

NEXXT MATRIXX® Stand Alone Cervical - TL System

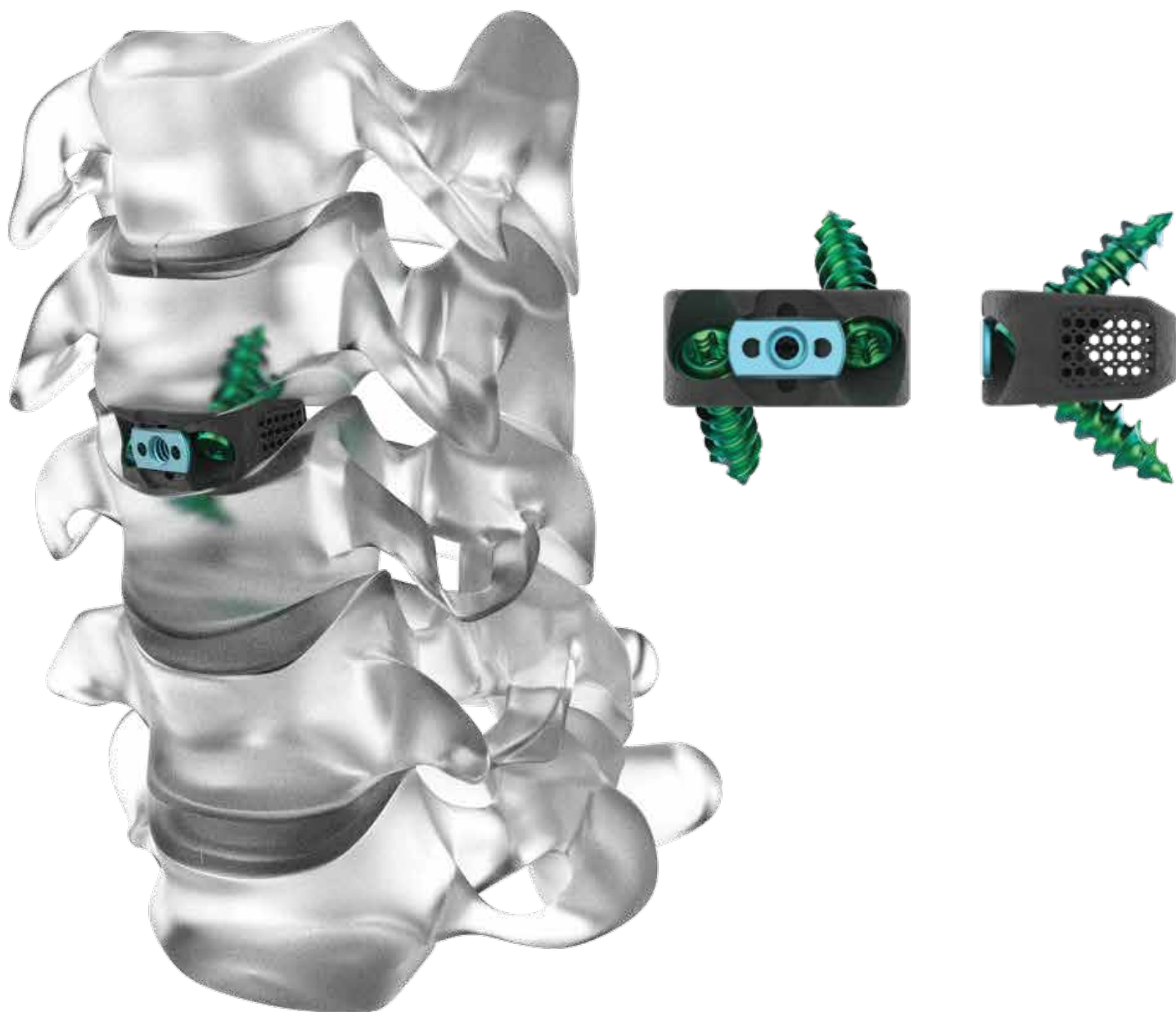


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Nexxt Spine does not practice medicine. Every physician should utilize his or her own discretion in the diagnosis and treatment of a patient, and this information does not intend to replace the comprehensive training physicians have received.

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® Stand Alone Cervical - TL System. Detailed preoperative clinical and diagnostic evaluation followed by carefully executed surgical technique is essential.

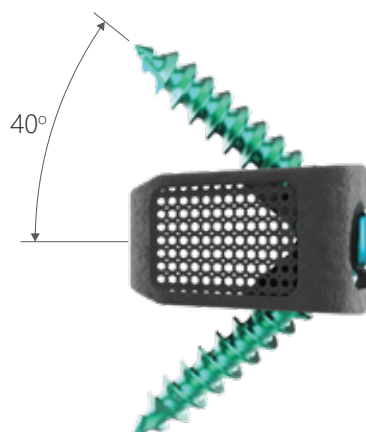
Refer to the Instructions for Use (IFU) for a complete list of prescribing information. This technique guide was developed in conjunction with health care professionals.

SYSTEM FEATURES

- Nexxt Matrix[®] 3D Printed Titanium Technology - Titanium Alloy (Ti-6Al-4V) per ASTM F3001
- 40° Cephalad / Caudal Screw Angulation
- 12.5° Medial Screw Convergence
- One-Step Turn Lock

STAND ALONE CERVICAL - TL SPECS

Cephalad / Caudal Angulation



Medial Angulation

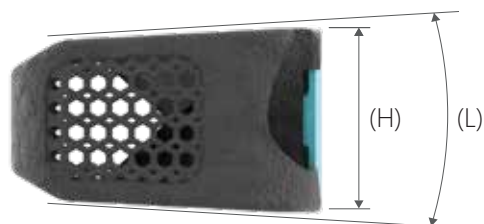


CAGE SPECS

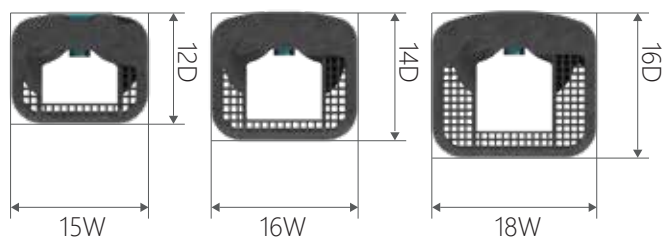
Lordosis (L) + Height (H) Options

(L): 6°

(H): 5, 6, 7, 8, 9, 10, 11, and 12mm

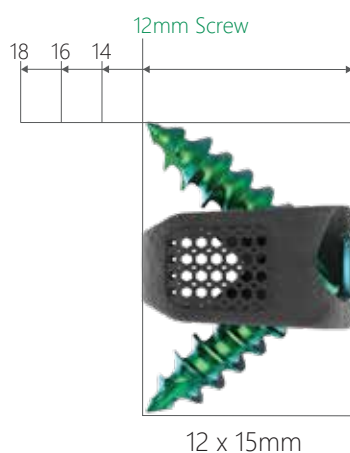


Footprints

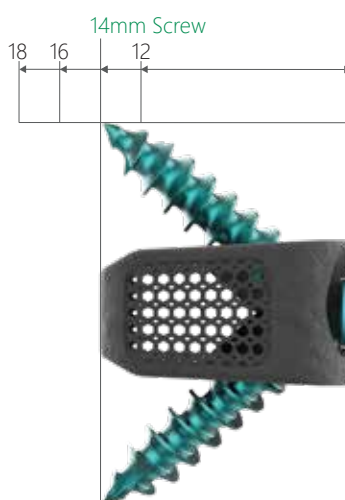


SCREW SPECS

- Screw Length Designed to Match Cage Depth
- Titanium Alloy (Ti-6Al-4V) per ASTM F136
- Ø3.5 and Ø4.0mm
- 12mm, 14mm, 16mm, and 18mm Lengths
- Screw lengths are measured from the anterior to posterior of the footprint.
- Self-Retaining T10 Hexalobe Feature



12 x 15mm



14 x 16mm



16 x 18mm

The standard Screw lengths (12mm for the 12 x 15mm footprint, 14mm for the 14 x 16mm footprint, and 16mm for the 16 x 18mm footprint) are recommended as each terminate with the posterior edge of their respective Cage.

INDICATIONS FOR USE

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.

PATIENT POSITIONING



Figure 1a



Figure 1b

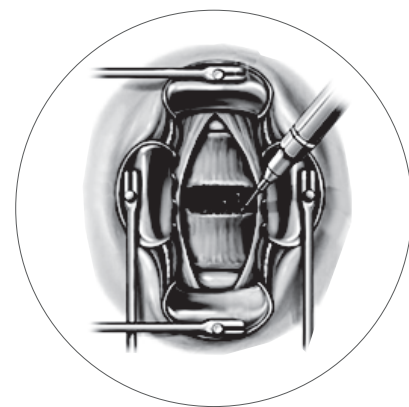


Figure 1c

STEP 1

Patient Positioning

- Following adequate general anesthesia, the patient is placed in the supine position with the head in slight extension. The mandible is tilted out of the surgical field. The posterior cervical spine is supported to establish and maintain normal lordosis (Figure 1a).

Exposure of Operative Levels

- Access the operative site and retract the 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 1b).

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 1c).

END PLATE PREPARATION



Figure 2



Figure 3a

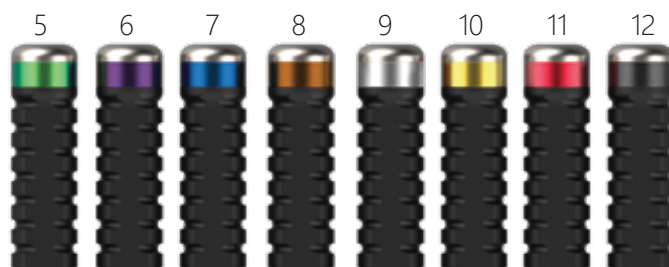


Figure 3b

STEP 2

Discectomy

- 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.

Note: Excessive removal of bone during endplate preparation may weaken the bone, leading to subsidence and/or segmental instability.

STEP 3

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 3a).
- The Trials are color coded according to the height of the Cage (Figure 3b).

CAGE INSERTION

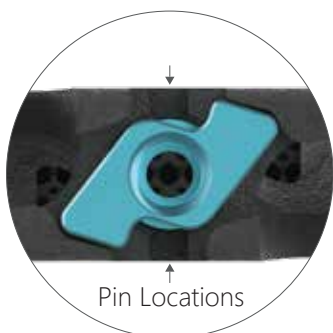


Figure 4a



Figure 4b

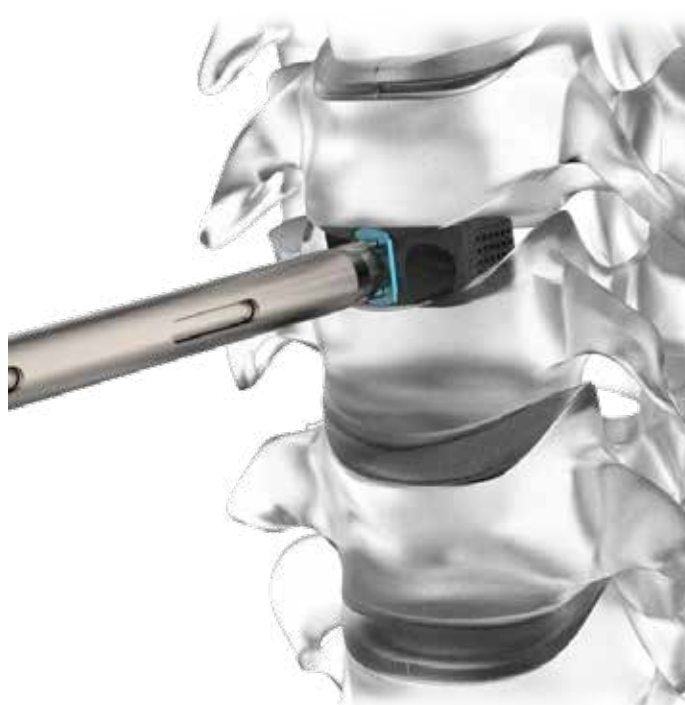


Figure 5

STEP 4

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 4b).
- 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 4a).

Note: If using the Guide Head, refer to page 13 for instructions on attaching the Modular Inserter to the Guide Head and Cage, then proceed to step 5.

STEP 5

Cage Packing and Insertion

- Pack the center cavity of the Cage with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Introduce the Cage into the disc space, mallet when necessary (Figure 5).
- 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.

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

HOLE PREP + SCREW INSERTION INSTRUMENTS

There are three styles of Hole Preparation and Screw insertion Instruments: Straight, Poly Angle, and Fixed Angle to accommodate surgeon preference. These styles can be used interchangeably.

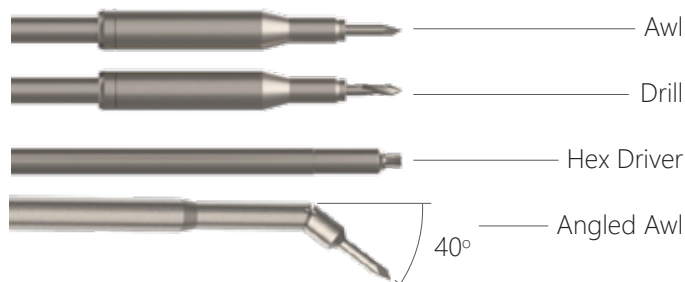


Figure 6a



Figure 6b

STRAIGHT: OPTION 1

Instrument Specs

- Straight instrumentation includes the Self - Guided Straight Awl, Self - Guided Straight Drill, Straight Hex Driver (Screw Insertor), and Angled Awl (Figure 6a).
- The Angled Awl offers a fixed 40° angle (Figure 6a).
- The Self - Guided Straight Awl and Self - Guided Straight Drill have spring - loaded sleeves which interface with the Screw hole pockets at a 40° angle, creating centered pilot holes (Figure 6b).

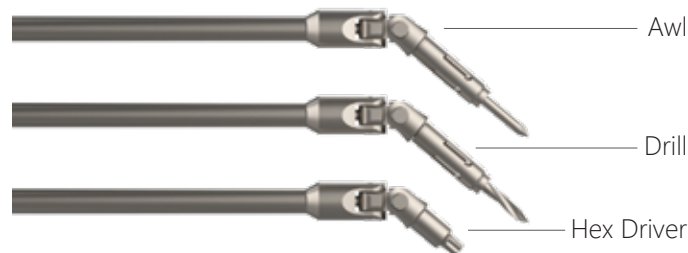


Figure 7a

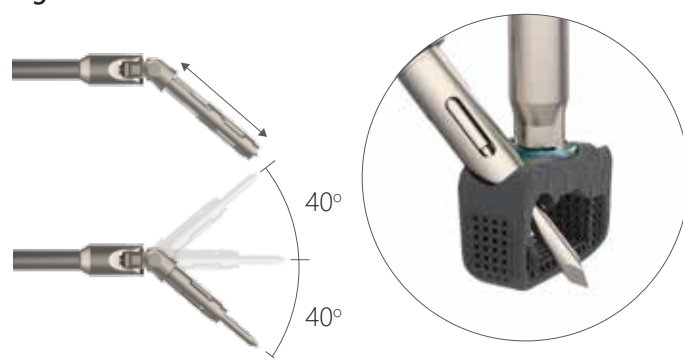


Figure 7b

POLY ANGLE: OPTION 2

Instrument Specs

- Poly Angle instrumentation includes the Self - Guided Poly Angle Awl, Self - Guided Poly Angle Drill, and Poly Angle Hex Driver (Screw Insertor) (Figure 7a).
- 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 7b).
- Poly Angle instruments have a 360° radial range and allow for 40° of angulation.
- Poly Angle instruments feature “friction - fit” position retention.

HOLE PREP + SCREW INSERTION INSTRUMENTS

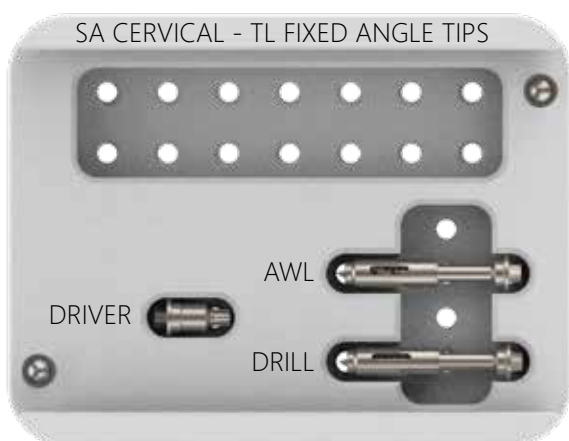


Figure 8a

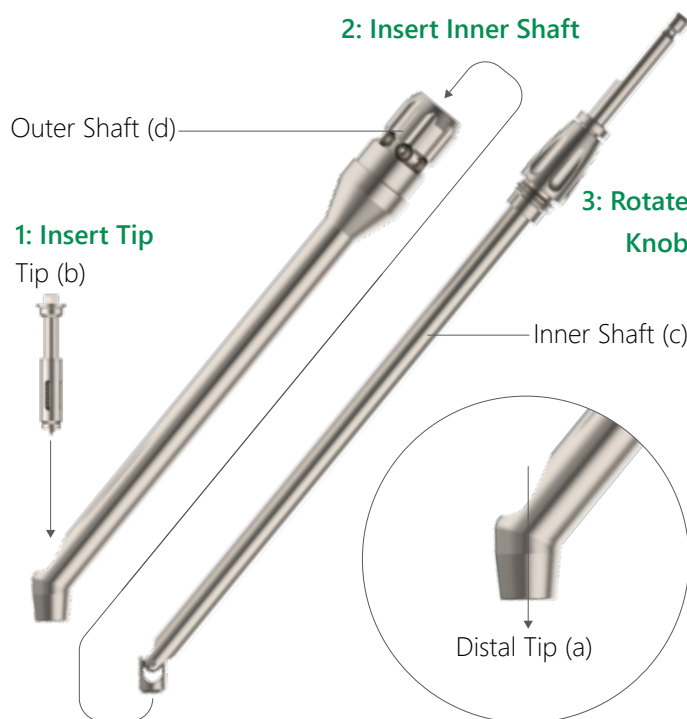


Figure 8b

FIXED ANGLE DRIVER: OPTION 3

Fixed Angle Driver Tip Caddy

- The Fixed Angle Driver is an instrument option which allows a fixed 40° approach to hole preparation and Screw insertion.
- The Fixed Angle Driver is provided unassembled. Self - Guided Fixed Angle Awl, Self - Guided Fixed Angle Drill, and Fixed Angle Hex Driver (Screw Inserter) tips come standard in the Fixed Angle Driver Tip Caddy (Figure 8a).

Fixed Angle Driver Assembly

- To assemble the Fixed Angle Driver, begin by facing the Distal Tip (a) of the Outer Shaft (d) down.
- While maintaining the downward facing position, insert the selected tip (b) into the Outer Shaft (d).
- Insert the Inner Shaft (c) through the top of the Outer Shaft (d) and turn the proximal knob clockwise to tighten (Figure 8b).

Note: If there is a visible gap between the Inner Shaft (c) and Outer Shaft (d), rotate the proximal knob counterclockwise, toggle, and rotate clockwise to fully thread in.

HOLE PREP + SCREW INSERTION INSTRUMENTS

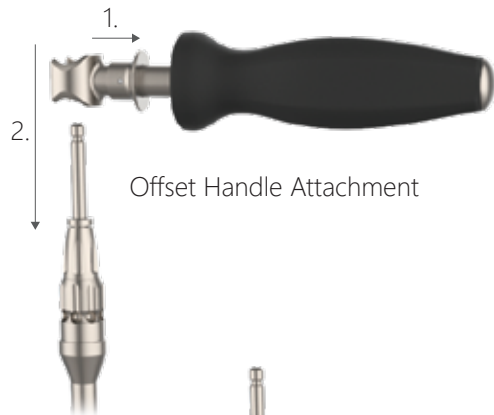


Figure 9a

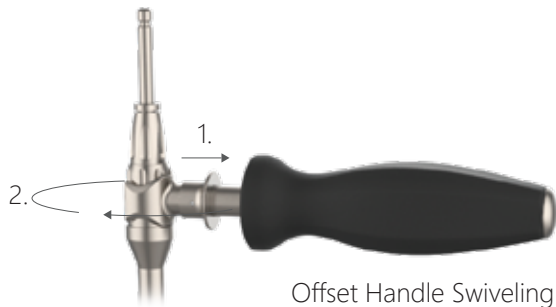


Figure 9b

FIXED ANGLE DRIVER (OPTION 3)

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 9a).
- 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 9b).

HOLE PREPARATION

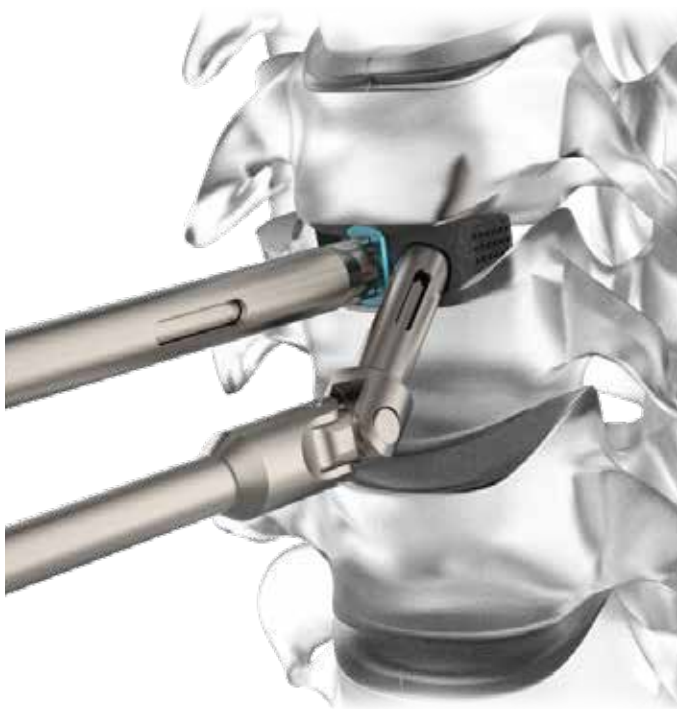


Figure 10

STEP 6

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 10). Repeat for the second pilot hole.

Note: Self - Guided Poly Angle Awl is shown.

Note: All hole preparation instruments have a Ø2.0mm diameter.

Note: All hole preparation instruments are designed such that the pilot hole does not extend past the posterior face of the Cage.

SCREW INSERTION

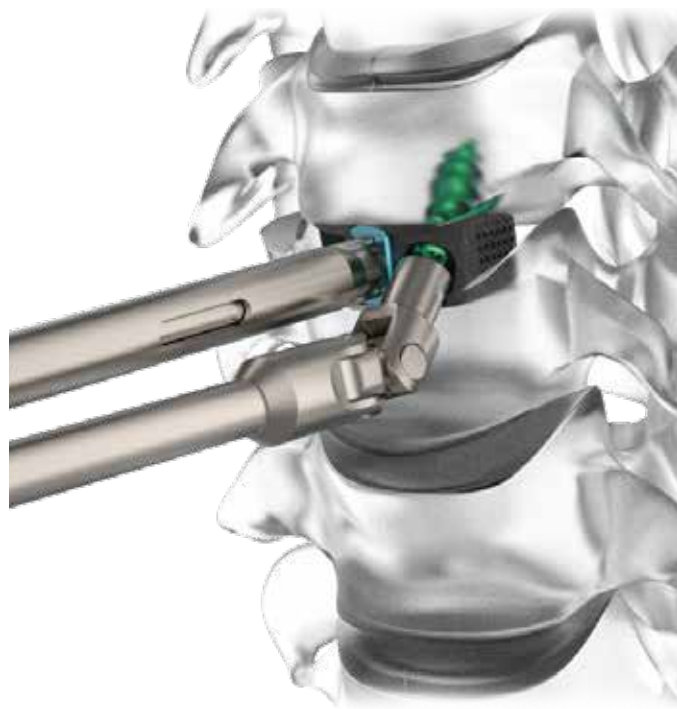


Figure 11

STEP 7

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 11).
- 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.

FINAL LOCKING

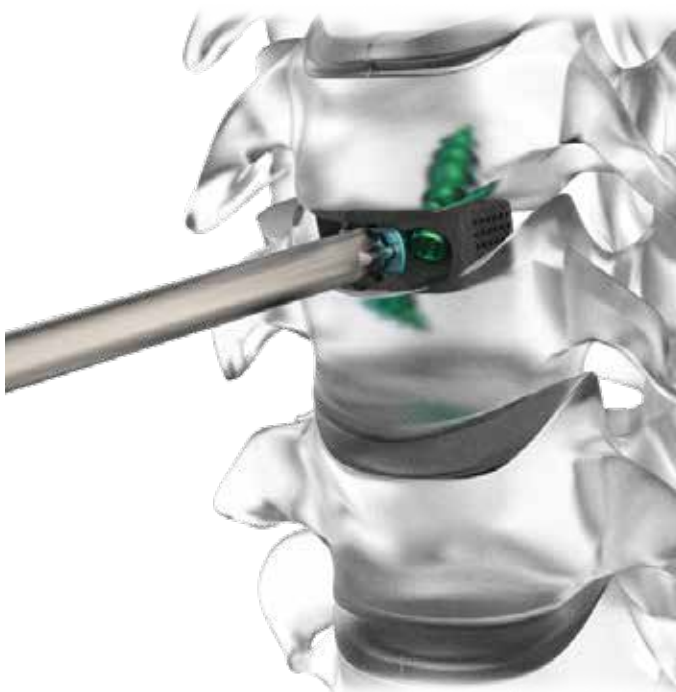


Figure 12

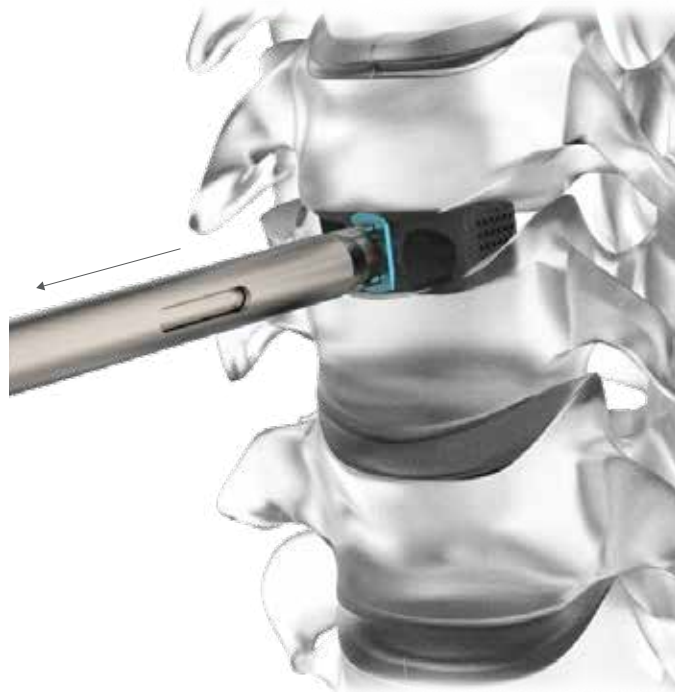


Figure 13

STEP 8

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 12).

Note: 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.

Note: 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.

IMPLANT REMOVAL

Removal

- In the event removal of the Nexxt Matrix[®] 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 13).

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.

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.



Figure 14a



Figure 14b



Figure 14c

GUIDE HEAD

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 14a).
- Align the Guide Head pins (Figure 14a) with the Turn Lock on the corresponding Cage (Figure 14b).
- Rotate the proximal knob of the Modular Inserter Shaft clockwise until the Cage and Modular Inserter are lagged to together (Figure 14c).
- Follow steps 5-8 while utilizing the Guide Head instrumentation.

Compatible Instruments

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

Incompatible Instruments

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

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).

NEXXT MATRIXX® STAND ALONE CERVICAL - TL IMPLANTS

12D x 15W x XXH



14D x 16W x XXH



16D x 18W x XXH*



Part Number	Description
52N-1215-05-SP	12D X 15W x 5H
52N-1215-06-SP	12D X 15W x 6H
52N-1215-07-SP	12D X 15W x 7H
52N-1215-08-SP	12D X 15W x 8H
52N-1215-09-SP	12D X 15W x 9H
52N-1215-10-SP	12D X 15W x 10H
52N-1215-11-SP*	12D X 15W x 11H
52N-1215-12-SP*	12D X 15W x 12H

Part Number	Description
52N-1416-05-SP	14D x 16W x 5H
52N-1416-06-SP	14D x 16W x 6H
52N-1416-07-SP	14D x 16W x 7H
52N-1416-08-SP	14D x 16W x 8H
52N-1416-09-SP	14D x 16W x 9H
52N-1416-10-SP	14D x 16W x 10H
52N-1416-11-SP*	14D x 16W x 11H
52N-1416-12-SP*	14D x 16W x 12H

Part Number	Description
52N-1618-05-SP*	16D x 18W x 5H
52N-1618-06-SP*	16D x 18W x 6H
52N-1618-07-SP*	16D x 18W x 7H
52N-1618-08-SP*	16D x 18W x 8H
52N-1618-09-SP*	16D x 18W x 9H
52N-1618-10-SP*	16D x 18W x 10H
52N-1618-11-SP*	16D x 18W x 11H
52N-1618-12-SP*	16D x 18W x 12H

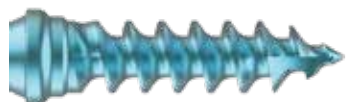
*By Request Only.

52N-35-XX-SP

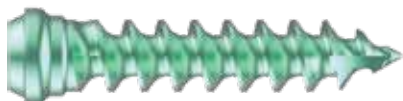
Part Number	Description
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52N-35-12-SP	Ø3.5 x 12mm Screw
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52N-35-14-SP	Ø3.5 x 14mm Screw
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52N-35-16-SP	Ø3.5 x 16mm Screw
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52N-35-18-SP*	Ø3.5 x 18mm Screw
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52N-40-XX-SP

Part Number	Description
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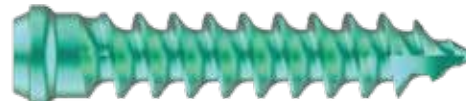
52N-40-12-SP	Ø4.0 x 12mm Screw
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52N-40-14-SP	Ø4.0 x 14mm Screw
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52N-40-16-SP	Ø4.0 x 16mm Screw
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52N-40-18-SP*	Ø4.0 x 18mm Screw
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*By Request Only.

NEXXT MATRIXX® STAND ALONE CERVICAL - TL INSTRUMENTS

I52-RUS-05



Part Number	Description
I52-RUS-05	Cerv. Universal Rasp, 6°, 12 x 14 x 5

I50-40-01



Part Number	Description
I50-40-01	Cervical Tamp

I52N-RA25-XX*



Part Number	Description
I52N-RA25-05*	Rasp, 6°, 12 x 15 x 5
I52N-RA25-06*	Rasp, 6°, 12 x 15 x 6
I52N-RA25-07*	Rasp, 6°, 12 x 15 x 7
I52N-RA25-08*	Rasp, 6°, 12 x 15 x 8
I52N-RA25-09*	Rasp, 6°, 12 x 15 x 9
I52N-RA25-10*	Rasp, 6°, 12 x 15 x 10
I52N-RA25-11*	Rasp, 6°, 12 x 15 x 11
I52N-RA25-12*	Rasp, 6°, 12 x 15 x 12

I52N-RA46-XX*



Part Number	Description
I52N-RA46-05*	Rasp, 6°, 14 x 16 x 5
I52N-RA46-06*	Rasp, 6°, 14 x 16 x 6
I52N-RA46-07*	Rasp, 6°, 14 x 16 x 7
I52N-RA46-08*	Rasp, 6°, 14 x 16 x 8
I52N-RA46-09*	Rasp, 6°, 14 x 16 x 9
I52N-RA46-10*	Rasp, 6°, 14 x 16 x 10
I52N-RA46-11*	Rasp, 6°, 14 x 16 x 11
I52N-RA46-12*	Rasp, 6°, 14 x 16 x 12

I52N-RA68-XX*



Part Number	Description
I52N-RA68-05*	Rasp, 6°, 16 x 18 x 5
I52N-RA68-06*	Rasp, 6°, 16 x 18 x 6
I52N-RA68-07*	Rasp, 6°, 16 x 18 x 7
I52N-RA68-08*	Rasp, 6°, 16 x 18 x 8
I52N-RA68-09*	Rasp, 6°, 16 x 18 x 9
I52N-RA68-10*	Rasp, 6°, 16 x 18 x 10
I52N-RA68-11*	Rasp, 6°, 16 x 18 x 11
I52N-RA68-12*	Rasp, 6°, 16 x 18 x 12

*By Request Only.

NEXXT MATRIXX® STAND ALONE CERVICAL - TL INSTRUMENTS

I52N-TR25-XX



I52-TR46-XX



I52-TR68-XX*



Part Number	Description
I52N-TR25-05	Trial, 6°, 12 x 15 x 5
I52N-TR25-06	Trial, 6°, 12 x 15 x 6
I52N-TR25-07	Trial, 6°, 12 x 15 x 7
I52N-TR25-08	Trial, 6°, 12 x 15 x 8
I52N-TR25-09	Trial, 6°, 12 x 15 x 9
I52N-TR25-10	Trial, 6°, 12 x 15 x 10
I52N-TR25-11*	Trial, 6°, 12 x 15 x 11
I52N-TR25-12*	Trial, 6°, 12 x 15 x 12

Part Number	Description
I52-TR46-05	Trial, 6°, 14 x 16 x 5
I52-TR46-06	Trial, 6°, 14 x 16 x 6
I52-TR46-07	Trial, 6°, 14 x 16 x 7
I52-TR46-08	Trial, 6°, 14 x 16 x 8
I52-TR46-09	Trial, 6°, 14 x 16 x 9
I52-TR46-10	Trial, 6°, 14 x 16 x 10
I52-TR46-11*	Trial, 6°, 14 x 16 x 11
I52-TR46-12*	Trial, 6°, 14 x 16 x 12

Part Number	Description
I52-TR68-05*	Trial, 6°, 16 x 18 x 05
I52-TR68-06*	Trial, 6°, 16 x 18 x 06
I52-TR68-07*	Trial, 6°, 16 x 18 x 07
I52-TR68-08*	Trial, 6°, 16 x 18 x 08
I52-TR68-09*	Trial, 6°, 16 x 18 x 09
I52-TR68-10*	Trial, 6°, 16 x 18 x 10
I52-TR68-11*	Trial, 6°, 16 x 18 x 11
I52-TR68-12*	Trial, 6°, 16 x 18 x 12

**By Request Only.*

I52N-01-01



I52N-01-02*



I52N-02-XX*









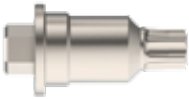


Part Number	Description
I52N-01-01	Fixed Inserter

Part Number	Description
I52N-01-02*	Modular Inserter

Part Number	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




**By Request Only.*




NEXXT MATRIXX® STAND ALONE CERVICAL - TL INSTRUMENTS


I52N-03-01		I52-23-01		I52-23-02	
					
Part Number	Description	Part Number	Description	Part Number	Description
I52N-03-01	Lock Tool	I52-23-01	Fixed Angle Driver, Outer Shaft	I52-23-02	Fixed Angle Driver, Inner Shaft
I52-23-03		I52N-23-04		I52N-23-05	
					
Part Number	Description	Part Number	Description	Part Number	Description
I52-23-03	Offset Handle	I52N-23-04	Self - Guided Fixed Angle Drill	I52N-23-05	Self - Guided Fixed Angle Awl
I52N-23-06		I52-22-09		I10-01-41	
					
Part Number	Description	Part Number	Description	Part Number	Description
I52N-23-06	Fixed Hex Driver	I52-22-09	Angled Awl	I10-01-41	Fixed AO Handle

*By Request Only.

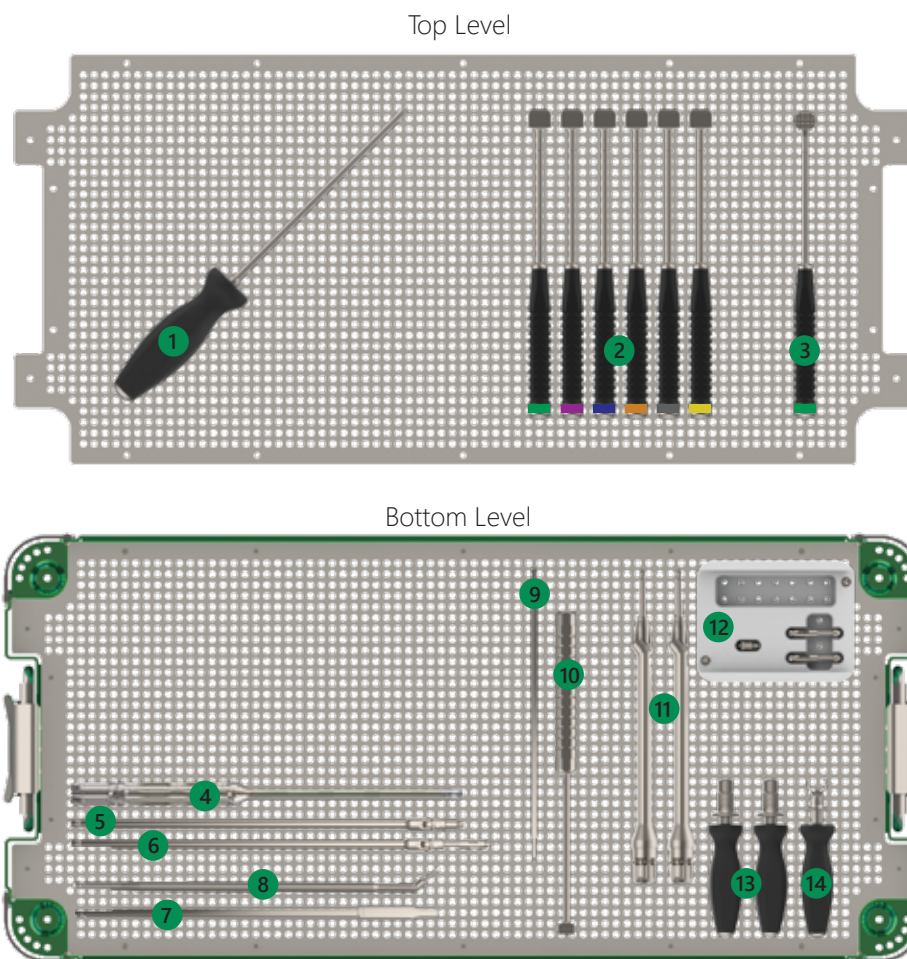
NEXXT MATRIXX® STAND ALONE CERVICAL - TL INSTRUMENTS

I52N-22-06		I52N-22-04		I52N-22-05	
					
Part Number	Description	Part Number	Description	Part Number	Description
I52N-22-06	Straight Hex Driver	I52N-22-04	Straight Self - Guided Drill	I52N-22-05	Straight Self - Guided Awl

I52-30-01		I52N-21-04		I52N-21-05	
					
Part Number	Description	Part Number	Description	Part Number	Description
I52-30-01	Screw Removal Tool	I52N-21-04	Self - Guided Poly Angle Drill	I52N-21-05	Self - Guided Poly Angle Awl

I52N-21-06	
	
Part Number	Description
I52N-21-06	Poly Angle Hex Driver

STANDARD INSTRUMENT CASE



Part Number

Description

1. I52N-03-01	Lock Tool
2. I52N-TR25-05:10 (Top) / I52-TR46-05:10 (Bottom)	Trials: 12x15x05-10mm (Top) / 14x16x05-10mm (Bottom)
3. I52-RUS-05	Rasp: 12x14x5mm
4. I52N-01-01 (2x)	Fixed Interbody Inserter (2x)
5. I52N-21-06	Self - Guided Poly Angle Hex Driver (Screw Inserter)
6. I52N-21-04 (Top) / I52N-21-05 (Bottom)	Self - Guided Poly Angle Drill (Top) / Awl (Bottom)
7. I52N-22-04 (Top) / I52N-22-05 (Bottom)	Self - Guided Straight Drill (Top) / Awl (Bottom)
8. I52N-22-06 (Top) / I52-22-09 (Bottom)	Straight Hex Driver (Screw Inserter) (Top) / Angled Awl (Bottom)
9. I52-30-01	Screw Removal Tool
10. I50-40-01	Cervical Tamp
11. I52-23-01 (2x) (Top) / I52-23-02 (2x) (Bottom)	Fixed Angle Driver, Outer Shaft (2x) (Top) / Inner Shaft (2x) (Bottom)
12. I52N-23-04/05/06	Self - Guided Awl Tip / Drill Tip / Hex Driver (Screw Inserter) Tip
13. I10-01-41 (2x)	Fixed AO Handle (2x)
14. I52-23-03	Fixed Angle Driver Handle

INDICATIONS

Description

• NEXXT MATRXXX® 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 MATRXXX® 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 MATRXXX® 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 MATRXXX® 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 MATRXXX® Stand Alone Cervical - TL System is intended to be used with the bone screw fixation provided and requires no additional fixation.

Contraindications

The NEXXT MATRXXX® 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. The NEXXT MATRXXX® Stand Alone Cervical - TL System devices should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Prior to use, surgeons should be trained in the surgical procedures recommended for use of these devices.
3. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the device.
4. These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.

INDICATIONS

5. The NEXXT MATRIXX® Stand Alone Cervical -TL System is used to augment the development of a spinal fusion by providing temporary stabilization. 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 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.

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.

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



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