

Distributor Name -

Distributor Address -

Phone Number:

Fax:

Distributor Email Address:

After Hours Phone Number:

Operation Date:	<input style="width: 95%;" type="text"/>	Instruments /Procedure	Implant System:  Manufactured by: Orthofix 3451 Plano Parkway Lewisville, TX 75056 www.orthofix.com
Surgeon:	<input style="width: 95%;" type="text"/>	Implant Label	<input style="width: 95%; height: 80px;" type="text"/>
Hospital:	<input style="width: 95%;" type="text"/>		
Patient:	<input style="width: 95%;" type="text"/>		

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

CSSD Count \_\_\_\_\_ Date \_\_\_\_\_

## CONSTRUX® Mini PTC Spacer System

### Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the CONSTRUX® Mini PTC 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 PTC Spacer System is comprised of a variety of implants that have a PEEK core with integrated porous titanium end plates.

##### **What is the device for?**

The CONSTRUX® Mini PTC 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). CONSTRUX Mini PTC spacers are implanted in the cervical intervertebral disc space and are intended to facilitate vertebral fusion by stabilizing adjacent vertebrae, maintaining disc height and preventing the collapse of one vertebra onto another.

##### **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).

##### **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 PTC Spacer System is intended to facilitate spinal fusion at one or two contiguous levels within the cervical spine (C2-T1) in skeletally mature patients.

### **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 patient or a health professional**

The CONSTRUX® Mini PTC 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 PTC 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 endplates 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](mailto: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.)