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 _____

Hallmark® Anterior Cervical Plate System

Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the Hallmark® 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 Hallmark Anterior Cervical Plate System is comprised of a variety of non-sterile, single use, titanium alloy (6AL-4V ELI, per ASTM F136) components that allow a surgeon to build an anterior cervical implant construct. The system is attached to the anterior aspect of the vertebral body by means of screws to the cervical spine. The system consists of an assortment of screws, plates and associated instrumentation, which assists in the surgical implantation of the devices.

What is the device for?

The Hallmark Anterior Cervical Plate System is a temporary implant intended for anterior fixation to the cervical spine from C2 to C7. An ACDF is an operation that is commonly performed to treat herniated discs in the cervical spine, spinal stenosis, tumors and infections.

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

The Hallmark Anterior Cervical Plate System is a temporary implant intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies).
2. Spondylolisthesis.
3. Fracture.
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 Hallmark Anterior Cervical Plate System is a temporary implant intended for anterior fixation to the cervical spine from C2 to C7. The Hallmark Anterior Cervical Plate System:

-Align the spine in an anatomical position
-Maintain graft position
-Increase the likelihood of fusion
-Allow patients to increase activity in a timely fashion

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

Note: Additional surgery may be necessary to correct some of these anticipated adverse events.

Risk that can remain despite preventive measure

Refer to side effects

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

- The Hallmark Anterior Cervical Plate System is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
- The Hallmark Anterior Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Hallmark Anterior Cervical Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury

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

- When performing a corpectomy procedure using a Hallmark anterior cervical plate, ensure that the top locking mechanisms are only used on the superior and inferior portions of the cervical plate prior to final tightening the top locking plates to avoid potential plate performance deterioration.
- To optimize bony union, perform an anterior microdiscectomy or corpectomy as indicated
- To facilitate fusion, a sufficient quantity of autologous bone or other appropriate material should be used
- 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 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.

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 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.

Exected lifecycle 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 Hallmark 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 Hallmark Anterior Cervical Plate System. You must contact Orthofix Inc and the Therapeutic Goods Administration.

Orthofix Inc

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.)