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 _____

LONESTAR® Cervical Stand Alone System

Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the LONESTAR® Cervical Stand Alone 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 LONESTAR® Cervical Stand Alone System is a stand-alone spacer system designed to provide biomechanical strength to a traditional or minimally invasive ACDF procedure with less disruption of patient anatomy and preservation of the anatomical profile. The system helps to preserve the natural sagittal anatomic profile of the cervical spine while providing anterior column support and stability.

The LONESTAR® implant consists of a hybrid PEEK and titanium spacer along with titanium bone screws and a titanium cover plate. The spacers are designed with a zero degree anterior profile and are implanted using an anterior approach.

What is the device for?

The LONESTAR® Cervical Stand Alone System is indicated for spinal fusion procedures at one level in the cervical spine (C2-T1) in skeletally mature patients with degenerative disc disease (DDD). The system helps to preserve the natural sagittal anatomic profile of the cervical spine while providing anterior column support and stability.

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

The LONESTAR® Cervical Stand Alone System is indicated for spinal fusion procedures at one level in the cervical spine (C2-T1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies.

The LONESTAR® Cervical Stand Alone System is used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and the two titanium alloy screws which accompany the implant.

Patients must have undergone a regimen of at least six weeks of non-operative treatment prior to being treated with the LONESTAR® Cervical Stand Alone System in the cervical spine.

Special operating instructions for the use of the device

There are no special operating instructions for the patient.

Intended performance of the device

LONESTAR® is a stand-alone cervical interbody fusion device used to provide structural stability in skeletally mature individuals following discectomy. The system helps to preserve the natural sagittal anatomic profile of the cervical spine while providing anterior column support and stability.

Side Effect

Potential adverse events include, but are not limited to:

- Failure of the device to provide adequate mechanical stability.
- Loss of fixation of the implant.
- Device component failure.
- Migration or bending of the device.
- Loss of bony alignment.
- Non-union.
- Fracture of bony structures.
- Resorption without incorporation of any bone graft utilized.
- Immunogenic response to the implant materials.
- Dysphagia.

Risk that can remain despite preventive measure

Refer to Side Effects

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

- No implant can be expected to withstand the unsupported stresses of full weight bearing. The size, shape and condition of human bones are also contributing factors to the success of the surgery.
- The LONESTAR Cervical Stand Alone 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 LONESTAR Cervical Stand Alone 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 patient or a health professional

- Postoperative care is important. The patient should be instructed in the limitations of the implant and should be cautioned regarding weight bearing and body stress on the device prior to secure bone healing.
- The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- 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.
- The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient

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.

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 LONESTAR system made from PEEK (Polyetheretherketone per ASTM F2026) and titanium alloy (Ti6Al4V ELI per ASTM F136) material.

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 LONESTAR® Cervical Stand Alone 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.)