BLADE® Anterior Cervical Plate System

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BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION

IMPORTANT
This booklet is designed to assist in using the Blade® Anterior Cervical Plate System. It is not a reference for surgical techniques.

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 Blade® 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 instructions on the important aspects of this surgical procedure and can be requested from Nexxt Spine at the address or phone number above.

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 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.

CLEANING/REPROCESSING OF NEXXT SPINE SURGICAL INSTRUMENTS

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 ***Hospital Reprocessing Procedure*** document available at www.NexxtSpine.com/Resources/Indications-For-Use or by calling 317-436-7801 for a copy of the detailed cleaning instructions.

DESCRIPTION

The Blade® Anterior Cervical Plate System consists of self-tapping screws, self-drilling screws and plates. Screws are offered in 4.0mm and 4.3mm diameters with overall lengths ranging from 10mm to 20mm. One-, two-, three-, four- and five-level plates are offered.
The Blade 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 m titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136 or commercially pure titanium (Grade 2 or Grade 4) according to ASTM F67.

STERILIZATION

The Blade® 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.

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 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.
   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 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 <u>not</u> 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 reimplanted 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.

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.

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