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This package leaflet applies to

Spinal implants of the system
Oyster® ACIF

Table of Content

1. Contents

The package contains the Oyster ACIF Cage.

2. Description

The Oyster ACIF Cage is a Titanium (Ti grade 23) disc shaped open graft hole cervical interbody fusion cage.

3. Indications for use

The Oyster ACIF Cage is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Oyster ACIF Cage is intended for use for anterior cervical interbody fusion in patients with cervical disc disease (DDD) at up to two contiguous levels from C2 to T1. The System is intended to be used with supplemental fixation; the Oyster ACIF Cage is required to be used with an anterior cervical plate as the form of supplemental fixation. The System is intended for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The Oyster ACIF Cage is to be used in patients who have had at least six weeks of non-operative treatment.

4. (Relative) contra-indications

Do not use the Oyster ACIF Cage in cases of:

- Reduced bone quality
- Anomaly/fracture
- Any condition compromising success of the procedure
- Rapidly destructive joint disease
- Bone resorption, osteopenia, and/or osteoporosis
- Active infection
- Local inflammation
- Primary spinal deformities
- Allergy or foreign body reaction to titanium or it's alloys
- Patients in whom the implant may impinge upon natural structures or interfere with a physiological function
- Use of these implants is relatively contraindicated in patients with reduced ability to follow postoperative restrictions and rehabilitation programs

In addition, patients who smoke have been shown to have an increased incidence of pseudo arthrosis. See also the WARNINGS and PRECAUTIONS sections of this IFU.

5. Potential adverse events

As with any major surgical procedure, there are risks involved in orthopedic surgery, including procedures involving the Oyster ACIF Cage. Potential risks identified with the use of the Oyster ACIF Cage and/or System include, but are not limited to:

- Device fracture
- Loss of fixation
- Nonunion
- Implant subsidence
- Neurologic injury and/or vascular/ visceral injury

- Infection
- Postoperative migration of the implant
- Intolerance to the material

Further adverse events identified, not directly linked to product or procedure, are:

- Degeneration of the vertebrae adjacent to the arthrodesis

Note:
Adverse events may occur when the Oyster ACIF Cage and/or System is used either with or without associated devices/instrumentation. The identified adverse events as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed.

6. Warnings/ Precautions

- **MR NOT EVALUATED** The Oyster ACIF Cage 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 Oyster ACIF Cage in the MR environment is unknown. Scanning a patient who has the Oyster ACIF Cage may result in patient injury.

- **INSTRUMENTATION** Only use dedicated instruments set and accessories as listed in the surgical technique to avoid adverse affecting Oyster ACIF Cage performance or surgical outcome.

- **TRAINING** The surgeon should strictly follow the recommendations in the surgical technique. All staff involved should be familiar with the surgical procedures associated with the cervical interbody fusion technique to avoid adversely affecting Oyster ACIF Cage performance or surgical outcome.

- **PATIENT SELECTION** Appropriate patient selection is critical to the surgical outcome. Only patients who satisfy the indications AND who do not have any of the contraindications should be considered for interbody fusion surgery using the Oyster ACIF Cage to avoid adversely affecting Oyster ACIF Cage performance or surgical outcome. In addition, patients who smoke have been shown to have an increased incidence of pseudo arthrosis.

- **PATIENT EDUCATION** Preoperative instructions to the patient are essential. The patient must be made aware of the limitations and potential adverse effects of the surgery. The patient must be instructed to limit the postoperative activity as this will reduce the risk of bent, broken and/ or loose Oyster ACIF Cage components. The patient must be made aware that Oyster ACIF Cage components may bend, break and/ or loosen, even though restrictions in activity are followed.

- **DISTRACTION** Adequate distraction is one of the preconditions for the primary stability of the Oyster ACIF Cage; however it is critical to ensure that the segment is not over distracted to avoid damage of ligaments and or endplates.

- **ENDPLATE PREPARATION** Appropriate removal of the cartilaginous layers of the endplates is important for the vascularisation of the bone transplant. However, make sure to clean the endplates carefully and maintain the integrity of the underlying bony endplate, as damage of the endplate can lead to Oyster ACIF Cage subsidence.

- **IMPLANT SELECTION** The Oyster ACIF Cage and Systems Oyster cervical cage system offers a broad selection of different lengths, widths and anatomic shapes, each with 5° lordosis. This portfolio enables individual customization to different patient anatomies and intraoperative requirements. With the trial sizers, you can determine the length, width and height and at the same time check which anatomic shape is suitable for the situation. It is recommended to use a Oyster ACIF Cage implant that is as wide as possible to achieve a large contact surface and to ensure support on the anterior and posterior cortical region of the endplates. To determine the height, it is important to make sure that the Oyster ACIF Cage implant is neither too tight nor too loose. In correspondence with the endplate preparation, allowing minimal removal of bone, choose the anatomical variant that is most-suitable: either anatomic or wedge shape.

- **INSERTION DEPTH** Insertion shall be performed under fluoroscopy control to avoid too deep placement resulting in spinal cord injury.

- **EXPIRY DATE** Before use of the Oyster ACIF Cage check the expiration date (yyyy/mm/dd). The Oyster ACIF Cage shall not be used after its expiration date. Use after the expiration date can lead to infection.

- **PACKAGING INTEGRITY** Before use of the Oyster ACIF Cage check if the secondary packaging, labelling and sterile primary packaging are intact. The sterile packaging should be free of cracks, holes, tears and any other damage. Use of the Oyster ACIF Cage unpacked from damaged packaging can lead to an untraceable product or infection.

- **IMPLANT HANDLING** The Oyster ACIF Cage should be handled appropriately to protect it from unintentional damage. Avoid scratching or damaging the Oyster ACIF Cage at any time (specifically during attachment of the Oyster ACIF Cage to the inserter and Oyster ACIF Cage placement), as this may lead to premature failure of the Oyster ACIF Cage. Care must be taken when placing the Oyster ACIF Cage to avoid damage.

- **IMPLANT PLACEMENT** The Oyster ACIF Cage has teeth to maximize primary stability, however make sure the soft tissue and esophagus are adequately retracted when inserting the Oyster ACIF Cage to avoid damage from contact with the Oyster ACIF Cage (in particular the

teeth). Adequate positioning of the Oyster ACIF Cage is critical; an improperly placed Oyster ACIF Cage can adversely affect Oyster ACIF Cage performance or surgical outcome.

- **PERMANENT IMPLANTATION** The Oyster ACIF Cage is intended for permanent implantation and shall not be removed in case of good outcome. Removal of a stable Oyster ACIF Cage can lead to loss of stability and damage to the surrounding tissue.

- **SINGLE USE ONLY** The Oyster ACIF Cage is provided as a single use implant only, and is not to be reused, resterilized or reimplanted in any situation as this might adversely affect Oyster ACIF Cage performance and/or increase risk of infection.

7. Sterility

The Oyster ACIF Cage is packed individually and delivered in a sterile package. The Oyster ACIF Cage is sterilized by irradiation with a dose of 25 kGy

8. Storage

The Oyster ACIF Cage must be stored in its original packaging under the storage conditions specified on the packaging to prevent deterioration. Where appropriate, monitor and record storage conditions periodically.

9. Disposal

The disposal of the Oyster ACIF Cage requires no special measures. Be sure to observe all national/local regulations and guidelines when disposing of the packaging material and potentially infectious items.

10. Materials used in implantable devices

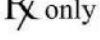
Manufacturing materials are:

Cage: Titanium (Ti grade 23)

11. Information

To obtain a surgical technique manual or should any information regarding the products or their uses be required, please contact the legal manufacturer or your local distributor

12. Glossary of Symbols

	Manufacturer
	Catalog number
	Lot number
	Quantity
	Use-by date
	Sterilized using irradiation
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight
	Caution
	Do not resterilize
	Do not re-use
	Consult instructions for use
	Upper limit of temperature
	Package contains wedge shape cage
	Package contains anatomic shape cage
	Lordotic angle
	Legal manufacturer
	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a licensed healthcare practitioner