Indications for Use
Envision® Anterior Cervical Plate System

Manufacturer
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DESCRIPTION

The Envision®Anterior Cervical Plate System is composed of plates with pre-assembled collets, bone screws, and unassembled collets. These components can be assembled with the associated instruments to provide immobilization of the cervical spine. All components are made from Titanium Alloy (Ti-6Al-4V ELI, ASTM F-136).

INDICATIONS

The Envision®Anterior Cervical Plate System is intended for the treatment of the cervical spine in skeletally mature patients receiving fusion by autogenous and/or allogenic bone graft. The implants are attached to the anterior cervical spine (C2-T1) with removal of the implants after the attainment of a solid fusion mass. The Envision®Anterior Cervical Plate System is intended for use under the following indications:

1. Degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies).
2. Spondylolisthesis.
3. Trauma (i.e., fracture).
4. Tumor.
5. Deformity (i.e., kyphosis, lordosis, and scoliosis).
6. Spinal stenosis.
7. Pseudarthrosis.
8. Failed previous fusion.

CONTRAINDICATIONS

Contraindications may include, but are not limited to:
1. Infection.
2. Morbid obesity.
3. Mental illness.
4. Fever or leukocytosis.
5. Pregnancy.
6. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
7. Cardiovascular complications.
8. Allergic or other reaction to the metallic implants.
9. Inadequate tissue coverage over operative site.
10. Any case not needing a fusion.
11. Any patient unwilling to cooperate with the postoperative instructions.

ADVERSE EFFECTS

All patients considered candidates for fusion using the cervical plate should be informed concerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation, and the potential adverse effects associated with the procedure. The potential adverse effects include, but are not limited to:

1. Bending, disassembly, loosening, fracture, slippage, and/or migration of the components.
2. Foreign body reaction to the implants.
3. Skin or muscle sensitivity.

4. Non-union or delayed union.
5. Infection.
6. Loss of proper spinal curvature, correction, height, and/or reduction.
7. Loss of neurological function, dural tear, pain, and/or discomfort.
8. Epidural bleeding, hemorrhage of blood vessels, and/or hematomas.
9. Loss of bladder and/or bowel control.
10. Sterility, impotency, and/or loss of consortium.
11. Bone loss and/or bone fracture due to stress shielding.
12. Bursitis.
13. Bone graft donor site pain.
14. Cardiovascular disorders including venous thrombosis, pulmonary embolism, cerebrovascular accident, and/or myocardial infarction.
15. Dysphagia.
16. Injury to esophagus and/or trachea.
17. Injury to recurrent laryngeal nerve resulting in alteration of voice.
18. Death.

WARNINGS AND PRECAUTIONS

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Only surgeons trained and experienced in spinal decompression and bone grafting techniques should use the cervical plate. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants are essential considerations in the utilization of this device.

Based on 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.

Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition, and/or poor bone quality are poor candidates for spinal fusion. Patients who smoke or abuse alcohol are poor candidates for spinal fusion.

A successful result is not always achieved in every surgical case due to many extenuating circumstances. This device is intended for temporary immobilization of the cervical spine in order to obtain a solid fusion mass using a bone graft. The durability and success of the implant will be compromised in cases where a non-union develops, or when used without a bone graft.

1. The screws of this device are not intended for insertion into the pedicles to facilitate cervical spinal fusion.
2. The benefit of spinal fusion utilizing any cervical plating system has not been adequately established in patients with stable spines.
3. Potential risks identified with the use of this device system, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebrae, neurological injury, and/or vascular or visceral injury.

Preoperative

1. Patients who meet the criteria in INDICATIONS should be considered for surgery.
2. Patients with conditions such as those addressed in CONTRAINDICATIONS should not be considered for surgery.
3. The surgeon should make sure that implants and all instruments are sterilized and available prior to surgery.
4. Implants and instruments should be inspected for surface flaws and scratches and should not be used in the presence thereof.

Intraoperative

1. The surgical technique manual should be followed.
2. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Mishandling of instruments may cause injury to patient and/or operative personnel.

4. Plates should not be bent and then re-bent in the opposite direction. Excessive bending or re-bending in an opposite direction should be avoided, as this can significantly weaken the plate.
5. Bone grafts should be used to insure stability.
6. Notching and scratching of implants should be avoided.
7. All implants are to be tightened firmly and rechecked before closing soft tissue.

Postoperative
1. For best possible results, patients should be counseled to avoid lifting, twisting, physical activities, smoking, consuming alcohol and any other activity that would compromise or delay the healing process.
2. The patient should be warned about the limitation of bending at the point of spinal fusion.
3. After the spinal fusion is complete, the surgeon must consider removing the implant, as this device serves no functional purpose after complete spinal fusion. If this device is not removed, the following complications may occur: implant corrosion, migration, bending, breaking and/or loosening, infection, bone loss, pain, and/or soft tissue reaction.

PACKAGING AND STERILITY
The cervical plate, screws, and collets are supplied as non-sterile implants and must be sterilized prior to use. Remove all packaging prior to sterilization. Please see implant and instrument case lids for sterilization parameters.

INSTRUMENT STERILITY
All instruments should be thoroughly cleaned prior to sterilization. The following steam sterilization cycles must be followed in order to insure sterility of the implants and instruments:

Gravity Cycle: 40 minutes at 121° C (250° F)
Prevacuum Cycle: 4 minutes at 132° C (270° F)

PRODUCT HANDLING
Implants should be used only if received with packaging and labeling intact. Protect the implants from contact with objects that may damage the surface finish. Inspect each implant prior to use for visible damage. Damaged packaging and implants should not be used and should be returned to Ortho Development Corporation.

PRODUCT COMPLAINTS
Any complaint or dissatisfaction with product quality, performance, labeling, and/or safety should be reported to Ortho Development Corporation. If any of the implants or instruments “malfunction” (i.e., do not meet any of their performance specifications or does not perform as intended), and/or are suspected to have caused or contributed to the death or serious injury of the patient, Ortho Development Corporation should be notified immediately by phone, fax or written correspondence.

When filing a complaint, please provide the product description, product number, lot number, complainant’s name and address, and the nature of the complaint.

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

351-1-10639 07/2011