NEXXT Spine

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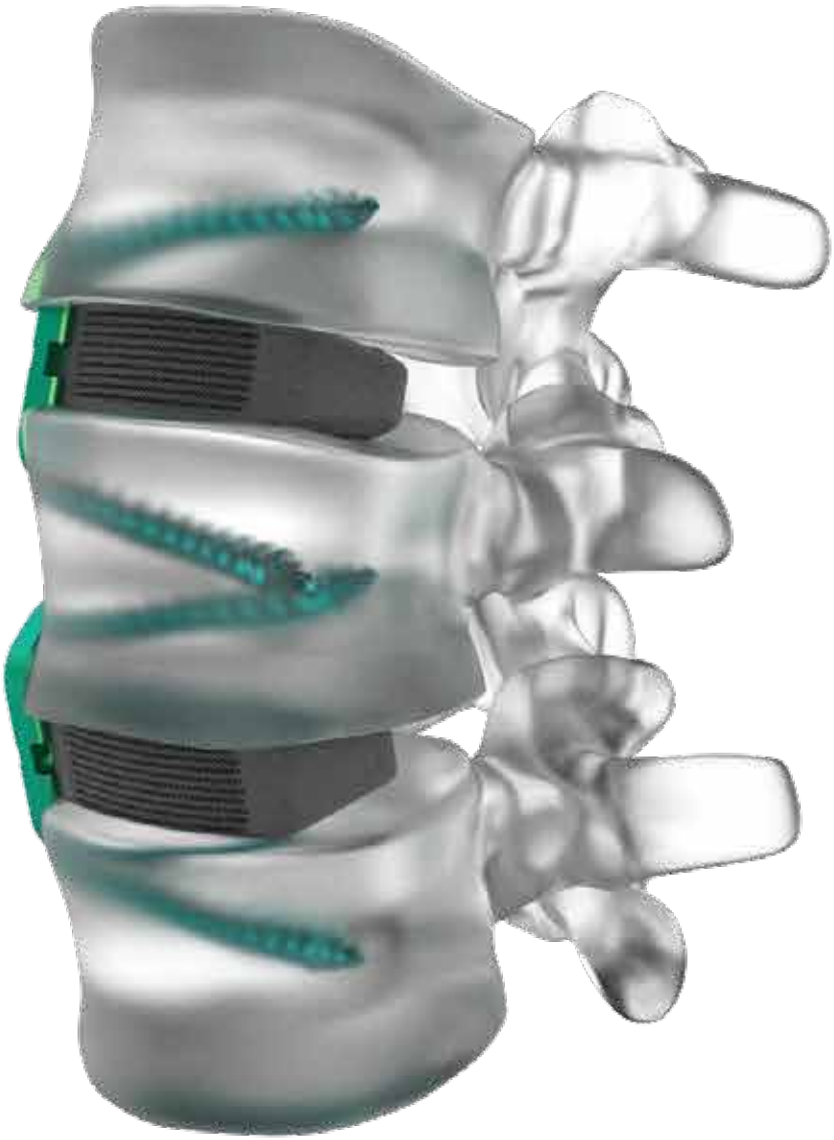
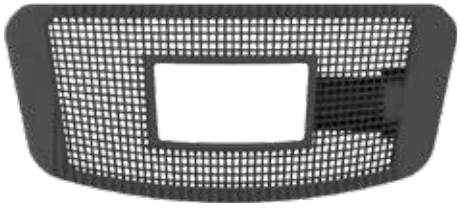
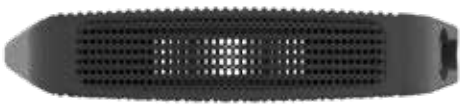
Surgical Technique Guide

NEXXT MATRIXX® Lateral







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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® Lateral.

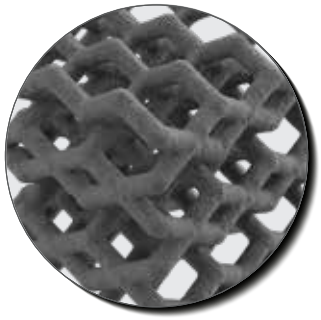
Every physician should utilize his or her own discretion in the diagnosis and treatment of a patient, and this information does not intend to replace the comprehensive training physicians have received.

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® Lateral. 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

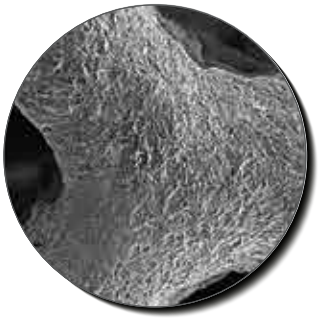
10X



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]

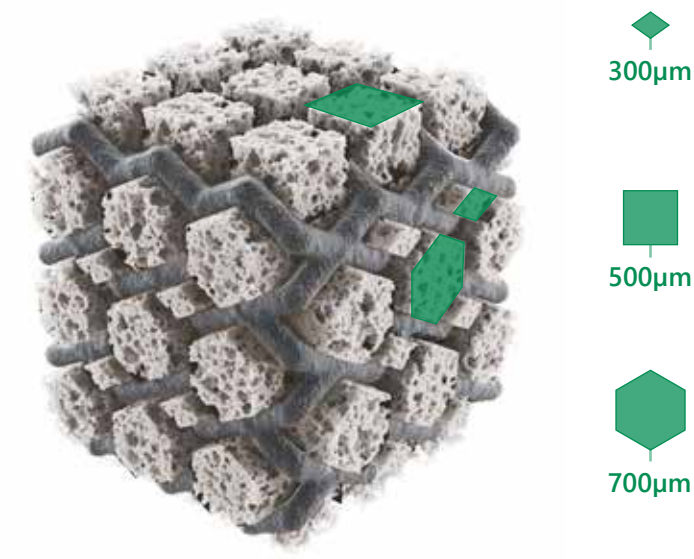


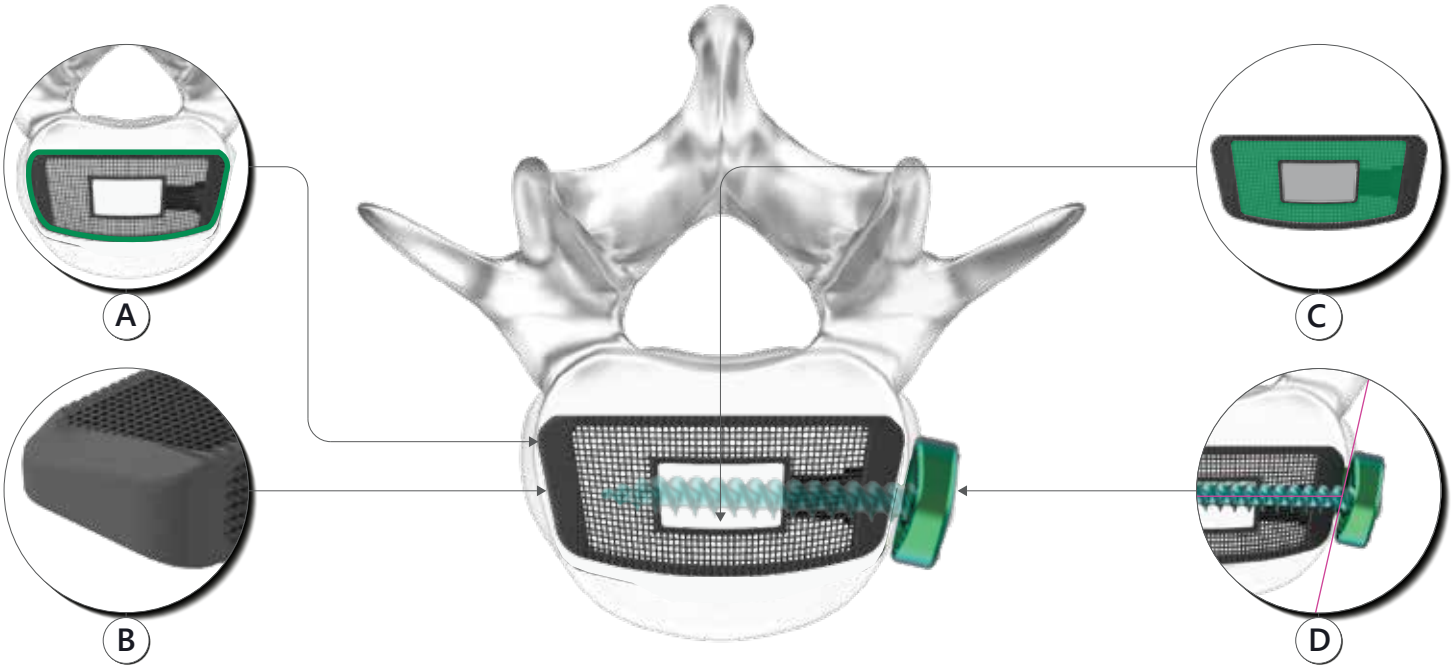
Image above used to illustrate available volume for bony ingrowth.

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** Anatomically matched profile designed to provide appropriate endplate coverage and placement on apophyseal rim for stability.
- **B** Bulleted nose design simplifies insertion in collapsed degenerative discs without compromising the apophyseal rim.
- **C** Ample graft window balanced with lattice landscape designed to create environment for bone growth and is based on published data.
- **D** Intentional angle design on implant compatible with STRUXXURE®-L for single position procedural solution.
- **E** Instrumentation provides intraoperative flexibility with oblique and angled instrumentation.



E

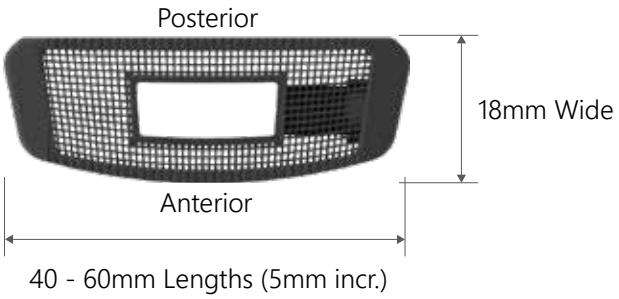
Straight

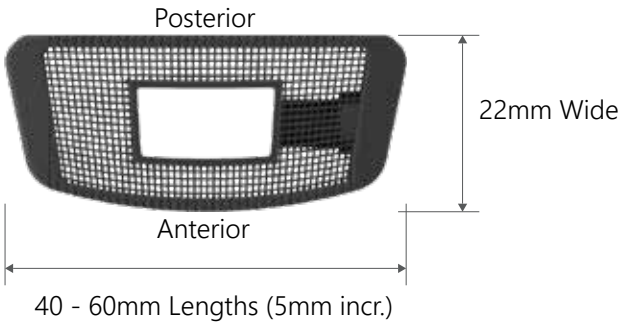
Oblique (OLIF)

Left & Right Angled

CAGE SPECS

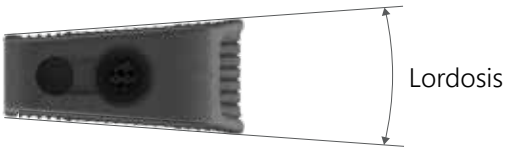
Footprints





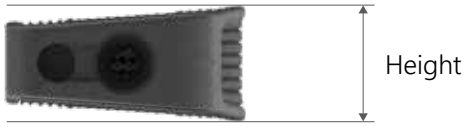
Lordoses

0°, 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.

SURGICAL CONSIDERATIONS

The lateral procedure enables access to the spine and affected discs via a lateral, retroperitoneal approach. The anatomic landmarks the surgeon should take into account when preparing for the lateral technique are the iliac crest, the 12th rib, and the lateral border of the dorsal musculature.

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.

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 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.

TRANSPSOAS ACCESS

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.

1. PATIENT POSITIONING

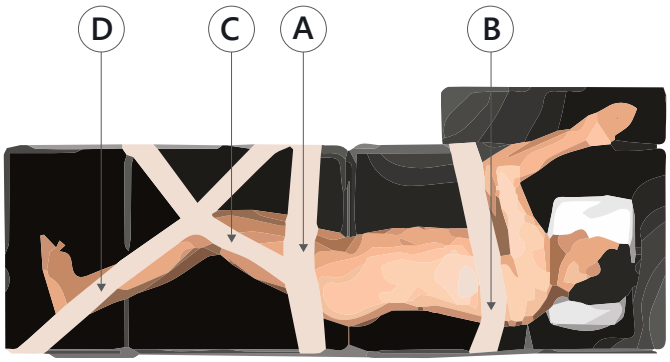


Figure 1

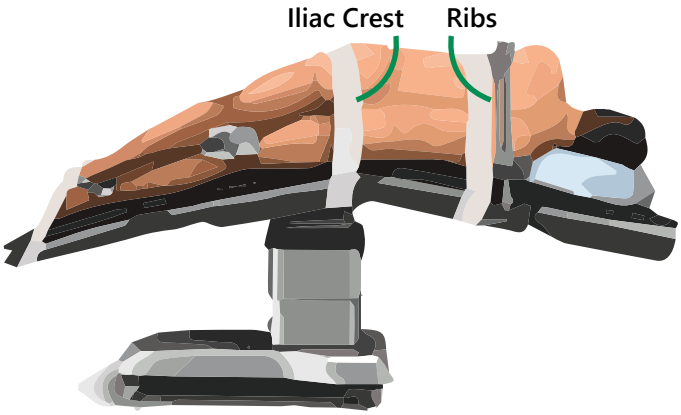


Figure 2

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).*

2. ANATOMY IDENTIFICATION & MARKING

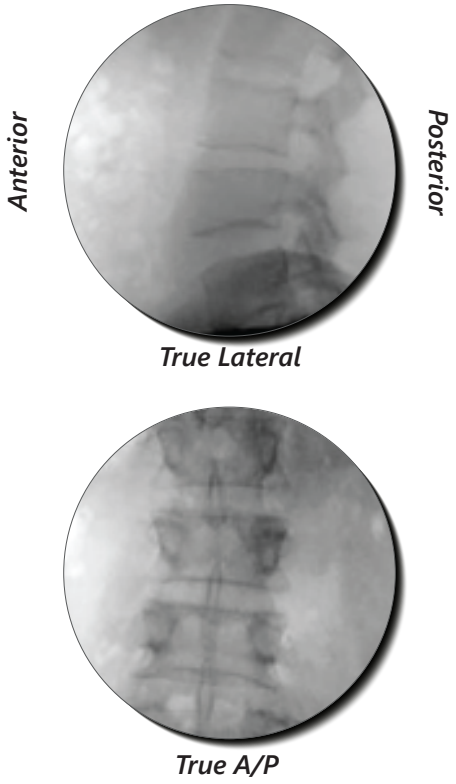


Figure 3

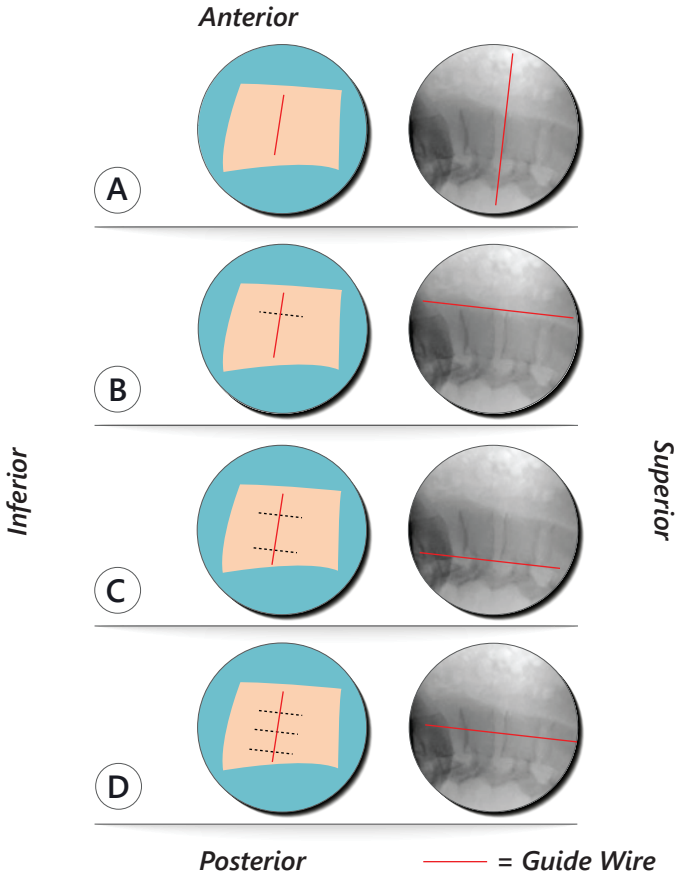


Figure 4

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 so as to ensure proper imaging.

Anatomic Landmark Identification 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.*

3. RETRACTOR INSERTION

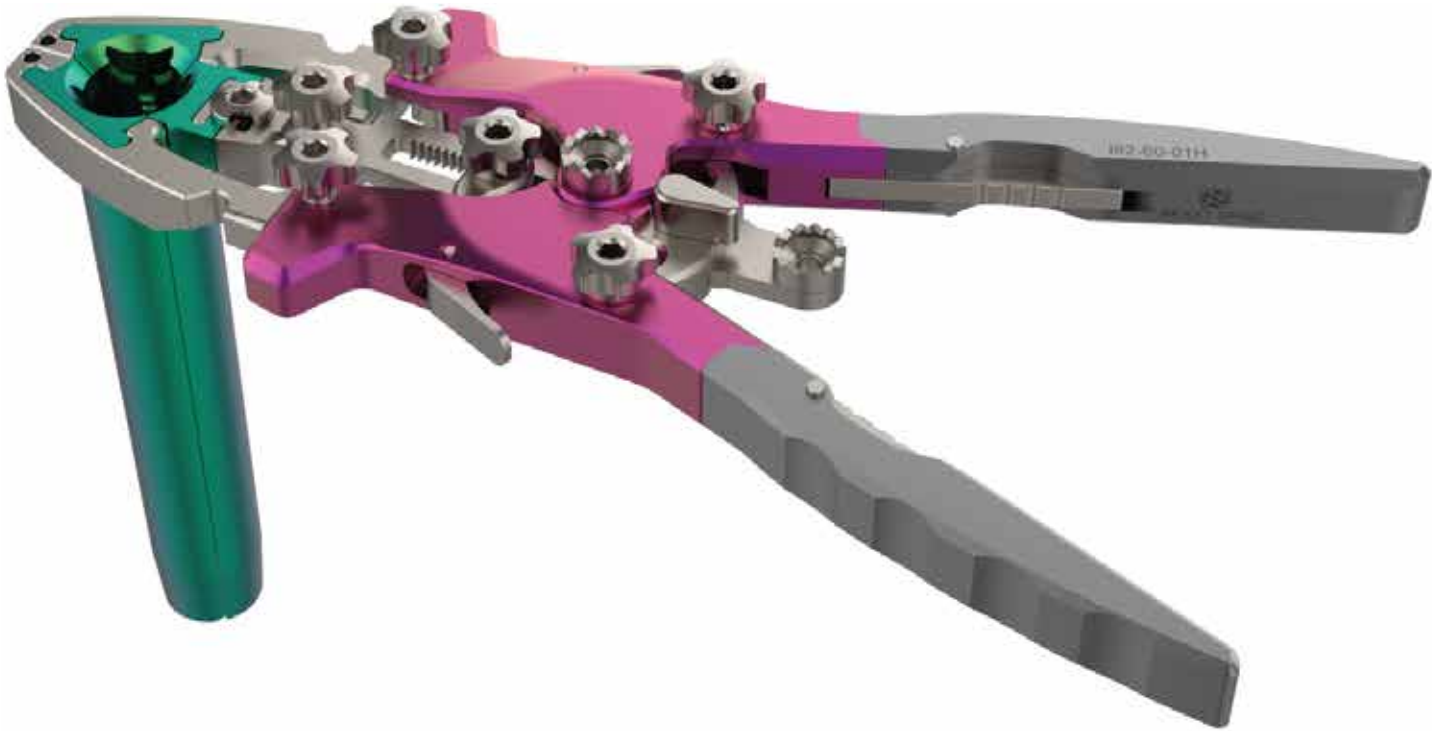


Figure 5

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.*

4. DISCECTOMY

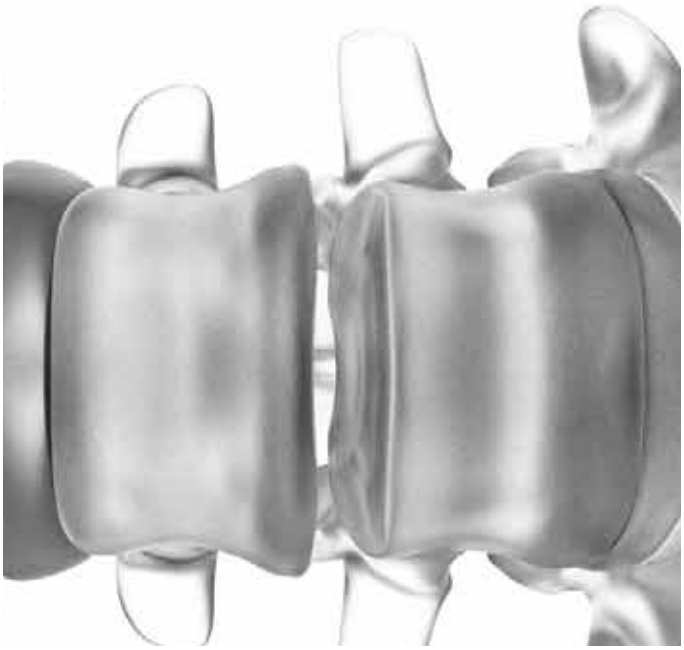


Figure 6

Discectomy

Create a box annulotomy (either 18mm or 22mm in A/P length, depending on the anticipated Cage size) on the lateral face of the disc. 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 Cage 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 6)***.

Note: *Excessive endplate preparation may compromise endplate stability and may contribute to endplate subsidence.*

5.1. INSERTER SELECTION

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.*

Straight

Figure 7

Oblique (OLIF)

Figure 8

Left & Right Angled

Figure 9

Inserter Selection

The Straight Inserter ***(Figure 7)*** is provided for standard approach or true lateral perpendicular access.

The Oblique Inserter ***(Figure 8)*** has a 20° angle relative to the Cage/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 ***(Figure 9)*** have a 15° angle relative to the Cage/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.*

5.2. INSERTER INSTRUCTION

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

Figure 10

Figure 12

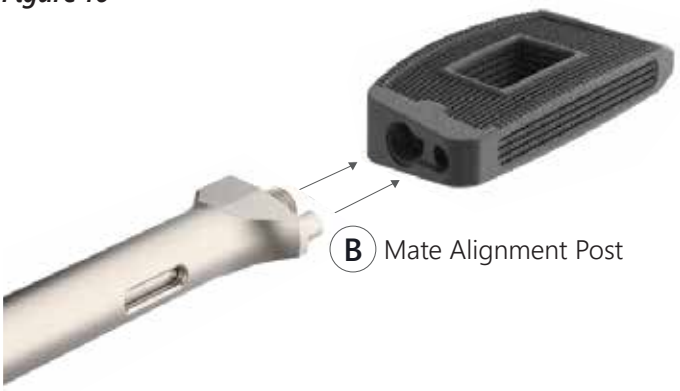


Figure 11

Figure 13

Inserter +Trial/Cage Attachment

Rotate the Locking Collar counterclockwise until lined up with the "Unlocked" laser etch line ***(Figure 10A)***.

Mate the Inserter Alignment Post to the holes of the Trial/Cage ***(Figure 11B)***.

Turn the Thumb Wheel on the Inserter clockwise to tighten to the Trial/Cage ***(Figure 12C)***.

Rotate the Locking Collar on Inserter clockwise to lock the Trial/Cage to the Inserter ***(Figure 13D)***.

Note: *Surgeon should verify assembly before placing in the working corridor. Instrument should seat flush with the proximal face of the Trial/Cage without 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 counter-clockwise to loosen.*

5.3. HANDLE INSTRUCTION

Slap Hammer Hudson Connect

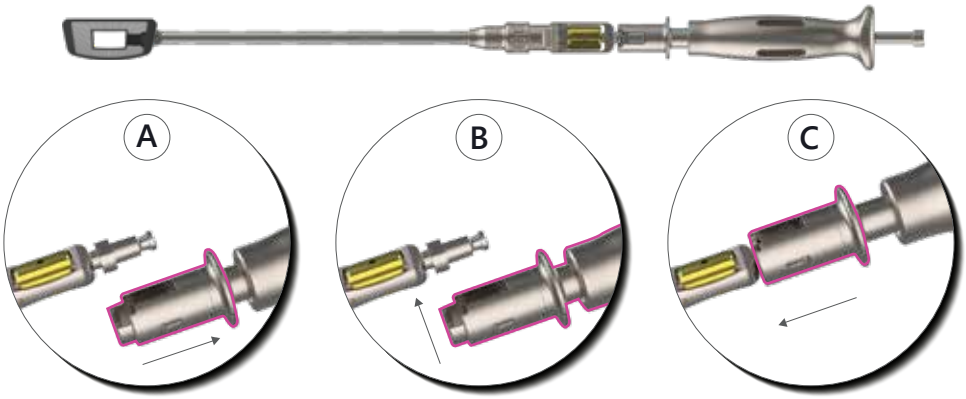


Figure 14

Inline Hudson Connect Handle

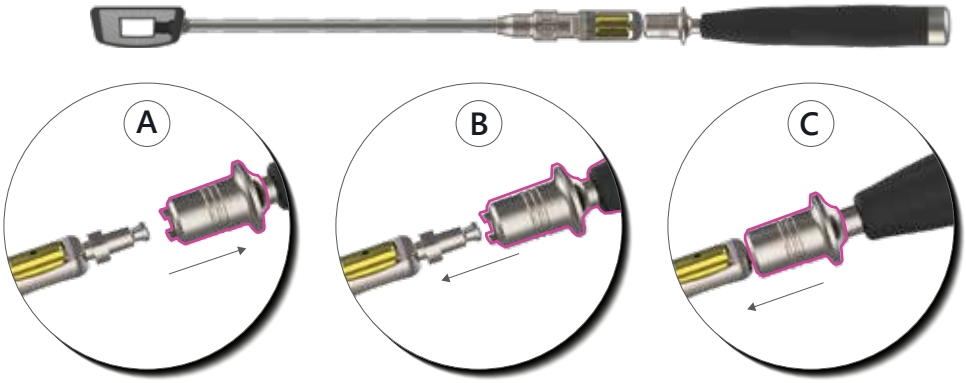


Figure 15

Inserter + Slap Hammer Attachment

Pull Hudson Connect Sleeve up ***(Figure 14A)***.
Align Hudson Connect Sleeve with Inserter ***(Figure 14B)***.
Release Hudson Connect Sleeve ***(Figure 14C)***.

Inserter + Inline Handle Attachment

Pull Hudson Connect Sleeve up ***(Figure 15A)***.
Slide Hudson Connect Sleeve onto Inserter ***(Figure 15B)***.
Release Hudson Connect Sleeve ***(Figure 15A)***.

6. TRIALING

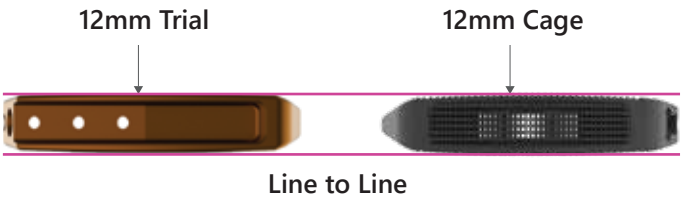


Figure 16

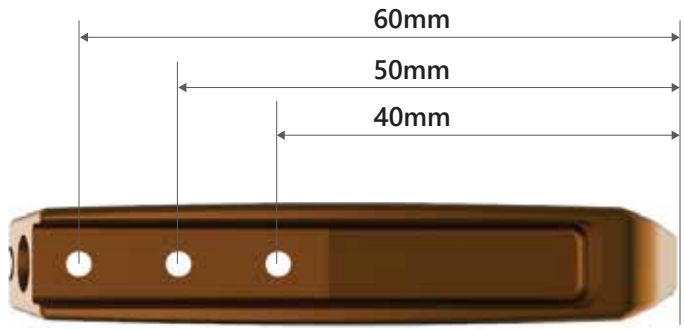


Figure 17

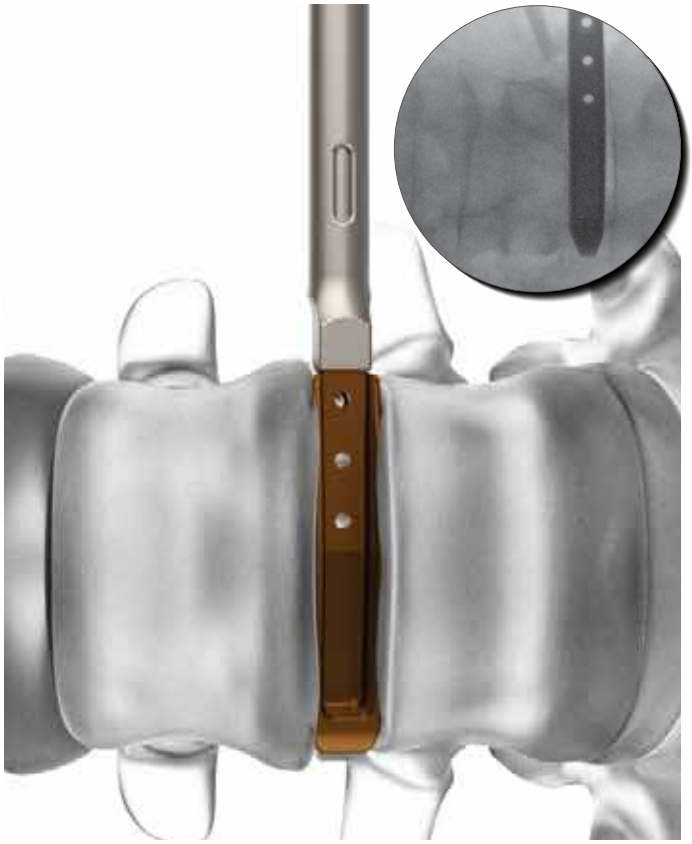


Figure 18

Cage Selection

Once the disc space and endplate is adequately prepared, the optimal Cage 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 Cage footprint and height to be utilized.

Note: *The height of the Trial is line-to-line with the Cage* ***(Figure 16)***.

Cage 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 17)***.

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

Proper A/P position is verified using true lateral fluoroscopy. 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: *Surgeon should apply downward pressure on Retractor when removing all instruments from the disc space so as to prevent migration of the blades.*

7. CAGE INSERTION

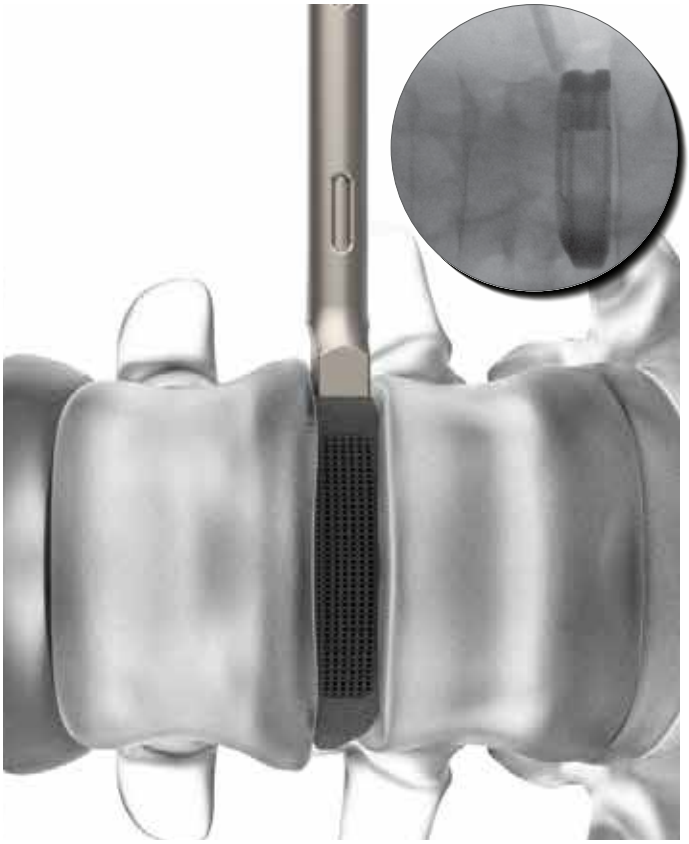


Figure 19

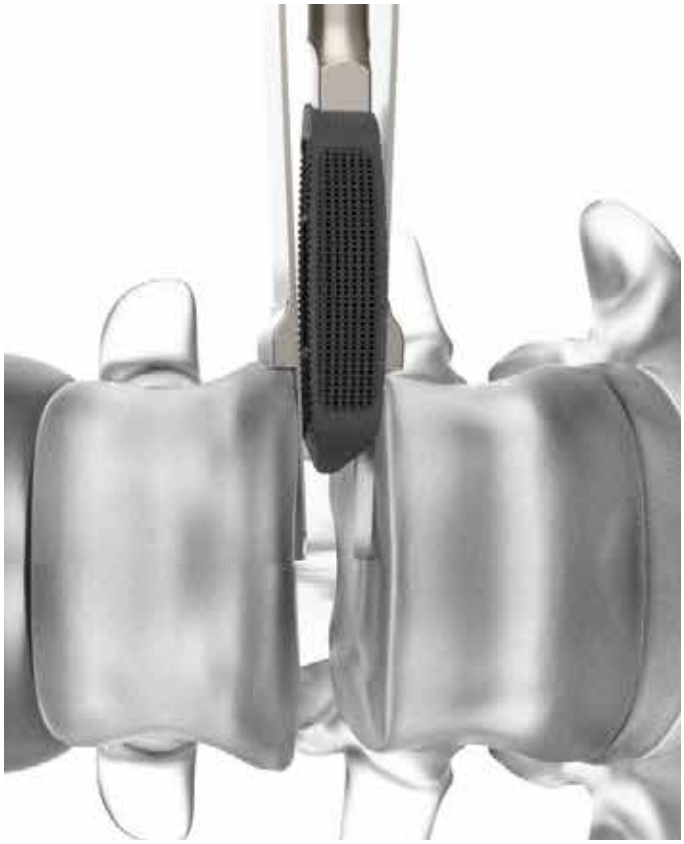


Figure 20

Cage + Inserter Attachment

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

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 19).*** Placement of the Cage is dictated by patient anatomy and the spinal pathology that is being treated. Generally, the Cage 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.

A small or large Graft Slide may be used to protect the endplates and contain graft material during Cage insertion. Use small for 8-10mm height Cages and large for 12-16mm height Cages. Fluoroscopy should be used to verify slides are positioned properly ***(Figure 20)***. A Tamp may be used to adjust placement of the Cage.

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/Indications-for-use/*

8. RETRACTOR REMOVAL & CLOSURE

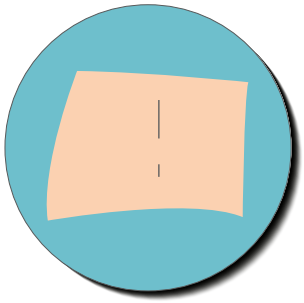


Figure 21

Closure

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 21)***.

Supplemental instrumentation is required.

CAGE REMOVAL (AS NEEDED)

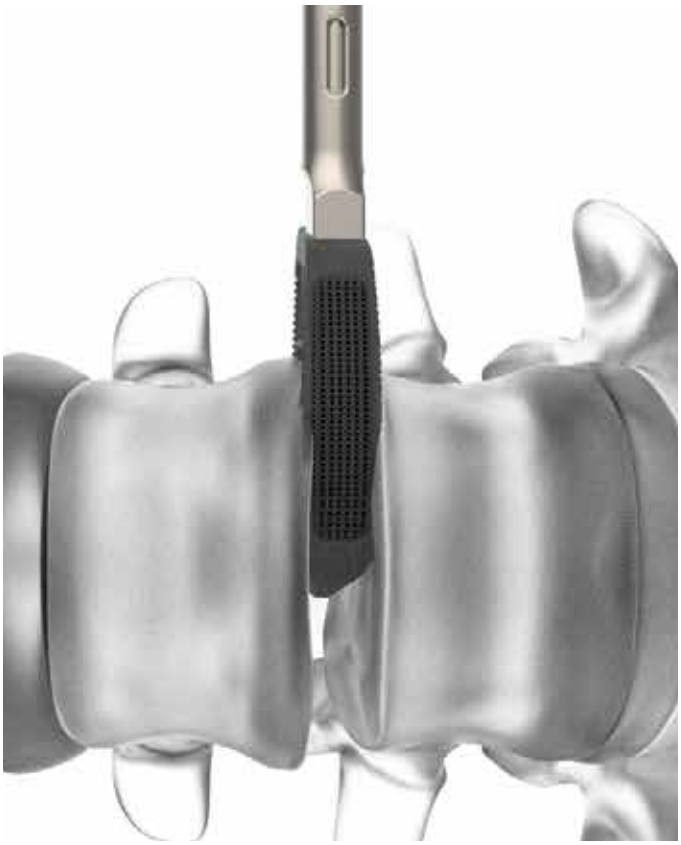


Figure 22

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 22)***. 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

LATERAL, 18W x XXL x XXH 0°	
Part Number	**Description**
62-1840-08-0-SP*	LATERAL, 18W x 40L x 08H 0°
62-1840-10-0-SP*	LATERAL, 18W x 40L x 10H 0°
62-1840-12-0-SP*	LATERAL, 18W x 40L x 12H 0°
62-1840-14-0-SP*	LATERAL, 18W x 40L x 14H 0°
62-1840-16-0-SP*	LATERAL, 18W x 40L x 16H 0°
62-1845-08-0-SP	LATERAL, 18W x 45L x 08H 0°
62-1845-10-0-SP	LATERAL, 18W x 45L x 10H 0°
62-1845-12-0-SP	LATERAL, 18W x 45L x 12H 0°
62-1845-14-0-SP*	LATERAL, 18W x 45L x 14H 0°
62-1845-16-0-SP*	LATERAL, 18W x 45L x 16H 0°
62-1850-08-0-SP	LATERAL, 18W x 50L x 08H 0°
62-1850-10-0-SP	LATERAL, 18W x 50L x 10H 0°
62-1850-12-0-SP	LATERAL, 18W x 50L x 12H 0°
62-1850-14-0-SP	LATERAL, 18W x 50L x 14H 0°
62-1850-16-0-SP*	LATERAL, 18W x 50L x 16H 0°
62-1855-08-0-SP	LATERAL, 18W x 55L x 08H 0°
62-1855-10-0-SP	LATERAL, 18W x 55L x 10H 0°
62-1855-12-0-SP	LATERAL, 18W x 55L x 12H 0°
62-1855-14-0-SP	LATERAL, 18W x 55L x 14H 0°
62-1855-16-0-SP*	LATERAL, 18W x 55L x 16H 0°
62-1860-08-0-SP	LATERAL, 18W x 60L x 08H 0°
62-1860-10-0-SP	LATERAL, 18W x 60L x 10H 0°
62-1860-12-0-SP	LATERAL, 18W x 60L x 12H 0°
62-1860-14-0-SP	LATERAL, 18W x 60L x 14H 0°
62-1860-16-0-SP*	LATERAL, 18W x 60L x 16H 0°

LATERAL, 22W x XXL x XXH 0°	
Part Number	**Description**
62-2240-08-0-SP*	LATERAL, 22W x 40L x 08H 0°
62-2240-10-0-SP*	LATERAL, 22W x 40L x 10H 0°
62-2240-12-0-SP*	LATERAL, 22W x 40L x 12H 0°
62-2240-14-0-SP*	LATERAL, 22W x 40L x 14H 0°
62-2240-16-0-SP*	LATERAL, 22W x 40L x 16H 0°
62-2245-08-0-SP	LATERAL, 22W x 45L x 08H 0°
62-2245-10-0-SP	LATERAL, 22W x 45L x 10H 0°
62-2245-12-0-SP	LATERAL, 22W x 45L x 12H 0°
62-2245-14-0-SP*	LATERAL, 22W x 45L x 14H 0°
62-2245-16-0-SP*	LATERAL, 22W x 45L x 16H 0°
62-2250-08-0-SP	LATERAL, 22W x 50L x 08H 0°
62-2250-10-0-SP	LATERAL, 22W x 50L x 10H 0°
62-2250-12-0-SP	LATERAL, 22W x 50L x 12H 0°
62-2250-14-0-SP	LATERAL, 22W x 50L x 14H 0°
62-2250-16-0-SP*	LATERAL, 22W x 50L x 16H 0°
62-2255-08-0-SP	LATERAL, 22W x 55L x 08H 0°
62-2255-10-0-SP	LATERAL, 22W x 55L x 10H 0°
62-2255-12-0-SP	LATERAL, 22W x 55L x 12H 0°
62-2255-14-0-SP	LATERAL, 22W x 55L x 14H 0°
62-2255-16-0-SP*	LATERAL, 22W x 55L x 16H 0°
62-2260-08-0-SP	LATERAL, 22W x 60L x 08H 0°
62-2260-10-0-SP	LATERAL, 22W x 60L x 10H 0°
62-2260-12-0-SP	LATERAL, 22W x 60L x 12H 0°
62-2260-14-0-SP	LATERAL, 22W x 60L x 14H 0°
62-2260-16-0-SP*	LATERAL, 22W x 60L x 16H 0°

LATERAL, 18W x XXL x XXH 8°	
Part Number	**Description**
62-1840-08-8-SP*	LATERAL, 18W x 40L x 08H 8°
62-1840-10-8-SP*	LATERAL, 18W x 40L x 10H 8°
62-1840-12-8-SP*	LATERAL, 18W x 40L x 12H 8°
62-1840-14-8-SP*	LATERAL, 18W x 40L x 14H 8°
62-1840-16-8-SP*	LATERAL, 18W x 40L x 16H 8°
62-1845-08-8-SP	LATERAL, 18W x 45L x 08H 8°
62-1845-10-8-SP	LATERAL, 18W x 45L x 10H 8°

LATERAL, 22W x XXL x XXH 8°	
Part Number	**Description**
62-2240-08-8-SP*	LATERAL, 22W x 40L x 08H 8°
62-2240-10-8-SP*	LATERAL, 22W x 40L x 10H 8°
62-2240-12-8-SP*	LATERAL, 22W x 40L x 12H 8°
62-2240-14-8-SP*	LATERAL, 22W x 40L x 14H 8°
62-2240-16-8-SP*	LATERAL, 22W x 40L x 16H 8°
62-2245-08-8-SP	LATERAL, 22W x 45L x 08H 8°
62-2245-10-8-SP	LATERAL, 22W x 45L x 10H 8°

Made to Order

IMPLANT PART NUMBERS (CONT)

LATERAL, 18W x XXL x XXH 8° (Cont)	
Part Number	**Description**
62-1845-12-8-SP	LATERAL, 18W x 45L x 12H 8°
62-1845-14-8-SP	LATERAL, 18W x 45L x 14H 8°
62-1845-16-8-SP*	LATERAL, 18W x 45L x 16H 8°
62-1850-08-8-SP	LATERAL, 18W x 50L x 08H 8°
62-1850-10-8-SP	LATERAL, 18W x 50L x 10H 8°
62-1850-12-8-SP	LATERAL, 18W x 50L x 12H 8°
62-1850-14-8-SP	LATERAL, 18W x 50L x 14H 8°
62-1850-16-8-SP*	LATERAL, 18W x 50L x 16H 8°
62-1855-08-8-SP	LATERAL, 18W x 55L x 08H 8°
62-1855-10-8-SP	LATERAL, 18W x 55L x 10H 8°
62-1855-12-8-SP	LATERAL, 18W x 55L x 12H 8°
62-1855-14-8-SP	LATERAL, 18W x 55L x 14H 8°
62-1855-16-8-SP*	LATERAL, 18W x 55L x 16H 8°
62-1860-08-8-SP	LATERAL, 18W x 60L x 08H 8°
62-1860-10-8-SP	LATERAL, 18W x 60L x 10H 8°
62-1860-12-8-SP	LATERAL, 18W x 60L x 12H 8°
62-1860-14-8-SP	LATERAL, 18W x 60L x 14H 8°
62-1860-16-8-SP*	LATERAL, 18W x 60L x 16H 8°

LATERAL, 22W x XXL x XXH 8° (Cont)	
Part Number	**Description**
62-2245-12-8-SP	LATERAL, 22W x 45L x 12H 8°
62-2245-14-8-SP	LATERAL, 22W x 45L x 14H 8°
62-2245-16-8-SP*	LATERAL, 22W x 45L x 16H 8°
62-2250-08-8-SP	LATERAL, 22W x 50L x 08H 8°
62-2250-10-8-SP	LATERAL, 22W x 50L x 10H 8°
62-2250-12-8-SP	LATERAL, 22W x 50L x 12H 8°
62-2250-14-8-SP	LATERAL, 22W x 50L x 14H 8°
62-2250-16-8-SP*	LATERAL, 22W x 50L x 16H 8°
62-2255-08-8-SP	LATERAL, 22W x 55L x 08H 8°
62-2255-10-8-SP	LATERAL, 22W x 55L x 10H 8°
62-2255-12-8-SP	LATERAL, 22W x 55L x 12H 8°
62-2255-14-8-SP	LATERAL, 22W x 55L x 14H 8°
62-2255-16-8-SP*	LATERAL, 22W x 55L x 16H 8°
62-2260-08-8-SP	LATERAL, 22W x 60L x 08H 8°
62-2260-10-8-SP	LATERAL, 22W x 60L x 10H 8°
62-2260-12-8-SP	LATERAL, 22W x 60L x 12H 8°
62-2260-14-8-SP	LATERAL, 22W x 60L x 14H 8°
62-2260-16-8-SP*	LATERAL, 22W x 60L x 16H 8°

LATERAL, 18W x XXL x XXH 14°	
Part Number	**Description**
62-1840-10-14-SP*	LATERAL, 18W x 40L x 10H 14°
62-1840-12-14-SP*	LATERAL, 18W x 40L x 12H 14°
62-1840-14-14-SP*	LATERAL, 18W x 40L x 14H 14°
62-1840-16-14-SP*	LATERAL, 18W x 40L x 16H 14°
62-1845-10-14-SP	LATERAL, 18W x 45L x 10H 14°
62-1845-12-14-SP	LATERAL, 18W x 45L x 12H 14°
62-1845-14-14-SP	LATERAL, 18W x 45L x 14H 14°
62-1845-16-14-SP*	LATERAL, 18W x 45L x 16H 14°
62-1850-10-14-SP	LATERAL, 18W x 50L x 10H 14°
62-1850-12-14-SP	LATERAL, 18W x 50L x 12H 14°
62-1850-14-14-SP	LATERAL, 18W x 50L x 14H 14°
62-1850-16-14-SP	LATERAL, 18W x 50L x 16H 14°
62-1855-10-14-SP	LATERAL, 18W x 55L x 10H 14°
62-1855-12-14-SP	LATERAL, 18W x 55L x 12H 14°

LATERAL, 22W x XXL x XXH 14°	
Part Number	**Description**
62-2240-10-14-SP*	LATERAL, 22W x 40L x 10H 14°
62-2240-12-14-SP*	LATERAL, 22W x 40L x 12H 14°
62-2240-14-14-SP*	LATERAL, 22W x 40L x 14H 14°
62-2240-16-14-SP*	LATERAL, 22W x 40L x 16H 14°
62-2245-10-14-SP	LATERAL, 22W x 45L x 10H 14°
62-2245-12-14-SP	LATERAL, 22W x 45L x 12H 14°
62-2245-14-14-SP	LATERAL, 22W x 45L x 14H 14°
62-2245-16-14-SP*	LATERAL, 22W x 45L x 16H 14°
62-2250-10-14-SP	LATERAL, 22W x 50L x 10H 14°
62-2250-12-14-SP	LATERAL, 22W x 50L x 12H 14°
62-2250-14-14-SP	LATERAL, 22W x 50L x 14H 14°
62-2250-16-14-SP	LATERAL, 22W x 50L x 16H 14°
62-2255-10-14-SP	LATERAL, 22W x 55L x 10H 14°
62-2255-12-14-SP	LATERAL, 22W x 55L x 12H 14°

Made to Order

IMPLANT PART NUMBERS (CONT)

LATERAL, 18W x XXL x XXH 14° (Cont)	
Part Number	**Description**
62-1855-14-14-SP	LATERAL, 18W x 55L x 14H 14°
62-1855-16-14-SP	LATERAL, 18W x 55L x 16H 14°
62-1860-10-14-SP	LATERAL, 18W x 60L x 10H 14°
62-1860-12-14-SP	LATERAL, 18W x 60L x 12H 14°
62-1860-14-14-SP	LATERAL, 18W x 60L x 14H 14°
62-1860-16-14-SP	LATERAL, 18W x 60L x 16H 14°

LATERAL, 22W x XXL x XXH 14° (Cont)	
Part Number	**Description**
62-2255-14-14-SP	LATERAL, 22W x 55L x 14H 14°
62-2255-16-14-SP	LATERAL, 22W x 55L x 16H 14°
62-2260-10-14-SP	LATERAL, 22W x 60L x 10H 14°
62-2260-12-14-SP	LATERAL, 22W x 60L x 12H 14°
62-2260-14-14-SP	LATERAL, 22W x 60L x 14H 14°
62-2260-16-14-SP	LATERAL, 22W x 60L x 16H 14°

LATERAL, 18W x XXL x XXH 20°	
Part Number	**Description**
62-1840-12-20-SP*	LATERAL, 18W x 40L x 12H 20°
62-1840-14-20-SP*	LATERAL, 18W x 40L x 14H 20°
62-1840-16-20-SP*	LATERAL, 18W x 40L x 16H 20°
62-1840-18-20-SP*	LATERAL, 18W x 40L x 18H 20°
62-1840-20-20-SP*	LATERAL, 18W x 40L x 20H 20°
62-1845-12-20-SP*	LATERAL, 18W x 45L x 12H 20°
62-1845-14-20-SP*	LATERAL, 18W x 45L x 14H 20°
62-1845-16-20-SP*	LATERAL, 18W x 45L x 16H 20°
62-1845-18-20-SP*	LATERAL, 18W x 45L x 18H 20°
62-1845-20-20-SP*	LATERAL, 18W x 45L x 20H 20°
62-1850-12-20-SP*	LATERAL, 18W x 50L x 12H 20°
62-1850-14-20-SP*	LATERAL, 18W x 50L x 14H 20°
62-1850-16-20-SP*	LATERAL, 18W x 50L x 16H 20°
62-1850-18-20-SP*	LATERAL, 18W x 50L x 18H 20°
62-1850-20-20-SP*	LATERAL, 18W x 50L x 20H 20°
62-1855-12-20-SP*	LATERAL, 18W x 55L x 12H 20°
62-1855-14-20-SP*	LATERAL, 18W x 55L x 14H 20°
62-1855-16-20-SP*	LATERAL, 18W x 55L x 16H 20°
62-1855-18-20-SP*	LATERAL, 18W x 55L x 18H 20°
62-1855-20-20-SP*	LATERAL, 18W x 55L x 20H 20°
62-1860-12-20-SP*	LATERAL, 18W x 60L x 12H 20°
62-1860-14-20-SP*	LATERAL, 18W x 60L x 14H 20°
62-1860-16-20-SP*	LATERAL, 18W x 60L x 16H 20°
62-1860-18-20-SP*	LATERAL, 18W x 60L x 18H 20°
62-1860-20-20-SP*	LATERAL, 18W x 60L x 20H 20°

LATERAL, 22W x XXL x XXH 20°	
Part Number	**Description**
62-2240-12-20-SP*	LATERAL, 22W x 40L x 12H 20°
62-2240-14-20-SP*	LATERAL, 22W x 40L x 14H 20°
62-2240-16-20-SP*	LATERAL, 22W x 40L x 16H 20°
62-2240-18-20-SP*	LATERAL, 22W x 40L x 18H 20°
62-2240-20-20-SP*	LATERAL, 22W x 40L x 20H 20°
62-2245-12-20-SP	LATERAL, 22W x 45L x 12H 20°
62-2245-14-20-SP	LATERAL, 22W x 45L x 14H 20°
62-2245-16-20-SP	LATERAL, 22W x 45L x 16H 20°
62-2245-18-20-SP	LATERAL, 22W x 45L x 18H 20°
62-2245-20-20-SP*	LATERAL, 22W x 45L x 20H 20°
62-2250-12-20-SP	LATERAL, 22W x 50L x 12H 20°
62-2250-14-20-SP	LATERAL, 22W x 50L x 14H 20°
62-2250-16-20-SP	LATERAL, 22W x 50L x 16H 20°
62-2250-18-20-SP	LATERAL, 22W x 50L x 18H 20°
62-2250-20-20-SP*	LATERAL, 22W x 50L x 20H 20°
62-2255-12-20-SP	LATERAL, 22W x 55L x 12H 20°
62-2255-14-20-SP	LATERAL, 22W x 55L x 14H 20°
62-2255-16-20-SP	LATERAL, 22W x 55L x 16H 20°
62-2255-18-20-SP	LATERAL, 22W x 55L x 18H 20°
62-2255-20-20-SP*	LATERAL, 22W x 55L x 20H 20°
62-2260-12-20-SP	LATERAL, 22W x 60L x 12H 20°
62-2260-14-20-SP	LATERAL, 22W x 60L x 14H 20°
62-2260-16-20-SP	LATERAL, 22W x 60L x 16H 20°
62-2260-18-20-SP	LATERAL, 22W x 60L x 18H 20°
62-2260-20-20-SP*	LATERAL, 22W x 60L x 20H 20°

Made to Order

INSTRUMENT PART NUMBERS

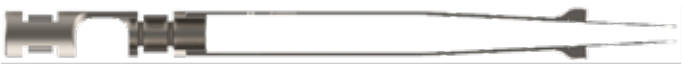
Note: *Images shown are not proportionate to one another.*

Part Number	Description
I62-01-01	Lateral Inserter Straight

Part Number	Description
I62-01-03	Lateral Inserter OLIF

Part Number	Description
I62-01-02R	Lateral Inserter Angled, R

Part Number	Description
I62-01-02L	Lateral Inserter Angled, L



Part Number	Description
I62-01-04S	Graft Containment Slide, Small

Part Number	Description
I62-01-04L	Graft Containment Slide, Large

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

Part Number	Description
I10-01-43	T-Handle, Hudson Connect

Made to Order

INSTRUMENTS PART NUMBERS (CONT)

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

Part Number	Description
I60-20-02	Thumb-Wheel Release

Part Number	Description
I60-20-01	Removal Tool

Part Number	Description
I60-41-01	Slap Hammer Hudson Connect

Part Number	Description
I62-42-02	Tamp

Made to Order

INSTRUMENT PART NUMBERS (CONT)

LATERAL TRIAL, 18W x XXL x XXH 0°	
Part Number	**Description**
I62-TR18-08-0*	LATERAL TRIAL, 18W x 08H, 0°
I62-TR18-10-0*	LATERAL TRIAL, 18W x 10H, 0°
I62-TR18-12-0*	LATERAL TRIAL, 18W x 12H, 0°
I62-TR18-14-0*	LATERAL TRIAL, 18W x 14H, 0°
I62-TR18-16-0*	LATERAL TRIAL, 18W x 16H, 0°

LATERAL TRIAL, 22W x XXL x XXH 0°	
Part Number	**Description**
I62-TR22-08-0*	LATERAL TRIAL, 22W x 08H, 0°
I62-TR22-10-0*	LATERAL TRIAL, 22W x 10H, 0°
I62-TR22-12-0*	LATERAL TRIAL, 22W x 12H, 0°
I62-TR22-14-0*	LATERAL TRIAL, 22W x 14H, 0°
I62-TR22-16-0*	LATERAL TRIAL, 22W x 16H, 0°

LATERAL TRIAL, 18W x XXL x XXH 8°	
Part Number	**Description**
I62-TR18-08-8	LATERAL TRIAL, 18W x 08H, 8°
I62-TR18-10-8	LATERAL TRIAL, 18W x 10H, 8°
I62-TR18-12-8	LATERAL TRIAL, 18W x 12H, 8°
I62-TR18-14-8	LATERAL TRIAL, 18W x 14H, 8°
I62-TR18-16-8*	LATERAL TRIAL, 18W x 16H, 8°

LATERAL TRIAL, 22W x XXL x XXH 8°	
Part Number	**Description**
I62-TR22-08-8	LATERAL TRIAL, 22W x 08H, 8°
I62-TR22-10-8	LATERAL TRIAL, 22W x 10H, 8°
I62-TR22-12-8	LATERAL TRIAL, 22W x 12H, 8°
I62-TR22-14-8	LATERAL TRIAL, 22W x 14H, 8°
I62-TR22-16-8*	LATERAL TRIAL, 22W x 16H, 8°

LATERAL TRIAL, 18W x XXL x XXH 14°	
Part Number	**Description**
I62-TR18-10-14	LATERAL TRIAL, 18W x 10H, 14°
I62-TR18-12-14	LATERAL TRIAL, 18W x 12H, 14°
I62-TR18-14-14	LATERAL TRIAL, 18W x 14H, 14°
I62-TR18-16-14	LATERAL TRIAL, 18W x 16H, 14°

LATERAL TRIAL, 22W x XXL x XXH 14°	
Part Number	**Description**
I62-TR22-10-14	LATERAL TRIAL, 22W x 10H, 14°
I62-TR22-12-14	LATERAL TRIAL, 22W x 12H, 14°
I62-TR22-14-14	LATERAL TRIAL, 22W x 14H, 14°
I62-TR22-16-14	LATERAL TRIAL, 22W x 16H, 14°

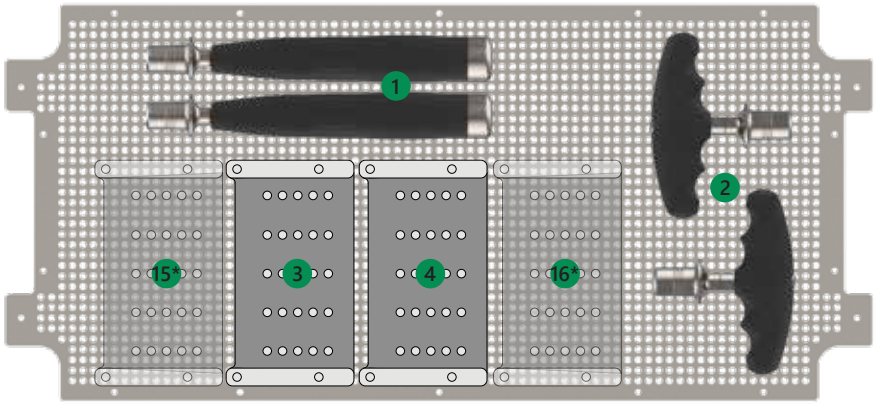
LATERAL TRIAL, 18W x XXL x XXH 20°	
Part Number	**Description**
I62-TR18-12-20*	LATERAL TRIAL, 18W x 12H, 20°
I62-TR18-14-20*	LATERAL TRIAL, 18W x 14H, 20°
I62-TR18-16-20*	LATERAL TRIAL, 18W x 16H, 20°
I62-TR18-18-20*	LATERAL TRIAL, 18W x 18H, 20°
I62-TR18-20-20*	LATERAL TRIAL, 18W x 20H, 20°

LATERAL TRIAL, 22W x XXL x XXH 20°	
Part Number	**Description**
I62-TR22-12-20*	LATERAL TRIAL, 22W x 12H, 20°
I62-TR22-14-20*	LATERAL TRIAL, 22W x 14H, 20°
I62-TR22-16-20*	LATERAL TRIAL, 22W x 16H, 20°
I62-TR22-18-20*	LATERAL TRIAL, 22W x 18H, 20°
I62-TR22-20-20*	LATERAL TRIAL 22W x 20H, 20°

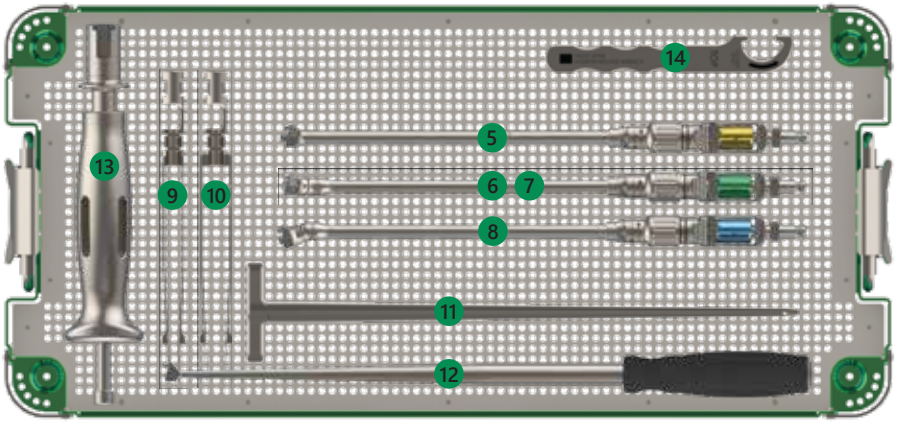
Made to Order

STANDARD INSTRUMENT CASE

Top Level



Bottom Level



Part Number	Description
1. I10-01-62 (2x)	Inline Handle Hudson Connect (2x)
2. I10-01-43 (2x)	T-Handle Hudson Connect, (2x)
3. C62-02-02	Lateral Trial Caddy, 8 Degree
4. C62-02-03	Lateral Trial Caddy, 14 Degree
5. I62-01-01 (2x)	Lateral Cage Inserter Straight (2x)
6. I62-01-02L	Lateral Cage Inserter Angled, Left
7. I62-01-02R	Lateral Cage Inserter Angled, Right
8. I62-01-03	Lateral Cage Inserter OLIF
9. I62-01-04S	Graft Containment Slide Small
10. I62-01-04L	Graft Containment Slide Large
11. I60-20-01	Cage Remover
12. I62-42-02	Tamp
13. I60-41-01	Slap Hammer
14. I60-20-02	Inserter Thumb Wheel Release Wrench
15. C62-02-01*	Lateral Trial Caddy, 0 Degree (Location in case if ordered)
16. C62-02-04*	Lateral Trial Caddy, 20 Degree (Location in case if ordered)

Made to Order

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 (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

• 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.

INDICATIONS (CONT)

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.*

Nexxt Spine
GROW WITH US

Nexxt Spine, LLC
14425 Bergen Blvd, Suite B
Noblesville, IN 46060
(317)-436-7801
Info@NexxtSpine.com
NexxtSpine.com

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.