

Instructions for Use

Product: DTRAX Cervical Cage-B

REF PD-31-200



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CAUTION: Federal law restricts this device to sale by or on the order of a physician.

PACKAGE CONTENTS:

Item #	Quantity	Description
1	1	DTRAX Cervical Cage -B



DESCRIPTION:

DTRAX Cervical Cages are titanium constructs offered in various footprints and heights. All DTRAX Cervical Cages are manufactured from implant grade titanium alloy (6Al-4V ELI Titanium). The implants are single-use only.

INDICATIONS FOR USE:

The DTRAX Cervical Cage is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-C7) with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Devices are intended to be used with autogenous bone graft and supplemental fixation, such as an anterior plating system.

CONTRAINDICATIONS:

Patients should be warned of these contraindications:

- Infection, local to operative site.
- Allergy to Titanium
- Stainless steel constructs, local to operative site.
- Local inflammation.
- Fever or leukocytosis.
- Pregnancy.
- Paget's disease
- Renal Osteodystrophy
- Cancer of the spine;
- Advanced Diabetes;
- Obesity.
- Rheumatoid Arthritis;
- Any medical or surgical condition that would preclude the potential benefit of spinal implant surgery (i.e. elevation of white blood count (WBC) or marked left shift in the WBC differential count).
- Grossly distorted anatomy due to congenital abnormalities.
- Rapid joint disease, bone absorption, osteopenia, poor bone quality, and/or osteoporosis.
- Inadequate tissue coverage over surgical site.
- Case not needing autogenous bone graft, fusion, or fracture healing.
- Prior fusion at the level(s) to be treated.

- A patient unwilling or unable to comply with postoperative instructions.
- Any instance in which the implant would interfere with anatomical structures or expected physiological performances.

WARNINGS:

In any surgical procedure, the potential for complications exists. The risks and complications with these implants include but are not limited to:

- Infection or painful, swollen or inflamed implant site
- Fracture of the implant
- Loosening, bending, breaking or dislocation of the implant requiring revision surgery
- Bone resorption
- Bone over-production
- Allergic reaction(s) to implant material(s)
- Histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism
- Subsidence of the device into the vertebral body.
- Bone loss and/or decrease in density due to stress shielding.
- Malalignment of anatomical structures (i.e. loss of normal spinal contours or change in height).
- Physiological reaction to implant devices due to foreign body intolerance including inflammation, local tissue reaction, and possible tumor formation.
- Loss of neurological function by several mechanisms, including direct compression by component parts, stretching of the spinal cord by component parts, vascular spinal cord compromise, or other mechanisms.

PRECAUTIONS:

Pre-operative Precautions:

- The surgeon must evaluate each situation individually based on the patient's clinical presentation in making any decisions regarding implant selection. The surgeon must be thoroughly familiar with the implant, instruments, and surgical procedure prior to performing surgery.
- The surgeon should also use medical devices in accordance with their labeled indications and the manufacturer's instructions for use, especially during insertion and removal.
- Patient selection should consider the following factors which may lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient's:
 - a) weight,
 - b) activity level,
 - c) occupation, and
 - d) other patient conditions which may impact on the performance of the DTRAX system.

Implant longevity and stability may be affected by these variables. The surgeon must consider the ability and willingness of the patient to follow instructions and to control their weight and activity level.

- Patient should be in the previously described diagnostic categories described under INDICATIONS FOR USE.
- Patient should not be in the contraindication groups listed under CONTRAINDICATIONS.
- Sterilization and handling procedures conforming to accepted standards are mandatory.
- The techniques for implanting this system should be reviewed by the surgeon prior to use of the system.
- The surgeon should inspect the available components prior to surgery to assure that all necessary components are present.
- The surgeon is expected to follow the instructions made available in training manuals and literature relative to implantation of DTRAX Cervical Cages.
- The surgeon is expected to exercise extreme care in the placement of implants, particularly in regard to neural elements.

- Radiographs should be made if there is any question as to the location of the intended or the actual placement of the implants.
- Components should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants and/or instruments should not be used.
- Components must be carefully handled and stored in a manner that prevents scratches, damage and corrosion.

Additional conditions presenting increased risk of failure include:

- a) Uncooperative patient or patient with neurologic disorders, incapable of following instructions;
- b) Marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved;
- c) Metabolic disorders that may impair bone formation;
- d) Osteomalacia; and
- e) Poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).

Intraoperative Precautions:

- Do not mix instruments from different manufacturers. While rare, breakage of instruments may occur especially with extensive use or excessive force.
- Inspect devices prior to use for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Proper implant selection must consider design, fixation, patient weight, age, bone quality, size, activity level, preoperative level of health, and also the surgeon's experience and familiarity with the device. Implant longevity and stability may be affected by these variables. Surgeons should inform the patient about these factors.
- Autogenous bone graft must be used in conjunction with DTRAX Cervical Cages to augment stability. Autogenous bone graft should be packed inside the device prior to insertion and around the device after insertion. The graft should extend from the upper vertebra being fused to the lower vertebra being fused.

Postoperative Precautions:

- The patient must be advised of the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred.
- Periodic follow-up is recommended to monitor the position and state of the implant components, as well as the condition of the bone. Periodic post-operative x-rays are recommended for close comparison with early post-op conditions to detect long-term evidence of changes in position, loosening, bending, or cracking of components.
- The patient is expected to follow the detailed instructions, limitations, and warnings from the operating surgeon. The patient and the surgeon must understand that the implant is not expected to support the spine if fusion does not occur. The risk of bending, loosening or breakage of the implants during postoperative rehabilitation may be increased if the patient is active, if the patient is debilitated, or otherwise unable to use crutches or other such weight supporting devices.
- The patient should not be exposed to mechanical vibrations that may loosen the device. They should also avoid falls or other sudden jolts in spinal position.
- - The patient should avoid the consumption of alcohol or the use of tobacco products during the postoperative phase.
- There is a risk of failure of the implant if the fusion of the spine does not occur. It should be recognized that this may occur and is a function of biology. More surgery may be required in such an event. If a nonunion develops or the components loosen, bend, and/or break the device should be removed immediately.
- The surgeon is expected to supply detailed instructions to the patient regarding postoperative activities. The patient should be advised at

their inability to bend at the point of spinal fusion and receive training on how to compensate for this loss of motion.

- The potential for multiple complications exist. These are not necessarily due to deficiencies of the implants, and may include fracture of the implants due to fatigue, late infection or sensitivity due to fretting-corrosion, prominence of the implants, and displacement of the implants due to failure of the supporting spinal structure.
- Retrieved implants should be properly disposed of and are not to be reused under any circumstance.

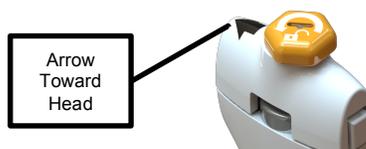


MRI WARNING
The DTRAX Cervical Cage-B device has not been evaluated for safety or compatibility in the MR environment. MR risks, including heating, migration, and imaging artifacts next to the implant are known, but have not been evaluated for the DTRAX Cervical Cage-B device.

INSTRUCTIONS AND TECHNIQUES:

CAUTION: The technique(s) employed in each surgery will depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

1. The DTRAX Cervical Cage-B (Cage) comes preloaded on a delivery instrument.
2. Prepare the Cage by packing with fusion material, e.g. autogenous bone graft.
3. **IMPORTANT:** Orient the Cage delivery instrument such that the printed arrow on the instrument handle is pointing toward the patient's head.



4. Under AP and lateral fluoroscopic control advance the Cage and delivery instrument into the target joint. Malleting may be required to fully insert implant and distract target joint.
5. If malleting is needed maintain downward pressure on the Guide Tube to ensure it remains positioned in the facet joint during malleting.
6. Use AP & Lateral fluoroscopy to confirm proper placement of the Cage.
7. Once proper Cage position is confirmed locate the Cage Release Knob on the handle of the Delivery Instrument and turn the knob counter clockwise to release the Cage from the Delivery Instrument.



8. **NOTE:** Turn the knob until the knob and cage holding wire is **completely free** from the Cage. Remove the Cage Release Knob assembly from the Delivery Instrument to verify that the Cage is released.



9. Use AP & Lateral fluoroscopy to confirm proper placement of the Cage.

CLEANING AND STERILIZATION:

DTRAX Cervical Cages are provided **STERILE** and are **SINGLE USE** devices.

CAUTION: The DTRAX Cervical Cages should never be re-sterilized or reused after contact with body tissues or fluids, but rather should be discarded. Providence does not take any responsibility for the use of implants re-sterilized after contact with body tissues or fluids.

STORAGE CONDITIONS:

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.



Verify package integrity prior to use. Do not use system components if packaging is damaged.

SYMBOLS USED ON THIS PRODUCT:



Sterilized using irradiation



Do not use if package is damaged



Do not reuse



Caution



Consult instruction for use



Keep Dry



Catalog Number



Lot code



Use-By date



Keep away from sunlight



Manufacturer



Authorized representative in the European Community



CE Mark by Notified Body number