INSTRUCTIONS FOR USE

Important Information – Please Read Prior to Use

Rx Only

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Lewisville, Texas 75056-9453 U.S.A.
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Device System Name:

Pillar™ SA Ti Spacer System

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English EN

Device System Name:

Pillar SA Ti Spacer System

Description:

The PILLAR SA Ti Spacer System is an integrated intervertebral body fusion device for use in anterior lumbar interbody fusion (ALIF) procedures. The PILLAR SA TI Spacer System is comprised of 3D printed titanium interbody spacers with porous titanium end plates and a functional gradient porous structure, and bone screws. The implants are offered in multiple footprints and lordotic options to accommodate individual patient anatomy. Each porous interbody has a large central window for graft material and a threaded hole with a zero-step locking mechanism for screw retention.

The PILLAR SA TI Spacer System implants are provided sterile.

PILLAR SA TI Spacer System implants are designed to be used with PILLAR SA TI Spacer System instrumentation and are not compatible with components from any other manufacturer's system.

Indications for Use:

The PILLAR SA Ti Spacer System is indicated for use as an adjunct to fusion in skeletally mature patients. The implants used of less than or equal to 20 degrees in lordosis may be used as a standalone device only when at least two Screws are inserted with one inferior and one superior screw trajectory. The implants of greater than 20 degrees in lordosis must be used with supplemental fixation cleared by the FDA for use in the lumbar spine in addition to the integrated screws.

The PILLAR SA Ti Spacer System is intended for use at one or two contiguous levels in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to a Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The PILLAR SA Ti Spacer System is intended for use in patients who have had at least six months of non-operative treatment. It is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

Contraindications:

The PILLAR SA Ti 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 appropriatetreatment 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 heading indications.

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, perma- nent pain and/or deformity. In rare instances, 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 isincreased by the selection of the proper size, shape, and design of the implant. No implant canbe expected to withstand the unsupported stresses of full weight bearing. The size, shape andcondition of the 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 insurface finish and may cause internal stress concentrations, which may become the focal pointfor eventual failure of the device.
3. PILLAR SA Ti spacers are provided STERILE. Do not use if the package is opened or damaged or ifthe expiration date has passed.
4. DO NOT re-sterilize PILLAR SA Ti spacers as this could result in injury or require reoperation dueto breakage.
5. PILLAR SA Ti bone screws are provided non-sterile, and therefore, must be sterilized prior toeach use.
6. 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.
7. All implants are intended for SINGLE USE ONLY. Any used implant should be discarded. Eventhough the device may appear undamaged, it may have small defects and internal stresspatterns that may lead to fatigue failure.
8. Non-Sterile; the PILLAR SA Ti Spacer instruments are provided non-sterile, and therefore, mustbe thoroughly cleaned and sterilized after each use.
9. Postoperative care is important. The patient should be instructed in the limitations of theimplant and should be cautioned regarding weight bearing and body stress on the device priorto secure bone healing.
10. 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 theperformance of the intervertebral body fusion device.
11. The implantation of the intervertebral body fusion device should be performed only byexperienced spinal surgeons with specific training in the use of this device because it is atechnically demanding procedure presenting a risk of serious injury to the patient.
12. Patients with previous surgery at the levels to be treated may have different clinical outcomescompared to those without a previous surgery. Non-sterile; the plates, screws and instruments are supplied non-sterile, and therefore, must be sterilized before each use.

MRI SAFETY INFORMATION

A person with the Orthofix Atlas (Pilar SA Ti) Implants and Bone Screws may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	Orthofix Atlas (Pilar SA Ti) Implants and Bone Screws
Static Magnetic Field Strength (B0)	1.5T or 3.0T
Maximum Spatial Field Gradient	330 T/m or 3000 gauss/cm
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Volume RF body coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	1 W/kg (normal operating mode)
Maximum Head SAR	3.2 W/kg
Scan Duration	Under the scan conditions defined, the Orthofix Atlas (Pilar SA Ti) Implants and Bone Screws can be scanned continuously for 60 minutes.
MR Image Artifact	The presence of this implant may produce an image artifact.

Cleaning:

The PILLAR SA Ti spacers are provided STERILE. Please discard all opened and unused implants.

The PILLAR SA bone screws are provided clean but not sterile. Once an implant comes in contact with any human tissue or bodily fluid it should not be re-sterilized or used. Please discard all contaminated implants.

The PILLAR SA Ti Spacer System instruments are compatible for use with the PILLAR SA Ti Spacer implants. All instruments must be thoroughly cleaned after each use. Cleaning may be done using validated hospital methods or following the validated cleaning processes described below.

Note: The PILLAR SA Ti Squid Inserter is the only instrument requiring disassembly prior to cleaning. The inner 'SHAFT' component must be unthreaded from the 'BLADES' component, and both placed in their corresponding tray locations for 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. Adapters (82-12XX) must be disassembled from the Anterior Inserter (82-1100) prior to cleaning.
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 otherhard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipecleaner brush).
2. Remove the instruments from the enzymatic detergent and rinse in tap water for a minimum of3 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 cleaningsolution 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 soilon the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and otherdifficult 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 until no visible soil is noted.

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 steps listed above 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. 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.

Sterilization:

The PILLAR SA Ti spacers are provided STERILE. They are sterilized using gamma irradiation sterilization. Do not re-sterilize.

Sterilization in Orthofix Cases:

The PILLAR SA Ti bone screws and instruments are supplied NON-STERILE. Prior to use, all non-sterile instruments and implants should be placed in the appropriate Orthofix case which will be wrapped in a FDA cleared sterilization wrap and placed in the autoclave for sterilization by the hospital using the following recommended cycle:

Sterilization in Orthofix Instrument cases & blue wrap:
Method: Steam
Cycle: prevac
Temperature: 270°F (132°C)
Exposure time: 4 minutes
Dry Time: 30 Minutes
(FDA cleared double wrap recommended)

Sterilization in Rigid Sterilization Containers:
Sterilization Method – Steam Prevac Cycle
Temperature: 270°F (132°C)
Exposure time: 4 minutes
Dry Time: 30 Minutes

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}. On the case marked PILLAR SA TI STANDARD TRIALS, the area with the pin mat should be loaded with loose Trials only to avoid exceeding the maximum 25 lb weight limit per ANSI/AAMI ST77.

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 PILLAR SA Ti instruments, bone screws, 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 and implants are provided in sealed poly bags with individual product labels.

PILLAR SA Ti spacers are provided STERILE. Do not use if the package is opened or damaged or if the expiration date has passed.

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, Telephone: 214-937-3199 or 1-888-298-5700 or via 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 PILLAR SA Ti 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		Use By Date
	Orthofix.com/IFU		Manufacturer
	Single Use Only Do Not Reuse	EC REP	Authorized Representative
REF	Catalogue Number		Do Not Resterilize
	Provided Non-Sterile	SN	Serial Number
STERILE R	Sterilized Using Irradiation	LOT	Lot Number
	MR Conditional		