Instruction for Use (D30287)

Oyster® ACIF

Important Information – please read before use!

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This Instruction for use covers the implants of the Oyster ACIF Cage System.

This and other product specific information (e.g. instrumentation guides) as well as product accompanying information in other relevant official languages are available under the following links:

- https://elabeling.silony-medical.com
- www.silonyspine.com

Instruction for Use D30003 must be used as reference for reprocessing instruments.

The summaries of safety and clinical performance (SSCP) of Silony implants are available in the European Database for Medical Products (EUDAMED) and are provided by Silony Spine upon request.

Any manufacturer liability is excluded in the event of non-compliance with the manufacturer's product information.

Prior to using a product distributed by Silony Spine, the surgeon is expected to carefully study the following indications/contraindications, recommendations, warnings, and advice as well as the product specific information. Silony Spine also recommends participation in appropriate user training.

Users and/or patients are required to report any (serious) incidents related to the device to the manufacturer and to the state competent authority.

This instruction for use does not apply to the USA or its territories.

1 Product description

1.1 General Information

The Oyster ACIF Cage (Anterior Cervical Interbody Fusion) is an interbody fusion implant for the cervical spine (C2-T1) manufactured by Silony Spine.

The aim of the bony fusion is to treat instabilities, correct deformities and support a physiological lordosis.

In order to be able to take into account the patient-specific anatomy and to restore the natural intervertebral height and lordosis, the implants are provided in different dimensions and heights.

1.2 Performance characteristics

The Oyster ACIF Cage system was developed to meet the requirements and complexity of cervical interbody fusion procedures. The Oyster portfolio is designed to restore segmental alignment and stability through different types of implants. Implants with different footprints (depth (anterior - posterior) x width (medial - lateral) ranging from 15 mm x 14 mm; 17 mm x 16 mm to 17 mm x 14 mm) are available with a selection of different heights (ranging from 4 mm to 10 mm in 1 mm increments). Implant variants with anatomic and wedge shape upper endplate geometry (wit a lordotic angulation of the implant of 5°) are available. The implants have a solid support structure combined with areas of open, porous lattice structure designed to support bone ingrowth and fusion. Variants with a bone window for filling with allograft or autograft are available. Tooth-shaped structures integrated into the endplates are designed to ensure stable fixation of the implant in the intervertebral disc space. The implant has a tapered bullet nose that facilitates insertion. To ensure correct placement, an arrow on the external support structures of the device indicates the direction from caudal to cranial.

1.3 Material

Implants of the Oyster ACIF cage system are additively manufactured from titanium alloy Ti6Al4V ELI (ELI = extra low interstitials) in accordance with ASTM F3001.

Chemical composition (elements) according to ASTM F3001	Percentage of chemical elements in the total product [% (mass/mass)]
[Al] Aluminum	5.5 - 6.5
[V] Vanadium	3.5 - 4.5
[Fe] Iron	0.25 maximum
[O] Oxygen	0.13 maximum
[C] Carbon	0.08 maximum
[N] Nitrogen	0.05 maximum
[H] Hydrogen	0.012 maximum
[Y] Yttrium	0.005 maximum
[..] other elements, individually*	0.10 maximum
[..] other elements, total*	0.40 maximum
[Ti] Titanium	87.973 - 91

**Not normatively specified in ASTM F3001*

1.4 Information about special substances

Implants of the Oyster ACIF cage system do not contain substances of biological or animal origin, medicinal substances, or substances derived from human blood.

2 Clinical application

2.1 Intended use

Implants of the Oyster ACIF system (Anterior Cervical Interbody Fusion) are indicated for the primary stabilization of the cervical spine (C2-T1). The implants are intended for anterior insertion between two adjacent vertebrae enabling for load support, increasing intervertebral height of the spinal segment and as an adjunct for fusion (in combination with autograft or allograft materials) in skeletally mature

patients. Depending on the stability and sagittal profile, the Oyster ACIF Cage can be combined with additional stabilization.

2.2 Indications

The Oyster ACIF Cage system is solely intended for use in the field of human medicine for the treatment of the following diseases of the cervical spine (C2-T1):

- Symptomatic cervical discopathy
- Cervical spinal canal stenosis (central and foraminal)
- Segmental dysfunction and instabilities of the corresponding spinal area (including clinical signs and symptoms of radiculopathy or myelopathy)
- Revision surgeries with implantation of a new implant

2.3 Contraindications

There may be absolute or relative factors for not using the product. The decision to use a particular implant must be carefully considered, taking into account the patient's anamnesis. The following circumstances can affect the success of the treatment.

2.3.1 Absolute Contraindications:

- Expected or documented allergy or intolerance to the materials used (e.g. titanium and its alloys)
- Missing bone structures, which would render stable fixation of the implant impossible (e.g. fractures, tumors, diagnosed osteoporosis (T-score < -2.5) or infections).

2.3.2 Relative Contraindications:

- Patient overweight
- Fever or leukocytosis
- Systemic diseases and metabolic disorders
- Unbalanced diet, medicinal drug abuse; nicotine, alcohol or drug abuse
- Physical activities involving strong vibrations during which the implant is exposed to impacts and/or excessive loads (e.g. heavy physical work, competitive sport, marathon, alpine skiing, jumping and team sport)
- Patient who is mentally unable to understand and follow the physician’s instructions
- Any patient for whom the use of the implant would be in conflict with the anatomical structures
- Pregnant women: surgeries should be avoided if possible or require special care. This is at the discretion of the surgeon.

2.4 Expected clinical benefit

As clinical benefits for the patient, the quality of life should be increased by reducing pain and a clinically relevant improvement in function, as well as decompressing neural structures and increasing the intervertebral height.

2.5 Target patient group

The implants are intended for use in human medicine in patients with a mature skeleton.
There is no restriction regarding the intended patient population additional to the indications/contraindications.

2.6 Target user group

The implants are intended for use by orthopedic surgeons and neurosurgeons familiar with spinal surgery and experienced in the product-specific surgical techniques.

2.7 Use environment

The implants are to be used in a standard surgical environment.

3 Risks and possible negative side effects

As with any major surgical procedures there is a risk for adverse events. Prevalence of the possible negative effects may vary depending on patient-specific pathology and anatomy, as well as implantation levels. Possible negative consequences include among others:

- Cardiovascular complications (blood loss, impaired blood supply, anaemia, thrombosis, blood pressure drop, heart attack, cardiac arrest, stroke)
- Neurologic complications (exacerbation of myelopathie, horner's syndrome, dural lesion, CSF leakage, (transient) neurologic impairment / deficits, increased / new-onset nerve root compression / irritation), injury to the spinal cord, paralysis)
- Pulmonary complications (pneumonia, embolus, atelectasis, pleural effusion)
- General anaesthesia risks
- Change of mental state
- Inability to resume activities of daily life
- Post-operative (persistent) pain
- Infections, sepsis
- Wound related complications (delayed wound healing, impaired scarring)
- Implant related complications (peri- and post-operative implant breakage, dislocation or loosening of the implants, subsidence of the implant in the inferior and / or superior endplates of the adjacent vertebral body, material intolerance or allergic reaction, reduction in the bone density due to stress shielding)
- Vascular / visceral injuries (a.o. hematoma / lesions of the trachea and esophagus)
- Soft tissue injury
- Heterotrophic ossification
- Restricted range of motion
- Loss of correct spinal curvature (deformities)
- Lack of or delay in bone healing / fusion (development of pseudarthrosis)
- Adjacent segment degeneration
- Damage / fracture of the vertebral bone
- Hoarseness and swallowing disorders (dysphagia)
- Osteolysis
- In rare cases, some complications can be lethal.

4 Packaging, sterility and storage

4.1 Storage

⚠ **Implants must be stored in the sealed packaging according to the storage conditions indicated on the product label until use.**

4.2 Packaging

- The sterile packaging is set up as a double sterile barrier as follows (from the outside to the inside):
  - transport carton
  - first sterile barrier
  - second sterile barrier
- protective packaging (no additional sterile barrier)
- The rules of asepsis must be observed during removal from the sterile and protective packaging.

4.3 Labeling

- The instructions and symbols given on the labels must be followed (see section 6).
- The main label is attached to the transport carton. This contains all the necessary information for clear identification of the sterile packaged product (e.g., product description, article and lot number) and further information on the use of the product.
- The first and second sterile barriers are also each marked with a label with reduced content but contain clear identification of the sterile packaged product. The individual packaging layer is labeled as a double or single sterile barrier using appropriate symbols.
- The individual inner protective packaging is not marked separately with a label.
- When withdrawing the implant from the packaging, the direct marking on the implant must be verified against the information on the labels.
- The patient labels in the primary packaging must be attached to the patient file or the surgical report.

4.4 Sterilization

- Implants are packaged and sterilized with gamma irradiation at a minimum dose of 25 kGy and delivered sterile. They can be used without further preparation.

⚠ **Implants delivered by the manufacturer in a sterile condition must not be resterilized!**

- Prior to use, labeling and each packaging layer should always be checked for integrity.
- Before using the implant, the expiration date (YYYY/MM/DD) and the sterility marker on the packaging must be checked.

⚠ **The implant must not be used if the packaging is damaged, if the expiry date has expired or if the sterility marking is not present or does not indicate that the product has been correctly irradiated (marker must be colored red).**

- Sterile packaged products whose protective packaging is damaged, even if the product was not used for the surgical procedure, are considered used and must be disposed

5 Notes for application

5.1 General

- The surgical technique for Silony Spine implants can be learned by observing surgical procedures for demonstration purposes, workshops, and courses in a hospital familiar with these implants.

⚠ **Implants and instruments are always part of a system. Only instruments, trials and accessories by Silony Spine and Baat Medical Products B.V. described in the accompanying manufacturer's instructions (e.g., instrumentation guides or note inserts) must be used in order not to impair the performance of the device or surgical outcome.**

⚠ **Compatibility is only guaranteed with these instruments and accessories.**

5.2 Handling of the implants

- Implants are sensitive to damage. Even minor scratches or impact sites on the surfaces can lead to premature failure result in complications. Careful handling is required.

⚠ **Implants must not be mechanically processed or modified.**

⚠ **Implants that are contaminated, non-sterile, damaged, or scratched or that have been improperly treated or processed in an unauthorized way must not be implanted under any circumstances.**

- In the event of overloading, damage, improper implantation, or improper handling, implants may fracture, become loose, wear out, or become functionally impaired. In rare cases, there may be corrosion of the implant.
- Any implant is subject to inevitable wear and tear. An implant that was initially stable upon implantation may become loose or functionally impaired over time, which can result in revision surgery.

5.3 Reuse

⚠ **Implants are for single use only and strictly must not be reprocessed after use in a patient and contamination with blood, tissue or other body fluids. Reuse, reprocessing or resterilization can lead to limited functionality, transfer of pathogens or cross-infection which may lead to patient injuries, diseases or death.**

- Even if the implant appears to be intact, it may have minor defects and invisible damages due to excessive stress that can lead to premature wear and tear.

5.4 Preoperative use instructions

- Implant surgery should generally only be considered if all other conservative treatment options have been carefully assessed and have not proven to be the better option. The surgeon is responsible for considering the possibility of implant surgery.
- The treating physician is responsible for the proper performance of the surgery, including:
  - Patient-specific selection of size, shape and design of the implant
  - Planning of the surgery based on X-ray images
  - Checking possible allergies of the patient to the implant material
  - Ensure availability of different implant sizes and required instruments for the surgical procedure

- Neglecting to carry out preoperative planning can have a negative impact on the surgical outcome and lead to health damage. The potential success of surgery depends directly on the correct choice of the implant.
- When planning implantation, the patient-specific pathology and anatomy as well as the implantation levels must also be taken into account.

⚠ **Silony Spine bears and accepts no responsibility for complications resulting from an incorrect diagnosis or indication, an unsuitable choice of implant, incorrectly combined implant components and/or an improper surgical technique or asepsis.**

5.5 Intra-operative use instructions

- Prior to implantation, the implant must be visually inspected for damage.

⚠ **Damaged implants must not be used.**

- Depending on the surgeon's decision a bone graft (autograft and/or allograft) may be placed in the area to be fused.

5.6 Post-operative use instructions

- Post-operative evaluation of the fusion and the implant status are mandatory.
- Post-operative mobilization and rehabilitation are at the discretion of the surgeon dependent on clinical and radiological progress.

5.7 Information to the patient

- Even a successfully implanted cage is inferior to the healthy motion segment(s) of the spine. Similarly, an implant can represent a beneficial replacement of one or more pathological and/or symptomatic motion segment(s) for the patient, as it can help eliminate pain and therefore achieve improved mobility and stability.
- Pre- and post-operative instructions and warnings of the surgeon to the patient and their compliance are essential. The surgeon is responsible for informing the patient about the risks of implantation and about the outcome of the surgery as well as any potential negative consequences. The patient should be made aware of the limitations and the measures to minimize the possible complications. The patient should be instructed to limit the post-operative activity as this will reduce the risk of bending, breaking and / or loosening the implants.
- The patient must be issued with an implant pass.
- The patient must be informed that implants can have an impact on the diagnostic imaging of CT scans or MRI examinations. The patient must also be instructed to inform the examining physician about the implant and to show the implant pass prior to a scheduled CT scan or MRI examination.
- All information given to the patient should be documented in writing by the surgeon.

5.8 Magnetic resonance (MR) compatibility

- The implants are MR conditional.

⚠ **The implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration or image artifact in the MR environment.**

- Based on a systematic literature search of the State-of-the-Art for similar devices and materials, it can be assumed that safe MR examination can be performed on patients under the following conditions:
  - Static magnetic field of 3 Tesla or less
  - Maximum spatial gradient of magnetic field of 720-Gauss/cm (a higher value for the spatial gradient of magnetic field may apply if properly calculated)
  - Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (per pulse sequence).
- MRI-related heating: Possible heat generation is acceptable for a whole body averaged specific absorption rate (SAR) of 2W/kg for 15 minutes (per pulse sequence) of scanning using a 3-Tesla MR system.
- Migration: Due to the material used (titanium alloy), no forces or moments are to be expected which cause the implant to migrate during the MR examination.

- Artifacts: MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the implant.
- In all cases, the treating physician is responsible for MR conditions, MR imaging quality and patient safety.

5.9 Implant removal and revision

- The implant is not intended to be removed in case of a good outcome.
- Removal of a stable implant can lead to loss of stability and damage to surrounding tissue.
- However, adverse events might warrant removal of the implant.
- Removal of the implant is possible. This should be carefully considered by the treating surgeon and the patient, evaluating the risks and benefits.

5.10 Disposal

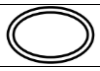
- Implants and instruments that can no longer be used can be disposed of in accordance with the national regulations applicable at the place of use or be returned to the manufacturer free of charge for proper disposal.
- Implants and instruments may only be returned to Silony Spine if they are still in the undamaged original package or have been cleaned, disinfected, and sterilized. Proof of such treatment must be attached to the outer packaging.

5.11 Traceability

- When passing on Silony Spine products (in return for payment or free of charge), each party passing on a product must ensure that appropriate traceability (lot tracking) is possible at all times.

6 Labeling and Symbols

Symbol	Description according to ISO 15223-1 and Silony specifications
	Manufacturer
	Date of manufacture *Including the date in the following format: YYYY-MM-DD*
CH REP	Swiss Authorized Representative
UK REP	United Kingdom Representative
CE 0483	The device meets the requirements of EU Regulation MDR 2017/745.
Rx only	Federal law in the USA restricts this device to sale by or on the order of a physician.
REF	Article number
LOT	Lot number
QTY	Number of items
MD	Medical device
UDI	Unique device identification
	Use by *Including the date in the following format: YYYY-MM-DD*
	Consult Instruction for use
	Caution
	Single sterile barrier system

Symbol	Description according to ISO 15223-1 and Silony specifications
	Double sterile barrier system
	Sterilized using irradiation
	Do not re-use
	Do not re-sterilize
	Do not use if the package is damaged
	Keep dry
	Keep away from sunlight
	MR conditional (The term MR is synonymous with MRI and means magnetic resonance imaging.)
	Metal detectors can trigger alarm due to the implant
	Patient Identification
	Health care centre or doctor
	Date (of implantation)
	Contact
	Silony Logo (for identification of the legal manufacturer in the course of direct marking of products)
	Cage angulation
	Domed cage
	Tapered cage

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