

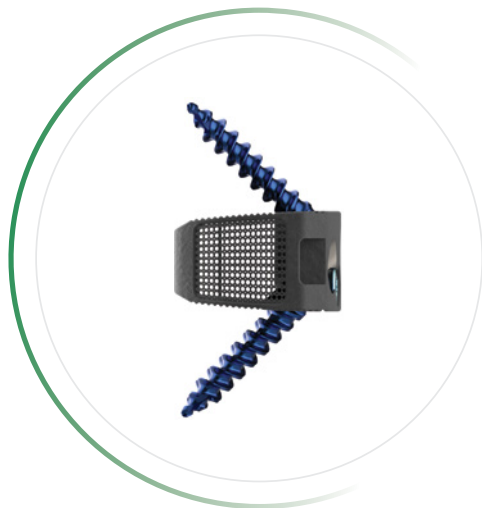
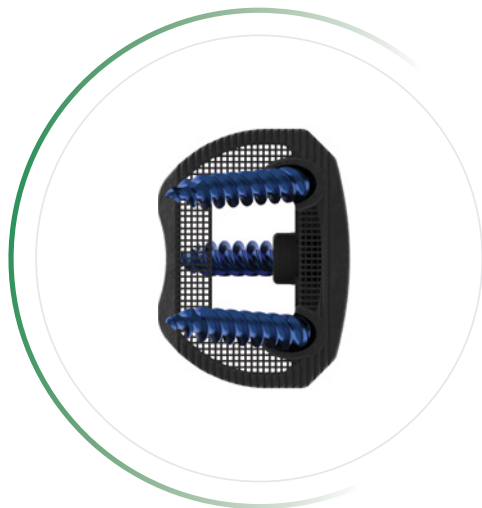
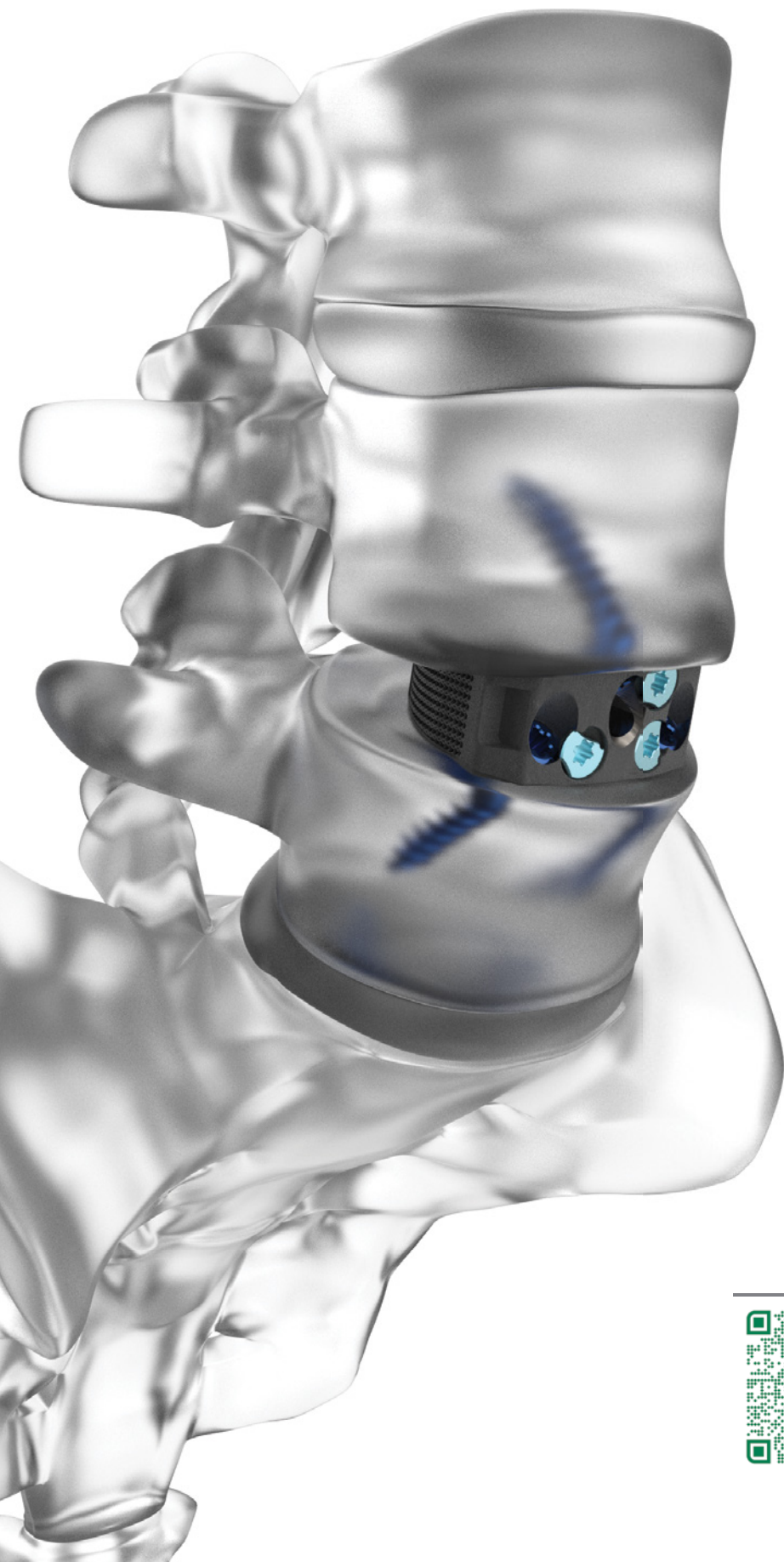




Table of Contents

NEXXT MATRIXX® Technology	3
System Specifications	4
Product Features	5
Surgical Technique Steps	
1. Patient Positioning + Surgical Preparation	6
2. Midline Verification + Disc Removal	7
3. Cage Inserter Instruction	8
4. Handle Instruction	10
5. Trialing	11
6. Cage Insertion	12
7. Hole Preparation	13
8. Screw Insertion	15
9. Locking + Closure	16
10. Removal	17
Product Part Numbers	18
Tray Layout	22
Indications For Use	24

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.

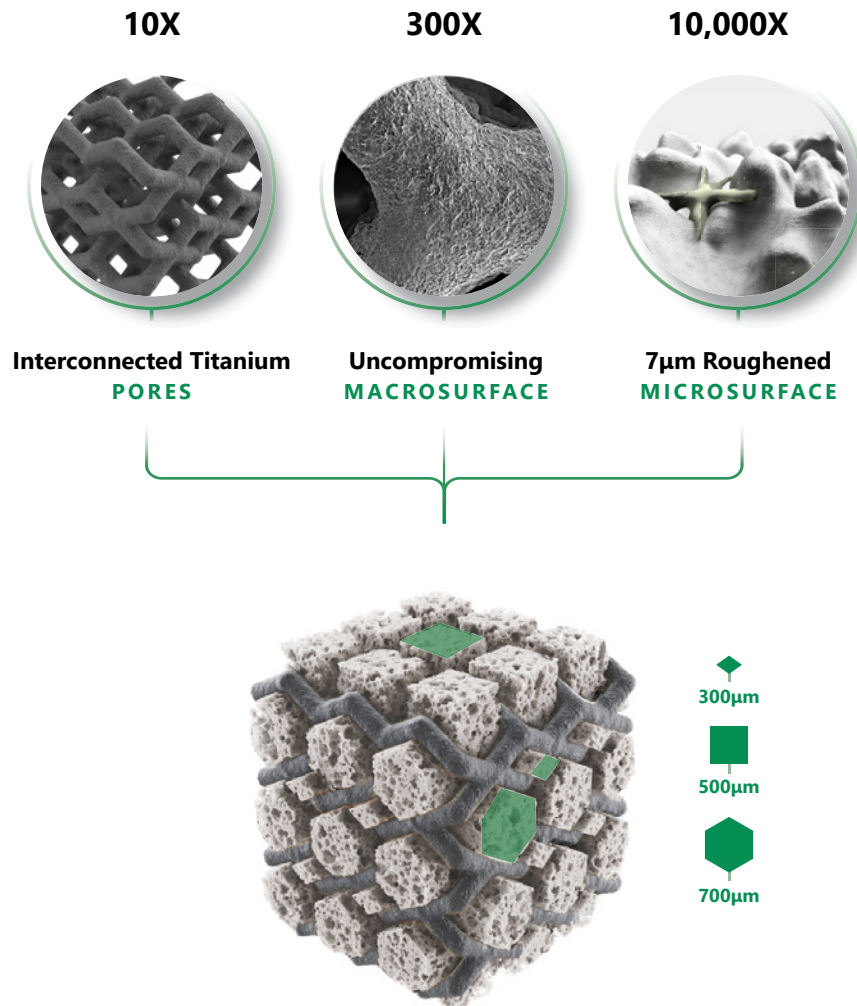


Image represents potential boney ingrowth

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.

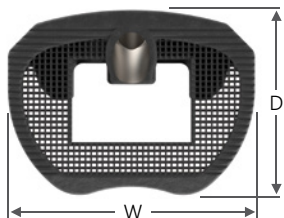


SPECIFICATIONS

CAGES

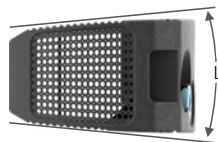
Footprints (mm)

24Dx32W
27Dx36W
30Dx40W



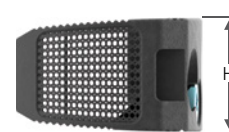
Lordoses

8°, 14°, 20°, and 25°*



Heights

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



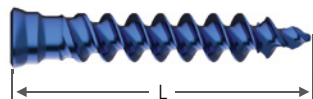
* By Request.

Contact Info@NexxtSpine.com for full SKU offering.

SCREWS

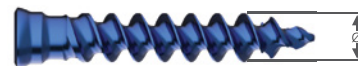
Length

20, 25, 30, and 35mm



Diameter

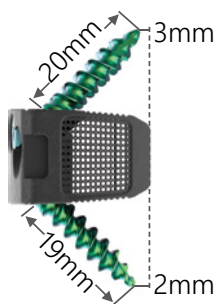
5.0 & 5.5Ø



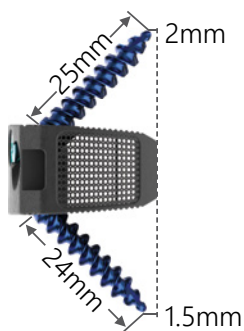
CONSTRUCTS

Bone Purchase

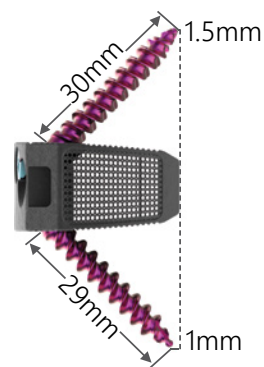
Cage: 24D x 32W
Screw: 25mm



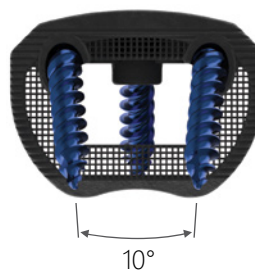
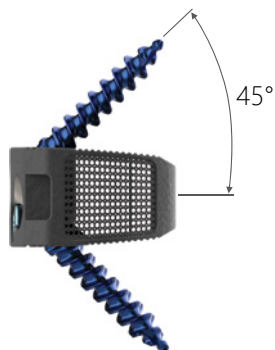
Cage: 27D x 36W
Screw: 30mm



Cage: 30D x 40W
Screw: 35mm

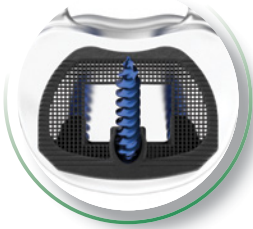


Angulation

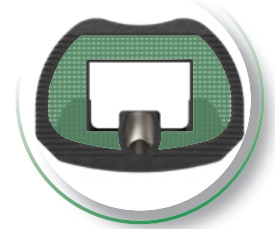




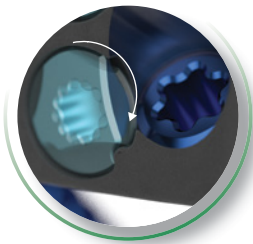
PRODUCT FEATURES



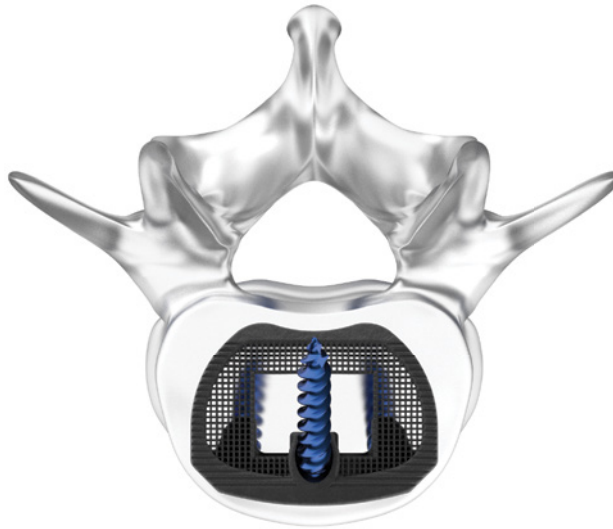
Anatomically matched profile
for appropriate endplate coverage
and placement on apophyseal rim
for stability



Ample graft window
balanced with lattice landscape
to promote bone growth



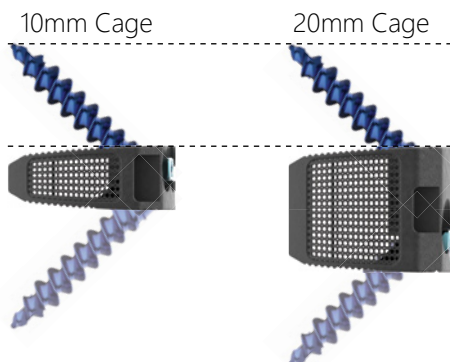
Integrated one-step turn
lock feature to prevent Screw
backout



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

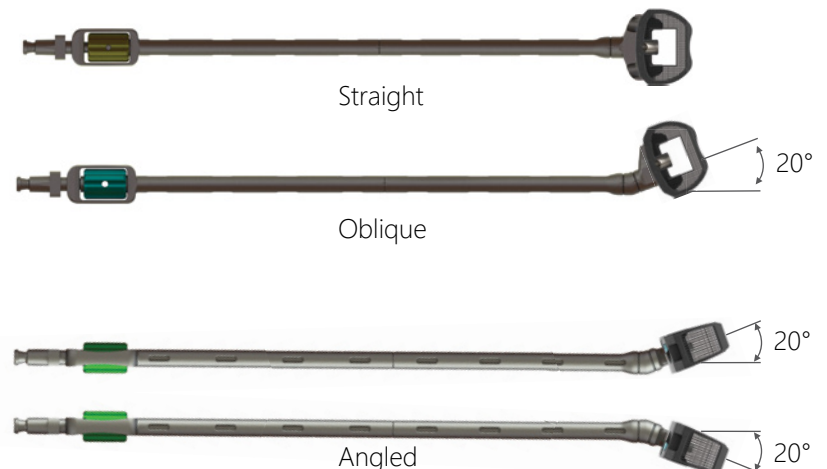
Optimized location of Screw Pockets

to allow for consistent bone purchase for each
Screw regardless of Cage height



Multiple insertion instrumentation options

to accommodate patient anatomy and spinal
pathology that is being treated





1. Patient Positioning + Surgical Preparation

1.1 - Patient Positioning

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

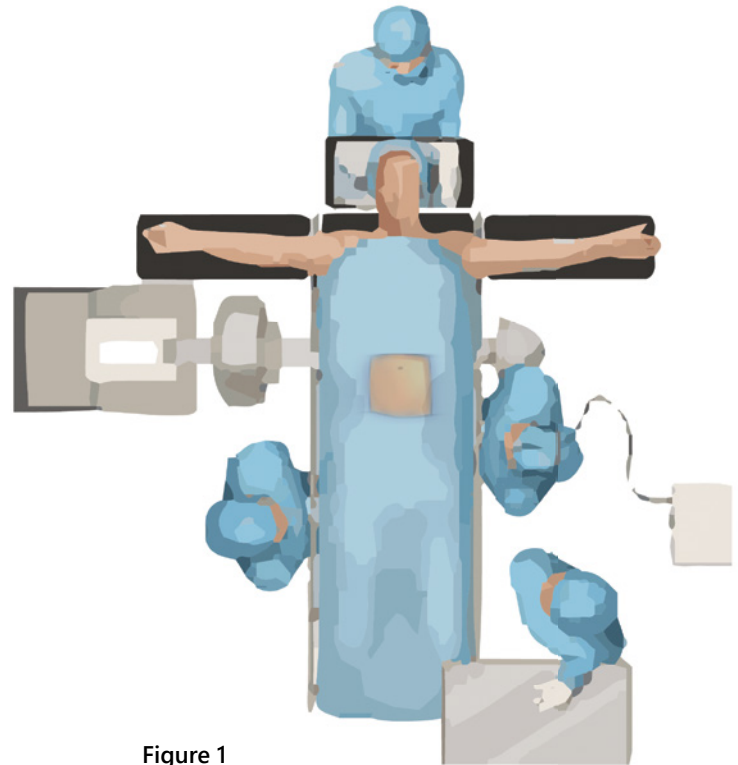


Figure 1

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.



2. Midline Verification + Disc Removal

2.1 - Midline Verification

Position the Annulotomy Template (32, 36, or 40mm wide) on the disc space and insert the Centering Pin (23mm deep) in the midline (Figure 2).

Note:

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

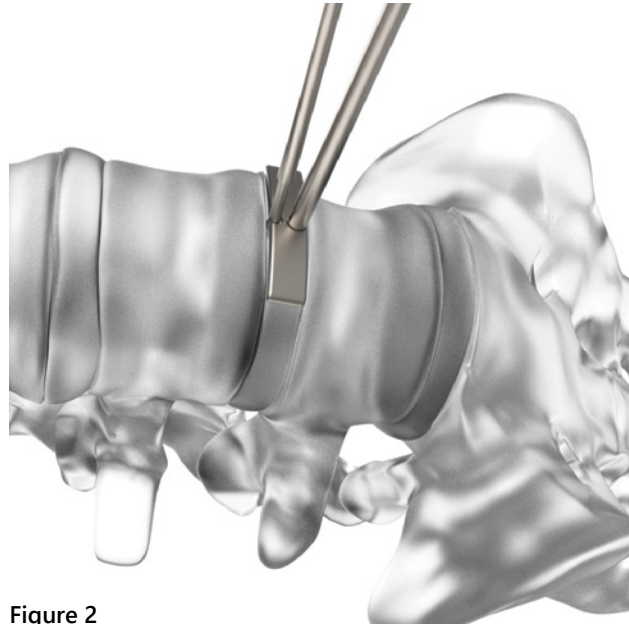


Figure 2

2.2 - 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.

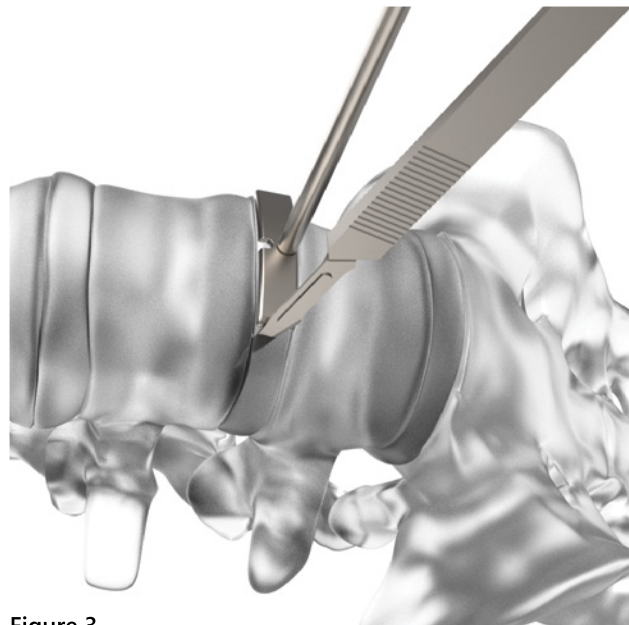


Figure 3



3. Cage Inserter Instruction

3.1 - Cage Inserter + Trial Attachment

Align the Cage Inserter to the Trial/Cage. When aligning with the Cage, ensure proper orientation by matching the laser etched icon and the Cage face hole(s) (Figure 4a). 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 4b).

Note:

Verify assembly before insertion. Due to their biased orientation, Oblique and Angled Inserter verification is especially important to ensure correct screw placement.



Figure 4a

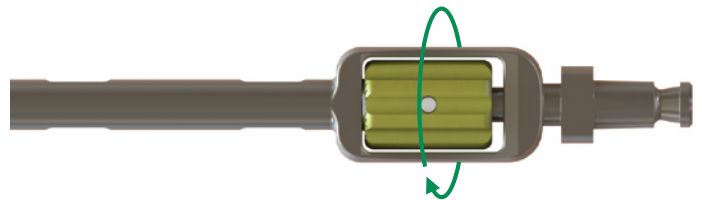


Figure 4b

Instrument Options

There are three types of Inserters available: Straight, Angled and Oblique (Figure 4c).



Straight Inserter

Angled Inserter

Oblique Inserter

Figure 4c



3. Cage Inserter Instruction (Continued)

3.2 - Cage Inserter + Trial Detachment

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

Thumb Wheel Rotater

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

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

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

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

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



Figure 5a

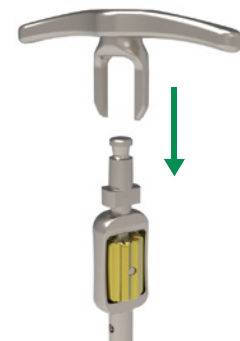


Figure 5b



Figure 5c



Figure 5d



4. Handle Instruction

4.1 - Cage Inserter + T-Handle Attachment

Pull the Hudson Connect Sleeve up (Figure 6a).

Align and connect the Hudson Connect Sleeve to the Cage Inserter (Figure 6b).

Release the Hudson Connect Sleeve (Figure 6c).

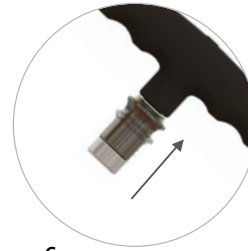


Figure 6a



Figure 6b

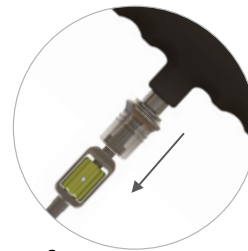


Figure 6c



4.1 - Cage Inserter + Slap Hammer Attachment

Pull the Hudson Connect Sleeve up (Figure 7a).

Align and connect the Hudson Connect Sleeve to the Cage Inserter (Figure 7b).

Release the Hudson Connect Sleeve (Figure 7c).

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.

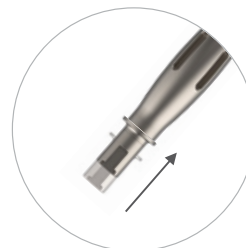


Figure 7a



Figure 7b



Figure 7c





5. Trialing

Step 10 - 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 8a).

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 8b). Center the Trial in the vertebral cavity.

Trial Insertor

Thread Trial inserter into hole on the anterior of the trial body until bottomed out (Figure 8c).

To determine the appropriate Cage size, gently impact the Trial into the disc space until it is centered under medial/lateral fluoroscopy (Figure 8d). 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.

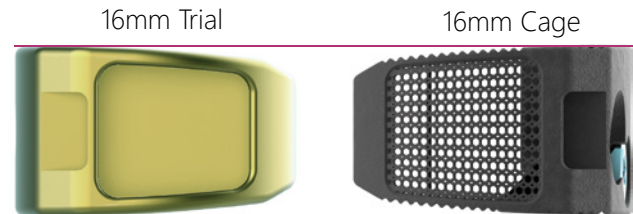


Figure 8a



Figure 8b



Figure 8c



Figure 8d



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.

Attach the Cage to the Cage Inserter then attach a T Handle to the proximal end of the Cage Inserter (Figure 9). Verify security of the assembly. Center the Cage in the vertebral cavity.



Figure 9

6.2 - Cage Placement

Impact the Cage into the prepared disc space (Figure 10). 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:

Cage Inserter may remain attached during preparation of lateral holes, however, Inserter must be removed to allow access to the medial hole.

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 10



7. Hole Preparation

7.1 - Hole Preparation

Instrument Options

There are two styles of Hole Preparation Instruments: Self-Guided and Poly Angle (used with the Single Barrel Guide). These styles can be used interchangeably.

Option 1: Self-Guided

- Self-Guided instrumentation includes the Self-Guided Angled Awl, Self-Guided Straight Awl, and Self-Guided Straight Drill (Figure 11a)
- The Self-Guided Angled Awl offers a fixed 45° angle
- Both Self-Guided Awls feature a proximal threaded hole for the Slap Hammer Adapter
- Awl and drill diameter is 3.0mm, and depth is 10mm

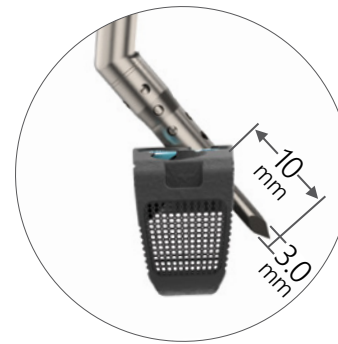


Figure 11a

Option 2: Poly Angle + Single Barrel Guide

- Poly Angle instrumentation includes the Poly Angle Awl, the Poly Angle Drill, and the Single Barrel Guide (Figure 11b)
- The Poly Angle Awl features a proximal threaded hole for the Slap Hammer Adapter
- Awl and drill diameter is 3.0mm, and depth is 10mm

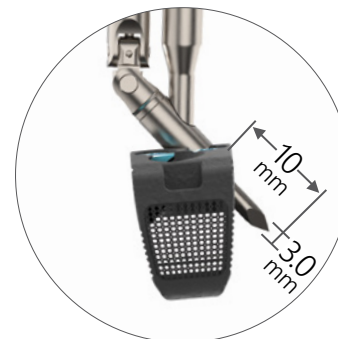


Figure 11b



7. Hole Preparation (Continued)

7.2 - Pilot Hole Execution

Using the Self-Guided Angled Awl, Self-Guided Straight Awl, and Self-Guided Straight Drill or the Poly Angle Awl, Poly Angle Drill, and the Single Barrel Guide, locate the Screw pocket within the Cage and dock. Plunge/drill to create the pilot hole. Repeat for all pilot holes (Figures 12a and 12b).

Note:

Use of power with hole preparation instrumentation is not recommended.

Note:

The Cage Inserter may remain attached to the Cage to provide additional support while creating pilot holes using Self-Guided instrumentation options for the lateral Screw pockets.

1. Locate



2. Dock



3. Plunge



Figure 12a

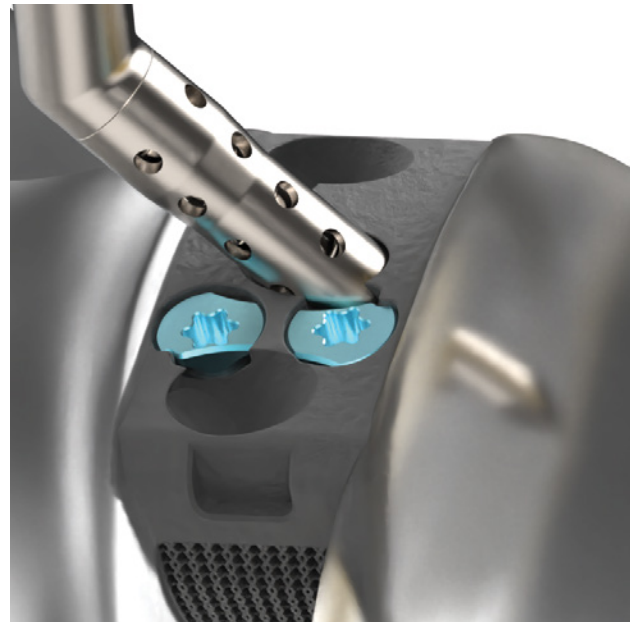


Figure 12b



8. Screw Insertion

8.1 - Screw Insertion

Instrument Options

Connect a Ratcheting T-Handle to either the Straight Driver (T20) or Fixed Angle Driver (T20) (Figure 13). Determine the desired Screw length and attach the Screw to the tip of the selected Driver.

Note:

The Fixed Angle Driver Tip is fixed at 60°.

Note:

The Straight Driver and Fixed Angle Driver have a self-retaining, press-fit connection with the Screw.



Figure 13

8.2 - Screw Placement

Insert the Screw into the desired Screw pocket and advance the Screw by turning the Ratcheting T-Handle clockwise until it bottoms out (Figure 14). Repeat for all Screws to complete the Construct.

Verify Screw placement via fluoroscopy.

Note:

Ensure all Screws are fully seated within the Screw pockets.

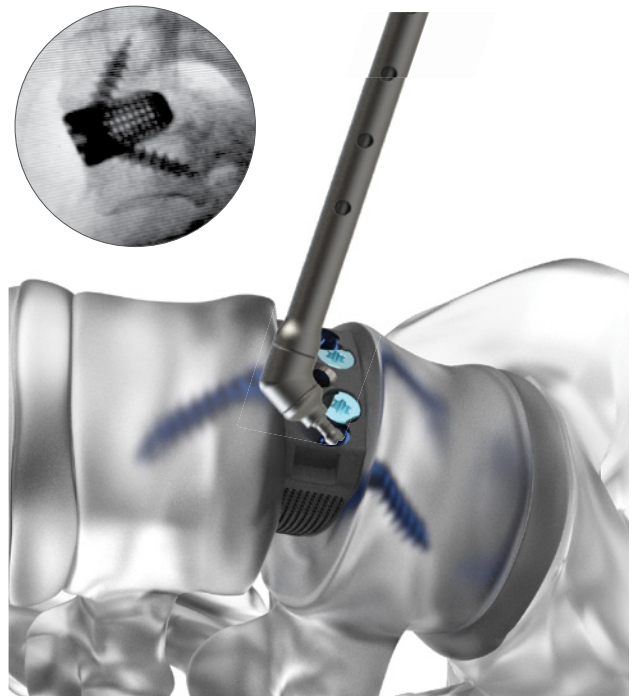


Figure 14



9. Locking + Closure

9.1 - Locking

Turn Lock Tool

The Turn Lock Tool (T15) is designed for use exclusively with the Cage Turn Locks (Figure 15a).



Figure 15a

Cage Turn Lock Locking

Mate the top of the Turn Lock Tool to the Turn Lock. Rotate clockwise, approximately 90° until the Turn Lock encounters a hard-stop with the Cage (Figure 15b). Repeat for all Turn Locks.

Note:

In the event a Turn Lock does not clear the Screw Head, drive the Screw deeper until it is bottomed out in the Screw pocket then rotate the Turn Lock.

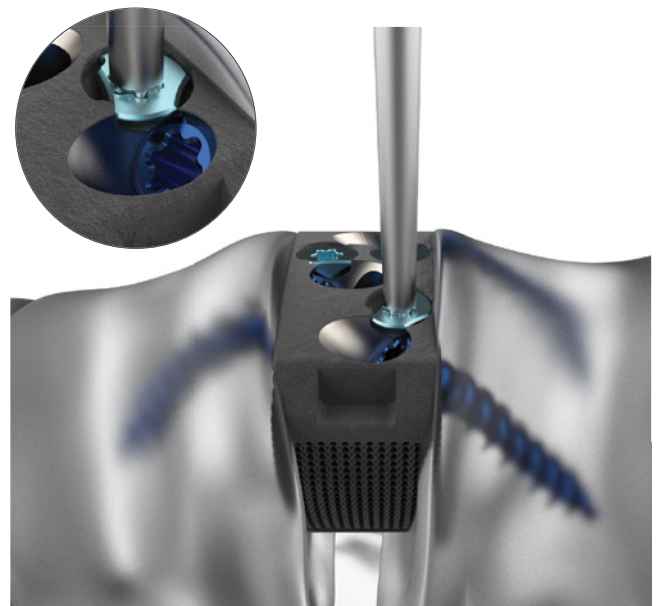


Figure 15b

9.2 - Closure

The skin is closed using the standard surgical technique.

NOTE: Hyperlordotic interbody devices (>20° lordosis) must be used with supplemental fixation (e.g. posterior fixation). Each interbody fusion device having a lordotic angle 20° or less is intended to be used with the bone screws provided and requires no additional fixation.



10. Removal

Removal (As Needed)

Cage Turn Unlocking

If it becomes necessary to revise the implanted Construct, access to the implantation site can be achieved in a similar fashion to the original access. Mate the tip of the Turn Lock Tool to the Turn Lock. Rotate counterclockwise, approximately 90° until the Turn Lock encounters a hard-stop with the Cage (Figure 16a). Repeat for all Turn Locks.

Screw Removal

Attach the Axial Ratcheting Handle to the Straight Driver or Fixed Angle Driver and remove the Screw by rotating the Axial Ratcheting Handle counterclockwise until the Screw can be safely removed from the surgical site. Repeat for all Screws.

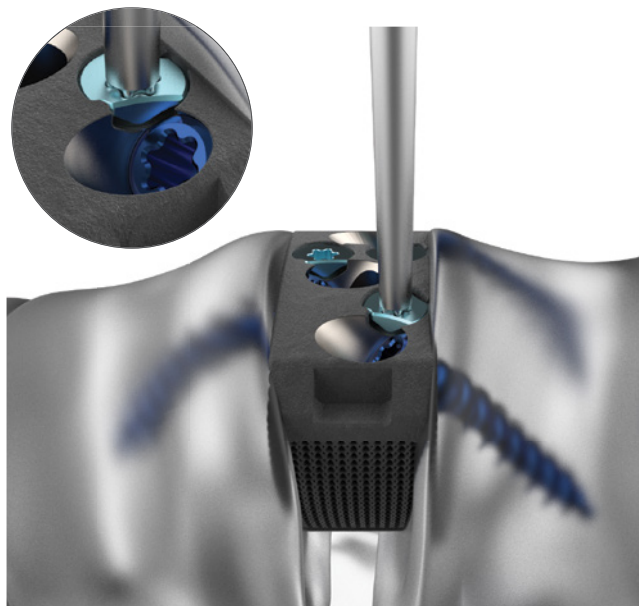


Figure 16a

Cage Removal

Reattach the Cage Inserter to the Cage and attach either the Inline Handle or Slap Hammer, if desired, to the Cage Inserter and proceed to removal (Figure 16b). If the Cage is difficult to remove, additional engagement or dislodging may be achieved with the Cage Removal Tool. Thread the Cage Removal Tool clockwise into the central hole of the Cage until it is tightly attached, then remove. Separation from the inferior and superior endplates and removal of bony ongrowth should be completed in order to limit iatrogenic damage.

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

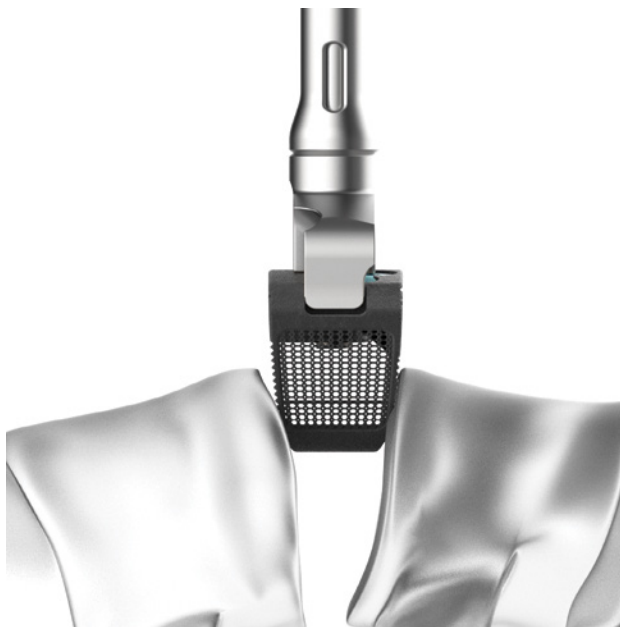


Figure 16b



NEXXT MATRIXX® Stand Alone ALIF Implant Part Numbers



Standard P/N	Description
24D x 32W x XXH Implants	
61-2432-10-8-SP	24Dx32Wx10H, 8°
61-2432-12-8-SP	24Dx32Wx12H, 8°
61-2432-14-8-SP	24Dx32Wx14H, 8°
61-2432-16-8-SP	24Dx32Wx16H, 8°
61-2432-18-8-SP	24Dx32Wx18H, 8°
61-2432-20-8-SP*	24Dx32Wx20H, 8°
61-2432-10-14-SP	24Dx32Wx10H, 14°
61-2432-12-14-SP	24Dx32Wx12H, 14°
61-2432-14-14-SP	24Dx32Wx14H, 14°
61-2432-16-14-SP	24Dx32Wx16H, 14°
61-2432-18-14-SP	24Dx32Wx18H, 14°
61-2432-20-14-SP	24Dx32Wx20H, 14°
61-2432-12-20-SP	24Dx32Wx12H, 20°
61-2432-14-20-SP	24Dx32Wx14H, 20°
61-2432-16-20-SP	24Dx32Wx16H, 20°
61-2432-18-20-SP	24Dx32Wx18H, 20°
61-2432-20-20-SP	24Dx32Wx20H, 20°
61-2432-14-25-SP*	24Dx32Wx14H, 25°
61-2432-16-25-SP*	24Dx32Wx16H, 25°
61-2432-18-25-SP*	24Dx32Wx18H, 25°
61-2432-20-25-SP*	24Dx32Wx20H, 25°

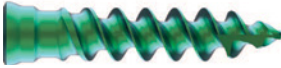
Standard P/N	Description
27D x 36W x XXH Implants	
61-2736-10-8-SP	27Dx36Wx10H, 8°
61-2736-12-8-SP	27Dx36Wx12H, 8°
61-2736-14-8-SP	27Dx36Wx14H, 8°
61-2736-16-8-SP	27Dx36Wx16H, 8°
61-2736-18-8-SP	27Dx36Wx18H, 8°
61-2736-20-8-SP*	27Dx36Wx20H, 8°
61-2736-10-14-SP	27Dx36Wx10H, 14°
61-2736-12-14-SP	27Dx36Wx12H, 14°
61-2736-14-14-SP	27Dx36Wx14H, 14°
61-2736-16-14-SP	27Dx36Wx16H, 14°
61-2736-18-14-SP	27Dx36Wx18H, 14°
61-2736-20-14-SP	27Dx36Wx20H, 14°
61-2736-12-20-SP	27Dx36Wx12H, 20°
61-2736-14-20-SP	27Dx36Wx14H, 20°
61-2736-16-20-SP	27Dx36Wx16H, 20°
61-2736-18-20-SP	27Dx36Wx18H, 20°
61-2736-20-20-SP	27Dx36Wx20H, 20°
61-2736-14-25-SP*	27Dx36Wx14H, 25°
61-2736-16-25-SP*	27Dx36Wx16H, 25°
61-2736-18-25-SP*	27Dx36Wx18H, 25°
61-2736-20-25-SP*	27Dx36Wx20H, 25°

Standard P/N	Description
30D x 40W x XXH Implants	
61-3040-10-8-SP	30Dx40Wx10H, 8°
61-3040-12-8-SP	30Dx40Wx12H, 8°
61-3040-14-8-SP	30Dx40Wx14H, 8°
61-3040-16-8-SP	30Dx40Wx16H, 8°
61-3040-18-8-SP	30Dx40Wx18H, 8°
61-3040-20-8-SP*	30Dx40Wx20H, 8°
61-3040-10-14-SP	30Dx40Wx10H, 14°
61-3040-12-14-SP	30Dx40Wx12H, 14°
61-3040-14-14-SP	30Dx40Wx14H, 14°
61-3040-16-14-SP	30Dx40Wx16H, 14°
61-3040-18-14-SP	30Dx40Wx18H, 14°
61-3040-20-14-SP	30Dx40Wx20H, 14°
61-3040-14-20-SP	30Dx40Wx14H, 20°
61-3040-16-20-SP	30Dx40Wx16H, 20°
61-3040-18-20-SP	30Dx40Wx18H, 20°
61-3040-20-20-SP	30Dx40Wx20H, 20°
61-3040-14-25-SP*	30Dx40Wx14H, 25°
61-3040-16-25-SP*	30Dx40Wx16H, 25°
61-3040-18-25-SP*	30Dx40Wx18H, 25°
61-3040-20-25-SP*	30Dx40Wx20H, 25°

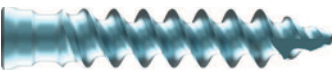
* By Request.

Contact Info@NexxtSpine.com for full SKU offering.

Standard Screws

Standard P/N	Description
	
61-50-15-SP	Ø5.0x20mm Screw
	
61-50-20-SP	Ø5.0x25mm Screw
	
61-50-25-SP	Ø5.0x30mm Screw
	
61-50-30-SP	Ø5.0x35mm Screw

Rescue Screws

Standard P/N	Description
	
61-55-15-SP	Ø5.5x20mm Screw
	
61-55-20-SP	Ø5.5x25mm Screw
	
61-55-25-SP	Ø5.5x30mm Screw
	
61-55-30-SP	Ø5.5x35mm Screw



NEXXT MATRIXX® Stand Alone ALIF Instruments

I61-02-01



Standard P/N

Description

I61-02-01

Straight Inserter

I61-01-02



Standard P/N

Description

I61-01-02

Angled Inserter

I61-01-03



Standard P/N

Description

I61-01-03

Oblique Inserter

I61-20-04



Standard P/N

Description

I61-20-04

Guided Straight Awl

I61-20-05



Standard P/N

Description

I61-20-05

Guided Angled Awl

I61-20-06



Standard P/N

Description

I61-20-06

Guided Drill

I61-32-01



Standard P/N

Description

I61-32-01

Lock Tool

I63-21-05



Standard P/N

Description

I63-21-05

Straight Driver, T20

I63-22-01*

Straight Driver Sleeve

I61-34-02



Standard P/N

Description

I61-34-02

Cage Remover

I60-41-01



Standard P/N

Description

I60-41-01

Slap Hammer

I62-52-01



Standard P/N

Description

I62-52-01

Slap Hammer
Adapter

I61-42-01



Standard P/N

Description

I61-42-01

Tamp



NEXXT MATRIXX® Stand Alone ALIF Instruments

I61-22-03



Standard P/N

I61-22-03

Description

Poly Awl

I61-22-04



Standard P/N

I61-22-04

Description

Poly Drill

I61-26-01



Standard P/N

I61-26-01

Description

Single Barrel Guide

I10-01-43



Standard P/N

I10-01-43

Description

Hudson T-Handle

I61-22-05



Standard P/N

I61-22-05

Description

Poly Angle Driver

I92-20-01



Standard P/N

I92-20-01

Description

Thumb Wheel Rotator

I10-01-63



Standard P/N

I10-01-63

Description

Hudson T-Handle, Ratcheting

I61-32-02



Standard P/N

I61-32-02

Description

Annulotomy Centering Pin

I10-01-63



Standard P/N

I61-03-01

Description

SA ALIF, Trial Insertor

I61-32-XX



Standard P/N

I61-32-32

Description

Annulotomy Template, 32mm

I61-32-36

Annulotomy Template, 36mm

I61-32-40

Annulotomy Template, 40mm

I61-24-01



Standard P/N

I61-24-01

Description

Fixed Angle Driver

I52-23-03*

Fixed Angle Driver Handle

* By Request.

Contact Info@NexxtSpine.com for full SKU offering.



NEXXT MATRXXX® Stand Alone ALIF Implant Part Numbers



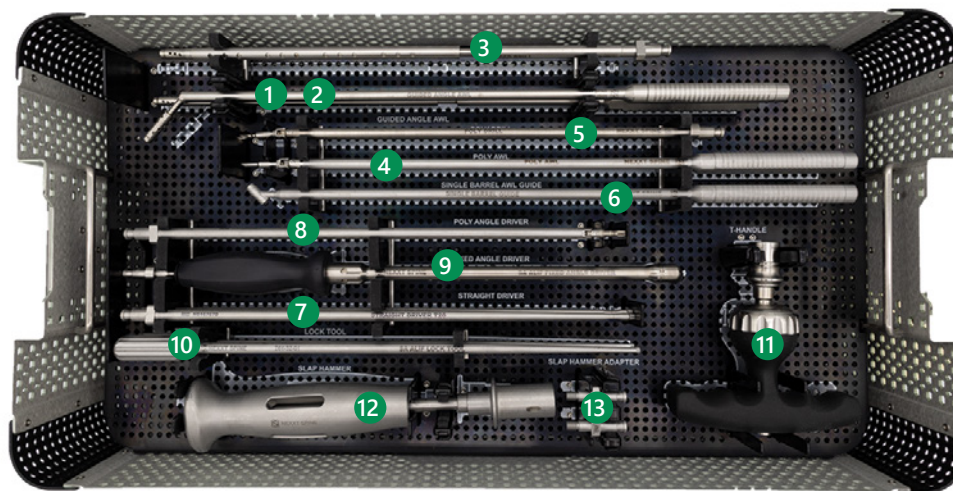
Standard P/N	Description
24D x 32W x XXH Trials	
I61-TR2432-10-8-SP	24Dx32Wx10H, 8°
I61-TR2432-12-8-SP	24Dx32Wx12H, 8°
I61-TR2432-14-8-SP	24Dx32Wx14H, 8°
I61-TR2432-16-8-SP	24Dx32Wx16H, 8°
I61-TR2432-18-8-SP	24Dx32Wx18H, 8°
I61-TR2432-20-8-SP*	24Dx32Wx20H, 8°
I61-TR2432-10-14-SP	24Dx32Wx10H, 14°
I61-TR2432-12-14-SP	24Dx32Wx12H, 14°
I61-TR2432-14-14-SP	24Dx32Wx14H, 14°
I61-TR2432-16-14-SP	24Dx32Wx16H, 14°
I61-TR2432-18-14-SP	24Dx32Wx18H, 14°
I61-TR2432-20-14-SP	24Dx32Wx20H, 14°
I61-TR2432-12-20-SP	24Dx32Wx12H, 20°
I61-TR2432-14-20-SP	24Dx32Wx14H, 20°
I61-TR2432-16-20-SP	24Dx32Wx16H, 20°
I61-TR2432-18-20-SP	24Dx32Wx18H, 20°
I61-TR2432-20-20-SP	24Dx32Wx20H, 20°
I61-TR2432-14-25-SP*	24Dx32Wx14H, 25°
I61-TR2432-16-25-SP*	24Dx32Wx16H, 25°
I61-TR2432-18-25-SP*	24Dx32Wx18H, 25°
I61-TR2432-20-25-SP*	24Dx32Wx20H, 25°

Standard P/N	Description
27D x 36W x XXH Implants	
I61-TR2736-10-8-SP	27Dx36Wx10H, 8°
I61-TR2736-12-8-SP	27Dx36Wx12H, 8°
I61-TR2736-14-8-SP	27Dx36Wx14H, 8°
I61-TR2736-16-8-SP	27Dx36Wx16H, 8°
I61-TR2736-18-8-SP	27Dx36Wx18H, 8°
I61-TR2736-20-8-SP*	27Dx36Wx20H, 8°
I61-TR2736-10-14-SP	27Dx36Wx10H, 14°
I61-TR2736-12-14-SP	27Dx36Wx12H, 14°
I61-TR2736-14-14-SP	27Dx36Wx14H, 14°
I61-TR2736-16-14-SP	27Dx36Wx16H, 14°
I61-TR2736-18-14-SP	27Dx36Wx18H, 14°
I61-TR2736-20-14-SP	27Dx36Wx20H, 14°
I61-TR2736-12-20-SP	27Dx36Wx12H, 20°
I61-TR2736-14-20-SP	27Dx36Wx14H, 20°
I61-TR2736-16-20-SP	27Dx36Wx16H, 20°
I61-TR2736-18-20-SP	27Dx36Wx18H, 20°
I61-TR2736-20-20-SP	27Dx36Wx20H, 20°
I61-TR2736-14-25-SP*	27Dx36Wx14H, 25°
I61-TR2736-16-25-SP*	27Dx36Wx16H, 25°
I61-TR2736-18-25-SP*	27Dx36Wx18H, 25°
I61-TR2736-20-25-SP*	27Dx36Wx20H, 25°

Standard P/N	Description
30D x 40W x XXH Implants	
I61-TR3040-10-8-SP	30Dx40Wx10H, 8°
I61-TR3040-12-8-SP	30Dx40Wx12H, 8°
I61-TR3040-14-8-SP	30Dx40Wx14H, 8°
I61-TR3040-16-8-SP	30Dx40Wx16H, 8°
I61-TR3040-18-8-SP	30Dx40Wx18H, 8°
I61-TR3040-20-8-SP*	30Dx40Wx20H, 8°
I61-TR3040-10-14-SP	30Dx40Wx10H, 14°
I61-TR3040-12-14-SP	30Dx40Wx12H, 14°
I61-TR3040-14-14-SP	30Dx40Wx14H, 14°
I61-TR3040-16-14-SP	30Dx40Wx16H, 14°
I61-TR3040-18-14-SP	30Dx40Wx18H, 14°
I61-TR3040-20-14-SP	30Dx40Wx20H, 14°
I61-TR3040-14-20-SP	30Dx40Wx14H, 20°
I61-TR3040-16-20-SP	30Dx40Wx16H, 20°
I61-TR3040-18-20-SP	30Dx40Wx18H, 20°
I61-TR3040-20-20-SP	30Dx40Wx20H, 20°
I61-TR3040-14-25-SP*	30Dx40Wx14H, 25°
I61-TR3040-16-25-SP*	30Dx40Wx16H, 25°
I61-TR3040-18-25-SP*	30Dx40Wx18H, 25°
I61-TR3040-20-25-SP*	30Dx40Wx20H, 25°



NEXXT MATRIXX® SA ALIF Standard Hole Prep and Screw Insertion Case



Standard P/N

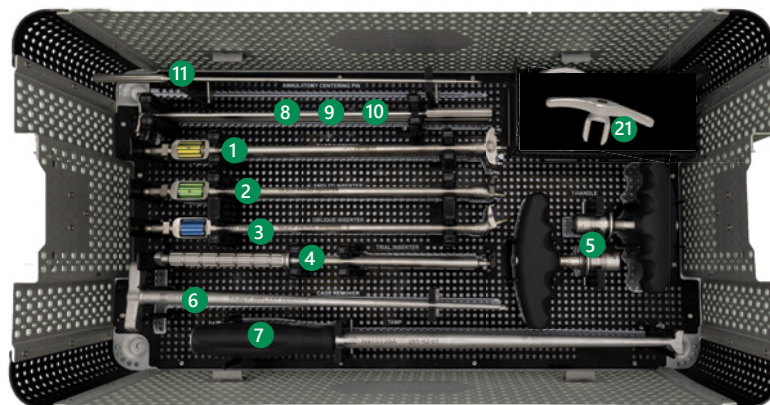
1. I61-20-04
2. I61-20-05
3. I61-20-06
4. I61-22-03
5. I61-22-04
6. I61-26-01
7. I63-21-05
8. I61-22-05
9. I61-24-01
10. I61-32-01
11. I10-01-63
12. I60-41-01
13. I62-52-01

Description

- Guided Straight Awl
- Guided Angle Awl
- Guided Drill
- Poly Awl
- Poly Drill
- Single Barrel Guide
- Straight Driver x2
- Poly Driver
- Fixed Angle Driver
- Lock Tool x2
- Hudson T-Handle, Ratcheting
- Slap Hammer
- Slap Hammer Adapter x2



NEXXT MATRIXX® SA ALIF Standard Interbody and Trial Case



Top Level



Bottom Level

Standard P/N

Description

1.	I61-02-01	Cage Inserters, Non Locking x2
2.	I61-01-03	Oblique Inserters, Non Locking x2
3.	I61-01-02	Angled Inserters, Non Locking x2
4.	I61-03-01	SA ALIF, Trial Inserters x2
5.	I10-01-43	Hudson T-Handle x2
6.	I61-34-02	Cage Remover
7.	I61-42-01	Tamp
8.	I61-32-32	Annulotomy Template, 32mm
9.	I61-32-36	Annulotomy Template, 36mm
10.	I61-32-40	Annulotomy Template, 40mm
11.	I61-32-02	Annulotomy Centering Pin
12.	I61-TR2432-HH-08	Trials, 8°, 24mm x 32mm x 10-18mm tall
13.	I61-TR2432-HH-14	Trials, 14°, 24mm x 32mm x 10-20mm tall
14.	I61-TR2432-HH-20	Trials, 20°, 24mm x 32mm x 12-20mm tall
15.	I61-TR2736-HH-08	Trials, 8°, 27mm x 36mm x 10-18mm tall
16.	I61-TR2736-HH-14	Trials, 14°, 27mm x 36mm x 10-20mm tall
17.	I61-TR2736-HH-20	Trials, 20°, 27mm x 36mm x 12-20mm tall
18.	I61-TR3040-HH-08	Trials, 8°, 30mm x 40mm x 10-18mm tall
19.	I61-TR3040-HH-14	Trials, 14°, 30mm x 40mm x 10-20mm tall
20.	I61-TR3040-HH-20	Trials, 20°, 30mm x 40mm x 12-20mm tall
21.	I92-20-01	Thumb Wheel Rotator

NOTE: HH represents height in steps of 2mm



Indications for Use

GENERAL DESCRIPTION

NEXXT MATRIXX® is a collection of additively manufactured implants. The NEXXT MATRIXX® Stand Alone ALIF System includes additively manufactured spacers and traditionally machined fixation screw implants. The spacer and screw components are available in an assortment of dimensional combinations to accommodate the individual anatomic and clinical circumstances of each patient. The basic shape of the spacer 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 300-700µm pores. The inferior/superior aspects of the spacer incorporates a vertical cavity which can be packed with bone graft material. Each interbody screw pocket is preassembled with a turn lock mechanism which secures the screw to the spacer component. NEXXT MATRIXX® Stand Alone ALIF System spacers and fixation screws are manufactured from Ti-6Al-4V ELI titanium alloy per ASTM F3001 and F136, respectively.

INDICATIONS

The NEXXT MATRIXX® Stand Alone ALIF System is a stand-alone lumbar interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (L2-S1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels and should have received at least six months of nonoperative treatment prior to treatment with the device. The NEXXT MATRIXX® Stand Alone ALIF System is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone. Hyperlordotic interbody devices (>20° lordosis) must be used with supplemental fixation (e.g. posterior fixation). Each interbody fusion device having a lordotic angle 20° or less is intended to be used with the bone screws provided and requires no additional fixation.

CONTRAINDICATIONS

NEXXT MATRIXX® Stand Alone 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.

WARNINGS AND PRECAUTIONS

1. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.
2. NEXXT MATRIXX® devices should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Prior to use, surgeons should be trained in the surgical procedures recommended for use of these devices.
3. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the device.
4. NEXXT MATRIXX® solid devices are not intended for interbody fusion as bone growth through the device has not been demonstrated.
5. These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition. NEXXT MATRIXX® solid devices are not intended for interbody fusion as bone growth through the device has not been demonstrated.
6. NEXXT MATRIXX® is used to augment the development of a spinal fusion by providing temporary stabilization. This device is not intended to be the sole means of spinal support – supplemental internal fixation must be used. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant's longevity.
7. The correct handling of the implant is extremely important. Use care in handling and storage of devices. Store the devices in a clean, dry area away from radiation and extreme temperatures and corrosive environments such as moisture, air, etc.
8. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
9. Components of this system should not be used with components of any other system or manufacturer.
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

STAND ALONE ALIF

Surgical Technique Guide

25



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

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