Distributor Name -

Distributor Address -

Phone Number:

Fax:

Distributor Email Address:

After Hours Phone Number:

Operation Date:

Instruments /Procedure

Implant System:

Manufactured by:
Orthofix
3451 Plano Parkway
Lewisville, TX 75056
www.orthofix.com

Surgeon:

Hospital:

Patient:

Implant Label

Catalog Number	Lot#	Item Name	Single Use Item	QTY	HOSP IN	HOSP OUT

CSSD Count _____ Date _____

CETRA™ Anterior Cervical Plate System

Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the CETRA™ Anterior Cervical Plate System were implanted in your body. Because of this, you must be aware of the following information.

GENERAL INFORMATION

Name and Model of the device

The Cetra Anterior Cervical Plate System is comprised of an assortment of non-sterile, single use, titanium alloy (Ti6Al4V ELI per ASTM F136) plates and screws that allow a surgeon to build a temporary anterior cervical implant construct. The plate is attached to the anterior aspect of the vertebral body, by means of screws, to the cervical spine. The system includes the necessary instrumentation to assist in the surgical implantation of the devices.

What is the device for?

The Cetra Anterior Cervical Plate System is a temporary implant intended for anterior fixation to the cervical spine from C2 to C7. The plate is attached to the anterior aspect of the vertebral body, by means of screws, to the cervical spine.

Kind of patient on whom the device is intended to be used

The Cetra Anterior Cervical Plate System is a temporary implant intended for anterior fixation to the cervical spine from C2 to C7 and indicated for:
1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies).
2. Spondylolisthesis.
3. Trauma (i.e., fracture or dislocation).
4. Spinal stenosis.
5. Deformities (i.e., scoliosis, kyphosis, and/or lordosis).
6. Tumor.
7. Pseudoarthrosis.
8. Revision of previous surgery

Special operating instructions for the use of the device

There are no special operating instructions for the patient.

Intended performance of the device

The Cetra Anterior Cervical Plate System is a temporary implant intended for anterior fixation to the cervical spine from C2 to C7. The plate is attached to the anterior aspect of the vertebral body, by means of screws, to the cervical spine.

Side Effect

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products, graft material including metallosis, straining, tumor formation, and/or auto-immune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Vertebral body fracture at, above, or below the level of surgery.
- Loss of neurological function, including paralysis (complete or incomplete).
- Non-union, delayed union.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Hemorrhage.
- Cessation of any potential growth of the operated portion of the spine.
- Death.
- Dysphagia

Risk that can remain despite preventive measure

Refer to Side Effects.

Warnings about risk that may arise from the use of the device

- The Cetra Anterior Cervical Plate System is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical spine.
- To optimize bony union, perform an anterior microdiscectomy or corpectomy as indicated.
- To facilitate fusion, a sufficient quantity of autograft or allograft material should be used.
- Always orient the plate along the midline of the spine.
- Excessive torque applied to the screws when seating the plate may strip the threads in the bone.
- Failure to place screws within intended angle range may result in plate locking mechanism fracture or screw back-out past the plate locking mechanism.
- Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
- Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, and fracture of the vertebra, neurological injury, and vascular or visceral injury.
- The Cetra Anterior Cervical Plate System has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. This system has not been tested for heating or migration in the MR environment.

Precautions and other measure to be taken by the patent or a health professional

- The safety, efficacy and performance of the system have been established for conditions in which the system is used as intended and when used as identified in the Indications for Use. Performance of the system has not been evaluated for use that is contrary to the intended use, indications for use or for

use that in contraindicated. Failure to use the system as indicated could detrimentally affect the performance of its components.

- As with any major surgical procedure, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur are: early or late infection, which may result in the need for additional surgeries, damage to blood vessels, spinal cord or peripheral nerves, pulmonary emboli, loss of sensory and/or motor function, impotence, permanent pain and/or deformity. Rarely, some complications may be fatal.
- Do not use this system in patients with known or suspected metal allergies

Regular Exams, check and/or care of the device

Routine follow-up after implantation is by the surgeon's decision. Usually, there are visits to check the fusion achieved after surgery. This happens in the first few weeks after surgery. Imaging is commonly done, according to the surgeon's post-operative guidelines. These are done until the time of fusion. Once healed, follow-up checks are done according to the surgeon's decision.

Symptoms that could indicate that the device is not functioning as it should

Some symptoms can indicate that the device is not functioning as it should. These include, among others (but not limited to), lasting pain, device component fracture, loss of fixation, non-union, and fracture of the vertebra, neurological injury, and vascular or visceral injury.

What to do if you suspect that device is malfunction

If you have any of the symptoms described above, contact your primary surgeon. If he/she is not available, contact a trained surgeon. Please seek medical assessment if a surgeon is not available.

Expected lifetime of the device, what influences it, and precautions to take

The length of the treatment phase until acceptable fusion is achieved is dependent on several factors including – surgical technique, type of bone graft, patient health, compliance, etc. Consequently, the prediction of expected life time of an implant is subjective. It also depends on if you follow the indications given in the section "Precautions and other measures to be taken by the patient or a health professional". This section contains precautions and other measures to take at, or near, the end of the expected device lifetime as well.

Other cases in which the patient should contact a health professional in relation to the device
Refer to Symptoms

Materials and substances included in the device

The Implants in Cetra Anterior Cervical Plate System are made from titanium alloy (Ti6Al4V ELI per ASTM F136).

Any residues from production that could put the patient at risk
There are no manufacturing residuals that could pose a risk to the patient. It is known that the production process may introduce residues, contaminants and additives with potential toxicity. The eventual presence of

these substances does not reach toxic levels. In addition, a final cleaning stage is capable of further reducing these substances under the level of concern.

Important Note:
Please report any serious problem with the *"Cetra™ Anterior Cervical Plate System"*. You must contact Orthofix Inc and the Therapeutic Goods Administration.

Orthofix

Orthofix Inc., 3451 Plano Parkway, Lewisville, TX 75056, USA.
Telephone: 1-214-937-3199 or 1-888-298-5700
E-mail: complaints@orthofix.com

Therapeutic Goods Administration:
https://www.tga.gov.au

(Please click on "Consumers", then click on button "Report a problem or side effect" and then follow the instructions reported in "I want to report a problem with a medical device (adverse event)" section.)