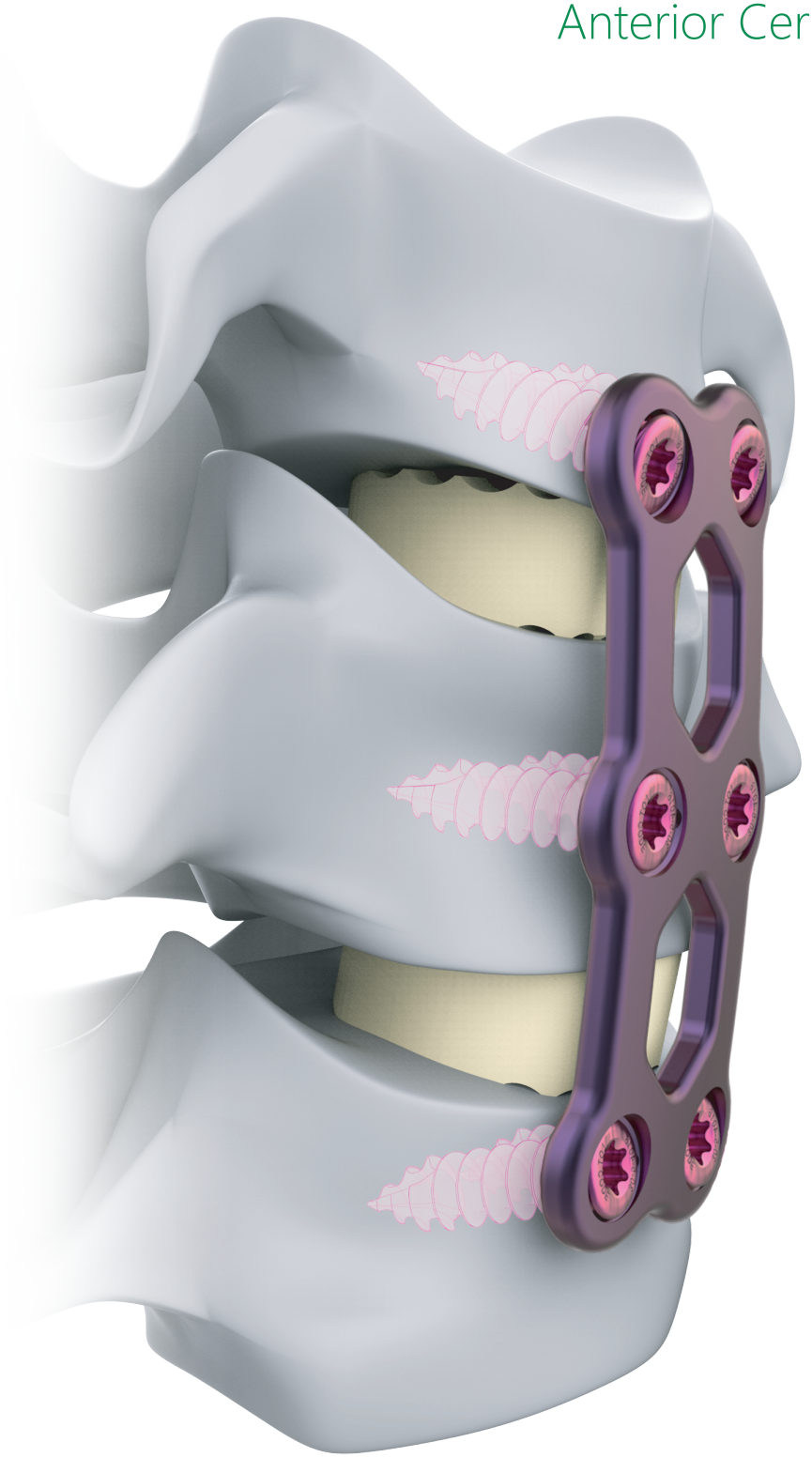
BLADE®

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.

INTRODUCTION

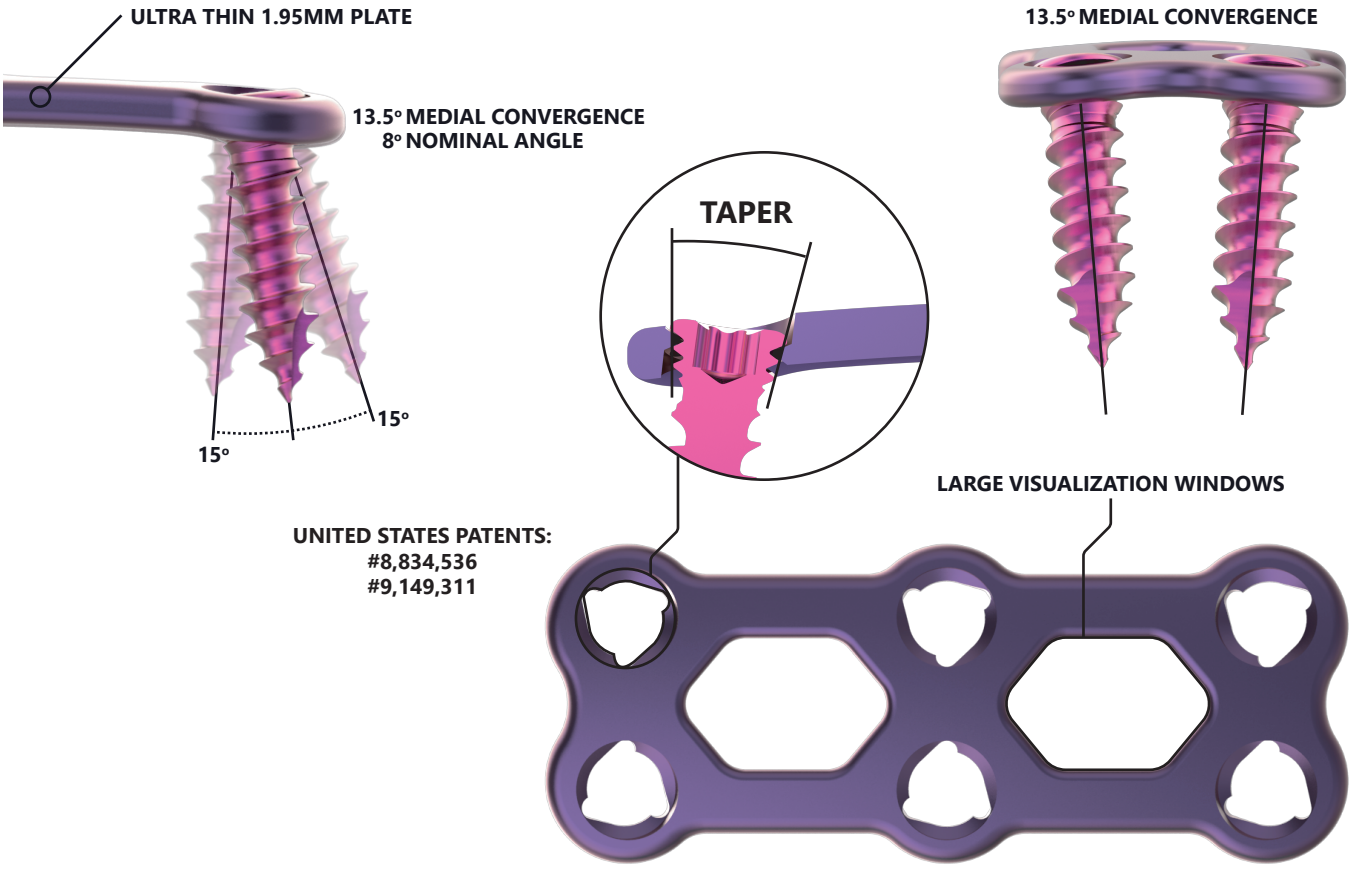
The Blade® Instrument Set complements the Blade® Anterior Cervical Plate. The system offers surgeons simplicity, efficiency and versatility. The system combines a low profile with oversized visualization windows. The multidirectional screws can be inserted conically up to 30° and lock upon insertion without additional locking steps. Repositioning and screw reinsertion can be achieved with the same high degree of locking success.

For indications, contraindications, precautions and warnings concerning Nexxt Spine's Blade® Anterior Cervical Plate System, refer to Essential Product Information at the end of this surgical technique manual or the product Instructions for Use. The procedure contained herein outlines the technique for open placement of the Blade® Anterior Cervical Plate System. For additional information please contact Nexxt Spine at (317) 436-7801.

DESCRIPTION

The Blade® Anterior Cervical Plate System is intended for anterior Screw fixation during the development of cervical spine fusion. The spinal fixation device includes Self-Drilling/Self-Tapping Screws, patented 'Hurricane' locking mechanism, and pre-contoured 1-5 level plates. Various instruments are also available as part of the Blade® Anterior Cervical Plate System for use by the surgeon to facilitate implantation of the device.

FEATURES AND BENEFITS



Hurricane Locking Technology	Ease of use for surgeon Screw threads engage 'Hurricane' hole pattern Screw self locks into plate No additional locking steps required Constrained: Restrict motion; provide additional stability
Fixation **Open Design**	Large 7mm visualization window for Intraoperative and Post-operative visualization of graft and end plate
Material	Titanium Alloys Ti 6Al-4V ELI and Ti CP for great imaging compatibility, biomechanical performance and excellent physical properties
Low Profile	Height: 1.8mm with rounded edges
Pre-Contoured Plates	Conforms to natural lordotic curvature of the spine
Plate Sizes	1 Level: 18-36mm in 2mm increments 2 Level: 34-54mm in 2mm increments 3 Level: 48-78mm in 3mm increments 4 Level by request: 56-104mm in 4mm increments 5 Level by request: 67-123mm in 4mm increments
Screws	Self-Drilling and Self-Tapping
Screw Sizes	Standard Major Ø 4.0mm, Lengths 10/12/14/16/18/20mm Rescue Major Ø 4.35mm, Lengths 10/12/14/16/18/20mm
Screw Angulation	30° Cone of angulation
Screw Convergence	13.5° in axial plane

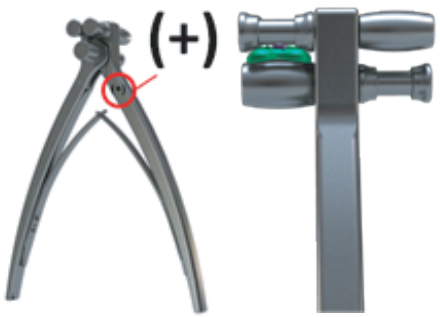
SURGICAL TECHNIQUE

Step 1. Patient Positioning: Anterior Surgical Exposure
Position the patient in the supine position. Surgical exposure of the ventral cervical spine is performed. Confirm the surgical level with X-ray or fluoroscopy.

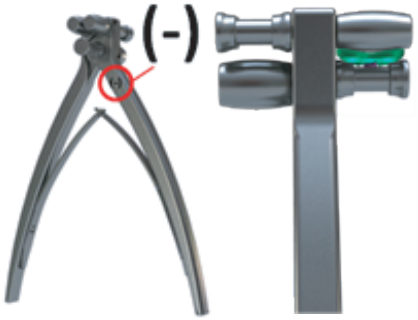
Step 2. Discectomy/Corpectomy
Perform the discectomy or corpectomy with grafting as required. Remove all osteophytes from the anterior surfaces to provide an adequately contoured surface for mating contact between the underside of the plate and the vertebra.

Step 3. Plate Selection & Placement
Select the correct Plate and Screw size to best fit the application. The Plate level is determined by the number of levels being fused. The appropriate Plate size may be selected by measuring with calipers, ruler, or other measuring device. Select the overall Plate length based on the measured length staying within the adjacent disc spaces.

Step 4. Plate Bending (optional)
Plates are manufactured with lordotic curvature. If desired, the Plate Bender can be used to add additional lordosis or kyphosis to the cervical plate to better match the cervical anatomy. The screws will engage independent of the additional bending, hence no need for 'bend zones'.



Lordose



Kyphose

Step 5. Plate Introduction
Place the Blade® cervical plate into the surgical opening performed in step 1 using the Blade plate holder. The plate may be held by the plate holder tongs across any material surrounding the center visualization window.

SURGICAL TECHNIQUE

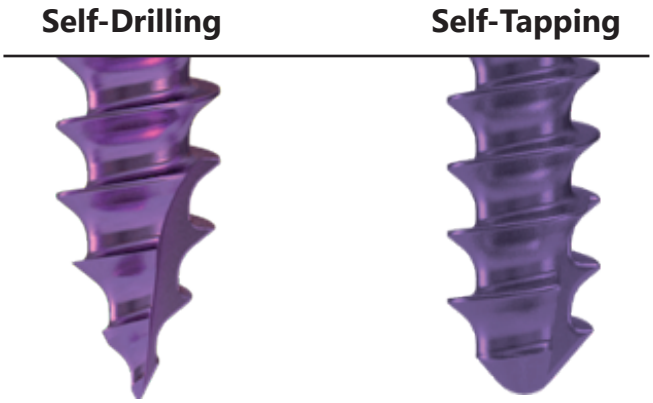
Step 6. Temporary Fixation Pins (optional)
Temporary Fixation Pins may be used to temporarily secure the cervical plate to the vertebra once the plate is placed onto the anterior cervical spine. The Temporary Fixation Pins are screwed *or tacked* through the plate holes using the Fixation Pin Inserter.

Temporary Fixation Pins

Screw Tip **Tack Tip**

Fixation Pin Inserter

Step 7. Screw Selection
The Blade Screws are color coded by length and diameter for ease on intra-operative identification. Two available Screw options are Self-Tapping *with a blunt tip* and Self-Drilling *with a sharp tip*. Screw diameters are 4.00mm and 4.35mm.



SURGICAL TECHNIQUE

Step 8. Establishing Screw Holes
Option A: Insert the Awl into the plate hole at the desired screw angle and push down while simultaneously twisting the Awl handle. Awl stops at depth of 9mm. Remove Awl while maintaining hole and plate alignment.
Option B: Alternatively, a drill guide may be utilized. Choose either a fixed-angle or variable-angle guide. Insert the tip of the guide into the plate hole to be drilled. Use the appropriate length drill bit and interchangeable handle to drill the pilot hole. The Drill Stop will contact the Drill Guide to limit the drilling depth.
Option C: Tap the hole with 4.0 mm x 10 mm Tap by turning instrument clockwise following intended screw path. The Tap instrument will stop when mating with the Plate. Taps are undersized 0.60mm to allow adequate thread purchase.
Note: The Self-Drilling Screws can be placed *without* the need of a pilot hole created by an Awl or Drill.

Step 9. Insert Screw
Insert the distal tip of the Screw Driver into the head of a screw. The Screw Driver is designed so that the screw head will adhere to the tip geometry of the instrument. Insert the Screw into the screw hole of the Plate and turn the Screw Driver clockwise. Continue advancing the Screw until the threads fully engage into the Plate.

Step 10. Final Locking
Once all screws are placed, use the Final, T10, Short Driver with the Torque Handle labeled 18 in-lbs. The Torque Limiting Driver must be used for final locking of screws into the plate. The Handle limits ("clicks") applied torque at 18 in-lbs.

Step 11. Placement Verification (optional)
Obtain radiographs intra-operatively to confirm appropriate plate and screw placement.

Step 12. Screw Removal (as needed)
If a screw has been locked in place but needs to be removed or repositioned, then back the screw out counterclockwise with the Screw Driver. A Plate Holder may be used to secure the Plate while applying force during screw removal. The same screw may be repositioned to screw into and lock securely to the plate.

Step 11. Closure
After implantation of the Blade® Anterior Cervical Plate System is complete, closure is performed in layers according to standard protocol.

POSTOPERATIVE CARE AND IMPLANT REMOVAL

Postoperative Care
Collar (soft or hard) immobilization may be used for patient comfort or may be indicated given the patient's bone density and quality of fixation on an individual basis. Postoperative radiographs should be taken to confirm appropriate patient outcome.

Implant Removal
Removal of the Blade® Anterior Cervical Plate System is performed by reversing the order of the implant procedure. The Screw Driver or Screw Extractor instrument may be used to remove the screws from the plate by turning counter clockwise. The Plate Holder may be used to securely grasp the plate for removal from the wound. Closure is performed in layers according to standard protocol.

IMPLANTS

Blade® Anterior Cervical Plate System

1 Level Plates	Product Code
1-18mm	30-1-18
1-20mm	30-1-20
1-22mm	30-1-22
1-24mm	30-1-24
1-26mm	30-1-26
1-28mm	30-1-28
1-30mm	30-1-30
1-32mm	30-1-32
1-34mm	30-1-34
1-36mm	30-1-36

2 Level Plates	Product Code
2-34mm	30-2-34
2-36mm	30-2-36
2-38mm	30-2-38
2-40mm	30-2-40
2-42mm	30-2-42
2-44mm	30-2-44
2-46mm	30-2-46
2-48mm	30-2-48
2-50mm	30-2-50
2-52mm	30-2-52
2-54mm	30-2-54

3 Level Plates	Product Code
3-48mm	30-3-48
3-51mm	30-3-51
3-54mm	30-3-54
3-57mm	30-3-57
3-60mm	30-3-60
3-63mm	30-3-63
3-66mm	30-3-66
3-69mm	30-3-69
3-72mm	30-3-72
3-75mm	30-3-75
3-78mm	30-3-78

ACP Screws

Self-Tapping — 30-0-XXXX

Ø4.0 x 10mm
Ø4.0 x 12mm
Ø4.0 x 14mm
Ø4.0 x 16mm
Ø4.0 x 18mm
Ø4.0 x 20mm
Ø4.35 x 10mm
Ø4.35 x 12mm
Ø4.35 x 14mm
Ø4.35 x 16mm
Ø4.35 x 18mm
Ø4.35 x 20mm

Self-Drilling — 30-5-XXXX

Ø4.0 x 10mm
Ø4.0 x 12mm
Ø4.0 x 14mm
Ø4.0 x 16mm
Ø4.0 x 18mm
Ø4.0 x 20mm
Ø4.35 x 10mm
Ø4.35 x 12mm
Ø4.35 x 14mm
Ø4.35 x 16mm
Ø4.35 x 18mm
Ø4.35 x 20mm

INSTRUMENTS

I10-01-01: Axial Mini Straight Handle

I10-01-17: Axial Torque Limiting Handle

I31-02-14: Screw Inserter

I30-02-11: Screw Extractor

I30-06-01/I30-06-02: 2.3mm Stop Drill 12mm-14mm

I30-07-01: Tap

I30-08-01: Plate Holder

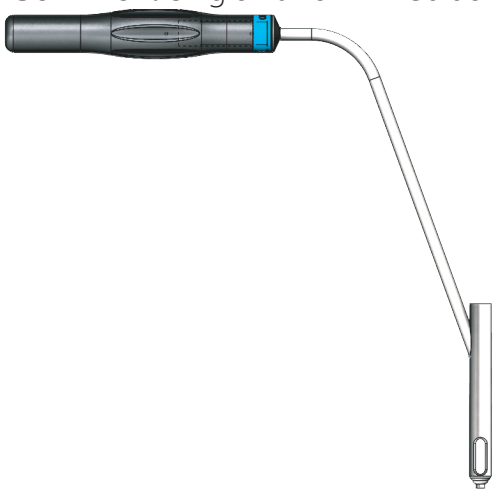
I30-13-01: Awl with Stop, 9mm

I31-08-05: Temporary Fixation Pin, Screw Tip

I31-08-06: Temporary Fixation Pin, Tack Tip

I30-14-01: Single Barrel Drill Guide - Fixed

I30-14-02: Single Barrel Drill Guide - Variable



I30-14-03: Double Barrel DTS Drill Guide

I31-30-01: Plate Bender

ESSENTIAL PRODUCT INFORMATION

GENERAL DESCRIPTION

The Blade® Anterior Cervical Plate System consists of Self-Tapping screws, Self-Drilling screws and plates. Screws are offered in 4.0mm and 4.35mm diameters with overall lengths ranging from 10mm to 20mm. One-, two-, three-, four-, and five-level plates are offered.
All components are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136 or commercially pure titanium (Grade 2 or Grade 4) according to ASTM F67.

INDICATIONS

The Blade® 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 Blade® 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 Blade® 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.

Visit www.nexxtspine.com/resources/indications-for-use/ to reference the Indications For Use with all potentials risks.

ESSENTIAL PRODUCT INFORMATION

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 Blade® 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 Blade® 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 Blade® 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 re-implanted regardless of an apparent undamaged condition.
7. DELAYED UNION OR NONUNION. The Blade® 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.

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