INSTRUCTIONS FOR USE

Important Information – Please Read Prior to Use

Rx Only

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Australia

Device System Name:

FORZA® XP Expandable Spacer System - Sterile

Click directory below for desired language

English EN 2-3

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Device System Name:

FORZA® XP Expandable Spacer System - Sterile

Description:
The sterile FORZA XP Expandable Spacer System is comprised of an assortment of sterile, single use, titanium alloy (Ti-6Al-4V ELI per ASTM F136) and Polyetheretherketone (PEEK) Polymer (PEEK OPTIMA® LT1 per ASTM F2026) spacers with height expansion capability. The expandable interbody spacer is inserted into the lumbar disc space and expanded to fit the patient anatomy.

The implants are offered in non-lordotic, lordotic, and hyper-lordotic configurations to help restore the natural curvature of the spine. The implants can be used in single placement or pairs with typical approaches being transforaminal lumbar interbody fusion (TLIF) and posterior lumbar interbody fusion (PLIF).

The implants feature a bulleted nose for ease of insertion and anti-migration ripples on both the inferior and superior surfaces to provide increased stability and help prevent anterior/posterior movement of the device.

The FORZA XP Expandable Spacer System is not intended to be used as a stand-alone device. The system must be used with a supplemental fixation system, FORZA XP Expandable implants are provided sterile.

Indications for Use:
The FORZA XP Expandable Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved levels. These patients may have had a previous non-fusion surgery at the involved level(s).

The FORZA XP Expandable Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft; and supplemental fixation system.

Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the FORZA XP Expandable Spacer System.

Contraindications:
The FORZA XP Expandable Spacer System, as with other orthopedic implants, is contraindicated for use in patients with:

1. Active infections in which the use of an implant could preclude adequate and appropriate treatment of the infection.
2. Rapidly progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis which may prevent adequate fixation.
3. Conditions that may place excessive stresses on bone and implants, such as severe obesity, pregnancy or degenerative diseases. The decision to use this system in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
4. Prior fusion at the level to be treated.
5. Any circumstances not listed under the Indications for Use section.

Potential Adverse Events:
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.

Note: 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.

Warnings and Precautions:
The surgeon should be aware of the following when using implants:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape, and design of the implant. 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.
2. Do not use damaged implants. The correct handling of the implant is extremely important. Implants should not be bent, notched or scratched. These operations can produce defects in surface finish and may cause internal stress concentrations which may become the focal point for eventual failure of the device.
3. FORZA XP implants are provided STERILE. Do Not use if the package is opened or damaged or if the expiration date has passed.
4. FORZA XP implants must be expanded upon insertion to reduce the risk of expulsion or migration post-operatively.
5. Do not place bone graft in the FORZA XP spacer prior to both final positioning and expansion of the implant. The bone graft will prevent the Stabilizer Driver from being able to seat into the implant expansion drive and will limit the FORZA XP spacer height adjustments.
6. Non-sterile; the FORZA XP Expandable Spacer instruments are provided non-sterile, and therefore, must be thoroughly cleaned and sterilized prior to each use.
7. Single use only. Reuse of devices labeled as single-use (e.g. implants, drills, tacks, trial rods) could result in injury or reoperation due to breakage or infection.
8. All implants are intended for SINGLE USE ONLY. Any used implant should be discarded. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to fatigue failure.
9. DO NOT re-sterilize these implants as this could result in injury or require reoperation due to breakage or infection.
10. 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.
11. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the intervertebral body fusion device.
12. 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.
13. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

MRI Compatibility Information:

Non-clinical testing and MRI simulations that included in-vivo, clinically relevant modeling were performed to evaluate the entire family of the Interbody System. Non-clinical testing demonstrated that the entire family of the system is MR Conditional. A patient with an implant from this family can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, an implant from the Interbody System is expected to produce a maximum temperature rise of 4.4°C after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by an implant from the Interbody System extends approximately 4-mm from this device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

Cleaning and Disinfection:

FORZA XP Spacer System implants are provided STERILE. Do not use the implant if the package is opened or damaged or if the expiration date has passed. Please discard all open and unused implant. Do not re-sterilize opened and unused implants.

FORZA XP sterile implants are used with FORZA XP Expandable Spacer System instruments. FORZA XP instruments are provided clean but not sterile. All instruments must be thoroughly cleaned after each use. Please refer to AW-10125289, Non-Sterile Surgical Instruments and Implants Reprocessing Guide, for instruction on the cleaning and disinfection of surgical instruments.

None of the instruments in the system require disassembly prior to cleaning.

Sterilization:

FORZA XP Expandable Spacer System implants are provided STERILE. They are sterilized using gamma irradiation sterilization. Do not re-sterilize.

The FORZA XP Expandable Spacer System instruments are supplied NON-STERILE. Please refer to AW-10125289, Non-Sterile Surgical Instruments and Implants Reprocessing Guide, for instruction on the sterilization of implants, components, and instrumentation.

Packaging:

The FORZA XP Expandable implants are sterilized using Gamma irradiation sterilization. Do not use if the package is opened or damaged or if the expiration date has passed.

Packages for each of the components should be intact upon receipt. If a consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for damage prior to use. Damaged packages or products should not be used and should be returned to Orthofix.

The FORZA XP Expandable Spacer System instruments are provided in a modular case specifically intended to contain and organize the system's components. The system's instruments are organized into trays within each modular case for easy retrieval during surgery. These trays also provide protection to the system components during shipping. Additionally, individual instruments are provided in sealed poly bags with individual product labels.

Product Complaints:

Any Health Care Professional (e.g., customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction with the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Orthofix Inc., 3451 Plano Parkway, Lewisville, TX 75056, USA, by telephone at 1-214-937-3199 or 1-888-298-5700 or by e-mail at complaints@orthofix.com.

Further Information:

A recommended Operative Technique for the use of this system is available upon request from Orthofix at the phone numbers provided above.

Latex Information:

The implants, instruments and/or packaging material for the FORZA XP Expandable Spacer System are not formulated with and do not contain natural rubber. The term "natural rubber" includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Rx Only	Federal (U.S.A.) law restricts this device to sale by or on the order of a physician		
	See Instructions for Use	LOT	Lot Number
	Orthofix.com/IFU		Manufacturer
	Single Use Only Do Not Reuse		Do Not Resterilize
REF	Catalogue Number	SN	Serial Number
	Provided Non-Sterile	MR	MR Conditional
STERILE R	Sterilized Using Irradiation		Use By Date

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