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 _____

CONSTRUX® Mini PEEK Spacer System

Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the CONSTRUX® Mini PEEK Spacer 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 CONSTRUX Mini PEEK Spacer System is comprised of a variety of implants manufactured from PEEK (Polyetheretherketone), as described by ASTM F2026, with titanium markers as described by ASTM F67. The implants are available in multiple sizes to accommodate various patient anatomies. The superior and inferior surfaces of the implant have a pattern of ripples to provide increased stability and help prevent anterior/posterior movement of the device.

What is the device for?

The CONSTRUX® Mini PEEK Spacer System is indicated for spinal fusion procedures at one or two contiguous levels within the cervical spine (C2-T1) in skeletally mature patients with degenerative disc disease (DDD), for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The CONSTRUX® Mini PEEK Spacer System is also indicated for treating fractures of the thoracic and lumbar spine. Lordotic implants greater than a 5° profile are not to be used for partial vertebral body replacement.

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

This device is intended to be used in skeletally mature patients with degenerative disc disease (DDD), patients with diseased vertebral body resected or excised for the treatment of tumors or with fractures of the thoracic or lumbar spine.

Special operating instructions for the use of the device

There are no special operating instructions for the patient.

Intended performance of the device

The CONSTRUX® Mini PEEK Spacer System is intended to facilitate spinal fusion at one or two contiguous levels within the cervical spine (C2-T1) in skeletally mature patients or to restore height of a collapsed vertebral body thoracolumbar spine (T1-L5).

Side Effect

Potential adverse events include, but are not limited to:

1. Failure of the device to provide adequate mechanical stability.
2. Loss of fixation of the implant.
3. Device component failure.
4. Migration or bending of the device.
5. Loss of bony alignment.
6. Non-union.
7. Fracture of bony structures.
8. Resorption without incorporation of any bone graft utilized.
9. Immunogenic response to the implant materials.
10. Dysphagia.

Risk that can remain despite preventive measure

Refer to Side Effects.

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

Postoperative care is important. Be aware of the limitations of the implant and use caution regarding weight bearing and body stress on the device prior to secure bone healing.

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

The CONSTRUX® Mini PEEK Spacer System has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of CONSTRUX Mini PEEK Spacer System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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, 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 implant is intended to remain implanted permanently.

Other cases in which the patient should contact a health professional in relation to the device
Refer to Symptoms that could indicate that the device is not functioning as it should.

Materials and substances included in the device
CONSTRUX® Mini Spacer System implants are made of PEEK (Polyetheretherketone), as described by ASTM F2026, with titanium markers as described by ASTM F67.

Any residues from production that could put the patient at risk
CONSTRUX® Mini Spacer implants have been evaluated for the presence of manufacturing residuals that could pose a risk to the patient. These evaluations determined that there are no residual materials present at toxic levels on finished devices. It is known that the production process may introduce residues, contaminants, and additives with potential toxicity. All CONSTRUX® Mini Spacer System implants undergo validated cleaning processes at multiple points in the manufacturing process to reduce the presence of residual materials below the level of concern

Important Note:
Please report any serious problem with the Implant System. You must contact Orthofix, and the Therapeutic Goods Administration.

Orthofix
3451 Plano Parkway, Lewisville, TX 75056
Tel: 1-214-937-3199 or 1-888-298-5700
Email: 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.)