NEXXT Spine

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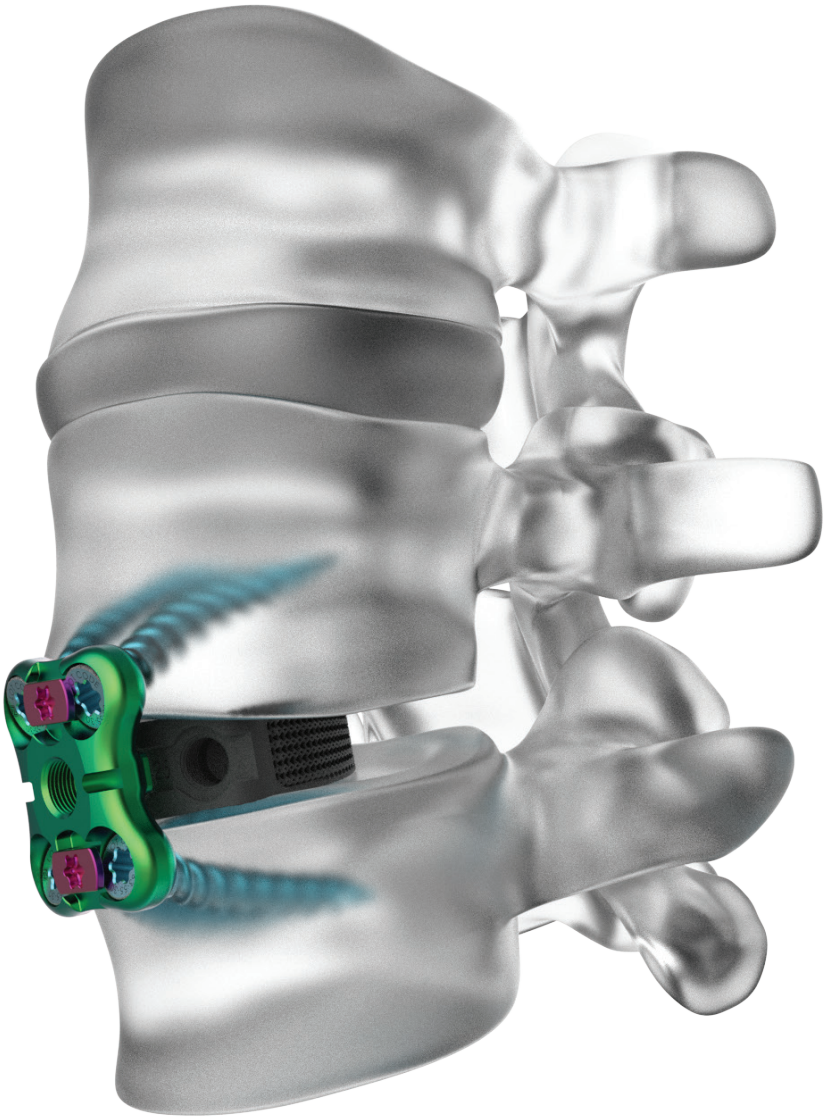
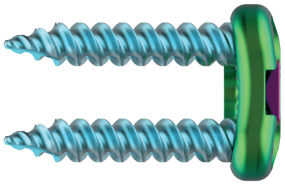
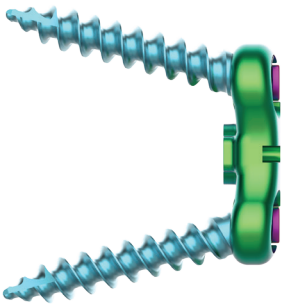
Surgical Technique Guide

STRUXXURE®-A Plate System







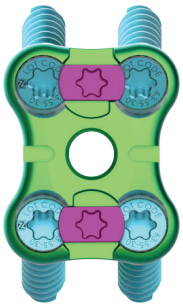


TABLE OF CONTENTS

Nexxt Spine is a medical device developer and manufacturer and provides this technique as a reference for recommended procedural steps for the placement of STRUXXURE®-A Plate System .

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 STRUXXURE®-A. 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.

PRODUCT FEATURES

A Integrated one-step turn lock feature to prevent Screw backout.

B Self-tapping, variable angle (0°-15° cephalad/caudal) Screws designed with tip-to-tail thread pattern for cancellous and cortical bone fixation.

C Anti-skid interface aids in Plate stabilization during placement and Screw fixation on vertebral body.

D Implant compatibility with **NEXXT MATRIXX®** ALIF for single position procedural solution.

E Instrumentation designed to provide intra-operative flexibility with Plate and Construct Inserters.

E

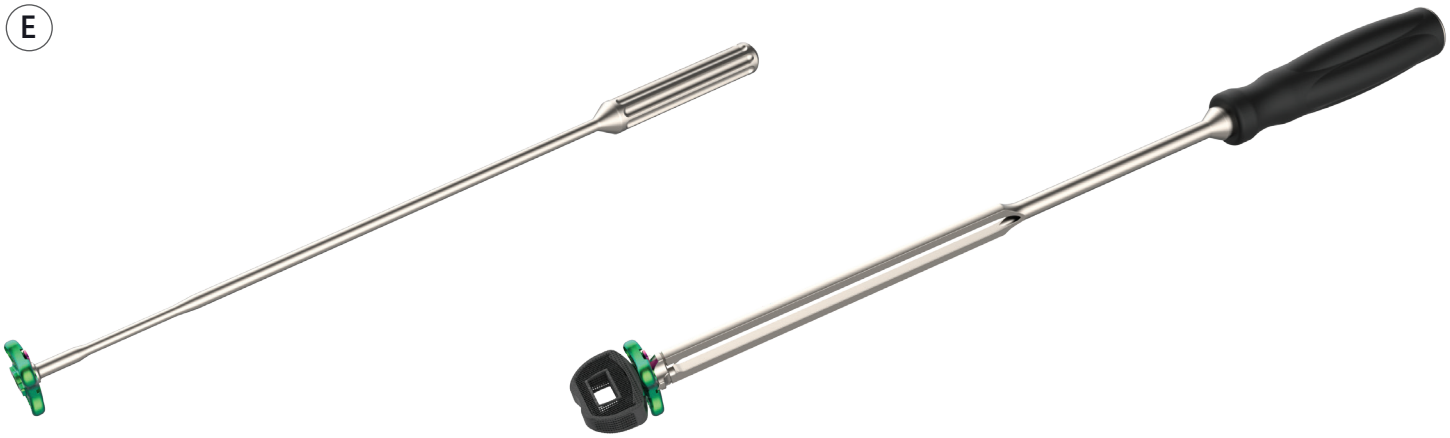
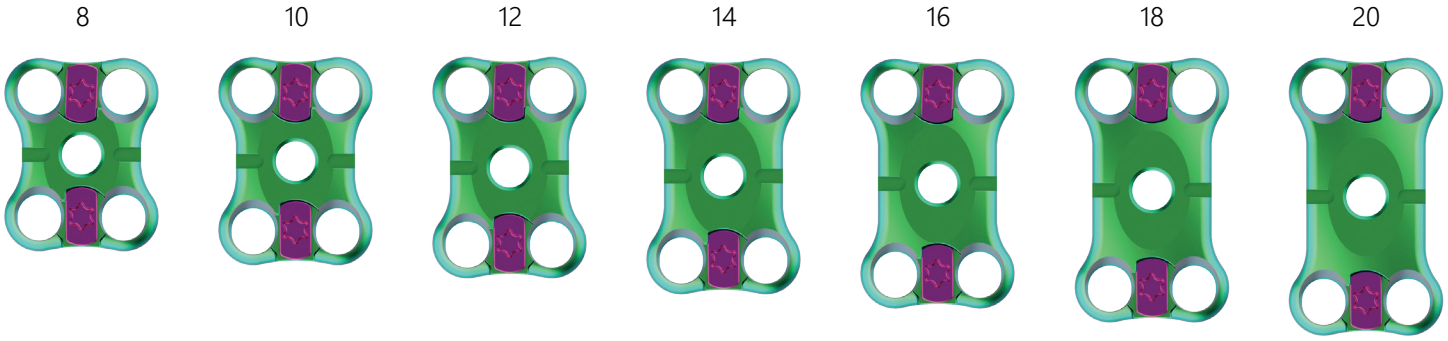


Plate Insertion

Plate and Cage Construct Insertion

PLATE SPECS

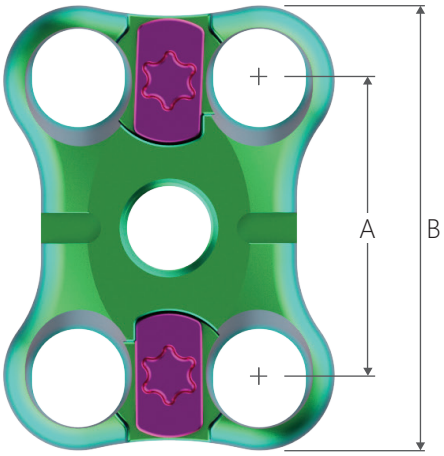
Sizes



Lengths

Screw to Screw length and Total length

Plate Size	Screw to Screw Length (A)	Plate Total (B)
8	17.5mm	27.5mm
10	19.5mm	29.5mm
12	21.5mm	31.5mm
14	23.5mm	33.5mm
16	25.5mm	35.5mm
18	27.5mm	37.5mm
20	29.5mm	39.5mm

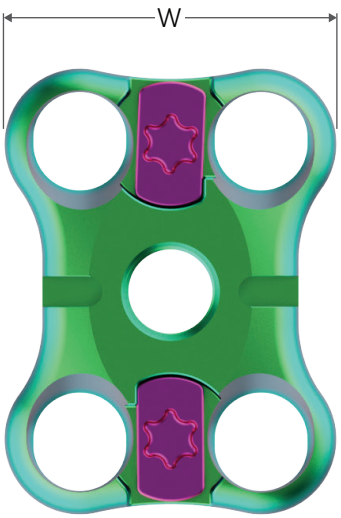


Thickness

All Plate thicknesses 5mm

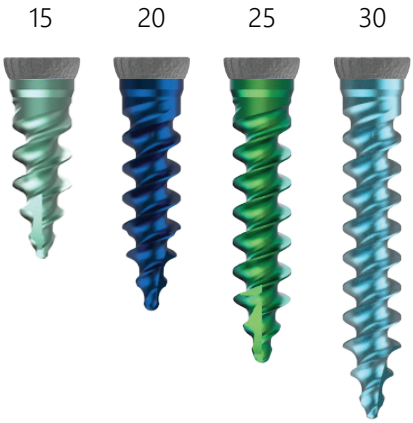
Widths

All Plate widths 22mm

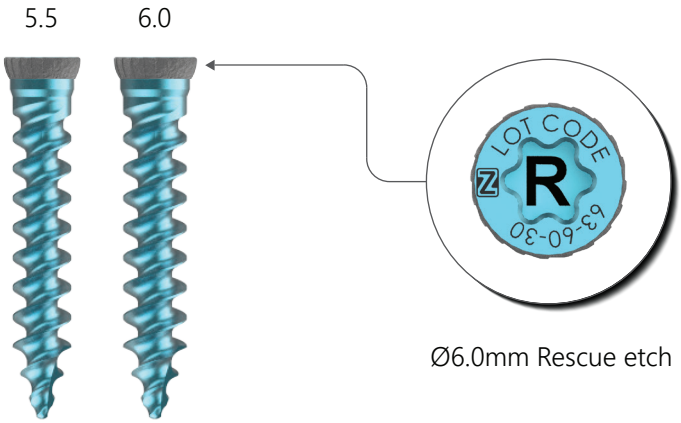


SCREW SPECS

Lengths (mm)



Diameters (mm)



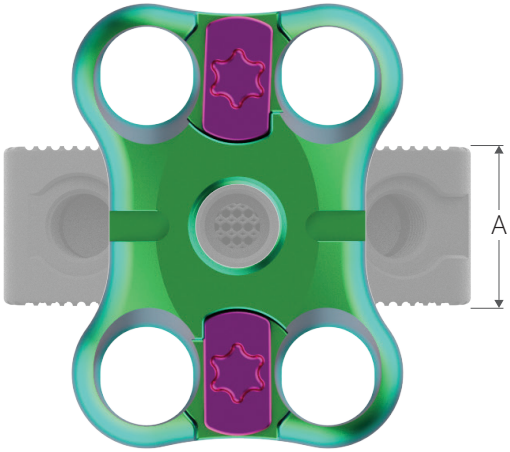
Ø6.0mm Rescue etch

CONSTRUCT SPECS

Congruence

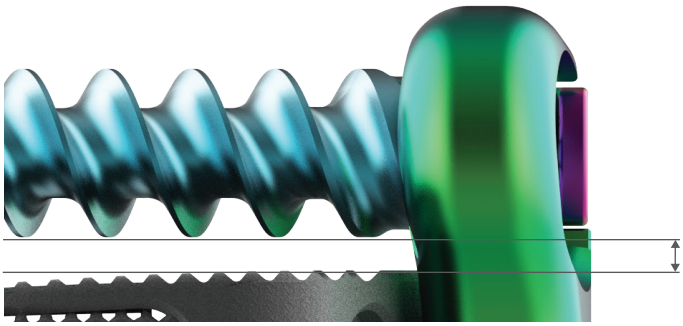
Recommended for **NEXXT MATRIXX®** ALIF heights

Plate Size	Cage Height (A)
8	8mm
10	10mm
12	12mm
14	14mm
16	16mm
18	18mm
20	20mm



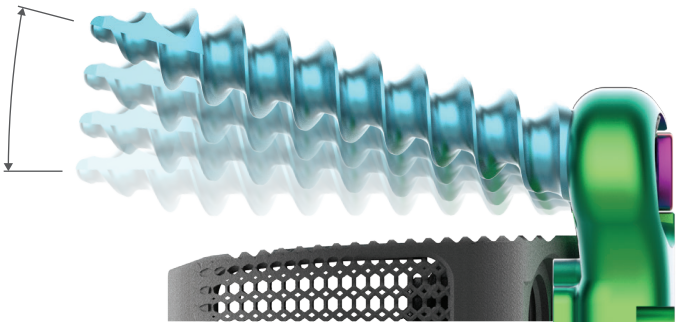
Clearance

Minimum of 2mm in between Ø5.5mm Screw



Angulation

Variable 0°-15°



INDICATIONS FOR USE

The STRUXXURE®-A Plate System is indicated for treatment of spine instability via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the thoracic and thoracolumbar (T1-L5) spine or via an anterior surgical approach below the bifurcation of the great vessels in the lumbar and lumbosacral (L1-S1) spine. The indications for use include fracture (including dislocation and subluxation), tumor, degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, spondylolysis, spondylolisthesis, pseudarthrosis and failed previous spine surgery.

1. PATIENT POSITIONING

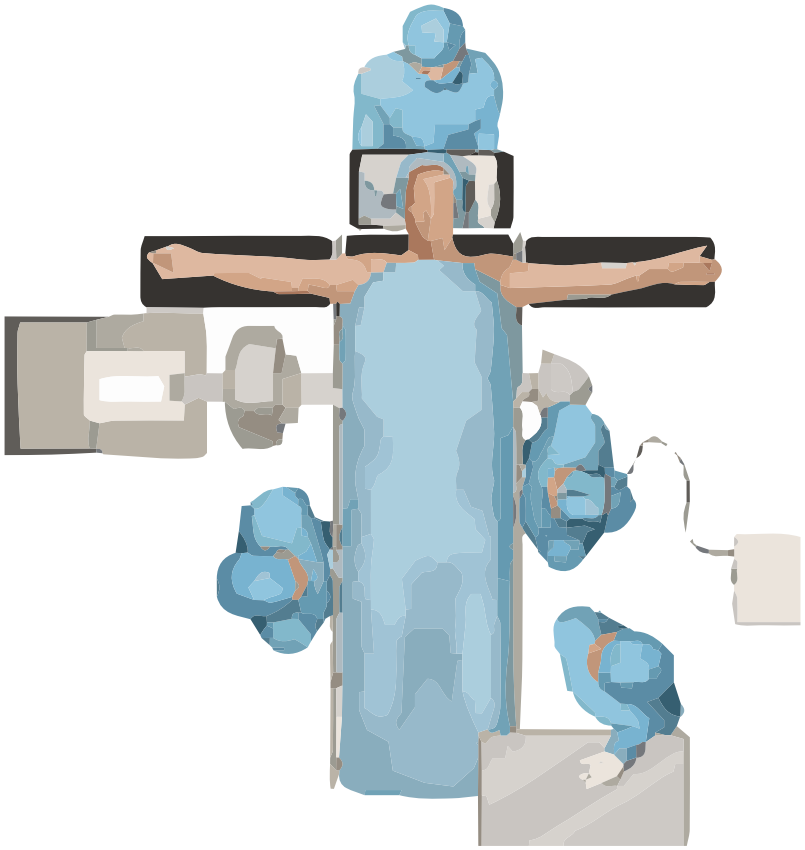


Figure 1

Approach to the Surgery

Perform the customary approach for an ALIF as chosen by the surgeon ***(Figure 1)***.

Note: *While cleared for use at L5-S1, the anatomic position of the iliac crest or left femoral artery can make an oblique approach challenging at the L5-S1 level.*

Confirm Disc Location with Fluoroscopy

A disc marker may be inserted into the affected disc and a radiographic image taken to confirm the appropriate level.

Retractor Insertion

Using fluoroscopy, identify the middle of the disc space. Mark the skin to indicate the intended incision location. Approach the desired disc space level and place the Retractor. Use of the intraoperative neuromonitoring is recommended to ensure patient safety. It is especially critical during approach and Retractor placement.

2. MIDLINE VERIFICATION + DISC REMOVAL

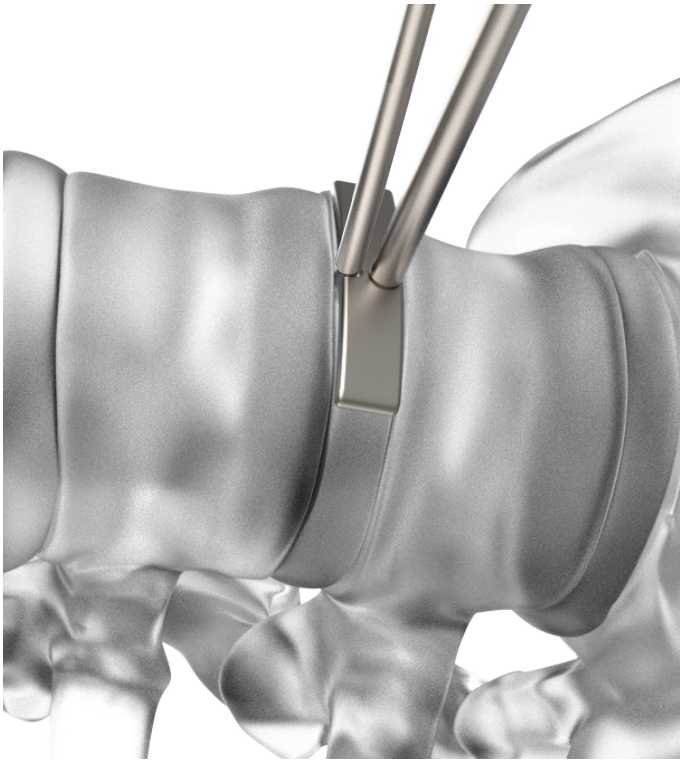


Figure 2

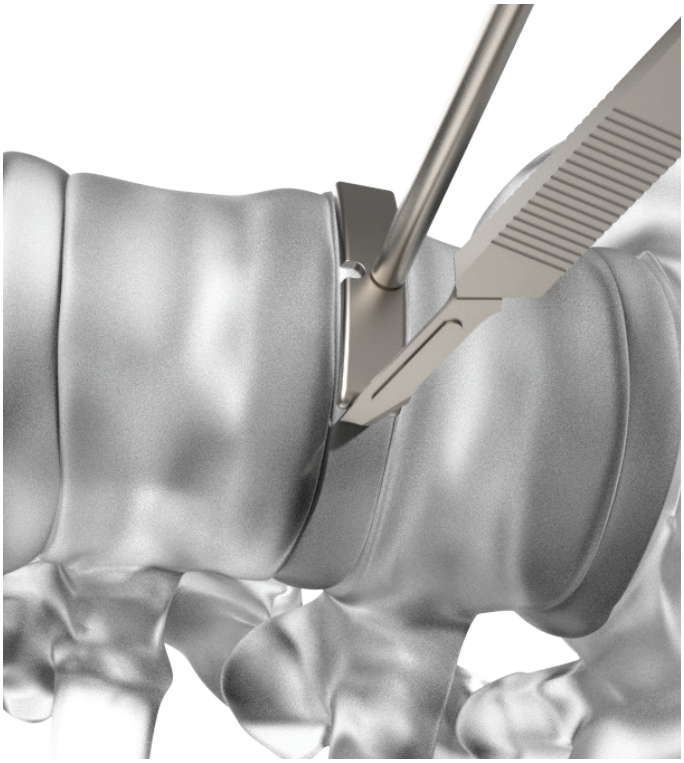


Figure 3

Midline Verification

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

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

Note: *Centering Pin depth is 23mm.*

Disc Removal

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

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

3. DELIVERY METHODS

Note: *There are two methods offered for delivery of STRUXXURE®-A. Method 3.1. illustrates Plate implantation given a placed NEXXT MATRIXX® ALIF. Method 3.2. illustrates Plate implantation simultaneously with NEXXT MATRIXX® ALIF.*

3.1. Plate Insertion Method

Figure 4

Method Components:

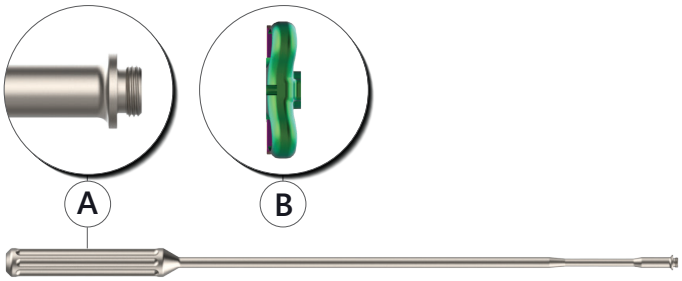


Figure 5

Method Details

3.1. Plate Insertion Method (Figure 4) utilizes the Plate Inserter ***(Figure 5A)*** to deliver the Plate ***(Figure 5B)***.

3.2. Plate and Cage Construct Insertion Method

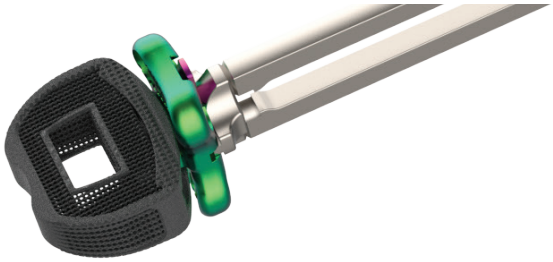


Figure 6

Method Components:

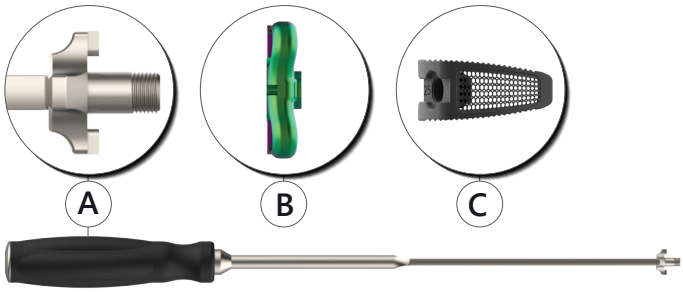


Figure 7

Method Details

3.2. Plate and Cage Construct Insertion Method (Figure 6) utilizes the Construct Inserter ***(Figure 7A)*** to deliver the Plate ***(Figure 7B)*** and NEXXT MATRIXX® ALIF (Cage) ***(Figure 7C)*** simultaneously. The Plate and Cage will not be permanently connected post-operatively.

Note: *STRUXXURE®-A may be used as supplemental fixation with an alternative ALIF device, however, Nexxt Spine does not endorse* ***3.2. Plate and Cage Construct Insertion Method (Figure 6)*** *with any other ALIF device except NEXXT MATRIXX® ALIF.*

3.1.1. PLATE INSERTION METHOD ATTACHMENT

Align Plate to Plate Inserter

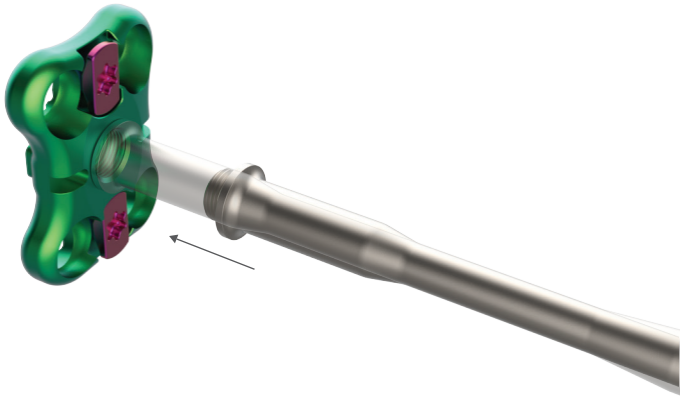


Figure 8

Rotate Plate Inserter clockwise into Plate

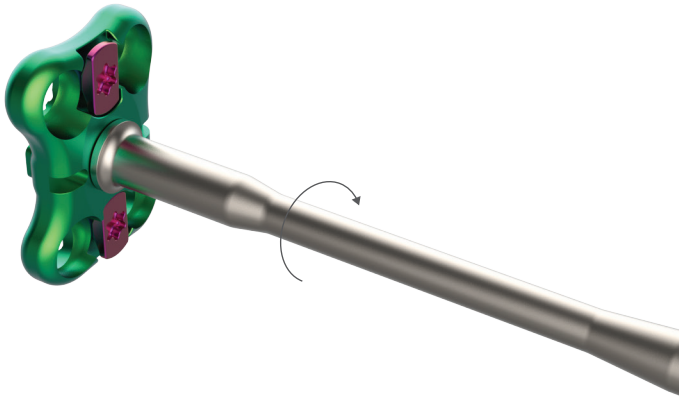


Figure 9

Attachment Steps

Align the Plate to the Plate Inserter ***(Figure 8)***.

Rotate the Plate Inserter clockwise until hard-stop is encountered with Plate ***(Figure 9)***.

Note: *Plates may be loaded to the Plate Inserter directly from the Plate Caddy.*

3.1.2. PLATE INSERTION METHOD IMPLANTATION

Note: *STRUXXURE®-A is designed for use in conjunction with NEXXT MATRIXX® ALIF. For the purpose of illustrating 3.1.2. Plate Insertion Method Implantation, NEXXT MATRIXX® ALIF is shown already implanted in the intradiscal space. Reference document 71-044, NEXXT MATRIXX® ALIF Surgical Technique Guide for Cage information and Cage surgical technique.*

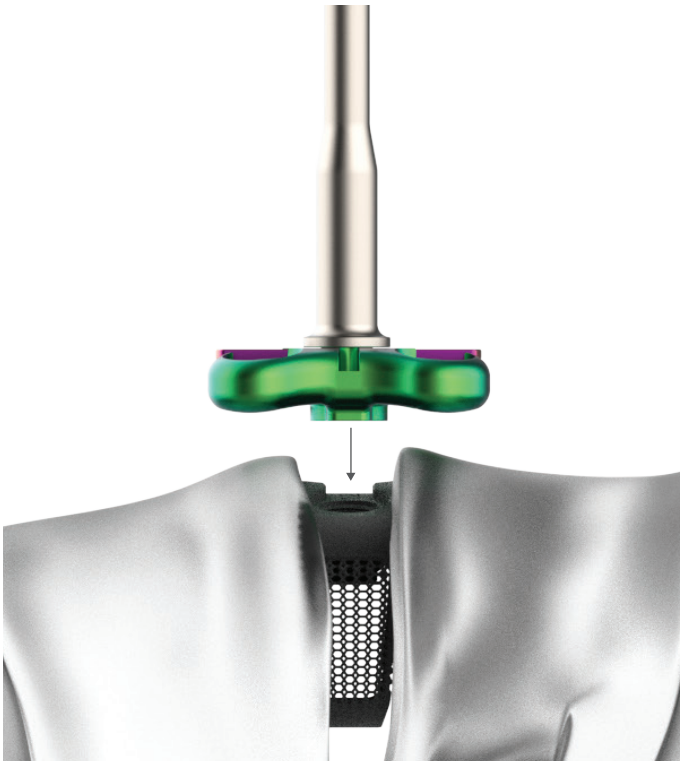


Figure 10

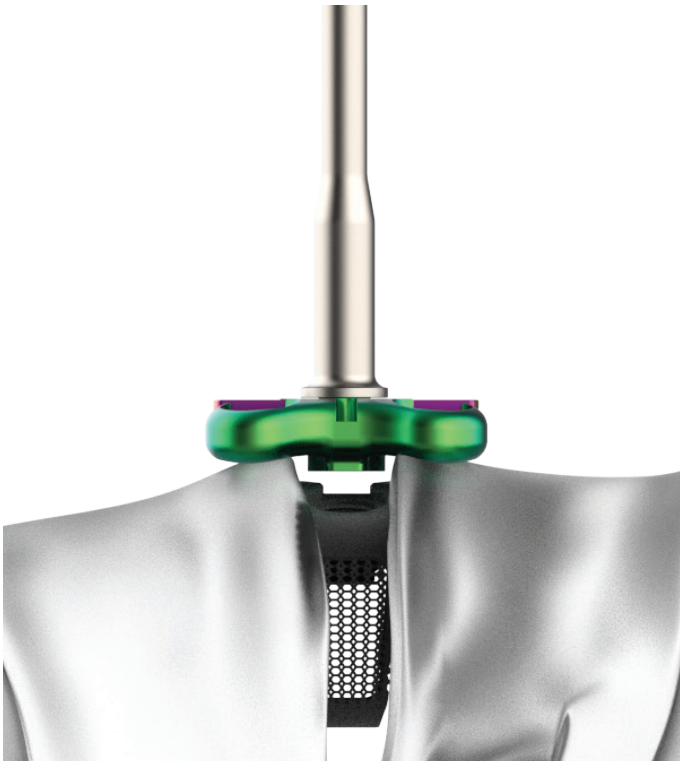


Figure 11

Osteophyte Removal (Optional)

The anterior surface of the vertebral bodies is prepared as required, removing anterior osteophytes with the pituitary or Kerrison ronguer. Caution should be taken to remove only the necessary amount of the osteophyte to aid is flush apposition of the plate. Removal may require the use of hemostatic agents.

Plate Alignment

While maintaining desired orientation, place the Plate over the Cage ***(Figure 10)***.

Note: *Anterior midline or anterolateral positioning of the Plate may be determined by anatomy and by surgeon preference. At L5-S1, the Plate may be implanted anteriorly and directly midline, below the level of the bifurcation of the vessels.*

At L4-L5 or the bifurcation, and/or lumbar levels above L4-L5, it may be more adventageous to implant the Plate in an anterolateral position. Surgeon preference ultimately determines the most adventageous position.

Plate Placement

Ensure the distal face of the Plate is fully seated against the anterior face of the vertebral body ***(Figure 11)***. Confirm proper placement via fluoroscopy.

Proceed to Step 4. Hole Preparation (page 14) to continue the surgical technique.

Note: *In the event the Plate is unable to seat against the vertebral bodies due to Cage placement, Cage recession may be necessary.*

3.2.1. PLATE AND CAGE CONSTRUCT INSERTION METHOD ATTACHMENT

Attach Torque Limiting Handle to Inserter Inner Shaft

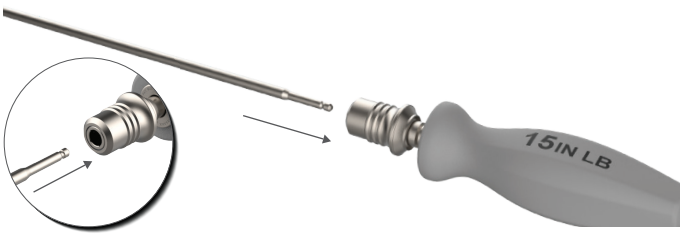


Figure 12

Insert Inserter Inner Shaft through cannula of Construct Inserter

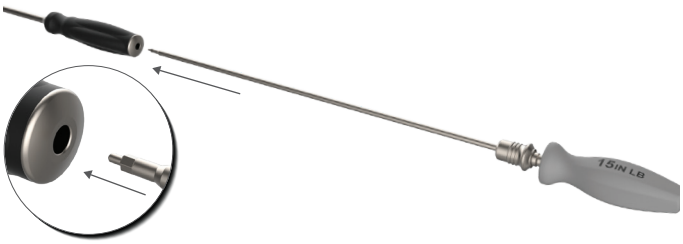


Figure 13

Align Plate to Construct Inserter

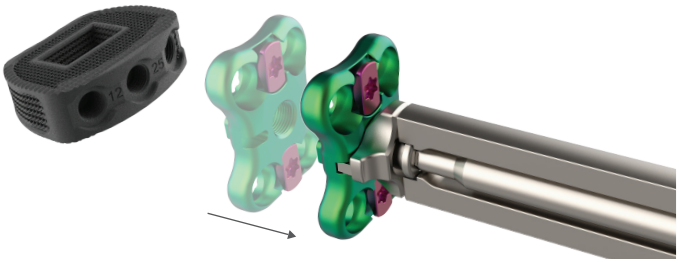


Figure 14

Mate Cage to Construct Inserter and turn Inserter Inner Shaft clockwise to attach

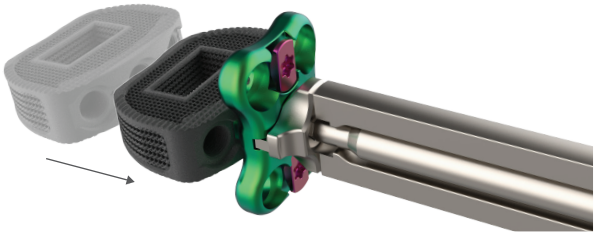


Figure 15

Attachment Steps

Attach the Torque Limiting Handle (15 in-lbs) to the Inserter Inner Shaft ***(Figure 12)***.

Insert the Inserter Inner Shaft through the cannula of the Construct Inserter ***(Figure 13)***.

Mate the Plate to the Construct Inserter ***(Figure 14)***.

Mate the corresponding Cage to the Construct Inserter and turn the Inserter Inner Shaft clockwise until audible and tangible clicking indicate the 15 in-lbs torque limit has been reached ***(Figure 15)***. Remove the Inserter Inner Shaft.

Note: *See Construct Specs (page 4) for Plate size and Cage height congruence.*

Note: *When inserting the Inserter Inner Shaft into the cannula of the Construct Inserter, ensure the tip of the Inserter Inner Shaft mates to the internal Set Screw of the Construct Inserter.*

3.2.2. PLATE AND CAGE CONSTRUCT INSERTION METHOD IMPLANTATION

Note: *3.2.2. Plate and Cage Construct Insertion Method Implantation demonstrates STRUXXURE®-A and NEXXT MATRIXX® ALIF entering in the intradiscal space simultaneously. Upon removing the Construct Inserter between Step 5. Screw Placement (page 15) and Step 6. Locking (page 16), STRUXXURE®-A and NEXXT MATRIXX® ALIF will not be connected.*

Figure 16

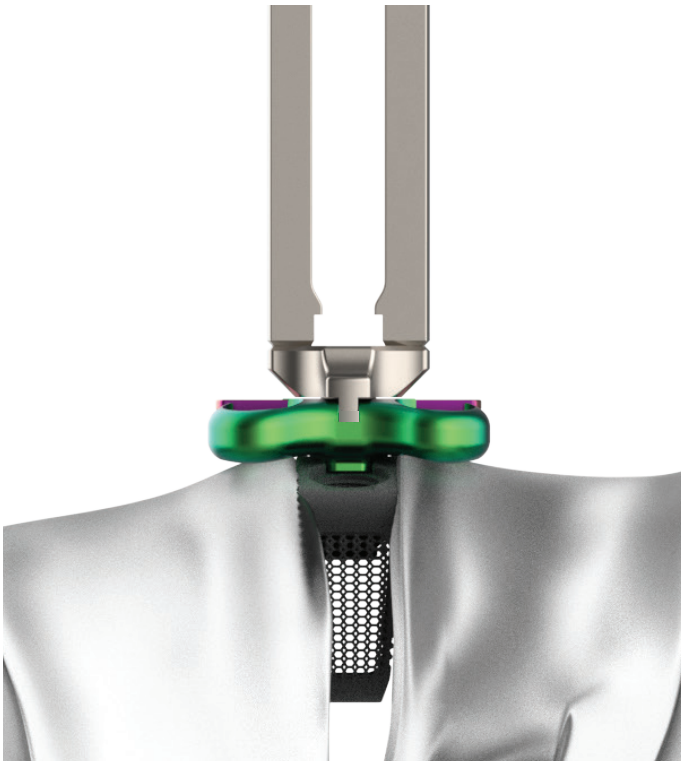


Figure 17

Construct Alignment

Center the Plate and Cage Construct in the disc space ***(Figure 16)***.

Note: *Anterior midline or anterolateral positioning of the Plate may be determined by anatomy and by surgeon preference. At L5-S1, the Plate may be implanted anteriorly and directly midline, below the level of the bifurcation of the vessels.*

Construct Placement

Impact the Plate and Cage Construct into the disc space until the distal face of the Plate is fully seated against the anterior face of the vertebral bodies ***(Figure 17)***. Confirm proper placement via fluoroscopy.

4. HOLE PREPARATION

Locate + Dock

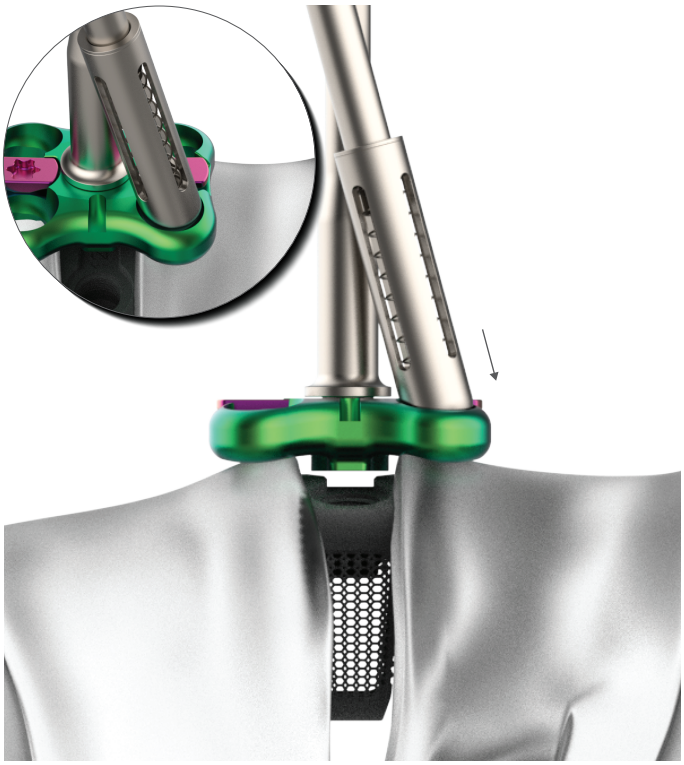


Figure 18

Plunge

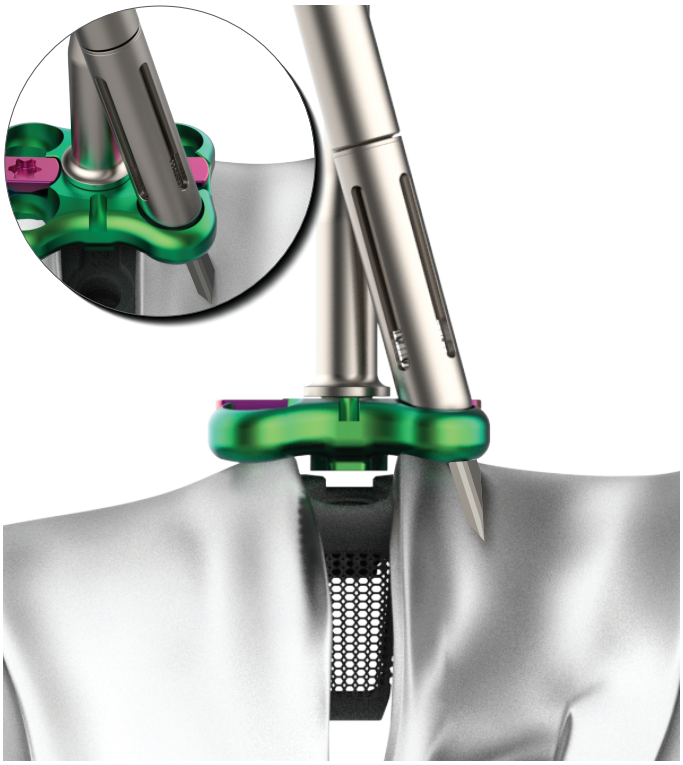


Figure 19

Self-Guided Instrument Placement

Using the Self-Guided Straight Awl, Self-Guided Angled Awl, or Self-Guided Straight Drill, locate the Screw Pocket within the Plate and dock ***(Figure 18)***.

Note: *The Self-Guided Angled Awl has a fixed 10° angle.*

Note: *The Self-Guided Straight Awl, Self-Guided Angled Awl, and Self-Guided Straight Drill have a maximum depth of 15mm and a 3mm diameter.*

Note: *Usage of the hole preparation tools with powered instrumentation is not recommended.*

Pilot Hole Execution

Plunge/drill the Self-Guided Awl/Self-Guided Straight Drill in the Screw Pocket to create the pilot hole ***(Figure 19)***. Repeat for all pilot holes.

Note: *The Self-Guided Straight Awl, Self-Guided Angled Awl, and Self-Guided Straight Drill self-center in the Screw Pocket and create 0°-15° pilot holes.*

5. SCREW INSERTION

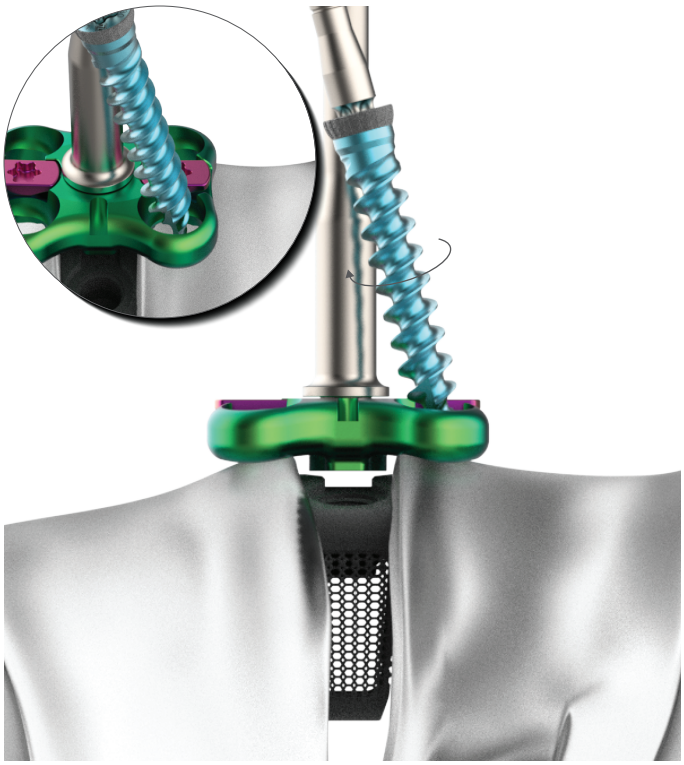


Figure 20

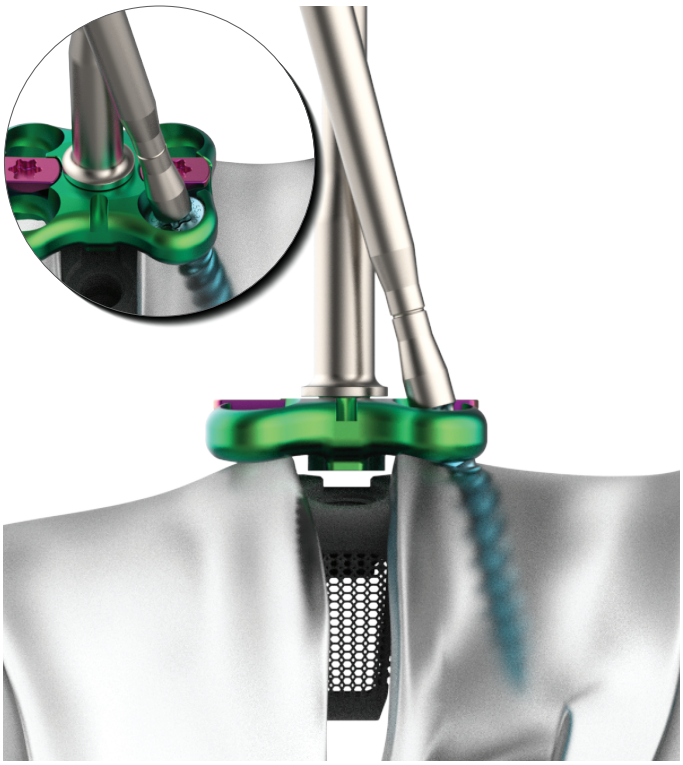


Figure 21

Screw Placement

Attach the desired handle to the Straight Driver (T20). Determine the desired Screw length, attach the Screw to the tip of the Straight Driver, and locate the Screw Pocket within the Plate ***(Figure 20)***.

Note: *The Straight Driver and Screw have a self-retaining, press-fit connection.*

Note: *The Screw Caddy may be used to verify the selected Screw diameter and Screw length.*

Screw Placement Verification

Drive the Screw in at the desired angle ***(Figure 21)***. Repeat for all Screws.

Verify Screw placement via fluoroscopy.

Note: *Ensure all Screws are fully seated within the Plate Screw pockets.*

Note: *The Plate size and congruent NEXXT MATRIXX® ALIF height provide a minimum of 2mm clearance in between a Ø5.5mm Screw major and Cage superior/inferior endplates. See Construct Specs (page 5) for Plate size and Cage height congruence.*

6. LOCKING

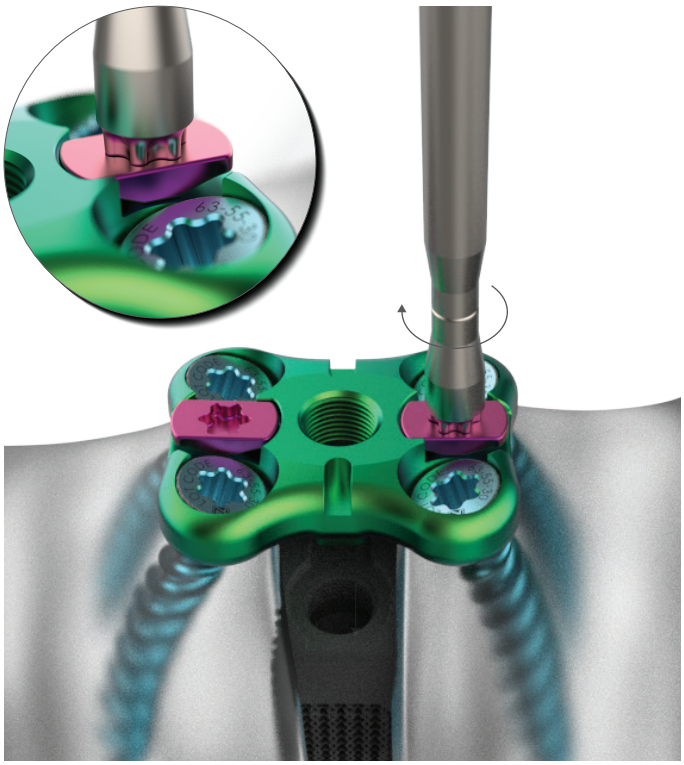


Figure 22

Figure 23

Inserter Detatchment

Prior to locking the Turn Locks, detach the Plate Inserter by rotating the Plate Inserter counterclockwise or if using the Construct Inserter, detach by attaching the torque limiting handle to the Inserter Inner Shaft, inserting the Inserter Inner Shaft through the cannula of the Inserter, and rotating the Inserter Inner Shaft counterclockwise until disengaged from Plate.

Plate Turn Lock

Attach the desired handle to the Straight Driver or and mate the tip to the Turn Lock (T20) ***(Figure 22)***. Alternatively, the Ball-Ended Lock Tool may be used. Rotate clockwise until Turn Lock encounters hard-stop with Plate ***(Figure 23)***. Repeat for both Turn Locks.

Note: *In the event a Turn Lock does not clear the Screw Head, drive the Screw deeper until bottomed out in the Plate. Rotate the Turn Lock.*

7. CLOSURE

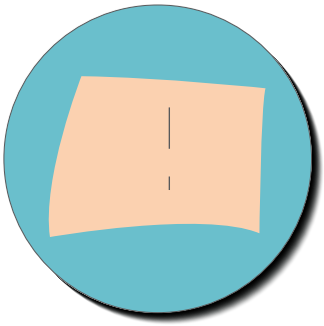


Figure 24

Closure

The skin is closed using standard surgical techniques ***(Figure 24)***.

Supplemental instrumentation is required.

REMOVAL (AS NEEDED)

Figure 25

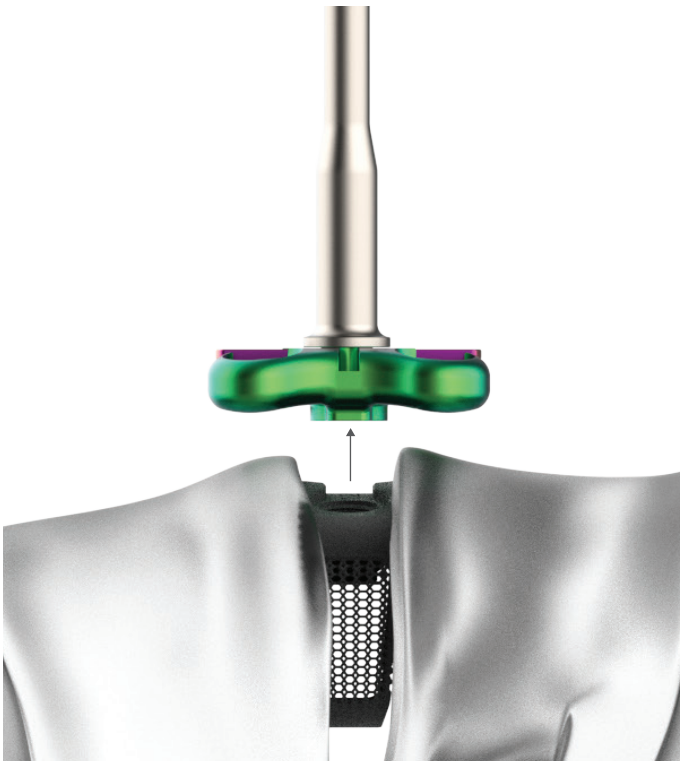


Figure 26

Plate Turn Lock Unlocking

Attach the desired handle to the Straight Driver and mate the tip to the Turn Lock (T20). Alternatively, the Ball-Ended Lock Tool may be used. Rotate counterclockwise until Turn Lock clears Screw Head and encounters hard-stop with Plate ***(Figure 25)***. Repeat for both Turn Locks.

Screw Removal

Prior to removing the Screws, attach the Plate Inserter to the Plate by rotating the Plate Inserter clockwise until hard-stop is encountered with Plate.

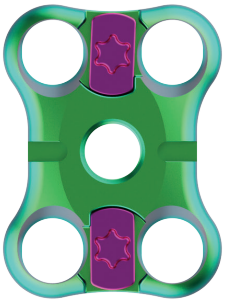
Attach the desired handle to the Straight Driver (T20) and remove the Screw by rotating counterclockwise. Repeat for all Screws.

Plate Removal

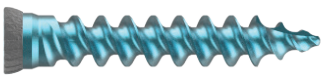
Once the Screws have been safely explanted, remove the Plate from the surgical site ***(Figure 26)***.

Note: *Reference document 71-044, NEXXT MATRIXX® ALIF Surgical Technique Guide for Cage removal information.*

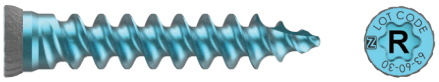
IMPLANT PART NUMBERS



ALIF Plate, 63-04-XX	
Part Number	**Description**
63-04-08	ALIF, 4 Hole Plate, Size 8
63-04-10	ALIF, 4 Hole Plate, Size 10
63-04-12	ALIF, 4 Hole Plate, Size 12
63-04-14	ALIF, 4 Hole Plate, Size 14
63-04-16	ALIF, 4 Hole Plate, Size 16
63-04-18	ALIF, 4 Hole Plate, Size 18
63-04-20	ALIF, 4 Hole Plate, Size 20



Ø5.5mm Lumbar Screw, 63-55-XX		
Part Number	**Description**	**Color**
63-55-15*	Ø5.5mm Lumbar Screw, 15mm	
63-55-20	Ø5.5mm Lumbar Screw, 20mm	
63-55-25	Ø5.5mm Lumbar Screw, 25mm	
63-55-30	Ø5.5mm Lumbar Screw, 30mm	



Ø6.0mm Lumbar Screw, 63-60-XX		
Part Number	**Description**	**Color**
63-60-15*	Ø6.0mm Lumbar Screw, 15mm	R
63-60-20	Ø6.0mm Lumbar Screw, 20mm	R
63-60-25	Ø6.0mm Lumbar Screw, 25mm	R
63-60-30	Ø6.0mm Lumbar Screw, 30mm	R

Made to Order

INSTRUMENT PART NUMBERS

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

Part Number	Description
I63-01-03	Construct Inserter, ALIF

Part Number	Description
I63-01-04	Plate Inserter, ALIF

Part Number	Description
I63-32-03	Inserter Inner Shaft

Part Number	Description
I63-20-03	Self-Guided Straight Drill

Part Number	Description
I63-20-01	Self-Guided Straight Awl

Part Number	Description
I63-20-02	Self-Guided Angle Awl

Part Number	Description
I63-21-05	Straight Driver, T20

Part Number	Description
I63-32-01	Ball-Ended Lock Tool

Part Number	Description
I10-01-64	Hudson Axial Handle, Ratcheting

Part Number	Description
I10-01-66	AO Axial Handle, Torque Lim, 15inlb

INSTRUMENT PART NUMBERS (CONT)

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

Part Number	Description
I10-01-43*	Hudson T-Handle, Fixed

Part Number	Description
I10-01-63*	Hudson T-Handle, Ratcheting

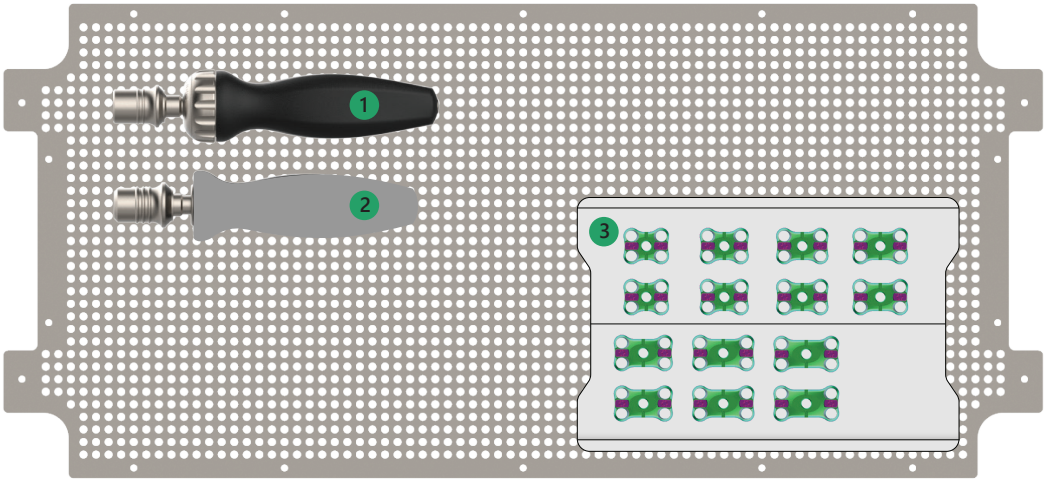
Part Number	Description
I10-01-68*	Hudson Axial Handle, Fixed

Part Number	Description
I10-01-67*	AO-AO Torque Lim Adaptor, 15inlb

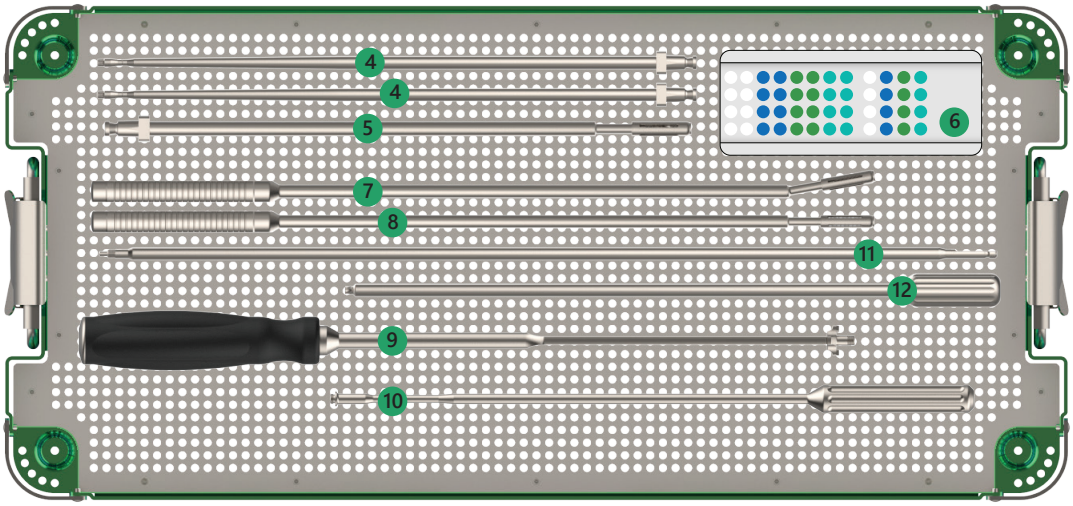
Made to Order

STANDARD INSTRUMENT SET

Top Level



Bottom Level



Part Number	Description
1. I10-01-64	Hudson Axial Handle, Ratcheting
2. I10-01-66	AO Axial Handle, Torque Lim, 15inlb
3. C63-02-02	ALIF Plate Caddy
4. I63-21-05 (2x)	Straight Driver, T20 (2x)
5. I63-20-03	Self-Guided Straight Drill
6. C63-02-05	ALIF Screw Caddy
7. I63-20-02	Self-Guided Angled Awl
8. I63-20-01	Self-Guided Straight Awl
9. I63-02-03	Construct Inserter
10. I63-02-04	Plate Inserter
11. I63-32-03 (2x)	Inserter Inner Shaft (2x)
12. I63-32-01	Ball-Ended Lock Tool

INDICATIONS

Description

• The STRUXXURE®-A Plate System is a lumbar plate and screw system. The system consists of variable angle screws having 5.5mm and 6.0mm diameters with self-tapping tips. Overall screw lengths range from 15mm to 30mm in 5mm increments. Plates are offered having sizes of 8 to 20 in increments of 2. All components are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136.

Indications

• The STRUXXURE®-A Plate System is indicated for treatment of spine instability via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the thoracic and thoracolumbar (T1-L5) spine or via an anterior surgical approach below the bifurcation of the great vessels in the lumbar and lumbosacral (L1-S1) spine. The indications for use include fracture (including dislocation and subluxation), tumor, degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, spondylolysis, spondylolisthesis, pseudarthrosis and failed previous spine surgery.

• The STRUXXURE®-A Plate System may also be attached to NEXXT MATRIXX® ALIF device. In this configuration the STRUXXURE®-A Plate System is used to treat skeletally mature patients having DDD at one or two contiguous levels from L2-S1 with up to Grade 1 spondylolisthesis or as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

Contraindications

• The STRUXXURE®-A Plate 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.

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 STRUXXURE®-A Plate 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.
5. These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.
6. The STRUXXURE®-A Plate System is used to augment the development of a spinal fusion by providing temporary stabilization. This device is not intended to be the sole means of spinal support. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant.

INDICATIONS (CONT)

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 manufacturer.

10. Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.

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

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

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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.

71-047, Rev A