DI184B-EN (Rev H)	InOrbit™ LATERAL LUMBAR DISC

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IMPORTANT INFORMATION ON InOrbit™ LATERAL LUMBAR DISC

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For symbols glossary, please refer to www.globusmedical.com/elFU

ENGLISH

OUTSIDE THE UNITED STATES ONLY

IMPORTANT INFORMATION ON THE InOrbit™ LATERAL LUMBAR DISC

DESCRIPTION

The InOrbit™ Lateral Lumbar Disc is an intervertebral disc replacement device designed to restore disc height and preserve motion at the implanted level of the lumbosacral spine. The device is implanted using a lateral lumbar approach. The assembly consists of a superior and inferior endplate with multiple serrated keels, and incorporates a ball and socket articulation. Implants are offered in a variety of configurations to accommodate varied patient anatomy.

The InOrbit™ endplates are manufactured from radiolucent polymer, as specified in ASTM F2026. The superior and inferior surfaces of the endplates are plasma sprayed with commercially pure titanium, as specified in ASTM 1580 and F1147. The endplates contain radiolucent titanium alloy or tantalum markers, as specified in ASTM F136, F1295 and F560.

Chemical composition for direct contacting materials used in implantable devices (Composition by Wt.%)

Material and Standard	Element	Composition mass %
Polyether-ether-ketone (PEEK / PEEK OPTIMA LT-1) per ASTM F2026	Carbon	74.2
	Hydrogen	4.6
	Oxygen	21.2
Commercially pure titanium per ASTM F1580 – Ti Sponge Powder	Aluminum	0.05 max
	Oxygen	0.40 max
	Iron	0.15 max
	Carbon	0.03 max
	Hydrogen	0.03 max
	Nitrogen	0.02 max
	Silicon	0.04 max
	Chlorine	0.20 max
	Sodium or Magnesium	0.50 max
	Titanium	Balance
Tantalum per ASTM F560	Carbon	0.010 max
	Oxygen	0.015 max
	Nitrogen	0.010 max
	Hydrogen	0.0015 max
	Niobium	0.10 max
	Iron	0.010 max
	Titanium	0.010 max
	Tungsten	0.050 max
	Molybdenum	0.020 max
	Silicon	0.005 max
	Nickel	0.010 max
	Cobalt	<0.1
	Tantalum	Balance
Titanium alloy (TAV) per ASTM F136	Nitrogen	0.05 max
	Carbon	0.08 max
	Hydrogen	0.0150 max
	Iron	0.25 max
	Oxygen	0.13 max
	Aluminum	5.5-6.50
	Vanadium	3.5-4.5
	Titanium	balance
Titanium alloy (TAN) per ASTM F1295	Aluminum	5.50-6.50
	Niobium	6.50-7.50
	Tantalum	0.50 max
	Iron	0.25 max
	Oxygen	0.20 max
	Carbon	0.08 max
	Nitrogen	0.05 max
	Hydrogen	0.009 max
	Cobalt	<0.10
	Other elements each	0.10 max
	Other elements total	0.4 max
	Titanium	Balance

INDICATIONS

The InOrbit™ Lateral Lumbar Disc is indicated for spinal arthroplasty in treating skeletally mature patients with degenerative disc disease, primary or recurrent disc herniation, spinal stenosis, or spondylosis in the lumbosacral spine (L1-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies, with or without leg (radicular) pain. Patients may have spondylolisthesis up to Grade 1 at the involved level.

CONTRAINDICATIONS

The InOrbit™ Lateral Lumbar Artificial Discs are contraindicated for patients with the following:

- Prior fusion surgery adjacent to the vertebral level being treated
- Prior surgery at the level to be treated
- Clinically compromised vertebral bodies at the affected level(s) due to current or past trauma
- Radiographic confirmation of facet joint disease or degeneration
- Osteoporosis, osteopenia, Paget's disease, osteomalacia or any other metabolic bone disease
- Active systemic or local infection
- Demonstrated allergy or foreign body sensitivity to any of the implant materials
- Conditions that may place excessive stress on the lumbar spine and implant, such as severe obesity or degenerative disease
- 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 healing and may be at a higher risk of implant failure

WARNINGS

Risks associated with this device and with the surgical procedure are not known but may include:

- Injury to nerves, vessels, and organs;
- Allergic or tissue reaction to implant materials;
- Hematoma and impaired wound healing;
- Migration or loosening of the device;
- Fracture of the device;
- Heterotopic ossification and fusion;
- Venous thrombosis, lung embolism, and cardiac arrest;
- Death;
- Clicking noises;
- Metallosis.

PRECAUTIONS

Implantation of the InOrbit™ Lateral Lumbar Disc device should be performed only by experienced spinal surgeons with specific training in the use of artificial discs 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.

The implants are provided sterile and for single use only. Surgical implants 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. Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, infection, mechanical failure and material degradation. Re-sterilization may result in damage or decreased performance.

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 on the performance of this system.

MRI SAFETY INFORMATION



The InOrbit™ Lateral Lumbar Disc devices are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/m (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2W/kg

Under the scan conditions defined above, the InOrbit™ Lateral Lumbar Disc devices are expected to produce a maximum temperature rise of less than or equal to 7.8°C after 15 minutes of continuous scanning.

The image artifact caused by the device is not expected to extend beyond 35mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

ATTENTION

Under no circumstances should the InOrbit™ Lateral Lumbar Disc device components be used in combination with components from other suppliers. Damage to weight bearing structures can give rise to loosening of the device components, dislocation, and migration, and other serious complications; the implant should be checked periodically.

PACKAGING

These implants and instruments 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 instrument sets are 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/DISPOSAL

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, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

The implant/device must be disposed of in accordance with applicable local regulations for handling of biological medical waste.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments 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 of instruments 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 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.

INFORMATION

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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

For information regarding the Patient Implant Card (PIC): The patient will be provided with a Patient Implant Card upon implantation, which contains important details about the implanted device.

STERILIZATION

These implants are ONLY available sterile. The instruments used with these devices may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed, double Tyvek pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged.

Nonsterile instruments have been validated to ensure an SAL of 10^{-6}. The use of a 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 are designed 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 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 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.

Accessing the Summary of Safety and Clinical Performance (SSCP)

The SSCP will be available in the European database on medical devices (Eudamed), where it will be linked to the basic UDI-DI 0193982LUMBARDISC9E. The web address for the Eudamed public website is: https://ec.europa.eu/tools/eudamed

Until Eudamed becomes mandatory, the SSCP is available upon request to: inquiries@globusmedical.com