NEXXT Spine
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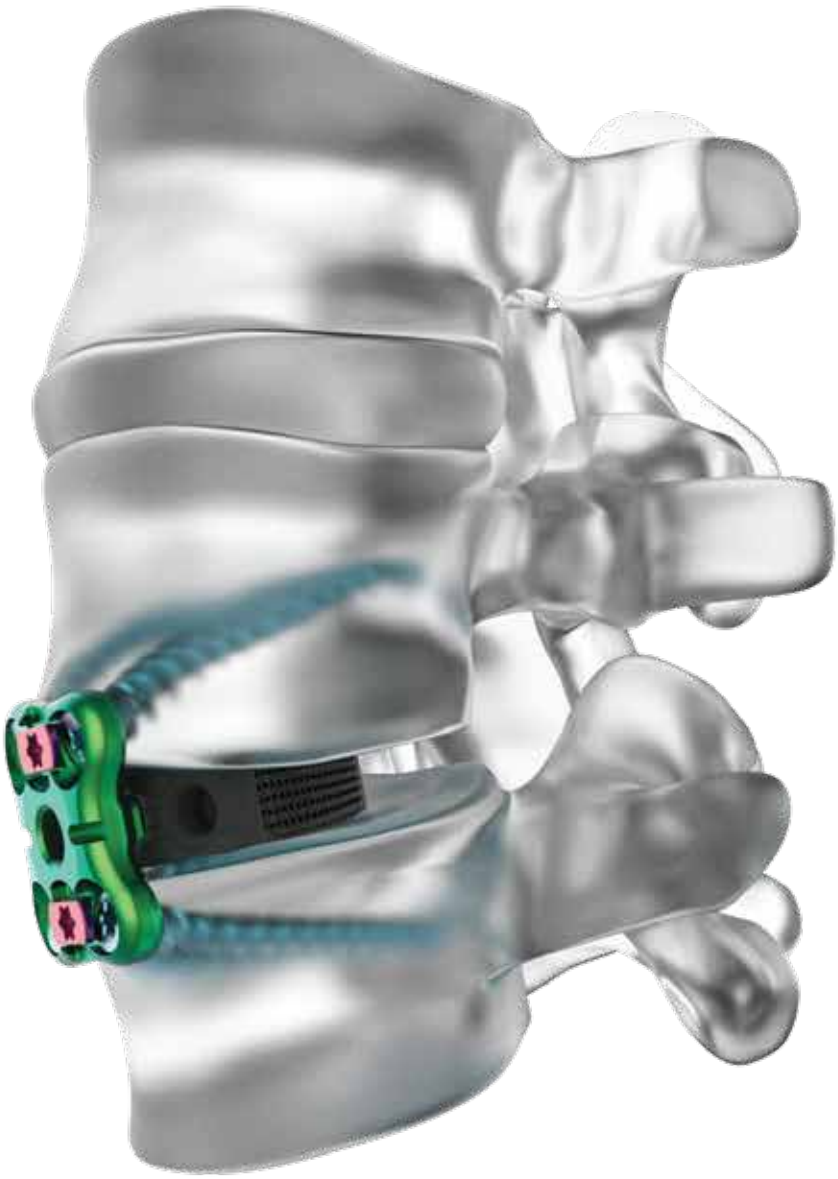
Surgical Technique Guide
NEXXT MATRIXX® ALIF



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NEXXT MATRIXX®
3D Printed Porous Titanium

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Nexxt Spine is a medical device developer and manufacturer and provides this technique as a reference for recommended procedural steps for the placement of the NEXXT MATRIXX® ALIF.

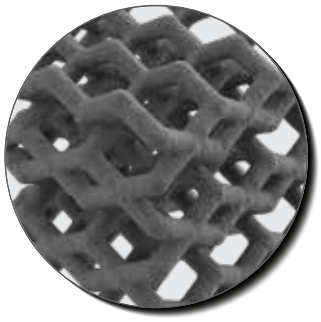
Every physician should utilize his or her own discretion in the diagnosis and treatment of a patient, and this information does not intend to replace the comprehensive training physicians have received.

The following general Surgical Technique Guide is for illustrative purposes only. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as to the best treatment for each patient. Only those individuals with specialized training and experience in spinal surgery should attempt to use the NEXXT MATRIXX® ALIF. Detailed preoperative clinical and diagnostic evaluation followed by carefully executed surgical technique is essential.

Refer to the Instructions for Use (IFU) for a complete list of prescribing information. This technique guide was developed in conjunction with health care professionals.

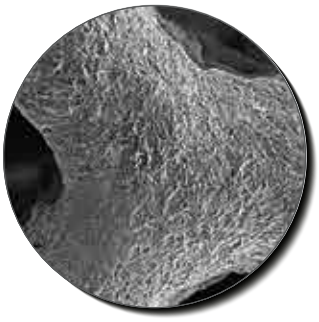
NEXXT MATRIXX®
3D Printed Porous Titanium

10X



Systematic Titanium
PORES

300X



Uncompromising
MACROSURFACE

10,000X

7µm Surface
MICROSURFACE

Pillars of NEXXT MATRIXX® Technology:

1. 7µm surface roughness designed to increase osteoblast differentiation, production of angiogenic factors, and surface osteointegration.[2,3,6]
2. Varied pore array of 300, 500, and 700µm designed to support vascularization and osteogenesis.[1,4,5]
3. 75% Porous, open titanium architecture developed for greater surface area and nutrient exchange, leading to increased volume for potential boney 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]

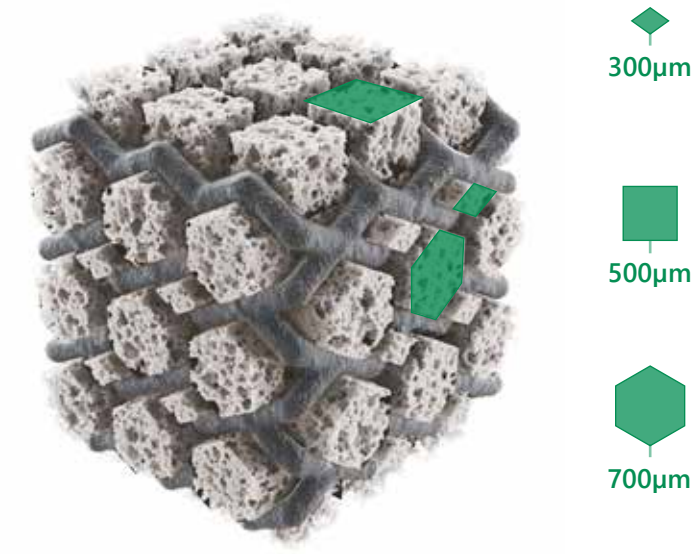
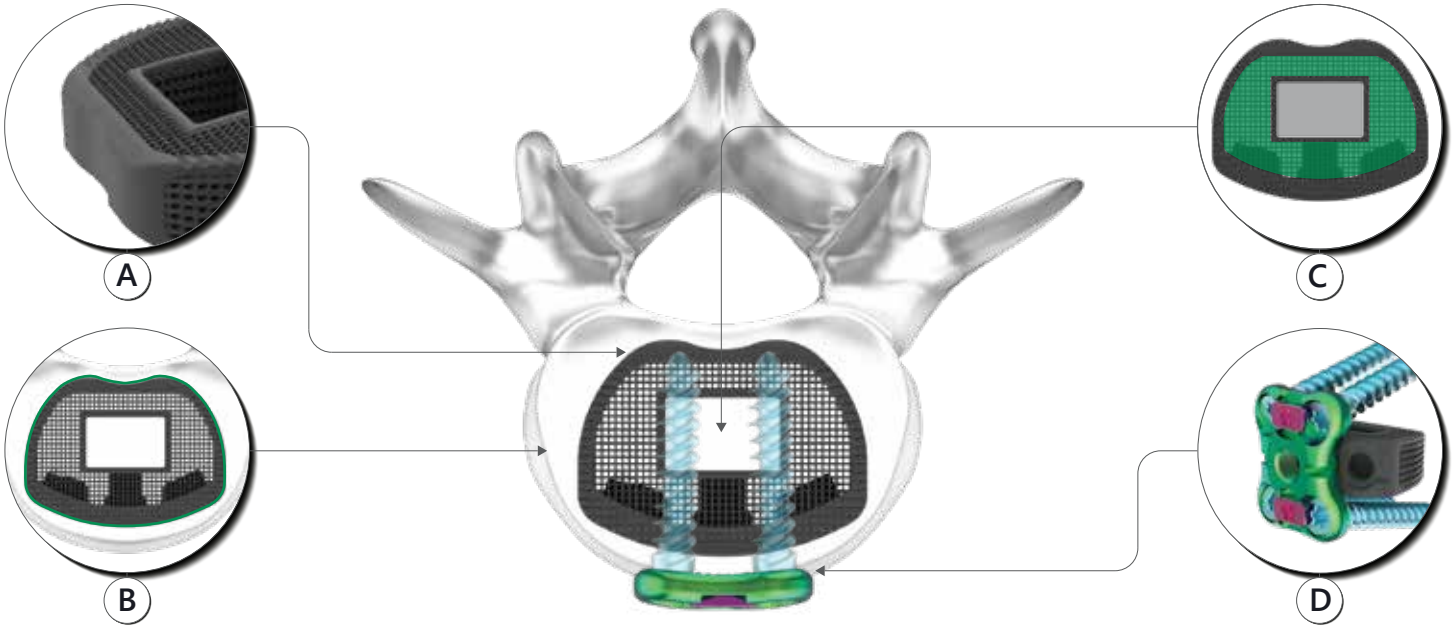


Image above used to illustrate available volume for bony ingrowth.

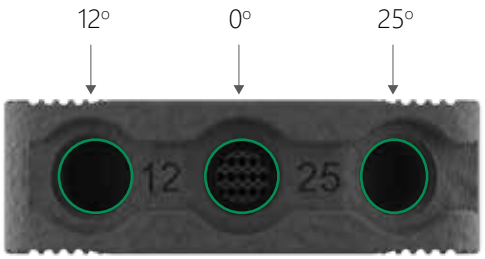
Studies referenced for the foundational design of NEXXT MATRIXX®:
1. Karageorgiou V, Kaplan D. Porosity of 3D biomaterial scaffolds and osteogenesis. Biomaterials. 2005;26(27):5474–91.
2. Olivares-Navarrete R, Hyzy SL, Slosar PJ et al. Implant materials generate different peri-implant inflammatory factors: 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.

PRODUCT FEATURES

- **A** Bulleted nose design simplifies insertion in collapsed degenerative discs without compromising the apophyseal ring.
- **B** Anatomically matched profile designed to provide appropriate endplate coverage and placement on apophyseal rim for stability.
- **C** Ample graft window balanced with lattice landscape designed to create environment for bone growth and is based on published data.
- **D** Implant compatibility with STRUXXURE®-A Plate System for single position procedural solution.
- **E** Cephalad/Caudal symmetry provides intraoperative flexibility for additional left or right insertion at either 12° and 25°.

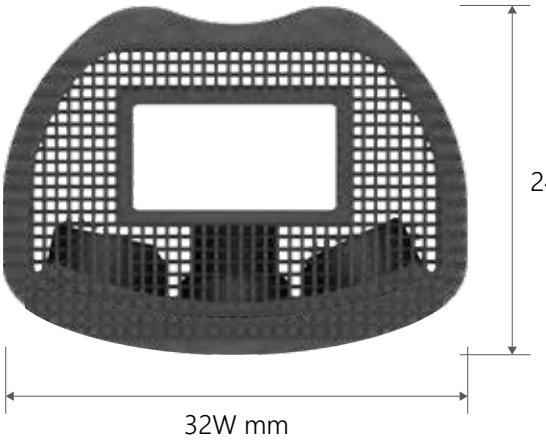


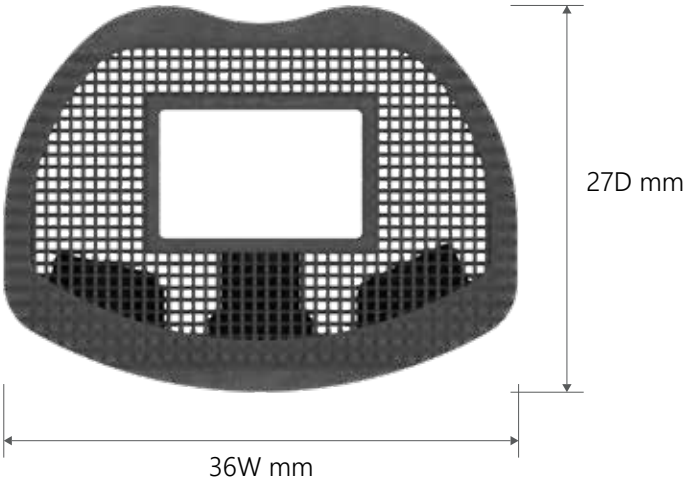
E



CAGE SPECS

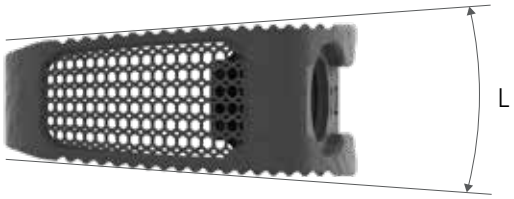
Footprints





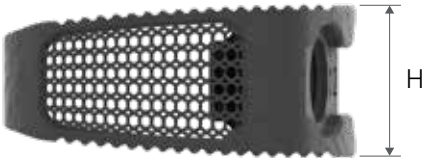
Lordoses

8°, 14°, and 20°



Heights

8, 10, 12, 14, 16, 18, and 20mm



INDICATIONS FOR USE

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.

1. PATIENT POSITIONING

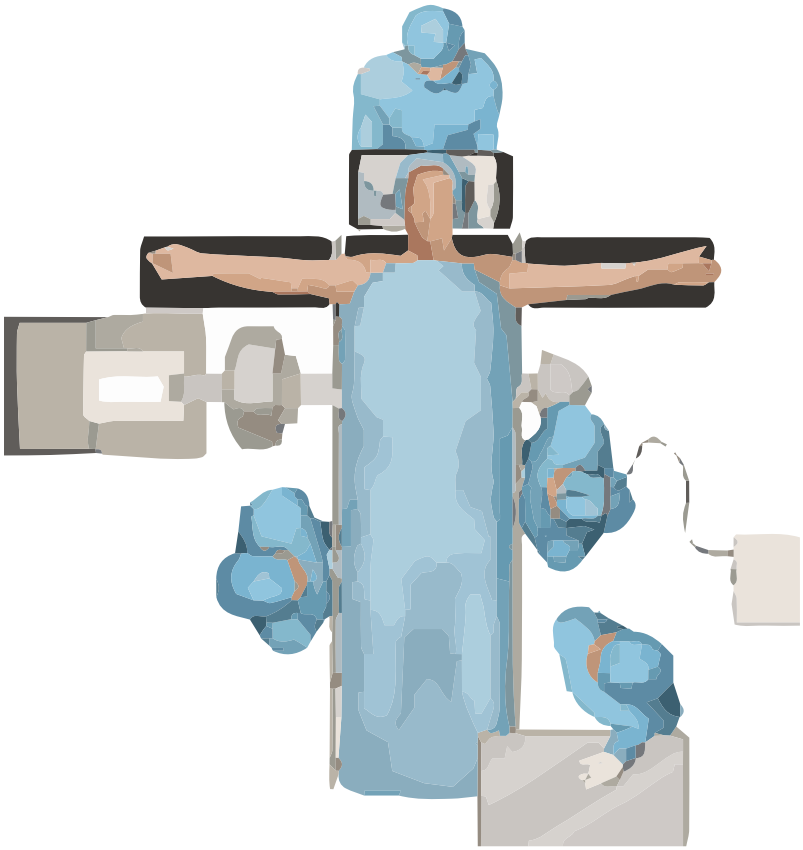


Figure 1

Approach to the Surgery

Perform the customary approach for an ALIF as chosen by the surgeon ***(Figure 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.*

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.

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 the intraoperative neuromonitoring is recommended to ensure patient safety. It is especially critical during approach and Retractor placement.

2. MIDLINE VERIFICATION + DISC REMOVAL

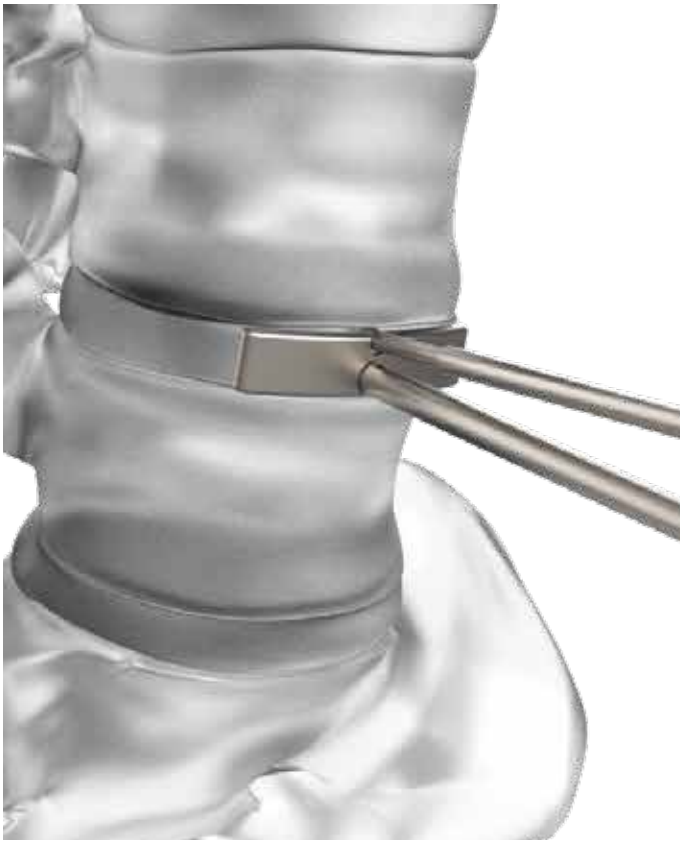


Figure 2

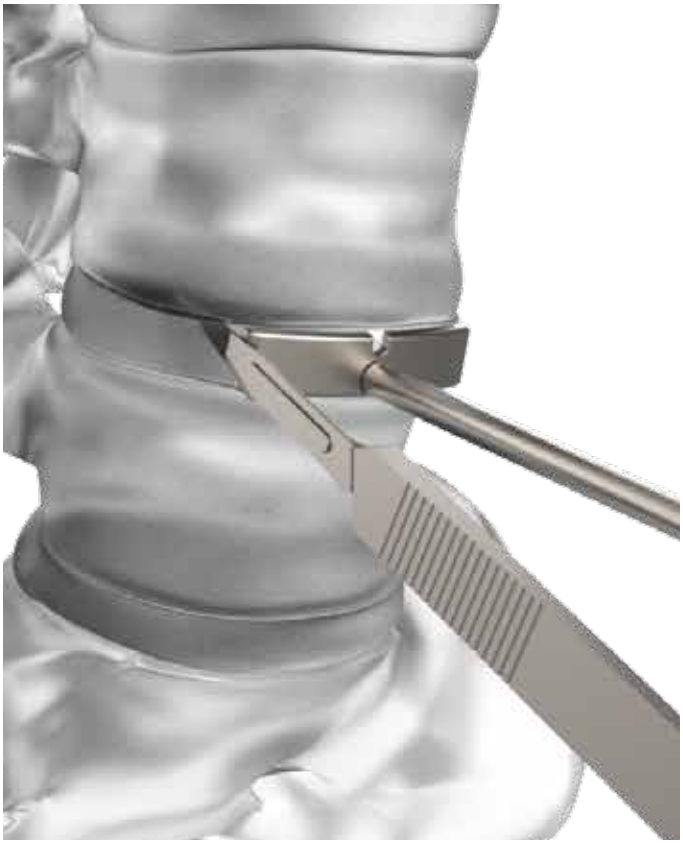


Figure 3

Midline Verification

Position the Annulotomy Template (32 or 36mm wide) on the disc space and insert the Centering Pin in the midline ***(Figure 2)***.

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

Note: *Centering Pin depth is 22.5mm.*

Disc Removal

Use an annulotomy knife to make incisions in the annulus along the lateral edges of the Annulotomy Template. ***(Figure 3)***.

Note: *The width of the Annulotomy Template matches the width of the Trial/Cage.*

3.1. INSERTER INSTRUCTION

Note: *Trial and Cage follow the same process of attachment/detachment.*

Figure 4

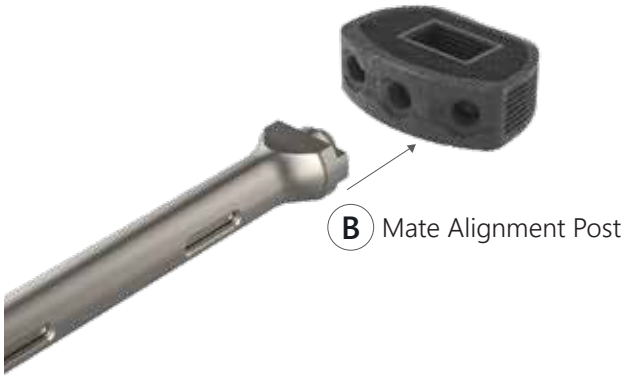


Figure 5

Figure 6

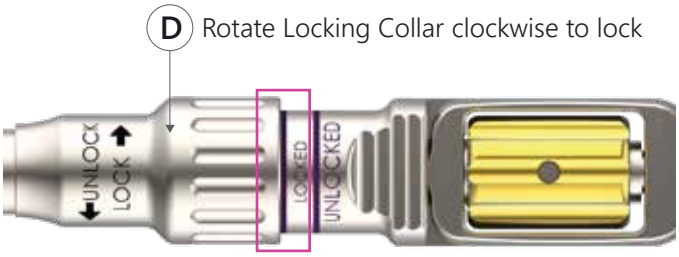


Figure 7

Inserter + Trial/Cage Attachment

Rotate the Locking Collar counterclockwise until lined up with the "Unlocked" laser etch line ***(Figure 4A)***.

Mate the Inserter to the face of the Trial/Cage ***(Figure 5B)***.

Turn the Thumb Wheel on the Inserter clockwise to tighten to the Trial/Cage ***(Figure 6C)***.

Rotate the Locking Collar on Inserter clockwise to lock the Trial/Cage to the Inserter ***(Figure 7D)***.

Note: *Surgeon should verify assembly before placing in the working corridor. Instrument and Trial/Cage should not toggle.*

Inserter + Trial/Cage Detachment

To disconnect the Trial/Cage, rotate the Locking Collar counterclockwise until lined up with the "Unlocked" laser etching and rotate the Thumb Wheel counterclockwise until Trial/Cage is released.

Note: *An Inserter Thumb Wheel Release Wrench may be used in the event additional leverage is required to rotate the Thumb Wheel. Slide the Inserter Thumb Wheel Release Wrench onto the Thumb Wheel grooves and rotate counterclockwise to loosen.*

3.2. HANDLE INSTRUCTION

Slap Hammer Hudson Connect

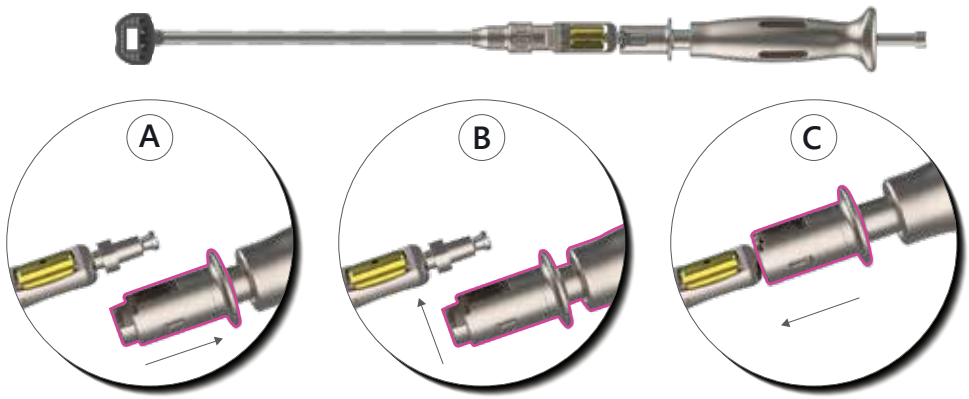


Figure 8

Inline Hudson Connect Handle

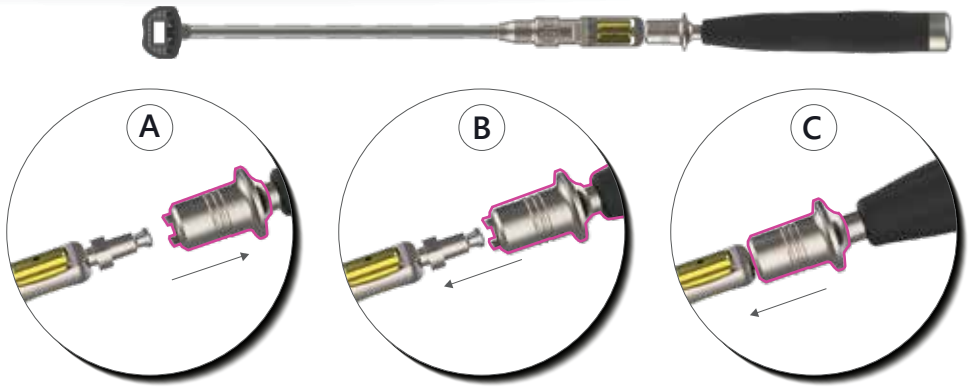


Figure 9

Inserter + Slap Hammer Attachment

Pull Hudson Connect Sleeve up ***(Figure 8A)***.

Align Hudson Connect Sleeve with Inserter ***(Figure 8B)***.

Release Hudson Connect Sleeve ***(Figure 8C)***.

Inserter + Inline Handle Attachment

Pull Hudson Connect Sleeve up ***(Figure 9A)***.

Slide Hudson Connect Sleeve onto Inserter ***(Figure 9B)***.

Release Hudson Connect Sleeve ***(Figure 9A)***.

4. TRIALING

Figure 10

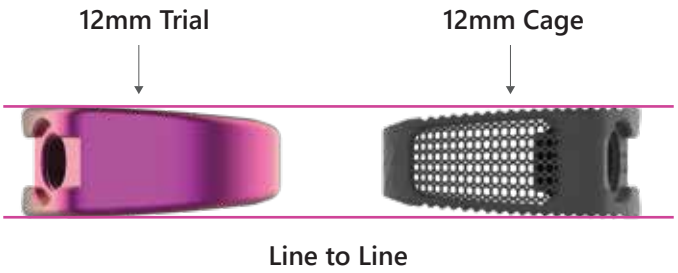


Figure 11

Figure 12

Cage Selection

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

Note: *The height of the Trial is line-to-line with the Cage* ***(Figure 11)***.

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

Under Medial/Lateral fluoroscopy, the Trial is gently impacted into the disc space until centered to determine the desired Cage size. 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: *Trials can be loaded directly from the Caddy.*

5. CAGE INSERTION

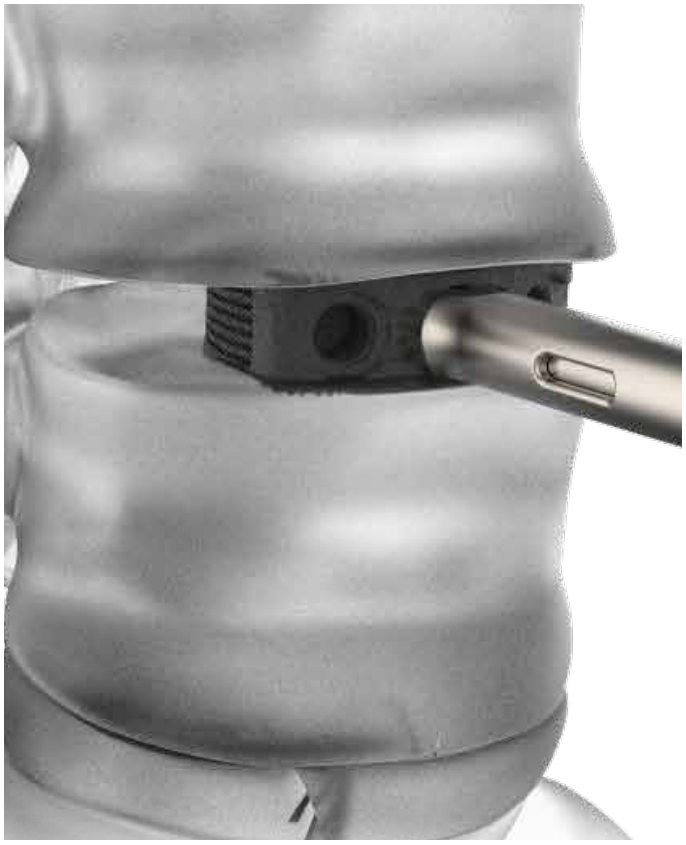


Figure 13

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

Placement

Impact the Cage into the prepared disc space ***(Figure 13).*** Placement of the Cage is dictated by patient anatomy and the spinal pathology that is being treated. Fluoroscopy should be used to verify Cage is positioned properly.

A Tamp may be used to adjust placement of the Cage. Generally, the Cage spans the apophyseal ring 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.

Supplemental Fixation

Nexxt Spine provides a full portfolio of supplemental fixation solutions such as the STRUXXURE®-A Plate System, 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/*

6. CLOSURE

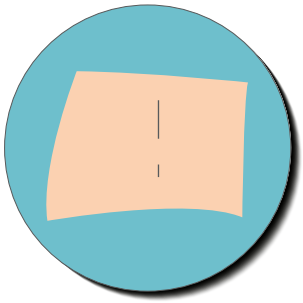


Figure 14

Skin Closure

The skin is closed using standard surgical techniques ***(Figure 14)***.

CAGE REMOVAL (AS NEEDED)

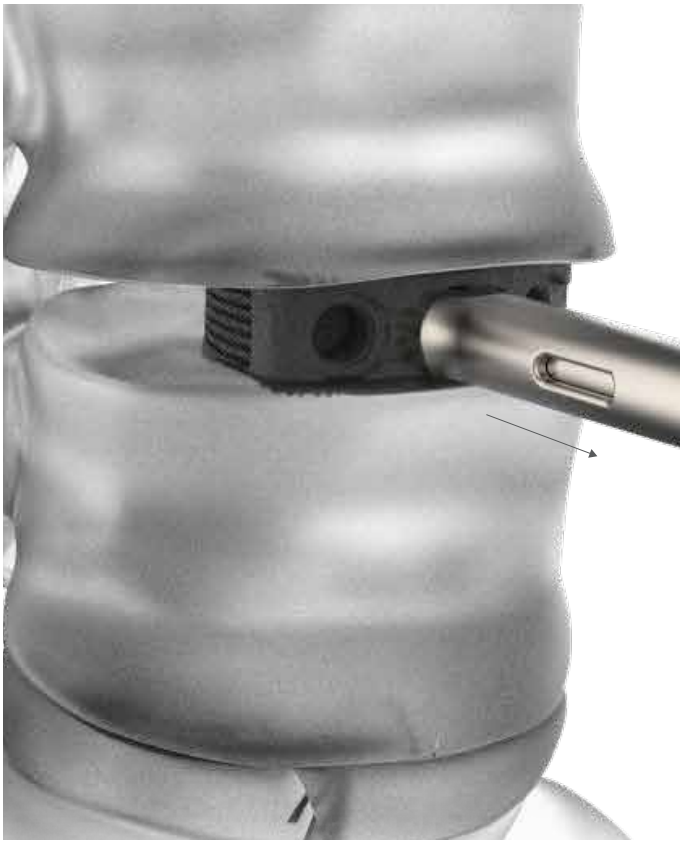


Figure 15

Removal

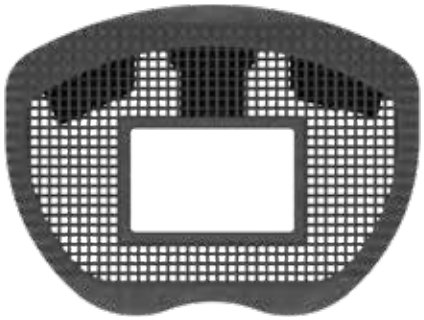
If it becomes necessary to revise the implanted Cage, access to the implantation site can be achieved in a similar fashion to the original access. Once the implanted Cage is exposed, it can be removed by reattaching the Inserter ***(Figure 15)***. If the device is difficult to remove, additional engagement 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.

IMPLANT PART NUMBERS

24D x 32W x XXH, X°

27D x 36W x XXH, X°



24D x 32W x XXH, 8°	
Part Number	**Description**
60-2432-08-8-SP	ALIF, 24Dx32Wx08H, 8°
60-2432-10-8-SP	ALIF, 24Dx32Wx10H, 8°
60-2432-12-8-SP	ALIF, 24Dx32Wx12H, 8°
60-2432-14-8-SP	ALIF, 24Dx32Wx14H, 8°
60-2432-16-8-SP	ALIF, 24Dx32Wx16H, 8°
60-2432-18-8-SP	ALIF, 24Dx32Wx18H, 8°
60-2432-20-8-SP*	ALIF, 24Dx32Wx20H, 8°

27D x 36W x XXH, 8°	
Part Number	**Description**
60-2736-08-8-SP	ALIF, 27Dx36Wx08H, 8°
60-2736-10-8-SP	ALIF, 27Dx36Wx10H, 8°
60-2736-12-8-SP	ALIF, 27Dx36Wx12H, 8°
60-2736-14-8-SP	ALIF, 27Dx36Wx14H, 8°
60-2736-16-8-SP	ALIF, 27Dx36Wx16H, 8°
60-2736-18-8-SP	ALIF, 27Dx36Wx18H, 8°
60-2736-20-8-SP*	ALIF, 27Dx36Wx20H, 8°

24D x 32W x XXH, 14°	
Part Number	**Description**
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60-2432-12-14-SP	ALIF, 24Dx32Wx12H, 14°
60-2432-14-14-SP	ALIF, 24Dx32Wx14H, 14°
60-2432-16-14-SP	ALIF, 24Dx32Wx16H, 14°
60-2432-18-14-SP	ALIF, 24Dx32Wx18H, 14°
60-2432-20-14-SP	ALIF, 24Dx32Wx20H, 14°

27D x 36W x XXH, 14°	
Part Number	**Description**
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60-2736-14-14-SP	ALIF, 27Dx36Wx14H, 14°
60-2736-16-14-SP	ALIF, 27Dx36Wx16H, 14°
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24D x 32W x XXH, 20°	
Part Number	**Description**
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60-2432-18-20-SP	ALIF, 24Dx32Wx18H, 20°
60-2432-20-20-SP	ALIF, 24Dx32Wx20H, 20°

27D x 36W x XXH, 20°	
Part Number	**Description**
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60-2736-14-20-SP	ALIF, 27Dx36Wx14H, 20°
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60-2736-18-20-SP	ALIF, 27Dx36Wx18H, 20°
60-2736-20-20-SP	ALIF, 27Dx36Wx20H, 20°

Made to Order

INSTRUMENT PART NUMBERS

Note: *Images shown are not proportionate to one another.*

Part Number	Description
I60-01-01	ALIF Inserter

Part Number	Description
I60-20-01	Removal Tool

Part Number	Description
I60-41-01	Slap Hammer

Part Number	Description
I60-42-01	Tamp

Part Number	Description
I60-20-02	Ins. Thumb Wheel Release Wrench

Part Number	Description
I61-32-02	Annulotomy Centering Pin

Part Number	Description
I61-32-32	Annulotomy Template, 32mm

Part Number	Description
I61-32-36	Annulotomy Template, 36mm

Part Number	Description
I10-01-62	Inline Handle Hudson Connect

INSTRUMENT PART NUMBERS (CONT)

ALIF TRIAL, I60-TR2432-8-XX	
Part Number	**Description**
I60-TR2432-8-08	ALIF Trial 24Dx32Wx08Hx8°
I60-TR2432-8-10	ALIF Trial 24Dx32Wx10Hx8°
I60-TR2432-8-12	ALIF Trial 24Dx32Wx12Hx8°
I60-TR2432-8-14	ALIF Trial 24Dx32Wx14Hx8°
I60-TR2432-8-16	ALIF Trial 24Dx32Wx16Hx8°
I60-TR2432-8-18	ALIF Trial 24Dx32Wx18Hx8°
I60-TR2432-8-20*	ALIF Trial 24Dx32Wx20Hx8°*

ALIF TRIAL, I60-TR2736-8-XX	
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I60-TR2736-8-14	ALIF Trial 27Dx36Wx14Hx8°
I60-TR2736-8-16	ALIF Trial 27Dx36Wx16Hx8°
I60-TR2736-8-18	ALIF Trial 27Dx36Wx18Hx8°
I60-TR2736-8-20*	ALIF Trial 27Dx36Wx20Hx8°*

ALIF TRIAL, I60-TR2432-14-XX	
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I60-TR2432-14-18	ALIF Trial 24Dx32Wx18Hx14°
I60-TR2432-14-20	ALIF Trial 24Dx32Wx20Hx14°

ALIF TRIAL, I60-TR2736-14-XX	
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I60-TR2736-14-16	ALIF Trial 27Dx36Wx16Hx14°
I60-TR2736-14-18	ALIF Trial 27Dx36Wx18Hx14°
I60-TR2736-14-20	ALIF Trial 27Dx36Wx20Hx14°

ALIF TRIAL, I60-TR2432-20-XX	
Part Number	**Description**
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I60-TR2432-20-18	ALIF Trial 24Dx32Wx18Hx20°
I60-TR2432-20-20	ALIF Trial 24Dx32Wx20Hx20°

ALIF TRIAL, I60-TR2736-20-XX	
Part Number	**Description**
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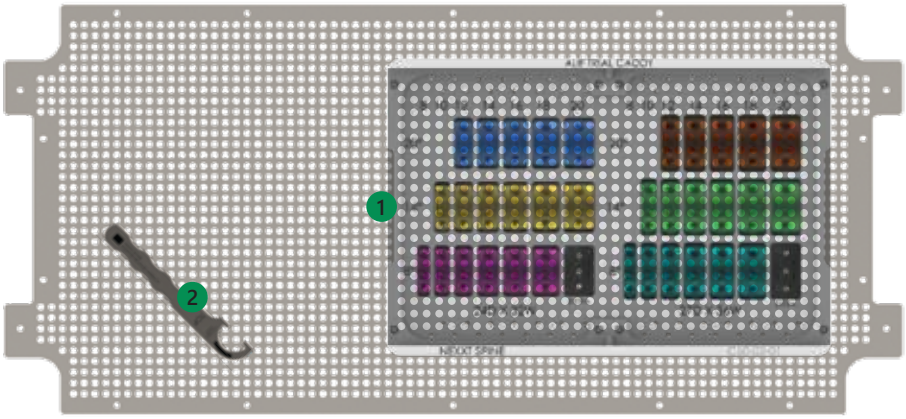
I60-TR2736-20-16	ALIF Trial 27Dx36Wx16Hx20°
I60-TR2736-20-18	ALIF Trial 27Dx36Wx18Hx20°
I60-TR2736-20-20	ALIF Trial 27Dx36Wx20Hx20°

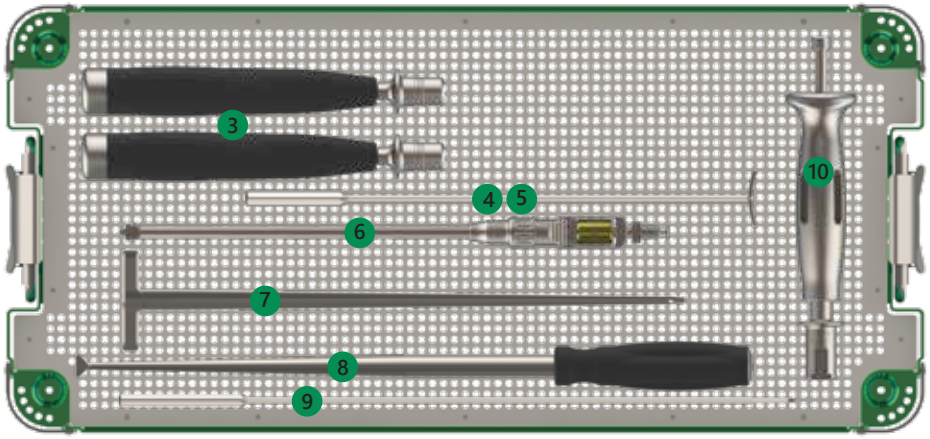
Made to Order

STANDARD INSTRUMENT CASE

Top Level



Bottom Level



Part Number	Description
1. C60-02-01	ALIF Trial Caddy
2. I60-20-02	Inserter Thumb Wheel Release Wrench
3. I10-01-62 (2x)	Inline Handle Hudson (2x)
4. I61-32-32	Annulotomy Template, 32mm
5. I61-32-36	Annulotomy Template, 36mm
6. I60-01-01 (2x)	ALIF Inserter (2x)
7. I60-20-01	Removal Tool
8. I60-42-01	Tamp
9. I61-32-02	Annulotomy Centering Pin
10. I60-41-01	Slap Hammer

INDICATIONS

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 (7µ m). The intervening geometric lattices have pores 300-700 µm. 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

The NEXXT MATRIXX® 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.

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® 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.

Warnings and Precautions

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® 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.

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.*

Caution: *Federal (USA) law restricts this device to sale by or on the order of a physician.*

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GROW WITH US

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

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