Nexxt Spine

Surgical Technique Guide

STRUXXURE® MCS

MODULAR CERVICAL SYSTEM

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

71-059, Rev F

Table of Contents

Indications and Contraindications 3

Warnings and Precautions 4

STRUXXURE® MCS System Introduction 5

Surgical Technique Steps

1. Patient Positioning 7
2. Exposure Of Operative Levels 7
3. Discectomy 7
4. Endplate Preparation 8
5. Implant Size Selection 8

6a. Implant Placement - Plate Only 9

- 1a. Plate Placement 9
- 2a. Screw Hole Preperation 9
- 3a. Screw Placement 10
- 4a. Screw Locking 10
- 5a. Screw Removal/Construct Revision 10

6b. Implant Placement - Plate and Cage Assembly 12

- 1b. Plate and Cage Placement 12
- 2b. Screw Hole Preperation 12
- 3b. Screw Placement 13
- 4b. Screw Locking 13
- 5b. Screw Removal/Construct Revision 13

7. Optional Construct Inserter Post - Small 14
8. Tamping 15

STRUXXURE® MCS Instrument Part Numbers 16

STRUXXURE® MCS Implant Part Numbers 17

Compatible Nexxt Spine Systems 18

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.

Indications for Use

GENERAL DESCRIPTION

The Struxxure® Anterior Cervical Plate System consists of fixed and variable angle screws of Ø4.0mm and Ø4.35mm diameters with self-drilling and tapping tips. Overall length of screws range from 10mm-20mm. Plates are offered from 1 to 5 levels. The Struxxure® system surgical technique is available at no charge upon request. For further information, please contact Customer Service at 317-436-7801.

MATERIALS

All components are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136 and commercially pure titanium (Grade 4) per ASTM F67.

INDICATIONS

The Struxxure® Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion.

Indications for the use of this implant system include degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion.

CONTRAINDICATIONS

Use of the Struxxure® Anterior Cervical Plate System and spinal fixation surgery are contraindicated when there was recent or local active infection near or at the site of the proposed implantation. Any conditions that preclude the possibility of fusion are relative contraindications. These include but are not limited to: cancer, fever, mental illness, alcoholism or drug abuse, osteoporosis or osteopenia, neurotrophic diseases, obesity, pregnancy and foreign body sensitivity. See also the WARNINGS, PRECAUTIONS AND POTENTIAL RISKS sections of this insert.

IMPORTANT NOTE TO OPERATING SURGEON

The Struxxure® Anterior Cervical Plate System is designed to provide biomechanical stabilization as an adjunct to fusion in skeletally mature patients. Spinal fixation should only be undertaken after the surgeon has had hands on training in this method of spinal fixation and has become thoroughly knowledgeable about spinal anatomy and biomechanics. A surgical technique is available for instruction on the important aspects of this surgical procedure and can be requested from Nexxt Spine at the address or phone number below.

Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential adverse effects of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

Postoperative evaluation of the fusion and implant status is necessary. The surgeon may remove the implant once a solid fusion is obtained. The patient must be informed of the potential of this secondary surgical procedure and the associated risks.

MRI SAFETY INFORMATION

The Struxxure Anterior Cervical Plate System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Struxxure Anterior Cervical Plate System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

CLEANING AND DECONTAMINATION

All implants and instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Refer to the Nexxt Spine Reprocessing Instructions for Reusable Instruments document available at www.NexxtSpine.com/Resources/Indications-For-Use or by calling 317-436-7801 for a copy of the detailed cleaning instructions.

STERILIZATION

The Struxxure® Anterior Cervical Plate System components are supplied clean and not sterile. All implants and instruments should be cleaned and sterilized prior to surgery. AORN recommended practices for in hospital sterilization should be followed. The use of an FDA cleared sterilization wrap is recommended.

Sterilization testing of components has shown the following recommendations for sterilization are effective to an SAL of 10-6:

Method:	Steam
Cycle:	Prevaccum
Temperature:	270°F (132°C)
Exposure Time:	4 minutes
Drying Time:	30 minutes

NOTE: Instruments that may have been exposed to Creutzfeldt-Jakob disease (CJD) should be treated according to the hospital's prior decontamination protocol. Nexxt Spine recommends contacting the Center for Disease Control and the World Health Organization for the most recent information on CJD transmission and deactivation

Indications for Use

WARNINGS

1. The Struxxure® Anterior Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
2. 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.
3. The Struxxure® Anterior Cervical Plate System has not been tested for heating or migration in the MR environment. See the Potential Risks section of the package insert for a complete list of potential risks.

PRECAUTIONS

1. **PATIENT SELECTION.** Proper patient selection is critical to the success of the procedure. Only patients who satisfy the criteria set forth under the INDICATIONS section of this document AND who do not have any of the conditions set forth under the CONTRAINDICATIONS section of this document should be considered for spinal fixation surgery using the Struxxure® System. In addition, patients who smoke have been shown to have an increased incidence of pseudarthrosis. Based upon the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.
2. **PATIENT EDUCATION**. Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.
3. **HANDLING.** Implant components should be handled and stored appropriately to protect them from unintentional damage. The surgeon should avoid introducing notches or scratches into the plate or screw surfaces as these may induce premature failure of the component.
4. **IMPLANT SELECTION.** The Struxxure® System components are available in a variety of sizes to insure proper fit of the implanted device. The potential for the success of the fusion is increased by selecting the correct size of the implant. These devices are not intended to be used as the sole support for the spine.
5. **MIXED METALS**. The Struxxure® System is available in titanium. It is imperative that this metal does not come into contact in vivo with other dissimilar metals. Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment.
6. **SINGLE USE ONLY.** These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.
7. **DELAYED UNION OR NONUNION.** The Struxxure® System is designed to assist in providing an adequate biomechanical environment for fusion. It is not intended to be and must not be used as the sole support for the spine. If a delayed union or nonunion occurs the implant may fail due to metal fatigue. Patients should be fully informed of the risk of implant failure.

POTENTIAL RISKS Potential risks identified with the use of this system, which may require additional surgery, include: Bending, fracture or loosening of implant component(s), Nonunion or delayed union, Fracture of the vertebra, Neurological, vascular or visceral injury, Metal sensitivity or allergic reaction to a foreign body, Infection, Decrease in bone density due to stress shielding, Pain, discomfort or abnormal sensations due to the presence of the device, Nerve damage due to surgical trauma, Bursitis, Dural Leak, Paralysis, Death.

PRODUCT COMPLAINTS The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Nexxt Spine immediately. Nexxt Spine should be notified immediately of any product malfunction by telephone, fax or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

MANUFACTURED BY:

Nexxt Spine, LLC
14425 Bergen Blvd, Suite B
Noblesville, IN 46060
Telephone: (317) 436-7801
Fax: (317) 245-2518
www.NexxtSpine.com

Product Specifications and Features

The STRUXXURE® MCS Anterior Cervical Plating system provides the surgeon three unique plates designed to meet the needs of the patient's anatomy and surgeon's surgical goals. STRUXXURE® MCS utilizes the proven technology of the STRUXXURE® ACP instrumentation and screw options for a streamlined approach to anterior cervical procedures.

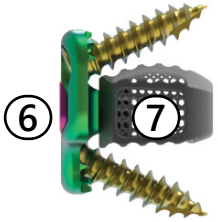


Key Features

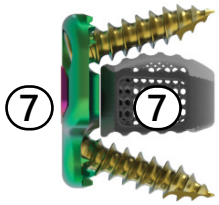
- Multiple plate configurations allows the surgeon to tailor the implant to the surgical needs of the patient's pathology.
- Ability to place the plate after interbody insertion or simultaneously with unique insertion instrumentation.
- Increased cephalad and caudal variable screw angulation of 14-26° allows for placement close to the endplate reducing required plate length and adjacent level impingement.
- Width and thickness of the plate designed to minimize working portal requirements.
- Single T10 for screw insertion and locking mechanism increases surgical efficiency and decreases instrument requirements.

Screw Angulation

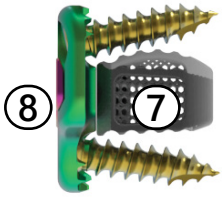
Assuming a 7mm Cage, these are the screw angulations based on a chosen plate size.
Convexx™ anatomic cages share the same angulation as standard Cervical cages.



Variable: 22° to 26°
Fixed: 22°



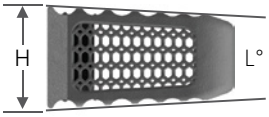
Variable: 14° to 26°
Fixed: 14° to 22°



Variable: 10° to 26°
Fixed: 10° to 22°

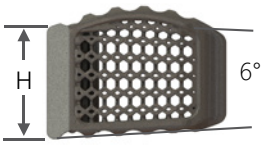
Cervical Interbodies

Nexxt Matrixx® Cervical

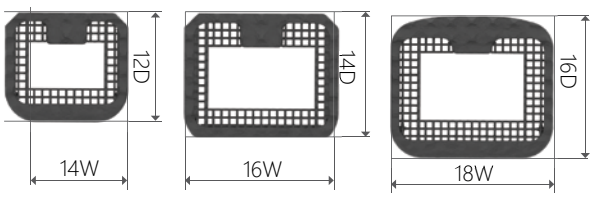


D x W (mm)	Heights (mm)	Lordosis
12 x 14	5-10, 11-18	0°, 6°, 10°
14 x 16	5-10, 11-18	0°, 6°, 10°
16 x 18	5-10, 11-18	0°, 6°, 10°

Nexxt Matrixx® CONVEXX™



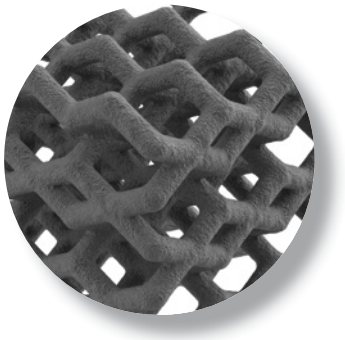
D x W (mm)	Heights (mm)	Lordosis
12 x 14	5-10, 11-12	6°
14 x 16	5-10, 11-12	6°
16 x 18	5-10, 11-12	6°



*Some footprints only availably By Request.
Contact **Info@NexxtSpine.com** for full SKU.

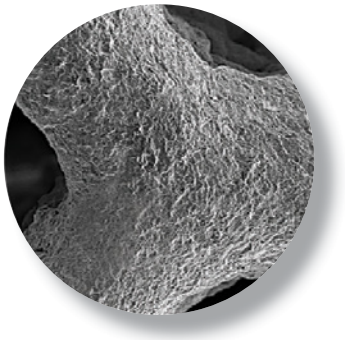
NEXXT MATRIXX® Technology

10X



Interconnected Titanium
PORES

300X



Uncompromising
MACROSURFACE

10,000X

7µm Roughened
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 by reducing overall titanium material and device density.[6]

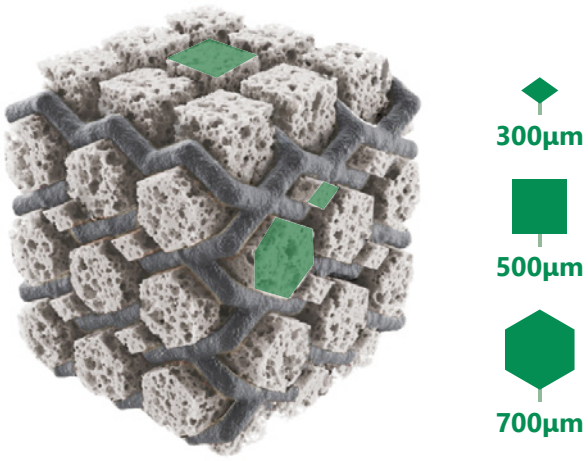


Image represents potential volume for bony in-growth

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.

Surgical Steps

1. PATIENT POSITIONING

Following adequate general anesthesia, the patient is placed in the supine position with the head in slight extension (Fig. 1.1). The mandible is tilted out of the surgical field. The posterior cervical spine is supported to establish and maintain normal lordosis.

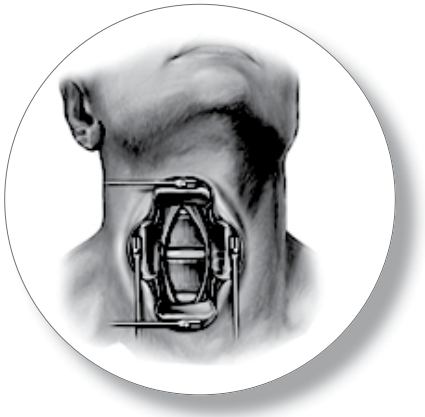


Figure 1.1

2. 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(s) and confirm the correct operative level(s) using a lateral radiograph (Fig. 2.1).

NOTE: *NEXXT MATRIXX® Cervical Interbodies are indicated for use at up to two contiguous levels in the cervical spine from C2-T1.*

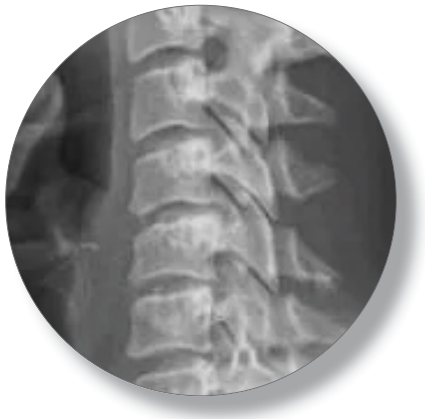


Figure 2.1

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 (Fig. 3.1). The posterior longitudinal ligament may be removed to access and remove any disc material that may be pressing on the neural elements.

NOTE: *Adequate preparation of the endplates is critical in facilitating vasular supply to promote fusion. Pre-operative and intraoperative fluoroscopic evaluation should be utilized for both NEXXT MATRIXX® Cervical or Convexx interbody devices.*

WARNING: *Excessive removal of subchondral bone during endplate preparation may weaken the bone, resulting in subsidence and/or segmental instability.*

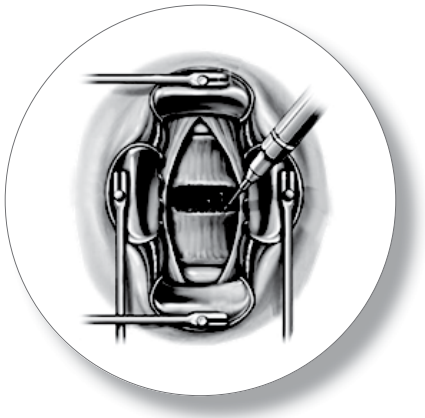


Figure 3.1

4. ENDPLATE PREPARATION

Rasps can be used sequentially, in 1mm increments, to remove the superficial layer on the endplates (Fig. 4.1). This will aid in creating bleeding bone to promote spinal fusion. Appropriate endplate preparation will optimize surface contact with the selected interbody.

NOTE: *It is not recommended to utilize the Rasp with the MATRIXX® CONVEXX™ device. Minimal manipulation of the endplate and retention of the natural morphology is important to maintain apposition of the device and the endplate.*

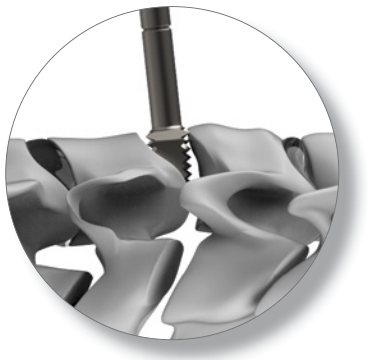


Figure 4.1

5. IMPLANT SIZE SELECTION

Selection of the Trial depends on the height, width, and depth of the intervertebral space. Based on pre-operative imaging and surgical technique, select a Trial of appropriate height (Fig. 5.1).

Each Trial is color coded to differentiate height and should be used incrementally to determine the appropriate dimensions of the interbody required (Fig. 5.2).

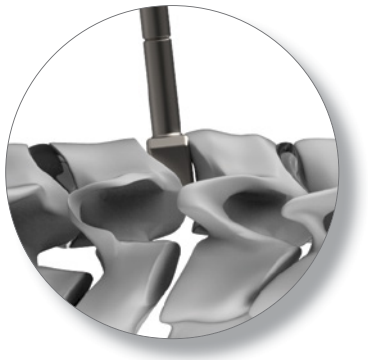


Figure 5.1

NOTE:

- Rasp and Trial sizes (W x D x H) are a line-to-line match to the corresponding interbody.
- Standard Angulation (Lordosis) of Rasps, Trials and corresponding interbodies is 6° (Optional 0° and 10°)
- The NEXXT MATRIXX Convexx™ cages and 6° Convexx trials are designed to be used exclusively together.
- All labeled heights are measured from the area representing the highest point on the anterior wall of the implant.

Figure 5.2

Plate Trialing

Depending on patient anatomy, use of Caspar Pins, or presense of adjacent-level plates, Plate Trials are designed to aid in plate placement and assist operative planning in a confined surgical area (Figure 5.3).

Thread the Plate Inserter into the desired Plate Trial from the Plate Trial Caddy. Use the assembled trial to plan the position of the MCS Plate by verifing spacing with anatomy, implants, and instruments.

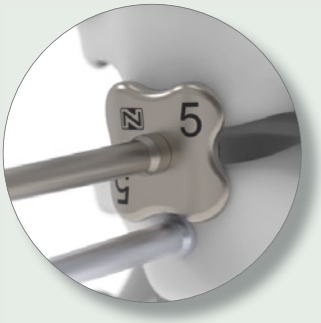


Figure 5.3

6a. IMPLANT PLACEMENT - Plate Only

The following steps outline traditional plate placement and insertion to an already existing cage. For assembled plate and cage instructions, please refer to Section 6b, Implant Placement - Plate and Cage Assembly. Refer to the NEXXT MATRIXX Cervical Surgical Technique Guide for insertion and positioning of the cage (Document 70-040).

1a. Plate Placement
Selection of the STRUXXURE MCS plate size is determined by the cage height to ensure that screw placement is close to the endplates without impinging on the borders of the cage.

Attach the Plate Inserter to the central threaded hole of the selected plate (Fig. 6a.1). Attachment can be accomplished by placing the plate on a flat surface or the Loading Block to prevent slipping of the plate.

Ensure proper anterior surface preparation has been performed to remove any large osteophytes.

Place the place onto the cervical spine and verify visually that the screw holes are not obscured by the previously placed cage (Fig. 6a.2). Under fluoroscopic guidance, verify rotation of the plate, and reposition if required.

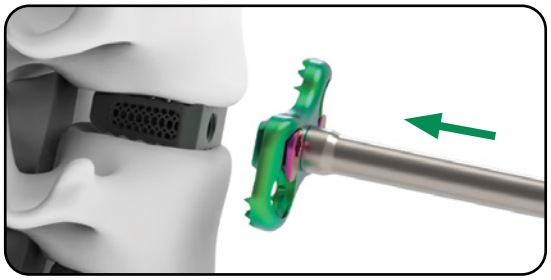


Figure 6a.1

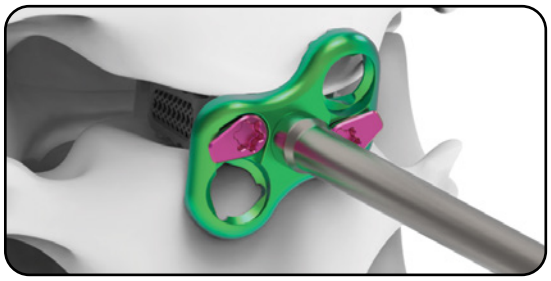


Figure 6a.2

2a. Screw Hole Preparation
Surgeon should verify via lateral fluoroscopy that cephalad or caudal trajectory will maintain angulation to clear the endplates and cage. Corresponding Plate and Cage angulations can be found on page 5.

Option 1: The Self-Drilling screws can be placed without the need of a pilot hole created by an Awl or Drill (Fig. 6a.3). Ensure that the Self Drilling Screws are in the center of the plate holes to prevent impingement on the cage.

Option 2: Screw holes can be created with a Spring Loaded Awl (Fig. 6a.4). The distal tip of the instrument has a guided tip to seat into the plate's screw hole and can pivot to desired trajectory. The Spring Loaded Awl will prepare a 9mm deep hole in the cervical body

Option 3: Screw holes can be created with a Drill or 10mm Awl and a Single Barrel Drill Guide that has a guided tip to seat into the plate's screw hole. The Single Barrel Drill Guide can pivot to desired trajectory.

The Fixed Depth Drills and 10mm Awl should be attached to the Axial AO Handle prior to use.

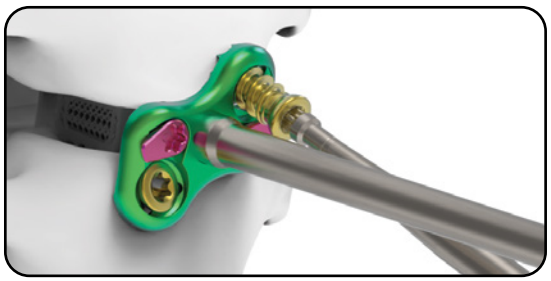


Figure 6a.3

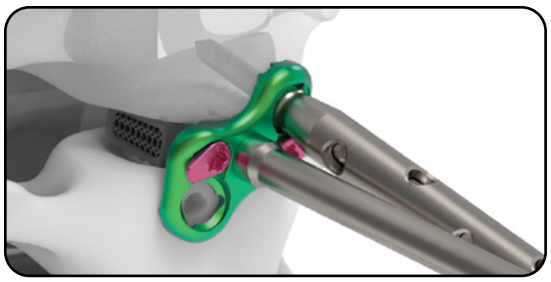


Figure 6a.4

6a. PLATE PLACEMENT - Plate Only (cont.)

3a. Screw Placement

Use the T10 Screw Inserter to load the desired Screw by "stabbing and grabbing" them from the provided implant caddy. Length of Screw can be confirmed via color coding or manual measurement gage on the Screw Caddy.

NOTE: *THR Screws utilize an internal thread for fixation, and require the optional THR Screw Inserter.*

CAUTION: *Review reference image for screw lengths depending on interbody length/depth (Fig. 6a.5).*

Implant the Screws into prepared holes in the vertebral body using an alternating pattern until the screws are fully seated within the implant (Fig. 6a.6.) Remove the Plate Inserter and T10 Screw Inserter after screw insertion (Fig. 6a.7).

TIP: *If the plate does not sit flush to the vertebral body, check for osteophytes and vertebral body misalignment. In some cases sequentially provisionally tightening the screws can be done to lag the plate to the vertebral bodies.*

NOTE: *When utilizing the 3-Hole Plate it is recommended to place the screw in the single hole side of the implant to reduce toggle and maintain central positioning of the construct.*

4a. Screw Locking

Use the T10 Screw Inserter to rotate the magenta locking mechanism over the proximal head of the screws. Torque required to rotate the mechanism is minimal so if resistance is encountered, verify that the Screw has been fully seated within the plate.

Different Plate geometries may have single or paired locking mechanisms. Refer to the images below for variations in the 2-Hole, 3-Hole, and 4-Hole options (Fig. 6a.8).

Using fluoroscopy, verify final anterior/posterior and lateral positioning is satisfactory

5a. Screw Removal/Construct Revision

Place T10 Screw Inserter into the mating hole in the center of the locking cam and rotate the lock to its original position such that the screw holes are no longer blocked.

Use a Screw Removal Instrument by inserting and turning counterclockwise or press the tip of the Inserter into the hexalobe feature of the screw head and turn screw(s) in a counterclockwise direction for removal.

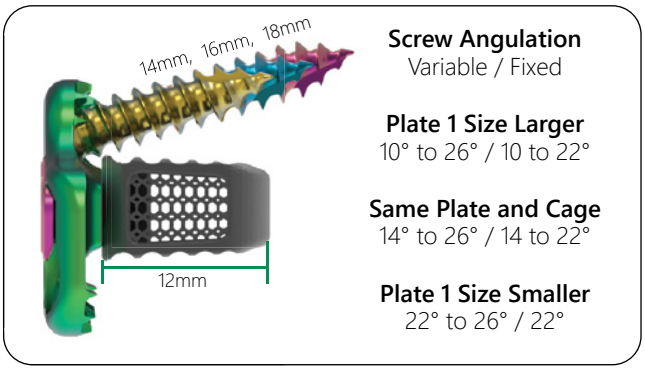


Figure 6a.5

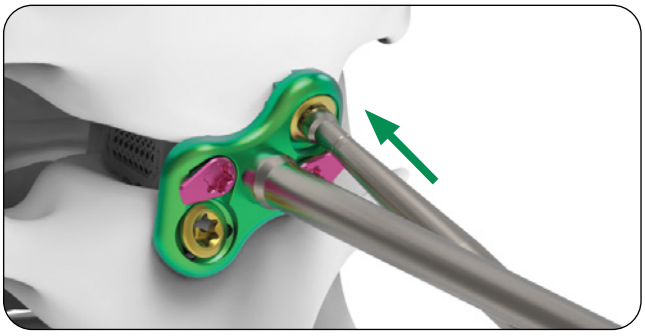


Figure 6a.6

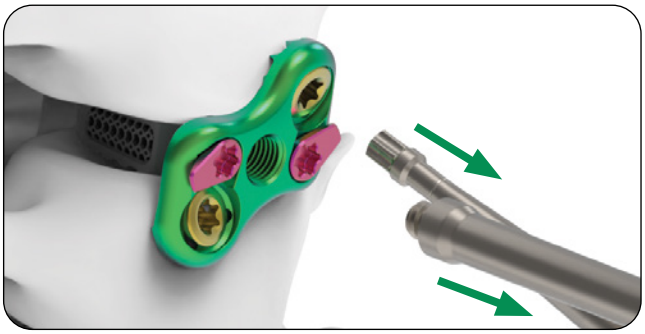


Figure 6a.7

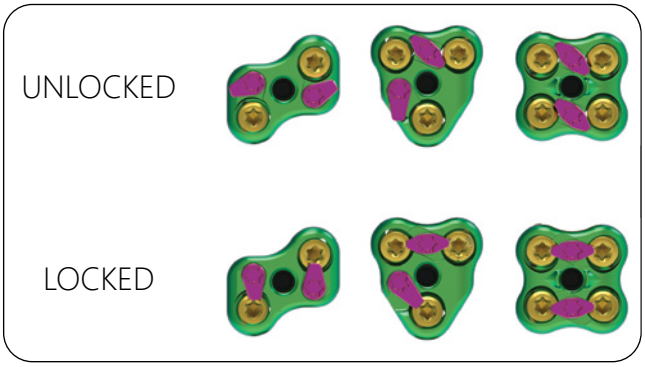


Figure 6a.8

6b. IMPLANT PLACEMENT - Plate and Cage Assembly

The following steps outline insertion of the plate to the cage as an assembly. This plate and cage will be temporarily mated for insertion, but then detached once screw insertion is complete. Refer to the NEXXT MATRIXX Cervical Surgical Technique Guide for insertion and positioning (Document 70-040).

1a. Plate and Cage Placement
Selection of the STRUXXURE MCS plate size is determined by the cage height to ensure that screw placement is close to the endplates without impinging on the borders of the cage.

Assemble the Construct Inserter to the Construct Inserter Post. Pull back on the outer shaft of the Construct Inserter and insert the Construct Inserter Post until it seats flush (Fig. 6b.1). The Construct Inserter Post has hex geometry that mates and prevents rotation when properly assembled.

NOTE: *A low profile Construct Insterter Post is available as an option. For details, see* *Section 8 - Optional Short Construct Inserter Post.*

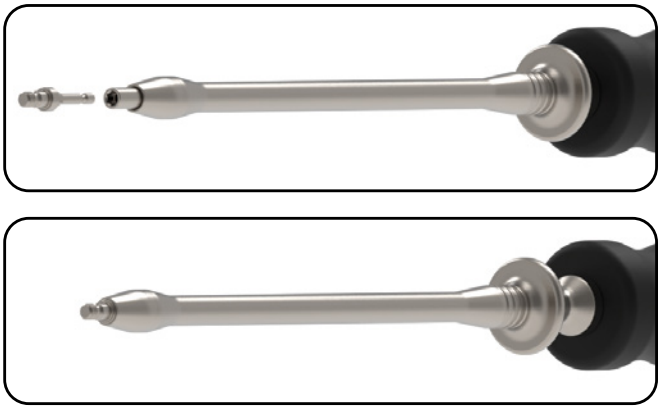


Figure 6b.1

Insert the MATRIXX Cervical Cage into the appropriately sized recess in the Loading Block with the anterior face of the cage facing out so it can be secured to the plate and Construct Inserter (Fig. 6b.2).

Figure 6b.2

Select the appropriate plate design and size, which corresponds to the height of the cage. The plate should seat into the recess on top of the previously placed cage. Verify visually that the central hole of the cage can be seen thru the central hole of the plate.

Thread the assembled Construct Inserter thru the central hole of the plate and into the cage (Fig. 6b.3). The Construct Inserter is designed to only thread into the cage. Remove the assembled implants and instrument from the loading caddy and verify that the implants are securely seated with no toggle (Fig. 6b.4).

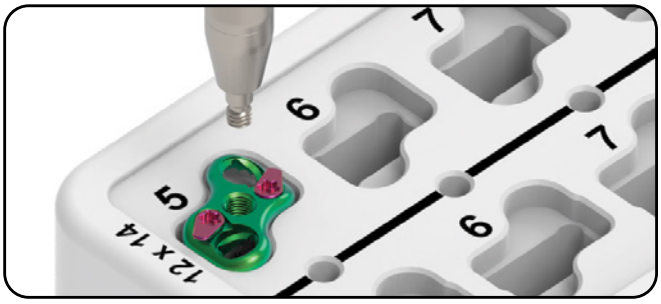


Figure 6b.3

NOTE: *CONVEXX cages and Honour® PEEK cages must be inserted into the loading block indicated 1 size larger than the implant height. Example: A 5mm tall Convexx cage will fit in the loading block "6" slot.*

NOTE: *If implanting a CONVEXX domed cage, implant orientation must be placed so the domed endplate is facing cranially.*

NOTE: *The STRUXXURE MCS Plates can be assembled in either a cranial or caudal orientation to NEXXT MATRIXX Cervical cages.*

Ensure proper anterior surface preparation has been performed to remove any large osteophytes.

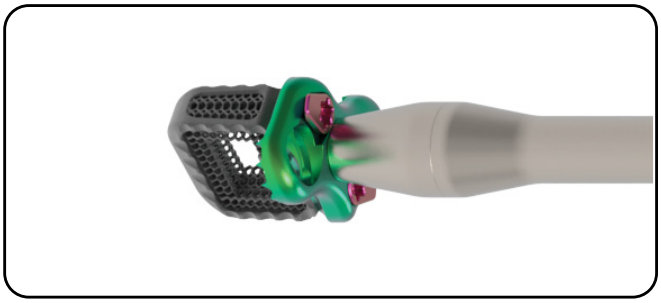


Figure 6b.4

6b. IMPLANT PLACEMENT - Plate and Cage Assembly (cont.)

Place the assembled construct onto the cervical spine and verify visually that the screw holes will allow for placement into the vertebral body and the cage will enter the disc space unimpeded (Fig. 6b.5). Tamp Construct Inserter to seat the cage and plate construct.

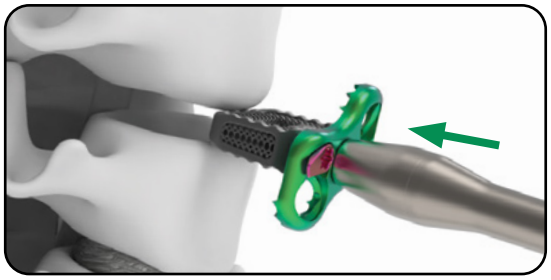


Figure 6b.5

Under fluoroscopic guidance, verify rotation of the plate, and reposition if required. Once the implants are properly positioned with the plate against the spine, remove the Construct Insert leaving the Construct Inserter Post in place (Fig. 6b.6). This will maintain proper positioning of the plate and cage during screw placement.

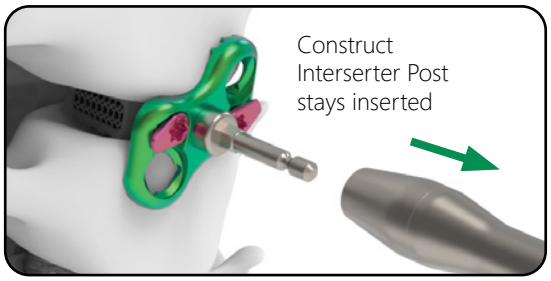


Figure 6b.6

NOTE: *If anatomy dictates, surgeon may prefer to remove Construct Inserter and Construct Inserter Post after implant placement. Sloped anterior cortex may require the cage to be positioned off angle from the trajectory of the disc space.*

TIP: *If the plate does not sit flush to the vertebral body, check for osteophytes and vertebral body misalignment. In some cases sequentially provisionally tightening the screws can be done to lag the plate to the vertebral bodies.*

2a. Screw Hole Preperation

Surgeon should verify via lateral fluoroscopy that cephalad or caudal trajectory will maintain angulation to clear the endplates and cage. Corresponding Plate and Cage angulations can be found on page 5.

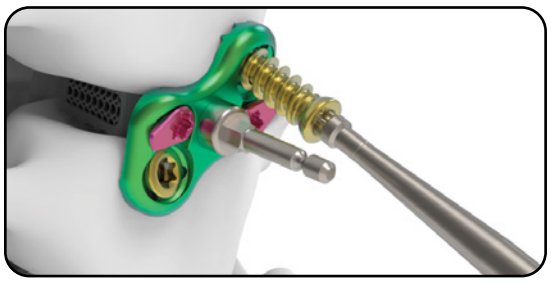


Figure 6b.7

Option 1: The Self-Drilling screws can be placed without the need of a pilot hole created by an Awl or Drill (Fig. 6b.7). Ensure that the Self Drilling Screws are in the center of the plate holes to prevent impingement on the cage.

Option 2: Screw holes can be created with a Spring Loaded Awl (Fig. 6b.8). The Distal tip of the instrument will seat into the plate hole ensuring concentric placement of the hole. The Spring Loaded Awl will prepare a 9mm deep hole into the cervical body.

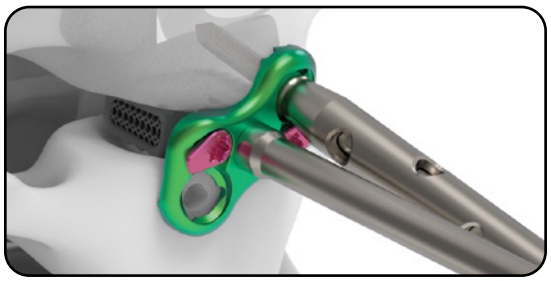


Figure 6b.8

Option 3: Screw holes can be created with a Drill or 10mm Awl and a Single Barrel Drill Guide that has a guided tip to seat into the plate's screw hole. The Single Barrel Drill Guide can pivot to desired trajectory.

The Fixed Depth Drills and 10mm Awl should be attached to the Axial AO Handle prior to use.

6b. IMPLANT PLACEMENT - Plate and Cage Assembly (cont.)

3a. Screw Placement

Use the T10 Screw Inserter to load the desired Screw by "stabbing and grabbing" them from the provided implant caddy. Length of Screw can be confirmed via color coding or manual measurement gage on the Screw Caddy.

NOTE: *THR Screws utilize an internal thread for fixation, and require the optional THR Screw Inserter.*

CAUTION: *Review reference image for screw lengths depending on interbody length/depth (Fig. 6b.9).*

TIP: *If the plate does not sit flush to the vertebral body, check for osteophytes and vertebral body misalignment. In some cases, sequentially provisionally tightening the screws can be done to lag the plate to the vertebral bodies.*

Implant the Screws into prepared holes in the vertebral body using an alternating pattern until the screws are fully seated within the plate (Fig. 6b.10).

Reattach the Construct Inserter Post to the Construct Inserter and remove to unmate the implants (Fig. 6b.11).

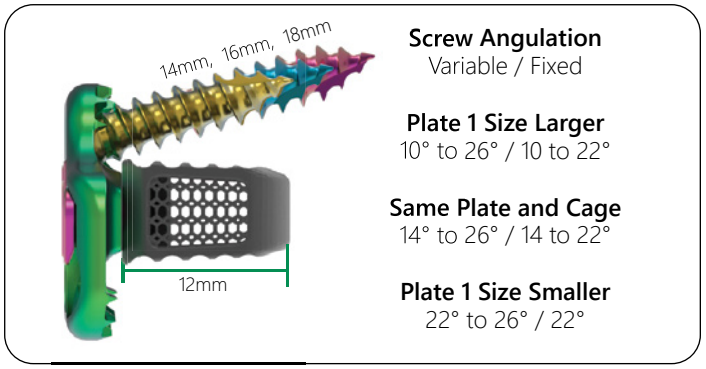


Figure 6b.9

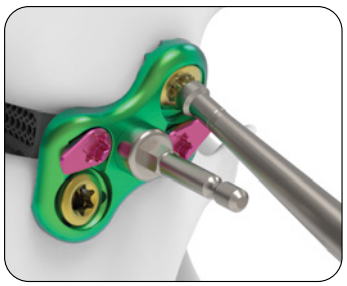


Figure 6b.10

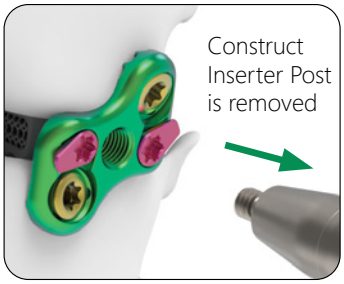


Figure 6b.11

Alternate Screw Placement - Plate Lagging

If placing the plate flush against the vertebral body is difficult due to the plate angulation being locked by the Constuct Inserter Post, an alternate screw insertion procedure may be used to lag the plate into a desired position.

When inserting the screws, pause after reaching approximately 75% insertion depth. With the plate now loosely supported by the screws, remove the Construct Inserter Post (Figure 6b.12).

With the Construct Inserter Post removed, the plate is no longer locked perpindicular to the cage and is free to toggle. The plate can now be lagged flush to the vetebral body by inserting the screws to full depth (Figure 6b.13).

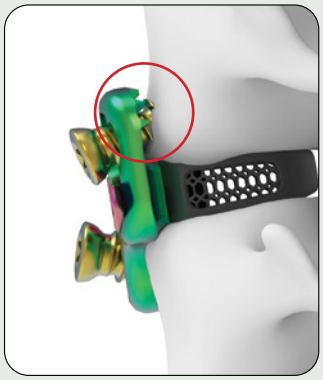


Figure 6b.12
Large space between the top of the plate and veterbral body.

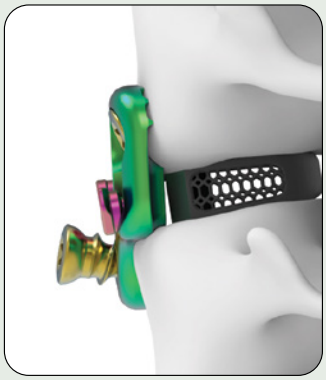


Figure 6b.13
Plate can lag seperately from the cage until flush.

6b. IMPLANT PLACEMENT - Plate and Cage Assembly (cont.)

4a. Screw Locking
Use the T10 Screw Inserter to rotate the magenta locking mechanism over the proximal head of the screws. Torque required to rotate the mechanism is minimal so if resistance is encountered, verify that the Screw has been fully seated within the plate.

Different Plate geometries may have single or paired locking mechanisms. Refer to the images for variations in the 2-Hole, 3-Hole, and 4-Hole options (Fig. 6b.14).

Using fluoroscopy, verify final anterior/posterior and lateral positioning is satisfactory

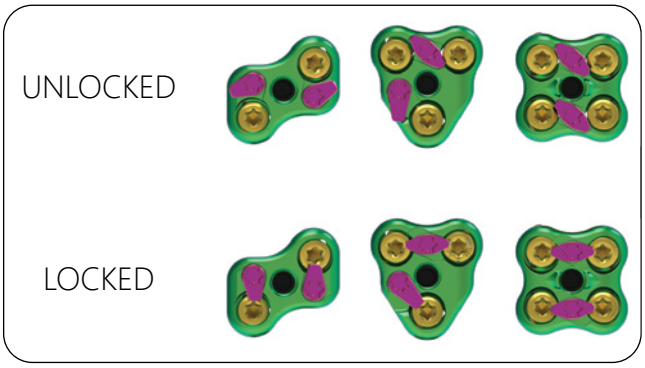


Figure 6b.14

5a. Screw Removal/Construct Revision
Place T10 Screw Inserter into the mating hole in the center of the locking mechanism and rotate the lock to its original position such that the screw holes are no longer blocked.

Use a Screw Removal Instrument by inserting and turning counterclockwise or press the tip of the Inserter into the hexalobe feature of the screw head and turn screw(s) in a counterclockwise direction for removal (Figure 6b.15).

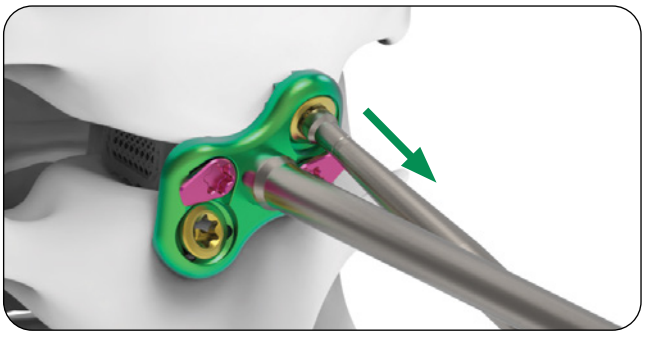


Figure 6b.15

7. OPTIONAL SMALL CONSTRUCT INSERTER POST

If a low profile alternative to the Construct Inserter Post is desired, the optional Construct Inserter Post - Small, can be utilized. (Figure 7.1). This optional shortened post must be specifically ordered and used exclusively with the Struxxure Threaded Inserter.

NOTE: *The Struxxure Threaded Inserter is only standard in Threaded Screw (THR) sets.*

NOTE: *Do not implant the Small Construct Inserter Post..*

After threading the Construct Inserter Post - Small onto the Struxxure Threaded Inserter, all operative steps follow the same procedure as outlined in Section 6b, Implant Placement - Plate and Cage Assembly, but the Struxxure Threaded Inserter is used instead of the Construct Inserter (Figure 7.2).

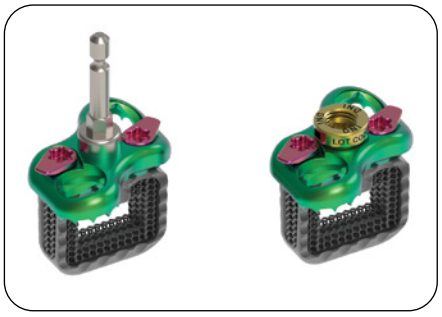


Figure 7.1

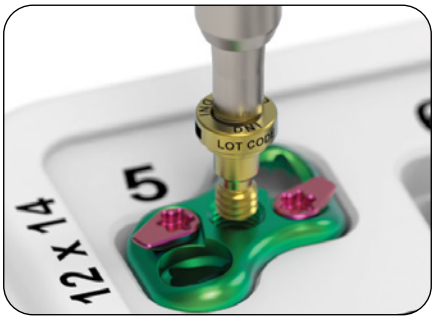


Figure 7.2

8. TAMPING

If additional implant depth is required, the cage can be tamped 2mm through the central hole of any MCS plate using the 2mm MCS Tamp (Figure 8.1). The tamp will engage with the anterior face of the cage and will reach a hard stop against the plate when 2mm of cage displacement has been achieved.

Figure 8.1

Insert the 2mm MCS Tamp through the central hole of the MCS plate and into the screw pocket of the implant (Figure 8.2). Verify planned final implant placement under fluoroscopy.

NOTE: *The tamp does not feature threads and will not screw into the implant.*

NOTE: *Combined with the 2mm boss from the MCS plate, the maximum implant displacement from the vertebra's anterior face is 4mm.*

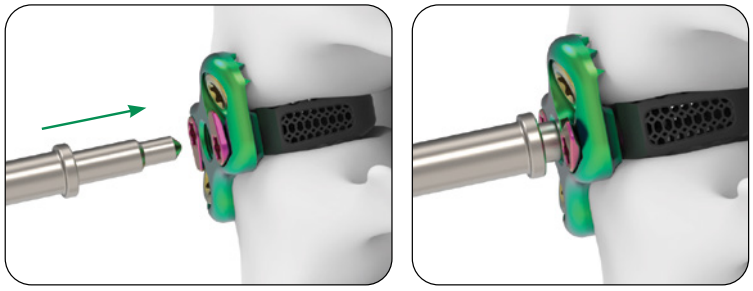


Figure 8.2

Tamp on the implant until desired positioning is achieved. The instrument will hit a hard stop against the plate when the maximum displacement of 2mm has been achieved (Figure 8.3). Remove the instrument and verify plate and cage positoning before proceeding with closure.

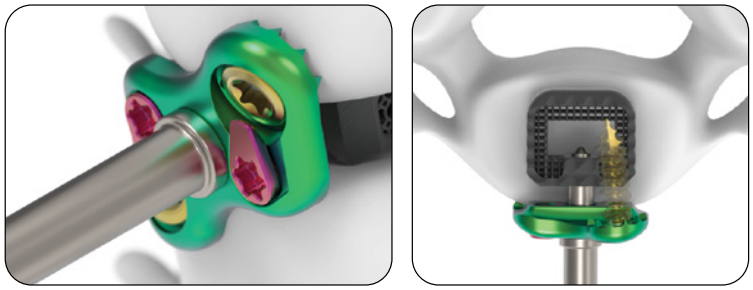


Figure 8.3

INSTRUMENT PART NUMBERS

Single Barrel Variable Guide

Standard P/N	Description
I31-14-03L	Struxxure, Single Barrel, Long

Struxxure Screw Inserter

Standard P/N	Description
I31-02-14	Screw Inserter, T10

Awls

Standard P/N	Description
I31-13-01	10mm Small AO Awl
I33-02-01	Punch Awl

Struxxure MCS Tamp

Standard P/N	Description
I33-01-05	Struxxure MCS 2mm Tamp

Plate Trials

Standard P/N	Description
I33-2PT-XX	2-Hole Plate Trial, Size XX
I33-3PT-XX	3-Hole Plate Trial, Size XX
I33-4PT-XX	4-Hole Plate Trial, Size XX

Construct Inserter

Standard P/N	Description
I33-01-01	Construct Inserter
I33-01-02	Construct Inserter Post

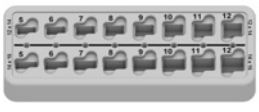
Plate Inserter

Standard P/N	Description
I33-01-03	Plate Inserter

Ø3.5mm Tap

Standard P/N	Description
I31-07-01	Ø3.5mm Tap

Loading Blocks



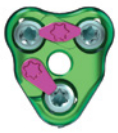
Standard P/N	Description
I33-03-02	2-Hole Plate Loading Block
I33-03-03	3-Hole Plate Loading Block
I33-03-04	4-Hole Plate Loading Block

Drills

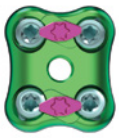
Standard P/N	Description
I31-06-12	Ø12mm Drill
I31-06-14	Ø14mm Drill
I31-06-16	Ø16mm Drill

IMPLANT PART NUMBERS

Standard P/N	Description	QTY
Struxxure MCS 2-Hole Plate		
33-02-05	2 Hole Plate, Size 5	3
33-02-06	2 Hole Plate, Size 6	3
33-02-07	2 Hole Plate, Size 7	3
33-02-08	2 Hole Plate, Size 8	3
33-02-09	2 Hole Plate, Size 9	3
33-02-10	2 Hole Plate, Size 10	3



Standard P/N	Description	QTY
Struxxure MCS 3-Hole Plate		
33-03-05	3 Hole Plate, Size 5	3
33-03-06	3 Hole Plate, Size 6	3
33-03-07	3 Hole Plate, Size 7	3
33-03-08	3 Hole Plate, Size 8	3
33-03-09	3 Hole Plate, Size 9	3
33-03-10	3 Hole Plate, Size 10	3



Standard P/N	Description	QTY
Struxxure MCS 4-Hole Plate		
33-04-05	4 Hole Plate, Size 5	3
33-04-06	4 Hole Plate, Size 6	3
33-04-07	4 Hole Plate, Size 7	3
33-04-08	4 Hole Plate, Size 8	3
33-04-09	4 Hole Plate, Size 9	3
33-04-10	4 Hole Plate, Size 10	3

Standard P/N	Description	QTY
Struxxure Self-Drilling, Variable		
31-6-4012	Ø4.0 x 12mm	8
31-6-4014	Ø4.0 x 14mm	8
31-6-4016	Ø4.0 x 16mm	8
31-6-4018	Ø4.0 x 18mm	4
31-6-4312	Ø4.35 x 12mm	2
31-6-4314	Ø4.35 x 14mm	2
31-6-4316	Ø4.35 x 16mm	2
31-6-4318	Ø4.35 x 18mm	2

Standard P/N	Description	QTY
Struxxure Self-Drilling, Fixed		
31-7-4012	Ø4.0 x 12mm	8
31-7-4014	Ø4.0 x 14mm	8
31-7-4016	Ø4.0 x 16mm	8
31-7-4018	Ø4.0 x 18mm	4
31-7-4312	Ø4.35 x 12mm	2
31-7-4314	Ø4.35 x 14mm	2
31-7-4316	Ø4.35 x 16mm	2
31-7-4318	Ø4.35 x 18mm	2

Standard P/N	Description	QTY
Struxxure Self-Tapping, Variable		
31-8-4012	Ø4.0 x 12mm	8
31-8-4014	Ø4.0 x 14mm	8
31-8-4016	Ø4.0 x 16mm	8
31-8-4018	Ø4.0 x 18mm	4
31-8-4312	Ø4.35 x 12mm	2
31-8-4314	Ø4.35 x 14mm	2
31-8-4316	Ø4.35 x 16mm	2
31-8-4318	Ø4.35 x 18mm	2

Standard P/N	Description	QTY
Struxxure Self-Tapping, Fixed		
31-9-4012	Ø4.0 x 12mm	8
31-9-4014	Ø4.0 x 14mm	8
31-9-4016	Ø4.0 x 16mm	8
31-9-4018	Ø4.0 x 18mm	4
31-9-4312	Ø4.35 x 12mm	2
31-9-4314	Ø4.35 x 14mm	2
31-9-4316	Ø4.35 x 16mm	2
31-9-4318	Ø4.35 x 18mm	2

COMPATIBLE NEXXT SPINE SYSTEMS

SAXXONY®
Posterior Cervical Screw System

NEXXT MATRIXX®
SA Cervical

NEXXT MATRIXX®
Corpectomy

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

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

71-059, Rev F