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ADIRA™ LATERAL PLATE SYSTEM

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IMPORTANT INFORMATION ON THE ADIRA™ LATERAL PLATE SYSTEM

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WITHIN THE UNITED STATES ONLY

ENGLISH

IMPORTANT INFORMATION ON THE ADIRA™ LATERAL PLATE SYSTEM

DESCRIPTION

The ADIRA™ Lateral Plate System consists of one-level thoracolumbar plates and buttress plates that are used with variable, fixed angle, or locking bone screws for attachment to the lateral or anterolateral portion of the vertebral body of the thoracolumbar spine. (T1-L5).

ADIRA™ plates may be assembled to lateral lumbar interbody fusion devices (HEDRON L®, TransContinental®, RISE®-L, Modulus® XLIF, Cohere® XLIF, or CoRoent®) with an alignment screw to create an ADIRA™ Plate-Spacer assembly, to provide structural stability in skeletally mature individuals following discectomy. The plate-spacer assembly is used with bone screws and/or lateral anchors.

ADIRA™ plates, alignment screws, bone screws, and anchors are manufactured from titanium alloy, as specified in ASTM F136 or F1295. Bone screws and anchors are available with hydroxyapatite (HA) coating, as specified in ASTM F1185. Locking screws are manufactured from cobalt chromium alloy, as specified in ASTM F1537.

INDICATIONS

ADIRA™ Lateral Plate System
The ADIRA™ 2-Hole and 4-Hole Plates, when used with screws only, are intended for use in the treatment of thoracolumbar (T1-L5) spinal instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or failed previous spinal surgery.

The ADIRA™ 1-Hole Plate is intended to stabilize allograft or autograft at one level (T1-L5), aiding in spinal fusion and to provide temporary stabilization and augment development of a spinal fusion. It may be used alone or with other anterior, lateral, anterolateral, or posterior spinal systems. The device is not intended for load bearing applications.

ADIRA™ Plate-Spacer Assemblies
ADIRA™ Plates may be assembled to a lateral lumbar interbody fusion device (HEDRON L®, TransContinental®, RISE®-L, Modulus® XLIF, CoRoent®, or Cohere® XLIF Spacers) to create a plate-spacer assembly. When assembled to HEDRON L®, TransContinental®, or RISE®-L Spacers, the plate-spacer assembly is indicated for use at one or more levels of the lumbosacral spine (L1-L5), as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. When ADIRA™ Plates are assembled to Modulus® XLIF, CoRoent®, or Cohere® XLIF Spacers, the plate-spacer assembly takes on the indications of the interbody device.

ADIRA™ Plate-Spacers are intended to be used with screws and/or anchors which accompany the implants. These devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). In addition, the 2-Hole or 4-Hole Plate-Spacers are intended for stand-alone use in patients with DDD at one or two levels only when <20° lordotic implants are used with two or four screws, respectively.

ADIRA™ Plate-Spacers are to be filled with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone.

WARNINGS

One of the following potential risks identified with this system is death. Other potential risks, which may require additional surgery, include:

- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- neurological injury, and
- vascular or visceral injury.

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis, or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture.

Patients with previous spinal surgery at the involved level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

Possible adverse effects that may occur include: failed fusion or pseudarthrosis leading to implant breakage; allergic reaction to implant materials; device fracture or failure; device migration or loosening; loss of fixation; vertebral fracture; decrease in bone density; pain, discomfort, or abnormal sensations due to the presence of the device; injury to nerves, vessels, and organs; venous thrombosis, lung embolism and cardiac arrest; and death.

The components of this system are manufactured from titanium alloy and cobalt chromium alloy. Mixing of stainless steel implant components with different materials is not recommended, for metallurgical, mechanical, and functional reasons.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

PRECAUTIONS

The implantation of these devices should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size and screw diameter and length.

Surgical implants are SINGLE USE ONLY and must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns, which could lead to breakage.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

For optimal implant performance, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

CONTRAINDICATIONS

Use of this system is contraindicated in patients with the following conditions:

- Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Signs of local inflammation.
- Severe osteoporosis, which may prevent adequate fixation.
- Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
- Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
- Any patient not willing to cooperate with postoperative instructions.
- Any condition not described in the indications for use.

MRI SAFETY INFORMATION

MRI Safety Information

A person implanted with the ADIRA™ Lateral Plate System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	ADIRA™ Lateral Plate System
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact.

PACKAGING
The implants may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The implants and instruments may be provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING AND USE
All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion (i.e. rust, pitting), discoloration, excessive scratches, notches, debris, residue, flaking, wear, cracks, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

CLEANING
Instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable. All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The products should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments and instrument trays and cases after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION
Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION
These implants may be provided sterile or nonsterile. Instruments are provided nonsterile.

Sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile devices are packaged in a heat-sealed double pouch or container/pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants that become nonsterile or have expired packaging are considered nonsterile and should be discarded. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated to ensure an SAL of 10^{-6}. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 minutes	30 minutes
Steam	Pre-vacuum	134°C (273°F)	3 minutes	30 minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (U.S.A.) Law Restricts this Device to Sale by or on the Order of a Physician.

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	NON STERILE	NON-STERILE
LOT	LOT NUMBER		MANUFACTURER
	CAUTION		USE BY (YYYY-MM-DD)
	SINGLE USE ONLY		DO NOT USE IF PACKAGE IS DAMAGED
	DO NOT RESTERILIZE	Rx ONLY	PRESCRIPTION USE ONLY
MD	MEDICAL DEVICE	MR	MR CONDITIONAL