Spine Spine

Surgical Technique Guide 70-024, Rev. F

# **STRUXXURE®** Anterior Cervical Plate System



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

Anterior Cervical Plate System

## SYSTEM INTRODUCTION

# STRUXXURE® Anterior Cervical Plate System

Designed for Maximum Screw Angulation to Decrease Plate Length and Potential for Adjacent Level Ossification (ALO)

The Struxxure<sup>®</sup> Anterior Cervical Plate System design is based upon an emerging trend in the peer-reviewed literature identifying a significant decrease in moderate to severe ALO when the plate to disc distance is greater than 5mm from the adjacent disc level.<sup>1-5</sup>

Struxxure<sup>®</sup> has a generous 27° variable screw angulation in the cephalad/caudal direction, allowing screws to be started at the anterior end plate corners and angled away from the end plates to accommodate the shortest possible plate and maximize the distance to adjacent disc levels.

Struxxure<sup>®</sup> is the only system combining a 1.95mm ultra-low profile plate with variable or fixed "E-Z Start" Self-Drilling Screws that can be hyperangulated in the cephalad/caudal direction to allow for a reduction in overall plate length.

One level plate lengths begin at 9mm measured hole-to-hole. The result is an anterior cervical plate construct of minimal length and thickness, while maintaining a maximum distance from the adjacent disc levels.

Combined with fully customizable instrument options to meet every surgeon's needs, Nexxt Spine's Struxxure® Anterior Cervical Plate System is designed to address a clinically relevant concern while maintaining a focus on streamlined procedural efficiency and positive clinical outcomes.



### References

The aforementioned published papers and poster did not utilize the Struxxure<sup>®</sup> System and findings are not necessarily indicative of results with the Struxxure<sup>®</sup> System.

### **STRUXXURE®** Anterior Cervical Plate System

<sup>1.</sup> Kim, HJ, Kelly, MP, Ely, CG, Riew, KD, Dettori, JR. The risk of adjacent-level ossification development after surgery in the cervical spine: are there factors that affect the risk? A systematic review. Spine (Phila Pa 1976). 2012 Oct 15;37(22 Suppl):S65-74

Lee DH, Lee JS, Yi JS, Cho W, Zebala LP, Riew KD. Anterior cervical plating technique to prevent adjacent-level ossification development. Spine J. 2013 Jul;13(7):823-9.
Park JB, Cho YS, Riew KD: Development of adjacent-level ossification in patients with an anterior cervical plate, J Bone Joint Surg Am 87:558–563, 2005.
Ipsen BJ, Kim DH, Jenis LG, et al. Impact of Anterior Cervical Plate Placement on Clinical Outcomes. Poster presentation at 33rd Annual meeting of the Cervical Spine

Research Society. Dec 2005; San Diego, CA. 5. Park JB, Watthanaaphisit T, Riew KD. Timing of development of adjacent-level ossification after anterior cervical arthrodesis with plates. Spine J. 2007

Nov-Dec;7(6):633-6.

## SYSTEM DESIGN FEATURES

Feature	Benefit
27° Maximum variable screw angulation cephalad/ caudal (54° total cone).	Allows screws to be started at the anterior end plate corners to accommodate shortest possible plate length.
20° Maximum Fixed Screw angulation cephalad/ caudal (40° total cone).	Fixed screws lock into plate at any desired trajectory within 40° cone of angulation.
1.95mm Ultra-Thin Plate.	Assists in reduction of dysphagia. <sup>1</sup>
Plates starting at 9mm length "hole to hole" (17mm overall length).	Accommodates severely degenerated 1 level segments.
Proprietary "E-Z Start" Self-Drilling Screw.	May reduce procedural time by eliminating need for pilot hole (awl and drill steps).
One-Step Integrated Locking Mechanism.	Provides visual and tactile confirmation of screw blockage.
End plate alignment features.	Simplify plate sizing and positioning.
1 - 5 Level plates available in multiple lengths.	Accommodates a wide variety of patient anatomies and pathologies.
Anti-skid under surface.	Resists plate migration during screw insertion.
Large windows.	Enables visualization of graft site and end plates.
"Blunt Tip", Self-Tapping Screws.	Accommodates varying surgeon preferences.
Screws available in 2 diameters and 5 lengths.	4.0 & 4.35mm diameters and lengths of 10, 12, 14, 16, & 18mm.
Fixed and Variable Screws.	Create Fixed, Variable or Hybrid Constructs.
Elongated screw/driver tapered hexalobe interface or threaded interface.	Assures rigid screw/driver connection, reduces stripping, and may simplify revision.
Pre-contoured plates.	Simplifies surgical procedure.
Fully customizable instrument options.	Supports streamlined procedural efficiency for surgeons and positive clinical outcomes for patients.

1. Lee MJ, Bazaz R, Furey CG, Yoo J. Influence of anterior cervical plate design on dysphagia: a 2-year prospective longitudinal follow-up study. J Spinal Disord Tech. 2005;18(5):406-409.

(4)



### INDICATIONS AND CONTRAINDICATIONS

**CAUTION**: Federal (or United States) law restricts these devices to sale by or on the order of a physician.

**PRECAUTION:** The implantation of anterior cervical spinal implant systems should be performed only by experienced spinal surgeons with specific training in the use of this anterior cervical spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

#### IMPORTANT NOTE TO OPERATING SURGEON

The Struxxure<sup>®</sup> 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.

#### 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.

#### DESCRIPTION

The Struxxure<sup>®</sup> 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<sup>®</sup> 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.

#### **CLEANING AND DECONTAMINATION**

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

#### STERILIZATION

The Struxxure<sup>®</sup> 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:	Prevacuum
Temperature:	270°F (132°C)
Exposure Time:	4 minutes
Drying Time:	30 minutes

#### 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.

#### WARNINGS

1. The Struxxure<sup>®</sup> Anterior Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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.
The Struxxure<sup>®</sup> Anterior Cervical Plate System has not been evaluated for safety and compatibility in the MR environment.

4. The Struxxure<sup>®</sup> 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 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

**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.

loosen even though restrictions in activity are followed.

### INDICATIONS AND CONTRAINDICATIONS

**4. IMPLANT SELECTION.** The Struxxure<sup>®</sup> 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<sup>®</sup> 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.

#### **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

### Step 1. Patient Positioning: Anterior Surgical Exposure

Position the patient on a radiolucent OR table in the supine position (Figure 1). To obtain optimal visualization of the cervical spine, the OR table should have enough clearance available for a fluoroscopic C-arm to rotate freely for AP and lateral views. For one or two-level procedures, a transverse incision parallel to the skin creases of the neck is recommended. For longer level procedures, a transverse or oblique incision is suggested along the anterior border of the sternocleidomastoid muscle. The implantation of the anterior cervical plate follows a discectomy or a corpectomy, including an appropriate interbody/bone graft insertion. Care should be taken to remove any osteophytes which would inhibit the Struxxure<sup>®</sup> plate from sitting flush against the vertebra.



Figure 1

#### **Step 2. Implant Selection**

Select the appropriate length plate size to best fit the application. The plate level is determined by the number of levels being fused. The cephalad and caudal screws are started at the anterior endplate corners and angled away from the Endplates so as to use the shortest possible plate and maximize the distance to the adjacent Endplates. The Endplate Alignment features ("notches") on both sides of the plate next to the cephalad and caudal screw holes provide a reference for plate sizing (Figure 2). The appropriate plate size may be selected by measuring with calipers, ruler, or other measuring devices. Plate lengths are labeled "End to End" (Figure 3). Subtract 8.0mm from plate length to determine "Hole to Hole" distance (Figure 4).





### 3. Plate Contouring

The Struxxure<sup>®</sup> Plate is designed with a slight longitudinal (lordotic) and transverse bend to match patient anatomy. If additional plate contouring is necessary, the Plate Bender may be used (Figure 5). The Plate Bender has two sides: (+) which will increase lordosis and (-) which will decrease lordosis. Position the plate face-up to increase lordosis or face-down to decrease lordosis (Figure 6). Confirm the groove in the roller provides clearance for the Locking Mechanism on the plate.



#### 4. Plate Positioning

The Struxure<sup>®</sup> Plate is designed with an Anti-Skid Undersurface to resist migration during positioning (Figure 7). The plate can be introduced into the surgical wound with the use of forceps, Plate Holding Double Barrel Fixed DTS Guide, or by hand. Temporary Fixation Pins are available to hold the plate during screw hole preparation (Figure 8). Threaded pins are standard in the Struxure<sup>®</sup> set. Non-threaded Fixation Pins are available by request. Position the plate so the cephalad and caudal screws can be started at the anterior Endplate corners in order to use the shortest possible plate and maximize the distance to the adjacent disc spaces (Figure 9). Load the Temporary Fixation Pin onto the Fixation Pin Inserter by pulling up the sleeve on the inserter shaft. Position the pin in the center of the screw hole. Apply slight downward pressure while threading the pin into the screw hole. When fully inserted, the pin can penetrate the bone up to 9.2mm. Placement of two pins diagonally from each other is recommended for stabilization of the plate on the anterior cervical spine. Remove the Temporary Fixation Pins after the plate is sufficiently stabilized with screws.



#### **5. Screw Selection**

Variable

Figure 10

The Struxxure<sup>®</sup> "E-Z" Start Self-Drilling Screws can reduce the number of surgical steps and procedural length because they can be placed without the need of a pilot hole. Self-Tapping (blunt tip) Screws are also available by request. Struxxure® provides Fixed or Variable Screws allowing surgeons to create Semi-Constrained, Rigid, or Hybrid Cervical Plate constructs. Variable Angle Screws are smooth underneath the screw head and do not contain a thread pattern (Figure 10). Fixed Angle Screws can be identified by the thread pattern directly underneath the screw head that allows the screw to lock into the plate. Fixed Screws also have a ring on the top of the screw head (Figure 11). The Struxxure® 27° variable screw angulation in the cephalad/caudal direction (54° total cone) allows variable screws to be started at the anterior endplate corners and angled away from the endplates to accommodate the shortest possible plate and maximize the distance to adjacent disc levels (Figure 12). Fixed and Variable Screw (hybrid) combinations allow the surgeon to customize biomechanical construct performance at each level based on unique patient needs (Figure 12).

**Fixed** 

Figure 11





### 5. Screw Selection (Continued)

Fixed Angle Screws lock into the plate at any desired trajectory within the 40° cone of angulation to create a rigid, fully constrained, construct. Variable Angle Screws are placed at any desired trajectory within the 54° cone of angulation (Figure 13). Screw measurement starts from the bottom of the screw head to the distal tip (Figure 14). With the Screw attached to the end of the inserter, the screw length and diameter can be verified using the Screw Gauges located on the Screw Caddy (Figure 15). All screws are color coded based on length and diameter (Figure 16).



20° Max. Angle 40° Cone Fixed Screws

27° Max. Angle 54° Cone Variable Screws



Figure 14



Figure 13

Figure 15

Screw Length		
Length (mm)	Shaft Color	
10	● Sea Foam	
12	🔘 Gold	
14	🔵 Aqua	
16	Magenta	
18	Vector Purple	

Figure 16

### Primary v. Rescue / Variable v. Fixed

Туре	Diam. (mm)	Head Color	Example
Variable	4.0	Same as Shaft	(C) ()
Variable	4.35	Green	<b>()))))))</b>
Fixed	4.0	Same as Shaft w/ Ring	
Fixed	4.35	Green w/ Ring	

### 6. Establishing Screw Holes

**Option 1:** The "E-Z" Start Self-Drilling screws can be placed *without* the need of a pilot hole created by an Awl or Drill.

Option 2: Screw holes can be created with an Awl (A) or Spring Loaded Awl (B)(Figure 17).

**Option 3:** Screw holes can be created with a Drill and a Single Barrel Drill Guide that has a lip that hooks the bottom side of the plate and is allowed to pivot to desired trajectory (Figure 18).

**Option 4:** Screw holes can be created with a Drill and a Double Barrel Drill Guides that can be used to introduce the plate and also allow the Tap and Screw to pass through the cannulas (Figure 19).





Screws	Ideal Angulation	Maximum Recommended Angulation	Over A	ngulation
Variable	24°	27°	28°-29°	30°+
	Screw top	Screw flush to	Screw will sit	Locking cover will not
	below plate	top of plate	proud of plate	operate properly
Fixed	18°	20°	24°	27°
	Screw top	Screw flush to	Screw will sit	Locking cover will not
	below plate	top of plate	proud of plate	operate properly



#### 7. Screw Placement

Load the appropriate length Fixed Angle Screw or Variable Angle Screw onto the Screw Inserter directly from the Screw Caddy by placing the tip on the inserter into the hexalobe feature of the screw head while pressing down firmly (Figure 20). The tapered hexalobe functionality between the Screw/Inserter interface should firmly retain the screw secondary to the elongated hexalobe depth in the screw head. Alternatively, THR Screws are attached to the THR Screw Inserter with a clockwise threading turn of the wheel (Figure 21).

Insert screws sequentially at opposite corners of the plate, working toward the center of the plate to help maintain desired positioning against the bone (Figure 22).







Figure 22



#### 8. Screw Locking

The One Step Integrated Locking Mechanism provides visual and tactile confirmation of screw blockage. The locking mechanism is preinstalled and positioned on the plate to allow insertion of the bone screws. Once all bone screws have been inserted, place the guide post of the Cam Locking Instrument into the small post hole in the center of the locking cam (Figure 23). The T-handle position is oriented the same as the starting position of cam. Turn clockwise approximately 90° to secure it properly (Figure 24). The cam will stop rotating once it abuts the stop post on the plate. The final position of the T-handle may be used to confirm orientation of the cam. Remove Cam Locking Instrument from cam by lifting upward. Visually confirm final locking position of cam and occlusion of screw holes at each level.

#### Note:

1. If the locking cam cannot be rotated 90°, the bone screws have not been inserted far enough into the plate. 2. In the event the guide post of the Cam Locking Instrument will not seat into the small post hole in the center of the locking cam, make sure the hole is free of debris.

**WARNING:** If excessive force is applied, the cam can rotate past the stop post. If this occurs, continue rotating the cam in a clockwise direction until visual confirmation of screw blockage occurs.



### 9. Screw Removal/Construct Revision

Place the guide post of the Cam Locking Instrument into the small post hole in the center of the locking cam and rotate the lock 90° counterclockwise to its original position (Cam Locking Instrument Lock Tool Handle will be vertical), 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.

### 10. Closure

Wound closure is performed in the customary manner.



## STRUXXURE® ACP IMPLANTS



4 and 5 Level Plates Available by Special Request

## STRUXXURE® ACP IMPLANTS

### Struxxure<sup>®</sup> "E-Z" Start"

Self-Drilling Variable and Fixed Screws

31-6-4010	Variable Angle, 4.0mm x 10mm
31-6-4012	Variable Angle, 4.0mm x 12mm
31-6-4014	Variable Angle, 4.0mm x 14mm
31-6-4016	Variable Angle, 4.0mm x 16mm
31-6-4018	Variable Angle, 4.0mm x 18mm
31-7-4010	Fixed Angle, 4.0mm x 10mm
31-7-4012	Fixed Angle, 4.0mm x 12mm
31-7-4014	Fixed Angle, 4.0mm x 14mm
31-7-4016	Fixed Angle, 4.0mm x 16mm
31-7-4018	Fixed Angle, 4.0mm x 18mm
31-6-4310	Variable Angle, 4.35mm x 10mm
31-6-4312	Variable Angle, 4.35mm x 12mm
31-6-4314	Variable Angle, 4.35mm x 14mm
31-6-4316	Variable Angle, 4.35mm x 16mm
31-6-4318	Variable Angle, 4.35mm x 18mm
31-7-4310	Fixed Angle, 4.35mm x 10mm
31-7-4312	Fixed Angle, 4.35mm x 12mm
31-7-4314	Fixed Angle, 4.35mm x 14mm
31-7-4316	Fixed Angle, 4.35mm x 16mm
31-7-4318	Fixed Angle, 4.35mm x 18mm

### Struxxure<sup>®</sup> THR

Self-Drilling Variable and Fixed Screws

32-6-4010	THR Variable Screw, Self-Drilling, 4.0 x 10mm
32-6-4012	THR Variable Screw, Self-Drilling, 4.0 x 12mm
32-6-4014	THR Variable Screw, Self-Drilling, 4.0 x 14mm
32-6-4016	THR Variable Screw, Self-Drilling, 4.0 x 16mm
32-6-4018	THR Variable Screw, Self-Drilling, 4.0 x 18mm
32-6-4312	THR Variable Screw, Self-Drilling, 4.35 x 12mm
32-6-4314	THR Variable Screw, Self-Drilling, 4.35 x 14mm
32-6-4316	THR Variable Screw, Self-Drilling, 4.35 x 16mm
32-6-4318	THR Variable Screw, Self-Drilling, 4.35 x 18mm
32-7-4010	THR Fixed Screw, Self-Drilling, 4.0 x 10mm
32-7-4012	THR Fixed Screw, Self-Drilling, 4.0 x 12mm
32-7-4014	THR Fixed Screw, Self-Drilling, 4.0 x 14mm
32-7-4016	THR Fixed Screw, Self-Drilling, 4.0 x 16mm
32-7-4018	THR Fixed Screw, Self-Drilling, 4.0 x 18mm
32-7-4312	THR Fixed Screw, Self-Drilling, 4.35 x 12mm
32-7-4314	THR Fixed Screw, Self-Drilling, 4.35 x 14mm
32-7-4316	THR Fixed Screw, Self-Drilling, 4.35 x 16mm
32-7-4318	THR Fixed Screw, Self-Drilling, 4.35 x 18mm

1mm Screw Increments Available by Special Request 20mm Screws Available By Special Request "Blunt Tip" Self-Tapping Screws Available by Request

### Struxxure<sup>®</sup> "E-Z" Start"

Self-Drilling Variable and Fixed Screws

Primary v. Rescue / Variable v. Fixed		
Туре	Type Diam. (mm) Head	
Variable	4.0	Same as Shaft
Variable	4.35	Green
Fixed	4.0	Same as Shaft w/ Ring
Fixed	4.35	Green w/ Ring

Screw Length		
Length (mm)	Shaft Color	
10	🔘 Sea Foam	
12	🔵 Gold	
14	🔵 Aqua	
16	🔴 Magenta	
18	Vector Purple	

### STRUXXURE® ACP INSTRUMENTS









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