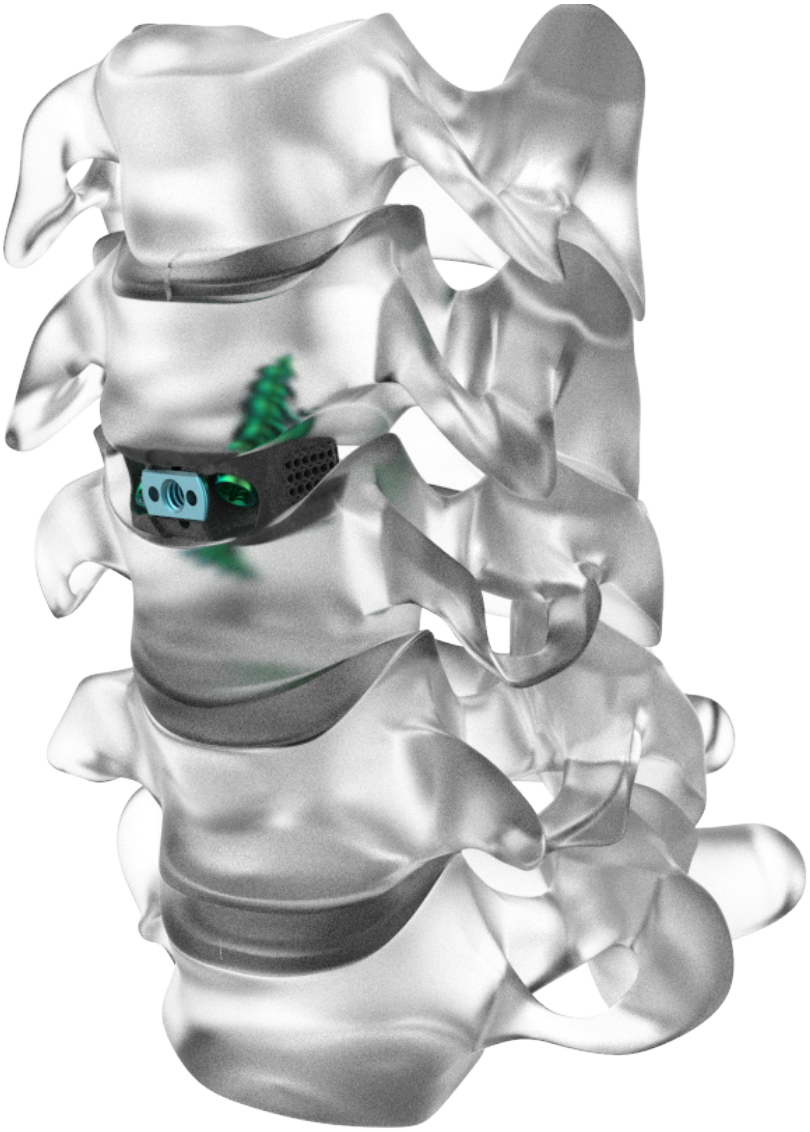
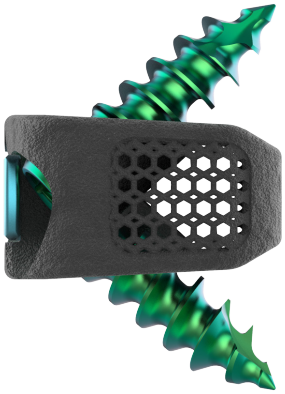
NEXXT Spine
GROW WITH US

Surgical Technique
NEXXT MATRIXX® Stand Alone Cervical





NEXXT Spine

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Noblesville, IN 46060
71-042, Rev D

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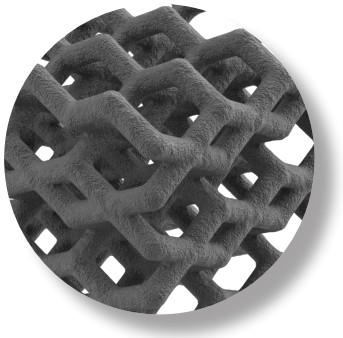
CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

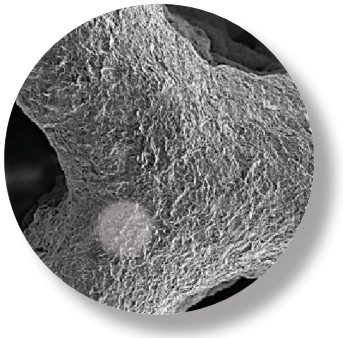
DISCLAIMER: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

10X



Systematic Titanium
PORES

300X



Uncompromising
MACROSURFACE

10,000X

7µm Surface
MICROSURFACE

Pillars of NEXXT MATRIXX® Technology:

1. Varied pore array of 300, 500, and 700µm designed to support vascularization and osteogenesis.[1,4,5]
2. 7µm surface roughness designed to increase osteoblast differentiation, production of angiogenic factors, and surface osteointegration.[2,3,6]
3. 75% porous, open titanium architecture developed for greater surface area and nutrient exchange, leading to increased volume for potential bony in-growth.[4,5,6]
4. Modulus of elasticity engineered to be comparable to PEEK devices leading to a more physiological product.[6]
5. 700µm A/P and lateral lattice geometry designed to provide robust radiographic imaging unimpeded by reducing overall titanium material and device density.[6]

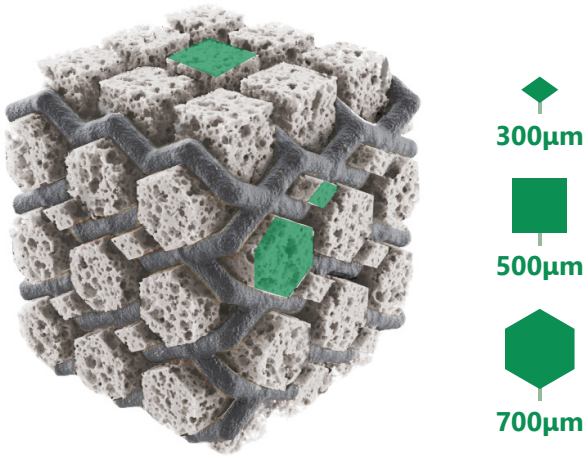


Image represents potential volume for bony in-growth

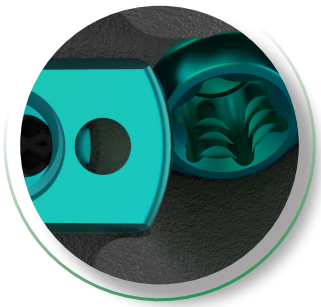
Studies referenced for the foundational design of NEXXT MATRIXX®

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.

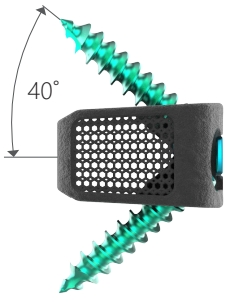
System Features & Specifications

FEATURES

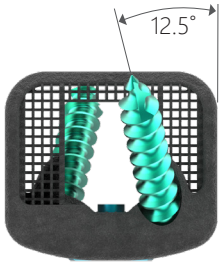
One-Step Turn Lock



40˚ Cephalad/Caudal Angulation

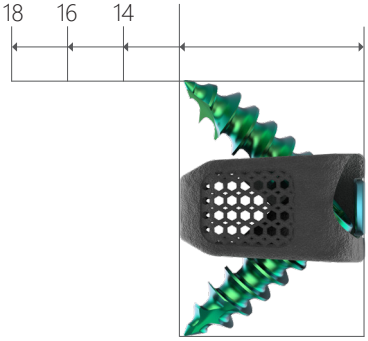


Medial Angulation



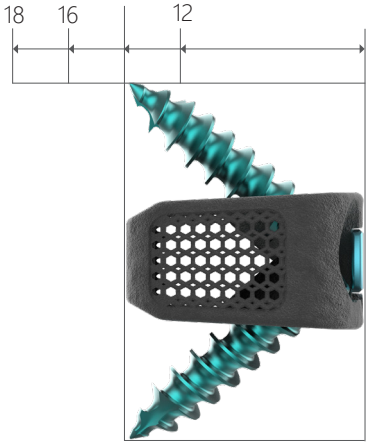
SPECIFICATIONS

12mm Screw



12 x 15mm

14mm Screw



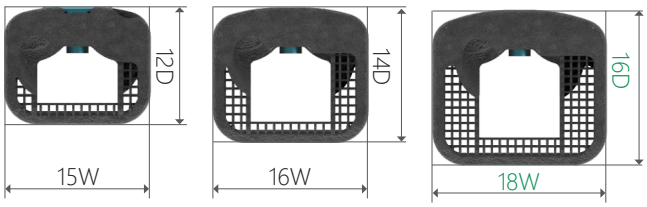
14 x 16mm

16mm Screw

16 x 18mm

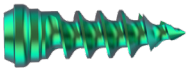
Depth of Interbody = Length of Screw

Recommended Screw Length:
12D x 15W: Use **12**mm screw | **14**D x 16W: Use **14**mm screw | **16**D x 18W: Use **16**mm screw



Self-Retaining T10 Hexalobe Feature

Lengths Measured Anterior to Posterior



IMPLANT OFFERING:

FOOTPRINTS:
12Dx15Wx5-10Hmm // 11+12mm
14Dx16Wx5-10Hmm // 11+12mm
16Dx18Wx5-12Hmm

LORDOSIS:
6˚
10˚

SCREWS:
∅3.5x12, 14, and 16 // 18mm
∅4.0x12, 14, and 16 // 18mm

Made to order.

Surgical Technique Steps

Step 1 - Patient Positioning

Following adequate general anesthesia, the patient is placed in a prone (thoracolumbar) or supine (cervical) position on a radiolucent spine table. The mandible is tilted out of the surgical field. The posterior cervical spine is supported to establish and maintain normal lordosis (Figure 1).

NOTE:
Due to potential risk of neural injury in the cervical spine, use of fluoroscopy and/or neuromonitoring during cervical procedures is recommended.

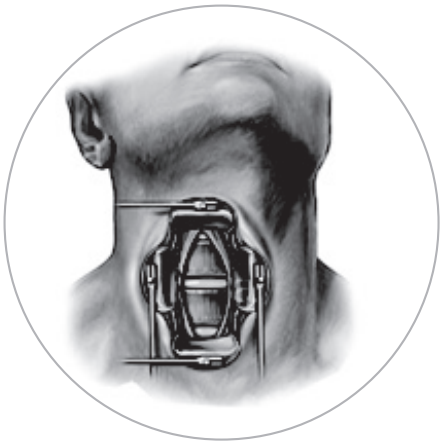


Figure 1

Step 2 - Exposure of Operative Levels

Access the operative site and retract soft tissues using preferred instruments. Retract the muscles, trachea, esophagus and carotid artery to clearly see the vertebral bodies and discs. Insert a marker into the disc and confirm the correct operative level using a lateral radiograph (Figure 2).

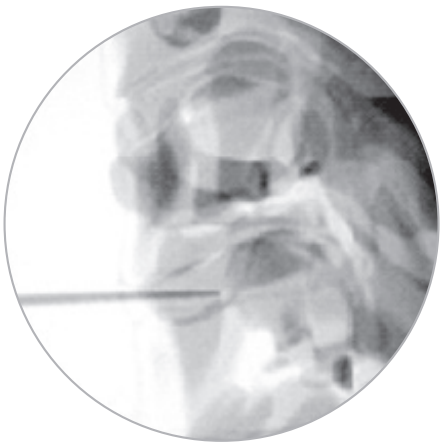


Figure 2

Step 3 - Discectomy

Perform a complete discectomy using preferred surgical instruments. Pituitaries, curettes, and rongeurs may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament and endplates. A high-speed burr may be used for removal of posterior osteophytes to achieve neural decompression. The posterior longitudinal ligament may be removed to access and remove any disc material that may be pressing on the neural elements (Figure 3).

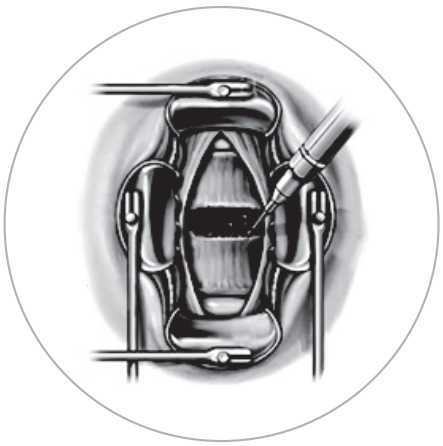


Figure 3

Surgical Technique Steps (Continued)

Step 4 - Endplate Preparation

A 12 x 14 x 5mm Cervical Universal Rasp is included standard in the surgical set to remove the superficial layer on the endplates. This will aid in creating bleeding bone to promote spinal fusion. Appropriate endplate preparation will optimize surface contact with the selected Cage. Additional Rasp sizes are available upon request.

Figure 4

Step 5 - Trialing

- Selection of Cage height and footprint is dependent on the Trial spacer. A mallet may be used to aid in insertion of the Trials. Trials should be used incrementally to determine the appropriate dimensions of the Cage to be implanted.
- All labeled heights are measured from the area representing the highest point on the anterior wall of the Cage. Trials are line to line with the corresponding Cage (Figure 5a).
- The Trials are color coded according to the height of the Cage (Figure 5b).

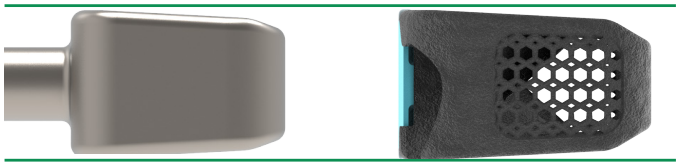


Figure 5a

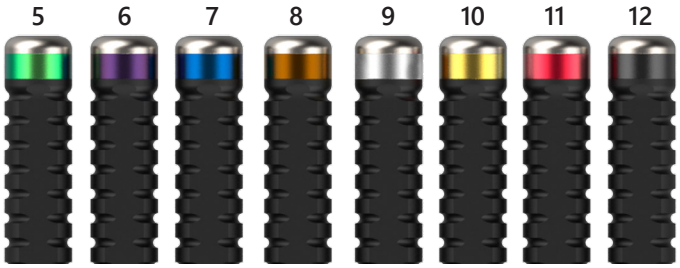


Figure 5b

Surgical Technique Steps (Continued)

Step 6 - Cage Selection and Inserter Attachment

- Remove the desired Cage from its sterile packaging.
- Dock the Fixed Cage Inserter to the chosen Cage by mating the pins on the tip of the Fixed Cage Inserter with the Superior and Inferior holes on the Cage's Turn Lock. Rotate the proximal knob of the Fixed Cage Inserter clockwise until Cage and Fixed Cage Inserter are lagged together (Figure 6b).
- Cage heights of 5 and 6mm have a unique style Turn Lock. The Fixed Cage Inserter will attach the same as stated above, but the pins will mate around the Turn Lock and directly with the Cage (Figure 6a).

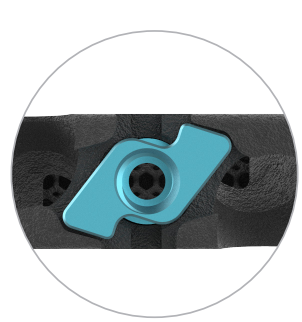


Figure 6a

Figure 6b

Step 7 - Cage Packing

- Pack the center cavity of the Cage with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

NOTE:
Do not overpack the Interbody with autograft and/or allograft to ensure the Cage's Screw hole pockets remain unobstructed.

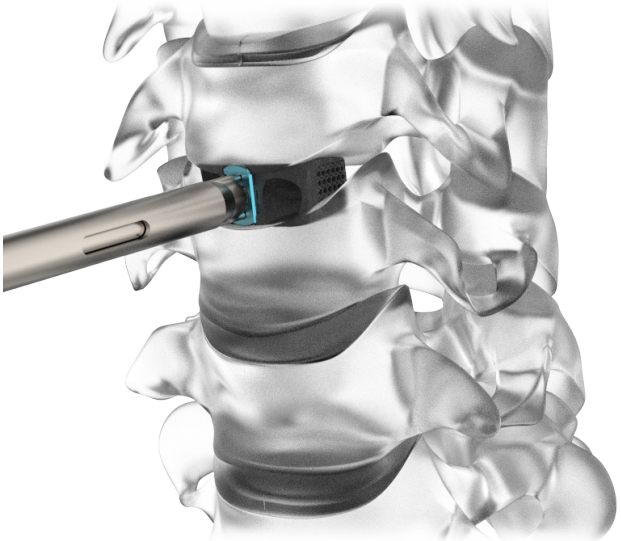


Figure 7

Step 8 - Cage Insertion

- Introduce the Cage into the disc space, mallet when necessary (Figure 7).
- Cages have been designed to have symmetric superior/ inferior surfaces relative to the vertebral endplates.
- Verify placement of the interbody in the AP and lateral direction before continuing the procedure.

Surgical Technique Steps (Continued)

Step 9 - Hole Preparation + Screw Insertion

Instrument Options

There are three styles of Hole Preparation and Screw Insertion Instruments: Straight, Poly Angle, and Fixed Angle. These styles can be used interchangeabley.

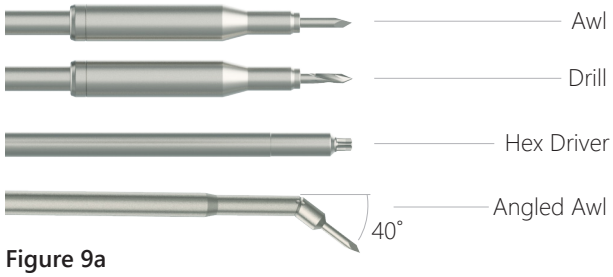


Figure 9a

Option 1: Straight

- Straight instrumentation includes the Self-Guided Straight Awl, Self-Guided Straight Drill, Straight Hex Driver (Screw Inserter), and Angled Awl (Figure 9a)
- The Angled Awl offers a fixed 40° angle (Figure 9a)
- The Self-Guided Straight Awl and Self-Guided Straight Drill have spring-loaded sleeves that interface with the Screw hole pockets at a 40° angle, creating centered pilot holes (Figure 9b)

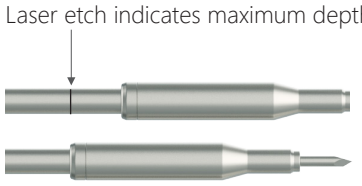


Figure 9b

Option 2: Poly Angle

- Poly Angle instrumentation includes the Self-Guided Poly Angle Awl, Self-Guided Poly Angle Drill, and Poly Angle Hex Driver (Screw Inserter) (Figure 9c).
- The Self-Guided Poly Angle Awl and Self-Guided Poly Angle Drill have spring-loaded sleeves which interface with the Screw hole pockets at a 40° angle, creating centered pilot holes (Figure 9d).
- Poly Angle instruments have a 360° radial range and allow for 40° of angulation.
- Poly Angle instruments feature “friction-fit” position retention.

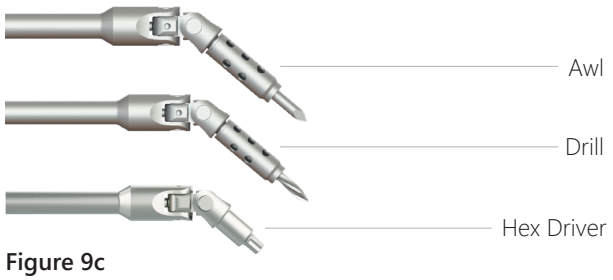


Figure 9c

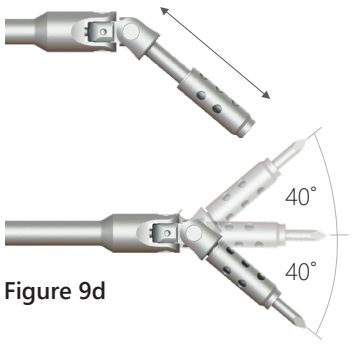


Figure 9d

Surgical Technique Steps (Continued)

Option 3: Fixed Angle Instruments

- Fixed Angle instrumentation includes the Self-Guided Fixed Angle Awl, Self-Guided Fixed Angle Drill, and Fixed Angle Driver (Screw Inserter).
- The Self-Guided Fixed Angle Awl and Self-Guided Fixed Angle Driver have spring-loaded sleeves which interface with the Screw hole pockets at a 40° angle, creating centered pilot holes.

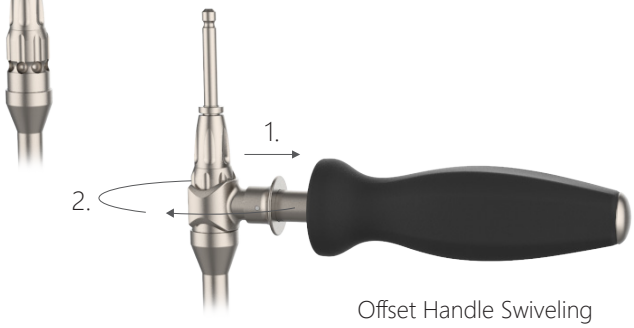
Fixed Angle Awl | Fixed Angle Drill | Fixed Angle Driver

Offset Handle (Optional)

- The Fixed Angle Driver comes with an optional Offset Handle if additional support is desired. To attach, pull the quick connect collar back (1.) and slide the Offset Handle onto the Outer Shaft (2.) (Figure 9e).
- While the Offset Handle is attached, it can be rotated about the Outer Shaft by pulling the quick connect collar (1.) and swiveling (2.) to the desired point (Figure 9f).

Offset Handle Attachment

Figure 9e



Offset Handle Swiveling

Figure 9f

Surgical Technique Steps (Continued)

Step 9.1 - Hole Preparation

Pilot Hole

- Begin the pilot hole with the desired hole preparation instrument(s) based on surgeon preference. Penetrate the cortex with the chosen instrument (Figure 9g). Repeat for the second pilot hole.

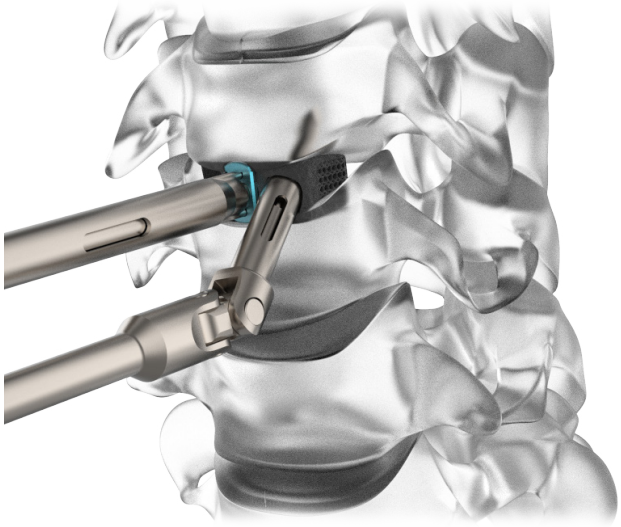


Figure 9g

Step 9.2 - Screw Insertion

Delivery

- Screws are color-coded by length and diameter.
- Press the tip of the chosen Hex Driver (Screw Inserter) into the T10 hexalobe drive feature of the Screw in order to retain the Screw onto the Hex Driver (Screw Inserter).
- Guide the attached Screw into the pilot hole and thread until fully seated. Ensure Screw is concentrically centered in Screw Pocket and aligned correctly (Figure 9b).
- Verify Screw placement and angulation via intraoperative imaging. Repeat the above steps for implanting the second Screw.
- Upon finalizing Screw placement, disengage the Fixed Cage Inserter by turning the proximal knob counterclockwise.

Note:
Poly Angle Hex Driver (Screw Inserter) shown.

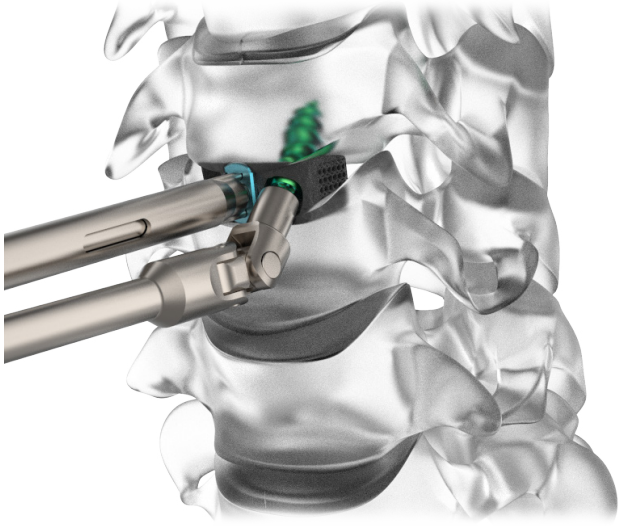


Figure 9h

Surgical Technique Steps (Continued)

Step 10 - Screw Locking

- Align the center tip of the Lock Tool with the center hole on the Cage.
- Mate the pins of the Lock Tool into the Superior and Inferior holes of the Cage's Turn Lock.
- Rotate Lock Tool 90° clockwise. The Integrated Turn Lock will encounter a positive stop with the Cage confirming it has reached the locked position (Figure 10).

Notes:

- If using a 5 or 6mm height Cage, the Lock Tool will engage the center hole of the Turn Lock and the pins will capture the exterior of the Turn Lock for engagement.
- If the Turn Lock does not rotate the full 90°, ensure debris is not blocking the Turn Lock's path and that the Screws are bottomed out into the Cage.

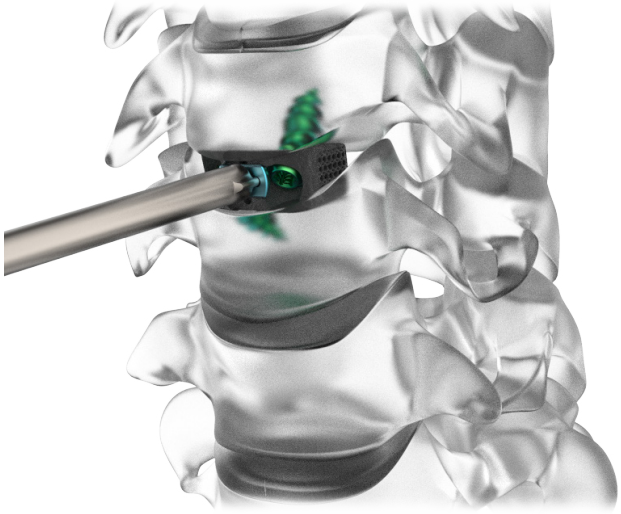


Figure 10

Step 11 - Implant Removal

- In the event removal of the Nexxt Matrixx® Stand Alone Cervical-TL System is desired, utilize the Lock Tool and rotate the Turn Lock counterclockwise until bottomed out such that the Turn Lock is in an open position. Use a Screw Inserter to back out the Screws. Lastly, attach the Fixed Cage Inserter to the Cage and gently remove (Figure 11).

Note:
If additional instrumentation is needed to remove the Screws, utilize the Straight Screw Removal Tool by threading into the Screw hexalobe drive feature counterclockwise. Continue to rotate counterclockwise while pulling out of the Screw hole pocket to extract the Screws.

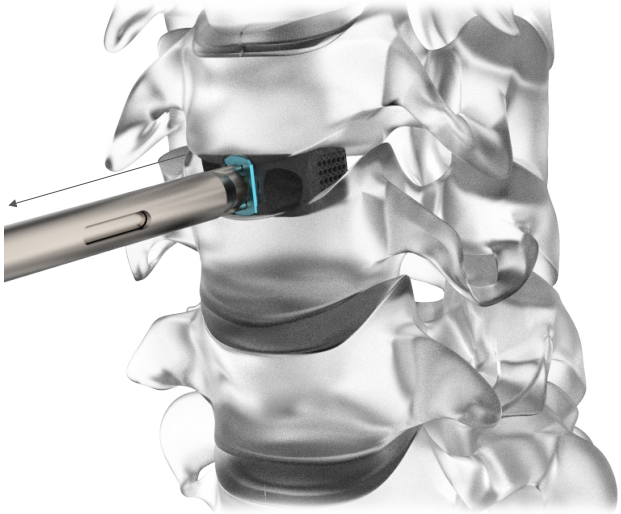


Figure 11

Surgical Technique Steps (Continued)

Guide Head Hole Prep + Screw Insertion Method
Guide Head instrumentation is non-standard in the Nexxt Matrixx® Stand Alone Cervical-TL set. If utilizing the Guide Head instrumentation, note the compatible instruments listed below.

Assembly

- Select Guide Head size based on Cage size chosen.
- Connect the Modular Inserter Shaft to the appropriate Guide Head via the integrated press-and-retain feature (Figure 12a).
- Align the Guide Head pins (Figure 12a) with the Turn Lock on the corresponding Cage (Figure 12b).
- Rotate the proximal knob of the Modular Inserter Shaft clockwise until the Cage and Modular Inserter are lagged to together (Figure 12c).
- Follow steps 5-8 while utilizing the Guide Head instrumentation.

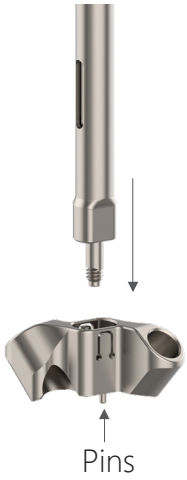


Figure 12a


Figure 12b


Figure 12c

Note:
Each height of the Guide Head has a 1:1 precise match for each Cage height available. For example, the 5mm Guide Head mates with all 5mm Nexxt Matrixx® Stand Alone Cervical-TL Cages: 12x15x5, 14x16x5, and 16x18x5mm).

Compatible Instruments

- Straight Hex Driver
- Screw Removal Tool
- Self-Guided Poly Angle Awl
- Self-Guided Poly Angle Drill
- Compact Angle Awl
- Compact Angle Drill

Compatible Instruments

- Self-Guided Straight Awl
- Self-Guided Straight Drill
- Poly Angle Hex Driver (Screw Inserter)
- Angle Hex Driver (Screw Inserter)
- Angle Awl

NEXXT MATRIXX® Stand Alone Cervical Implant Part Numbers

Standard P/N	Description
12D x 15W x XXH Implants	
52N-1215-05-SP	12Dx15Wx5H, 6°
52N-1215-06-SP	12Dx15Wx6H, 6°
52N-1215-07-SP	12Dx15Wx7H, 6°
52N-1215-08-SP	12Dx15Wx8H, 6°
52N-1215-09-SP	12Dx15Wx9H, 6°
52N-1215-10-SP	12Dx15Wx10H, 6°
52N-1215-11-SP*	12Dx15Wx11H, 6°
52N-1215-12-SP*	12Dx15Wx12H, 6°
52N-1215-10-06-SP*	12Dx15Wx6H, 10°
52N-1215-10-07-SP*	12Dx15Wx7H, 10°
52N-1215-10-08-SP*	12Dx15Wx8H, 10°
52N-1215-10-09-SP*	12Dx15Wx9H, 10°
52N-1215-10-10-SP*	12Dx15Wx10H, 10°
52N-1215-10-11-SP*	12Dx15Wx11H, 10°
52N-1215-10-12-SP*	12Dx15Wx12H, 10°

Standard P/N	Description
14D x 16W x XXH Implants	
52N-1416-05-SP	14Dx16Wx5H, 6°
52N-1416-06-SP	14Dx16Wx6H, 6°
52N-1416-07-SP	14Dx16Wx7H, 6°
52N-1416-08-SP	14Dx16Wx8H, 6°
52N-1416-09-SP	14Dx16Wx9H, 6°
52N-1416-10-SP	14Dx16Wx10H, 6°
52N-1416-11-SP*	14Dx16Wx11H, 6°
52N-1416-12-SP*	14Dx16Wx12H, 6°
52N-1416-10-06-SP*	14Dx16Wx6H, 10°
52N-1416-10-07-SP*	14Dx16Wx7H, 10°
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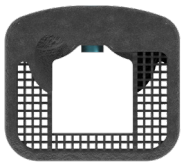
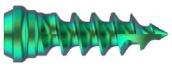
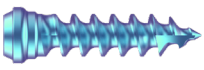
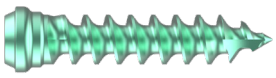
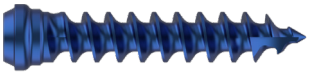
52N-1416-10-09-SP*	14Dx16Wx9H, 10°
52N-1416-10-10-SP*	14Dx16Wx10H, 10°
52N-1416-10-11-SP*	14Dx16Wx11H, 10°
52N-1416-10-12-SP*	14Dx16Wx12H, 10°



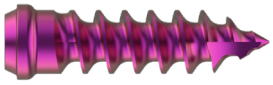
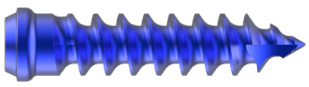
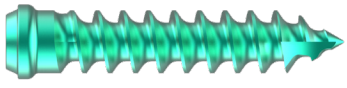
Standard P/N	Description
16D x 18W x XXH Implants	
52N-1618-05-SP	16Dx18Wx5H, 6°
52N-1618-06-SP	16Dx18Wx6H, 6°
52N-1618-07-SP	16Dx18Wx7H, 6°
52N-1618-08-SP	16Dx18Wx8H, 6°
52N-1618-09-SP	16Dx18Wx9H, 6°
52N-1618-10-SP	16Dx18Wx10H, 6°
52N-1618-11-SP*	16Dx18Wx11H, 6°
52N-1618-12-SP*	16Dx18Wx12H, 6°
52N-1618-10-06-SP*	16Dx18Wx6H, 10°
52N-1618-10-07-SP*	16Dx18Wx7H, 10°
52N-1618-10-08-SP*	16Dx18Wx8H, 10°
52N-1618-10-09-SP*	16Dx18Wx9H, 10°
52N-1618-10-10-SP*	16Dx18Wx10H, 10°
52N-1618-10-11-SP*	16Dx18Wx11H, 10°
52N-1618-10-12-SP*	16Dx18Wx12H, 10°

*By Request Only

Standard Screws
52N-35-XX-SP

Standard P/N	Description
	
52N-35-12-SP	Ø3.5x12mm Screw
	
52N-35-14-SP	Ø3.5x14mm Screw
	
52N-35-16-SP	Ø3.5x16mm Screw
	
52N-35-18-SP*	Ø3.5x12mm Screw

Rescue Screws
52N-40-XX-SP

Standard P/N	Description
	
52N-40-12-SP	Ø4.0x12mm Screw
	
52N-40-14-SP	Ø4.0x14mm Screw
	
52N-40-16-SP	Ø4.0x16mm Screw
	
52N-40-18-SP*	Ø4.0x18mm Screw

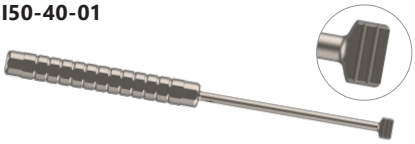
*By Request Only

NEXXT MATRIXX® Stand Alone Cervical -TL Instruments

I52-RUS-05

Standard P/N	Description
I52-RUS-05	Cerv. Universal Rasp, 6°, 12x14x5

I50-40-01



Standard P/N	Description
I50-40-01	Cervical Tamp

I52N-RA25-XX*

Standard P/N	Description
I52N-RA25-05*	Rasp, 6°, 12x15x5
I52N-RA25-06*	Rasp, 6°, 12x15x6
I52N-RA25-07*	Rasp, 6°, 12x15x7
I52N-RA25-08*	Rasp, 6°, 12x15x8
I52N-RA25-09*	Rasp, 6°, 12x15x9
I52N-RA25-10*	Rasp, 6°, 12x15x10
I52N-RA25-11*	Rasp, 6°, 12x15x11
I52N-RA25-12*	Rasp, 6°, 12x15x12

I52N-RA46-XX*

Standard P/N	Description
I52N-RA46-05*	Rasp, 6°, 14x16x5
I52N-RA46-06*	Rasp, 6°, 14x16x6
I52N-RA46-07*	Rasp, 6°, 14x16x7
I52N-RA46-08*	Rasp, 6°, 14x16x8
I52N-RA46-09*	Rasp, 6°, 14x16x9
I52N-RA46-10*	Rasp, 6°, 14x16x10
I52N-RA46-11*	Rasp, 6°, 14x16x11
I52N-RA46-12*	Rasp, 6°, 14x16x12

I52N-RA68-XX*

Standard P/N	Description
I52N-RA68-05*	Rasp, 6°, 16x18x5
I52N-RA68-06*	Rasp, 6°, 16x18x6
I52N-RA68-07*	Rasp, 6°, 16x18x7
I52N-RA68-08*	Rasp, 6°, 16x18x8
I52N-RA68-09*	Rasp, 6°, 16x18x9
I52N-RA68-10*	Rasp, 6°, 16x18x10
I52N-RA68-11*	Rasp, 6°, 16x18x11
I52N-RA68-12*	Rasp, 6°, 16x18x12

I52N-TR25-XX

Standard P/N	Description
I52N-TR25-05	Trial, 6°, 12x15x5
I52N-TR25-06	Trial, 6°, 12x15x6
I52N-TR25-07	Trial, 6°, 12x15x7
I52N-TR25-08	Trial, 6°, 12x15x8
I52N-TR25-09	Trial, 6°, 12x15x9
I52N-TR25-10	Trial, 6°, 12x15x10
I52N-TR25-11*	Trial, 6°, 12x15x11
I52N-TR25-12*	Trial, 6°, 12x15x12

I52-TR46-XX

Standard P/N	Description
I52-TR46-05	Trial, 6°, 14x16x5
I52-TR46-06	Trial, 6°, 14x16x6
I52-TR46-07	Trial, 6°, 14x16x7
I52-TR46-08	Trial, 6°, 14x16x8
I52-TR46-09	Trial, 6°, 14x16x9
I52-TR46-10	Trial, 6°, 14x16x10
I52-TR46-11*	Trial, 6°, 14x16x11
I52-TR46-12*	Trial, 6°, 14x16x12

I52-TR68-XX*

Standard P/N	Description
I52-TR68-05*	Trial, 6°, 16x18x5
I52-TR68-06*	Trial, 6°, 16x18x6
I52-TR68-07*	Trial, 6°, 16x18x7
I52-TR68-08*	Trial, 6°, 16x18x8
I52-TR68-09*	Trial, 6°, 16x18x9
I52-TR68-10*	Trial, 6°, 16x18x10
I52-TR68-11*	Trial, 6°, 16x18x11
I52-TR68-12*	Trial, 6°, 16x18x12

*By Request Only

NEXXT MATRIXX® Stand Alone Cervical -TL Instruments

I52N-01-01

Standard P/N	Description
I52N-01-01	Fixed Inserter

I52N-01-02*

Standard P/N	Description
I52N-01-02*	Modular Inserter

I52N-02-XX*

Standard P/N	Description
I52N-02-05*	Guide, 05H
I52N-02-06*	Guide, 06H
I52N-02-07*	Guide, 07H
I52N-02-08*	Guide, 08H
I52N-02-09*	Guide, 09H
I52N-02-10*	Guide, 10H
I52N-02-11*	Guide, 11H
I52N-02-12*	Guide, 12H

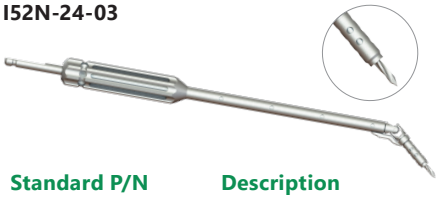
I52N-03-01

Standard P/N	Description
I52N-03-01	Lock Tool

I52-23-03

Standard P/N	Description
I52-23-03	Offset Handle

I52N-24-03



Standard P/N	Description
I52N-24-03	Fixed Angle Drill

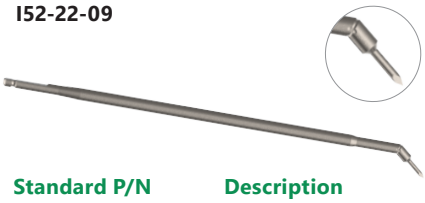
I52N-24-01

Standard P/N	Description
I52N-24-01	Fixed Angle Driver

I52N-24-02

Standard P/N	Description
I52N-24-02	Fixed Angle Awl

I52-22-09



Standard P/N	Description
I52-22-09	Angle Awl

I10-01-41

Standard P/N	Description
I10-01-41	Fixed AO Handle

*By Request Only

NEXXT MATRIXX® Stand Alone Cervical -TL Instruments

I52N-22-06

Standard P/N	Description
I52N-22-06	Straight Hex Driver

I52N-22-07

Standard P/N	Description
I52N-22-07	Self-Guided Straight Drill

I52N-22-08

Standard P/N	Description
I52N-22-08	Self-Guided Straight Awl

I52N-30-01

Standard P/N	Description
I52N-30-01	Screw Removal Tool

I52N-21-13

Standard P/N	Description
I52N-21-13	Self-Guided Poly Angle Drill

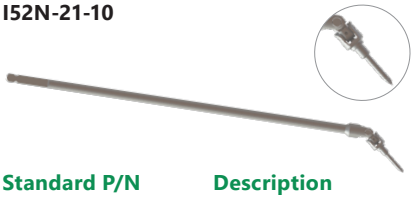
I52N-21-12

Standard P/N	Description
I52N-21-12	Self-Guided Poly Angle Awl

I52N-21-06

Standard P/N	Description
I52N-21-06	Poly Angle Hex Driver

I52N-21-10



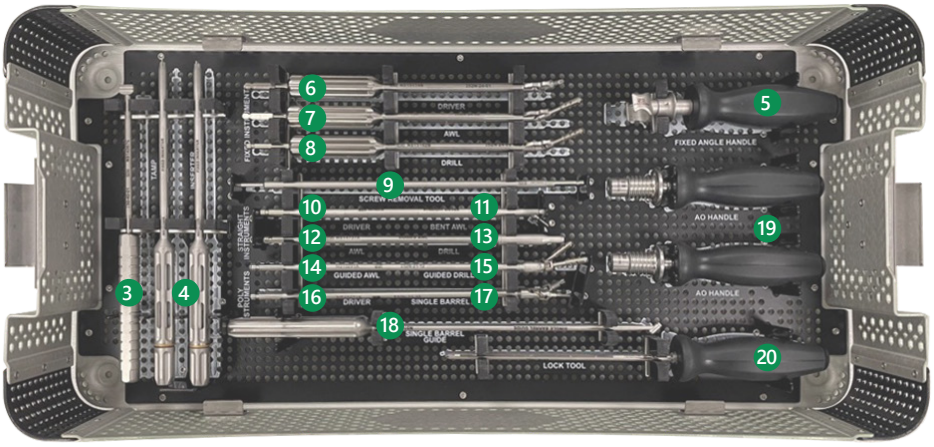
Standard P/N	Description
I52N-21-10	Single Barrel Poly Awl

I52N-04-01

Standard P/N	Description
I52N-04-01	Single Barrel Guide

NEXXT MATRIXX® Stand Alone Cervical -TL Standard Instrument Tray Layout

Top Level



Bottom Level

Standard P/N		Description
1.	I52N-TR25-05:10	Trials, 6°, 12mm x 15mm x 5mm:10mm tall (TOP)
	I52-TR46-05:10	Trials, 6°, 14mm x 16mm x 5mm:10mm tall (BOTTOM)
2.	I52-RUS-05	Cervical Universal Rasp
3.	I50-40-01	Cervical, Tamp
4.	I52N-01-01	Fixed Interbody Inserter (x2)
5.	I52-23-03	Fixed Angle Driver, Handle Assembly
6.	I52N-24-01	Fixed Angle Driver
7.	I52N-24-02	Fixed Angle Awl
8.	I52N-24-03	Fixed Angle Drill
9.	I52-30-01	Screw Removal, Threaded Shaft
10.	I52N-22-06	Straight Driver
11.	I52-22-09	Angle Awl
12.	I52N-22-08	Straight Guided Awl
13.	I52N-22-07	Straight Guided Drill
14.	I52N-21-12	Poly Guided Awl
15.	I52N-21-13	Poly Guided Drill
16.	I52N-21-06	Poly Driver
17.	I52N-21-10	Single Barrel Poly Awl
18.	I52N-04-01	Single Barrel Guide
19.	I10-01-41	Fixed AO Handle (x2)
20.	I52N-03-01	Lock Tool

Indications for Use

GENERAL DESCRIPTION

NEXXT MATRIXX® is a collection of additively manufactured implants. The Stand Alone Cervical-TL 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 is preassembled with a turn lock mechanism which secures the screw to the spacer component. NEXXT MATRIXX® Stand Alone Cervical-TL 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 Cervical-TL System is a stand-alone anterior cervical interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (C2-T1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). These patients should have received at least six weeks of non-operative treatment prior to treatment with the device. The NEXXT MATRIXX® Stand Alone Cervical-TL System is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and implanted via an open, anterior approach. The NEXXT MATRIXX® Stand Alone Cervical-TL System is intended to be used with the bone screw fixation provided and requires no additional fixation.

CONTRAINDICATIONS

NEXXT MATRIXX® Stand Alone Cervical - TL 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. 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.
5. 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.
6. 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.
7. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
8. Components of this system should not be used with components of any other system or manufacturer.
9. Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.

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