INSTRUCTIONS FOR USE

Important Information – Please Read Prior to Use

Rx Only

CE 2797

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EC REP Medical Device Safety Service
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30175 Hannover
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Device System Name:

CONSTRUX® Mini PEEK Spacer System

Cervical Intervertebral Body Fusion Device
Partial Vertebral Body Replacement (VBR) Device

Click directory below for desired language

AW-47-9903 Rev.AF

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English EN

Device System Name:

CONSTRUX® Mini PEEK Spacer System
Cervical Intervertebral Body Fusion Device
Partial Vertebral Body Replacement (VBR) Device

Description:
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.

The CONSTRUX Mini PEEK Spacer System is not intended to be used as a stand-alone device and must be used with supplemental fixation. The implants are used singly and are implanted using an anterior approach.

The CONSTRUX Mini PEEK implants are provided either in a sterile packaging configuration or non-sterile and requires sterilization prior to use. CONSTRUX Spacer System instruments are provided non-sterile and requires sterilization prior to use.

Indications for Use:
When Used as a Cervical Intervertebral Body Fusion System:
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). DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies.

The CONSTRUX Mini PEEK Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation system; the hyperlordotic implants (≥10°) are required to be used with an anterior cervical plate.

Patients must have undergone a regimen of at least six weeks of non-operative treatment prior to being treated with the CONSTRUX Mini PEEK Spacer System in the cervical spine.

When Used as a Partial Vertebral Body Replacement (VBR) System:
The CONSTRUX Mini PEEK Spacer System is indicated 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.

The CONSTRUX Mini PEEK Spacer System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period of time. The Partial VBR Device is intended to be used with autograft or allograft and supplemental fixation system.

Contraindications:
The CONSTRUX Mini PEEK 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.

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.
10. Dysphagia.

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.

Note: When used as a partial VBR device, the CONSTRUX Mini PEEK Spacer System is intended for use in affected vertebral body segments that are equal to or smaller than the size of the device. For larger affected vertebral body segments, a larger device indicated for partial or full VBR is recommended.

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 internal stress concentrations, which may become the focal point for eventual failure of the device.
3. STERILE CONSTRUX Mini PEEK Implants - Do not use if the package is opened or damaged or if the expiration date has passed. DO NOT re-sterilize these implants as this could result in injury or require reoperation due to breakage or infection.
4. Non-Sterile; some CONSTRUX Mini PEEK implants and all instruments are provided non-sterile and therefore must be thoroughly cleaned and sterilized before initial use and after each subsequent use.
5. 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.
6. All implants are intended for Single Use Only. Any used implant should be discarded. Even though the device may appears undamaged, it may have small defects and internal stress patterns that may lead to fatigue failure.
7. DO NOT re-sterilize single-use implants that come in contact with body fluids.
8. 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.
9. Based on dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level and other patient conditions that may impact the performance of the intervertebral body fusion device.
10. The implantation of the intervertebral body fusion device should be performed on by experienced spinal surgeons with specific training in the use of the device because it is a technically demanding procedure presenting a risk of serious injury to the patient.

MRI Compatibility Information:
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.

Cleaning:
Some CONSTRUX Mini PEEK implants are provided clean but not sterile and other CONSTRUX Mini PEEK implants are provided in a sterile packaging configuration.

CONSTRUX Mini PEEK Sterile Packaging Configuration - 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 implants. Do not re-sterilize an opened and unused implant.

All CONSTRUX Mini PEEK non-sterile implants and instruments must be thoroughly cleaned and sterilized after each use. Cleaning may be done using validated hospital methods or following the validated cleaning process described below.

None of the instruments require disassembly prior to cleaning.

From Point of Use:
Whenever possible, do not allow blood, debris or body fluids to dry on instruments. For best results and to prolong the life of the surgical instrument reprocess immediately after use.
1. Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place instruments in a basin of purified water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.
2. For optimal results, instruments should be cleaned within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning.
3. Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

Note: Soaking in proteolytic enzymatic detergents or other pre-cleaning solutions facilitates cleaning, especially in instruments with complex features and hard-to-reach areas (e.g. cannulated and tubular designs, etc.). These enzymatic detergents as well as enzymatic foam sprays break down protein matter and prevent blood and protein based materials from drying on instruments. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed.

Preparation for Cleaning:

1. All instruments with moving parts (e.g., knobs, triggers, hinges) should be placed in the open position to allow access of the cleaning fluid to areas that are difficult to clean.
2. Soak the instruments for a minimum of 10 minutes in purified water prior to the manual or automated cleaning process.
3. Use a soft cloth or a soft plastic bristle brush to remove any visible soil from the instruments prior to manual or automated cleaning. Use a soft plastic bristle brush or a pipe cleaner to remove soil from any inner lumens. You can also use a syringe (if appropriate) for hard to reach areas.
4. Enzymatic detergent should be used for manual and automated cleaning. All enzymatic detergents should be prepared at the use dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare the enzymatic detergents. Use of recommended temperatures is important for optimal performance of enzymatic detergent.

Manual Cleaning:

1. Completely submerge instruments in an enzymatic detergent and allow to soak for 20 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).
2. Remove the instruments from the enzymatic detergent and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
3. Place prepared cleaning solution in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes.
4. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
5. Repeat the sonication and rinse steps above.
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.
7. Inspect the instruments for visible soil.
8. If visible soil is noted, repeat the steps listed above.

Automated Cleaning:

1. Completely submerge the instruments in an enzymatic detergent and allow to soak and sonicate for 10 minutes each. Use a soft nylon bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard to clean areas. Lumens should be cleaned with a long, narrow, soft nylon bristled brush (i.e. pipe cleaner). Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.
2. Remove instruments from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes and other difficult to reach areas.
3. Place instruments in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle.
4. Orient instruments into the automated washer's carriers as recommended by the washer manufacturer.
5. The following minimum parameters are essential for thorough cleaning.
   a. 2 minute prewash with cold tap water
   b. 1 minute prewash with hot tap water
   c. 2 minute detergent wash with hot tap water (64-66°C/146-150°F)
   d. 1 minute hot tap water rinse
   e. 2 minute thermal rinse with purified water (80-93°C/176-200°F)
   f. 1 minute purified water rinse (64-66°C/146-150°F)
   g. 7 to 30 minute hot air dry (116°C/240°F)
6. Inspect the instruments for visible soil.
7. If visible soil is noted, repeat the above listed steps until no visible soil is noted.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach, and/or other alkaline cleaners may damage instruments. These solutions should not be used.

Note: Visually inspect instruments after cleaning and prior to each use. Discard or return to Orthofix any instruments that are broken, discolored, corroded, have cracked components, pits, gouges, or are otherwise found defective. Do not use defective instruments.

Instrument End of Life Determination:
Do not reuse Single Use instruments. Visually inspect the reusable instruments to determine if the instrument has reached end of life. Orthofix reusable instruments have reached End of Life when:

1. Instruments show signs of damage such as binding, bending, breakage, overt signs of wear and/or any other conditions which may impact the devices safe and effective use.
2. Instruments intended for cutting bone and/or tissue (e.g. tap, rasp, curette, rongeur) – when any of the cutting surfaces show signs of wear such as nicks, abrasions or otherwise dulled cutting surfaces.
3. Instruments that interface with other devices (e.g. implants, instruments, handles) - when the mating feature binds, fails to attach or fails to hold the device securely. The instrument function should be verified prior to each use.
4. Do not use instruments which reached End of Life. Discard End of Life instruments per your hospital procedure or return to Orthofix for disposal.

Sterilization:
The CONSTRUX Mini PEEK implants are provided either in a sterile packaging configuration or non-sterile and requires sterilization prior to use.

The STERILE CONSTRUX Mini PEEK implants are sterilized using gamma irradiation sterilization. Do not re-sterilize these implants.

CONSTRUX Spacer System instruments are provided non-sterile and requires sterilization prior to use.

Sterilization in Orthofix Cases with Blue Wrap:
The CONSTRUX Mini PEEK non-sterile implants and instruments should be placed in the appropriate Orthofix instrument/implant case which will be wrapped in an FDA cleared sterilization wrap and placed in the autoclave for sterilization by the hospital using one of the following recommended cycles:

Method: Steam	or:	Method: Steam
Cycle: Gravity		Cycle: Prevac
Temperature: 270°F (132°C)		Temperature: 270°F (132°C)
Exposure time: 15 minutes		Exposure time: 4 minutes
Drying time: 30 minutes		Drying time: 30 minutes
Double wrapped		Double wrapped

Sterilization in Rigid Sterilization Containers:
When using rigid sterilization containers, clean, inspect and prepare the rigid sterilization container according to the manufacturer's instructions.

Select the appropriate rigid sterilization container with either a filtered or solid bottom to properly enclose the Orthofix instrumentation cases (recommended 23¼" long x 11¼" wide container). The following sterilization cycle has been validated:

Method: Steam
Cycle: Prevac
Temperature: 270°F (132°C)
Exposure time: 4 minutes
Drying time: 30 minutes

Note: Rigid sterilization containers with solid bottoms cannot be used in gravity steam cycles.

Validation and routine monitoring should be performed per ANSI/AAMI ST79 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Other cycles may be used as long as they comply with the above practices and provide a sterility assurance level of 10^{-6}.

Packaging:
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 CONSTRUX Mini PEEK Spacer System instruments and non-sterile implants are provided in modular cases 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 Healthcare 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 email 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 CONSTRUX Mini PEEK 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 this device to sale by or on the order of a physician.

MICHELSON TECHNOLOGY AT WORK

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