

Device System Name:
PILLAR[™] SA PEEK Spacer System

Description: The PILLAR[™] SA PEEK Spacer System is comprised of a variety of implants manufactured from PEEK-OPTIMA[®] LT (Polyetheretherketone), as described by ASTM F-2026, with tantalum markers as described by ASTM F-560. The implants are available in multiple footprint sizes, a variety of heights, and two angles of lordosis: 7° and 12°. The implants incorporate integrated anterior screw holes to allow for medial placement of screws, as well as a titanium plate for securing the screws once in place. The superior and inferior surfaces of the implant have a pattern of ripples that provide increased stability and help prevent movement of the device.

The PILLAR[™] SA PEEK Spacer System is provided non-sterile.

Indications:

When used as an Intervertebral Body Fusion System:

The PILLAR[™] SA PEEK 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 PILLAR[™] SA PEEK Spacer System is intended for use with autograft.

The PILLAR[™] SA PEEK Spacer System is intended for use with the four titanium alloy screws provided with the device. If the physician chooses to use fewer than four of the provided screws, then supplemental internal fixation must be used to augment stability. As an example, the supplemental internal fixation system that may be used is the Blackstone Medical, Inc. Spinal Fixation System (SFS).

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the PILLAR[™] Spacer System.

When used as a Partial Vertebral Body Replacement (VBR) System:

The PILLAR[™] SA 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 PILLAR[™] SA PEEK Spacer System is also indicated for treating fractures of the thoracic and lumbar spine.

The PILLAR[™] SA 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 PILLAR[™] SA PEEK Spacer System is intended to be used with autograft or allograft.

The PILLAR[™] SA PEEK Spacer System is intended for use with the four titanium alloy screws provided with the device. If the physician chooses to use fewer than four of the provided screws, then supplemental internal fixation must be used to augment stability. As an example, the supplemental internal fixation system that may be used is the Blackstone Medical, Inc. Spinal Fixation System (SFS).

Contraindications: The PILLAR[™] SA PEEK Spacer System, as with other orthopedic implants, is contraindicated for use in patients:

1. With active infections in which the use of an implant could preclude adequate and appropriate treatment of the infection, or

2. Who have had prior fusion at the level to be treated.

Potential Adverse Effects: Potential adverse effects 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. The size and shape of the human bones present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
- 2) 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) Single use only. No surgical implants should be reused. Any implant once used should be discarded. Even though the device appears undamaged, it may already have small defects and internal stress patterns that may lead to fatigue failure.
- 4) Non-sterile; the PILLAR™ SA PEEK Spacer System implants and instruments are provided non-sterile, and therefore, must be sterilized before each use.
- 5) 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.
- 6) Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

Cleaning:

All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning can include the use of neutral cleaners followed by a deionized water rinse. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

Sterilization: The PILLAR™ SA PEEK Spacer System components are supplied NON-STERILE. Prior to use, all components should be steam sterilized by the hospital using the recommended cycle:

Method: Steam
Cycle: Gravity
Temperature: 250° F (121° C)
Exposure time: 30 minutes

Or:

Method: Steam
Cycle: Prevac
Temperature: 270° F (132° C)
Exposure time: 8 minutes

Product Complaints: Any Healthcare Professional (e.g., customer or user of this system), 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 Spine/Blackstone Medical, 1211 Hamburg Turnpike, Ste 300, Wayne, NJ 07470, USA, Telephone: 877-BMI-9494 (877-264-9494), email: complaints@blackstonemedical.com

Further information: A recommended surgical technique for the use of this system is available upon request from:



Orthofix Spine/Blackstone Medical, 1211 Hamburg Turnpike, Ste 300, Wayne, NJ 07470, USA
Telephone: 1-888-298-5400

Authorized European Representative:

Medical Device Safety Service (MDSS)
Schiffgraben 41
30175, Hannover
Germany

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

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