right insertion at 12° or 25°.

Attach the Cage to the Cage Inserter then attach a T Handle to the proximal end of the Cage Inserter (Figure 6.1). Verify security of the assembly. Center the Cage in the vertebral cavity.



Figure 6.1

6.2 - Cage Placement

Impact the Cage into the prepared disc space (Figure 6.2). Placement of the Cage is dictated by patient anatomy and the spinal pathology that is being treated. Fluoroscopy should be used to verify proper Cage positioning. Remove the Cage Inserter.

Note:

A Tamp may be used to adjust placement of the Cage. Generally, the Cage spans the apophyseal rim and is centered across the disc space from an anterior/posterior perspective, and is near the center of the disc space from a medial/lateral perspective.

Note:

Anterior midline or anterolateral positioning of the Cage may be determined by anatomy and/or surgeon preference. At L5-S1, the Cage may be implanted anteriorly and directly midline, below the level of the bifurcation of the vessels.



Figure 6.2



7. Supplemental Fixation and Closure

7.1 - Supplemental Fixation

Nexxt Spine provides a full portfolio of supplemental fixation solutions such as the STRUXXURE® -A Plate System, INERTIA® CONNEXX™, 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/Indications-for-use/



7.2 - Closure

The skin is closed using the standard surgical technique.

8. Removal (AS NEEDED)

8.1 - Cage Removal

If it becomes necessary to revise the implanted Cage, access to the implantation site can be achieved in a similar fashion to the original access. Once the implanted Cage is exposed, it can be removed by reattaching the Insertor (Figure 8.1). 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.

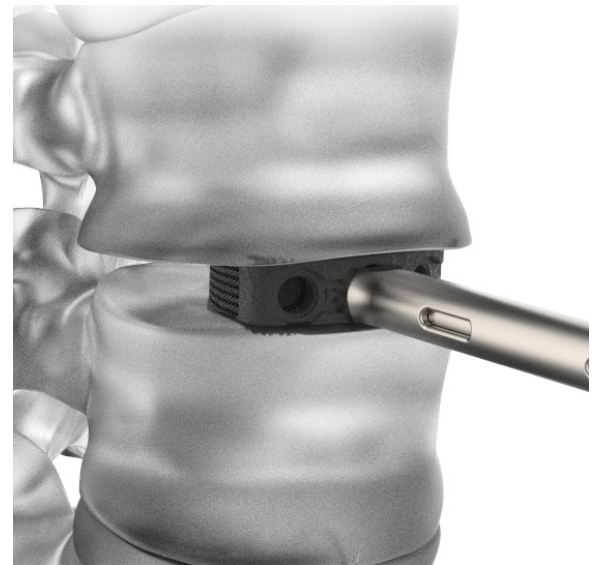


Figure 8.1



NEXXT MATRIXX® ALIF Instruments

ALIF Inserter



Standard P/N	Description
I60-02-01	ALIF Inserter

ALIF Trial Inserter



Standard P/N	Description
I60-03-01	ALIF Trial Inserter

ALIF Inserter*



Standard P/N	Description
I60-01-01	ALIF Inserter, Lockable

Cage Remover



Standard P/N	Description
I60-20-01	Cage Remover

Slap Hammer



Standard P/N	Description
I60-41-01	Slap Hammer

Tamp



Standard P/N	Description
I60-42-01	Tamp

Annulotomy Templates



Standard P/N	Description
I61-32-32	Annulotomy Template, 32mm
I61-32-36	Annulotomy Template, 36mm

Annulotomy Centering Pin



Standard P/N	Description
I61-32-02	Annulotomy Centering Pin

Inserter Release Wrench



Standard P/N	Description
I60-20-02	Inserter Thumb Wheel Release Wrench

Thumb Wheel Rotator



Standard P/N	Description
I92-20-01	Thumb Wheel Rotator

Inline Handle Hudson*



Standard P/N	Description
I10-01-62	Inline Handle Hudson

Slap Hammer Adapter



Standard P/N	Description
I62-52-01	Slap Hammer Adapter

Hudson T-Handle



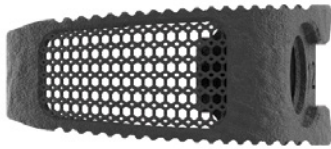
Standard P/N	Description
I10-01-43	T-Handle, Silicone, Hudson Connect

Standard Order

Special Order*



NEXXT MATRXXX® ALIF Implant Part Numbers



Standard P/N	Description
24D x 32W x XXH Implants	
60-2432-08-8-SP	24Dx32Wx08H, 8°
60-2432-10-8-SP	24Dx32Wx10H, 8°
60-2432-12-8-SP	24Dx32Wx12H, 8°
60-2432-14-8-SP	24Dx32Wx14H, 8°
60-2432-16-8-SP	24Dx32Wx16H, 8°
60-2432-18-8-SP	24Dx32Wx18H, 8°
60-2432-20-8-SP*	24Dx32Wx20H, 8°
60-2432-10-14-SP	24Dx32Wx10H, 14°
60-2432-12-14-SP	24Dx32Wx12H, 14°
60-2432-14-14-SP	24Dx32Wx14H, 14°
60-2432-16-14-SP	24Dx32Wx16H, 14°
60-2432-18-14-SP	24Dx32Wx18H, 14°
60-2432-20-14-SP	24Dx32Wx20H, 14°
60-2432-12-20-SP	24Dx32Wx12H, 20°
60-2432-14-20-SP	24Dx32Wx14H, 20°
60-2432-16-20-SP	24Dx32Wx16H, 20°
60-2432-18-20-SP	24Dx32Wx18H, 20°
60-2432-20-20-SP	24Dx32Wx20H, 20°

Standard P/N	Description
27D x 36W x XXH Implants	
60-2736-08-8-SP	27Dx36Wx08H, 8°
60-2736-10-8-SP	27Dx36Wx10H, 8°
60-2736-12-8-SP	27Dx36Wx12H, 8°
60-2736-14-8-SP	27Dx36Wx14H, 8°
60-2736-16-8-SP	27Dx36Wx16H, 8°
60-2736-18-8-SP	27Dx36Wx18H, 8°
60-2736-20-8-SP*	27Dx36Wx20H, 8°
60-2736-10-14-SP	27Dx36Wx10H, 14°
60-2736-12-14-SP	27Dx36Wx12H, 14°
60-2736-14-14-SP	27Dx36Wx14H, 14°
60-2736-16-14-SP	27Dx36Wx16H, 14°
60-2736-18-14-SP	27Dx36Wx18H, 14°
60-2736-20-14-SP	27Dx36Wx20H, 14°
60-2736-12-20-SP	27Dx36Wx12H, 20°
60-2736-14-20-SP	27Dx36Wx14H, 20°
60-2736-16-20-SP	27Dx36Wx16H, 20°
60-2736-18-20-SP	27Dx36Wx18H, 20°
60-2736-20-20-SP	27Dx36Wx20H, 20°

NEXXT MATRXXX® ALIF Trial Part Numbers



Standard P/N	Description
24D x 32W x XXH Trials	
I60-TR2432-8-08	24Dx32Wx08Hx8°
I60-TR2432-8-10	24Dx32Wx10Hx8°
I60-TR2432-8-12	24Dx32Wx12Hx8°
I60-TR2432-8-14	24Dx32Wx14Hx8°
I60-TR2432-8-16	24Dx32Wx16Hx8°
I60-TR2432-8-18	24Dx32Wx18Hx8°
I60-TR2432-8-20	24Dx32Wx20Hx8°
I60-TR2432-14-10	24Dx32Wx10Hx14°
I60-TR2432-14-12	24Dx32Wx12Hx14°
I60-TR2432-14-14	24Dx32Wx14Hx14°
I60-TR2432-14-16	24Dx32Wx16Hx14°
I60-TR2432-14-18	24Dx32Wx18Hx14°
I60-TR2432-14-20	24Dx32Wx20Hx14°
I60-TR2432-20-12	24Dx32Wx12Hx20°
I60-TR2432-20-14	24Dx32Wx14Hx20°
I60-TR2432-20-16	24Dx32Wx16Hx20°
I60-TR2432-20-18	24Dx32Wx18Hx20°
I60-TR2432-20-20	24Dx32Wx20Hx20°

Standard P/N	Description
27D x 36W x XXH Trials	
I60-TR2736-8-08	27Dx36Wx08Hx8°
I60-TR2736-8-10	27Dx36Wx10Hx8°
I60-TR2736-8-12	27Dx36Wx12Hx8°
I60-TR2736-8-14	27Dx36Wx14Hx8°
I60-TR2736-8-16	27Dx36Wx16Hx8°
I60-TR2736-8-18	27Dx36Wx18Hx8°
I60-TR2736-8-20	27Dx36Wx20Hx8°
I60-TR2736-14-10	27Dx36Wx10Hx14°
I60-TR2736-14-12	27Dx36Wx12Hx14°
I60-TR2736-14-14	27Dx36Wx14Hx14°
I60-TR2736-14-16	27Dx36Wx16Hx14°
I60-TR2736-14-18	27Dx36Wx18Hx14°
I60-TR2736-14-20	27Dx36Wx20Hx14°
I60-TR2736-20-12	27Dx36Wx12Hx20°
I60-TR2736-20-14	27Dx36Wx14Hx20°
I60-TR2736-20-16	27Dx36Wx16Hx20°
I60-TR2736-20-18	27Dx36Wx18Hx20°
I60-TR2736-20-20	27Dx36Wx20Hx20°

Standard Order

Special Order*



Instructions For Use (IFU)

GENERAL DESCRIPTION

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

1. The presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, any demonstrated allergy or foreign body sensitivity to any of the implant materials, drugs/alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, 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.

PRODUCT COMPLAINTS

The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Nexxt Spine immediately. Nexxt Spine should be notified immediately of any product malfunction by telephone, fax or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

WARNINGS AND PRECAUTIONS

1. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.
2. The NEXXT MATRIXX® ALIF System devices should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Prior to use, surgeons should be trained in the surgical procedures recommended for use of these devices.
3. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the device.
4. The 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. The NEXXT MATRIXX® ALIF System is used to augment the development of a spinal fusion by providing temporary stabilization. This device is not intended to be the sole means of spinal support - supplemental internal fixation must be used. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant's longevity.
7. The correct handling of the implant is extremely important. Use care in handling and storage of devices. Store the devices in a clean, dry area away from radiation and extreme temperatures and corrosive environments such as moisture, air, etc.
8. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
9. Components of this system should not be used with components of any other system or manufacturer.
10. Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.



NEXXT MATRIXX®

3D Printed Porous Titanium

ALIF

Surgical Technique Guide

15



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Info@NexxtSpine.com
NexxtSpine.com

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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