silony® MEDICAL

OYSTER® ACIF CAGE

INSTRUMENTATION GUIDE

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Introduction

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

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.

See also the "Potential Adverse Events" section and WARNINGS in this surgical technique (identified by a Warning symbol).

(Relative) Contraindications

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, it has been shown that smoking has an increased incidence of pseudarthrosis.

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:
• 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.

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.

OYSTER® ACIF INSTRUMENTATION

Pre-surgical planning

Only patients who satisfy the criteria set forth under the indications section of this document AND who do not have any of the conditions set forth under the contraindications section of this document may be considered for interbody fusion surgery using the Oyster ACIF cage.

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.

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

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.

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.

Surgical steps

PREPARATION AND APPROACH

Place the patient on the OR table using the standard positioning in cases of anterior cervical interbody fusion. Confirm the affected level(s) using imaging techniques and perform a standard anterior cervical approach.

Fig. 1: anterior approach

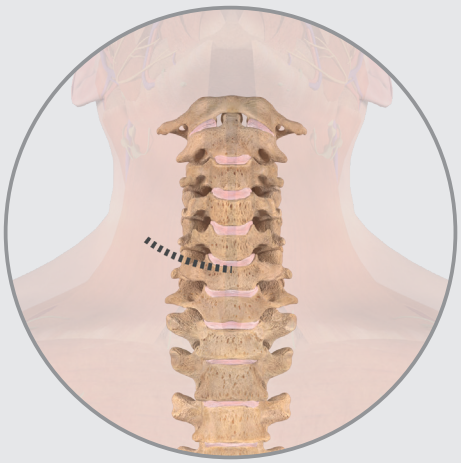


Fig. 2: anterior approach

DISTRACTION

Insert the Caspar pins in accordance with Caspar distractor IFU.

Spread the vertebrae in accordance with Caspar distractor IFU.

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.

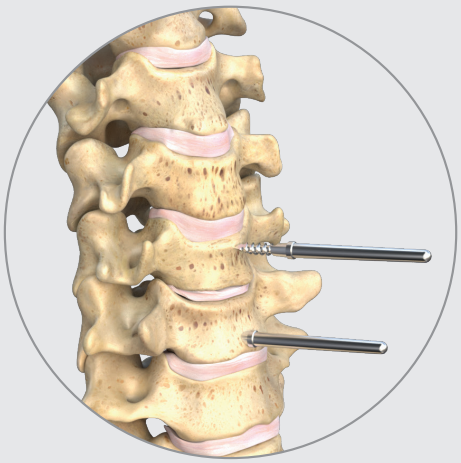


Fig. 3: Insert Caspar pins

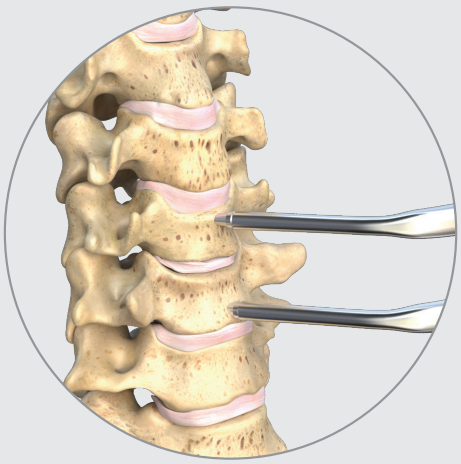


Fig. 4: Spread the vertebrae

Surgical steps

DISCECTOMY AND CURETTAGE
Remove the disc and if applicable perform curettage of the endplates.

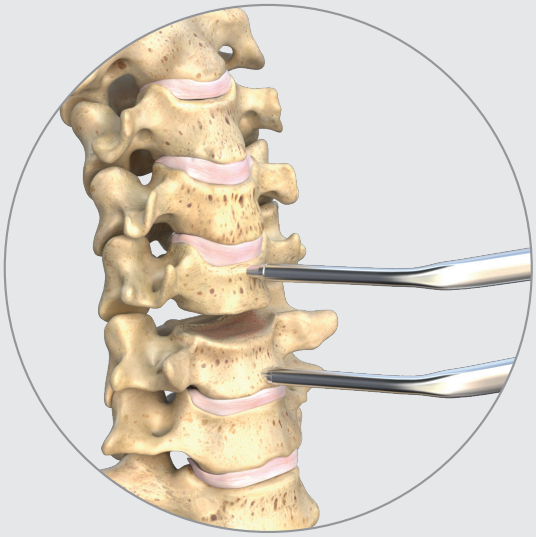


Fig. 5: Remove the disc and perform curettage of the endplates.

ENDPLATE PREPARATION Appropriate removal of the cartilaginous layers of the endplates is important for the vascularization 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.

Trial insertion and determination of cage size

Determine the appropriate Oyster ACIF Cage using the trial sizers. Use fluoroscopy control during insertion to determine proper placement. (Connect the trial sizers to the inserter in accordance with Figure 8 and Figure 9)

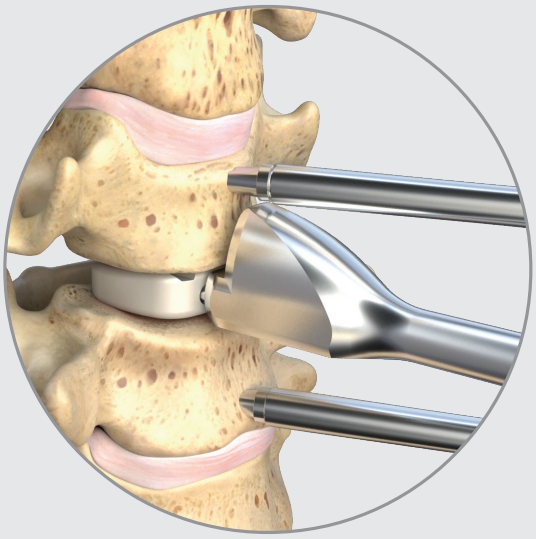


Fig. 6: Size disc space using trial sizers

Fig. 7: Use fluoroscopy control during insertion to determine proper placement

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

IMPLANT SELECTION The Oyster ACIF 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 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 end plates. To determine the height, it is important to make sure that the Oyster ACIF Cage 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.

Implant insertion

Remove Oyster ACIF Cage from packaging using standard aseptic practice.

Attach the Oyster ACIF Cage to the instrument[1].

Fig.8: Lock the implant to the implant holder

Fig. 9: Tighten the inserter by rotating the knob clockwise

[1] The Oyster Inserter shall be assembled prior to use. The Oyster Inserter Pin (OI-1005) is to be screwed in the Oyster Inserter Tube (OI-1015 or OI-1025) until the tip of the Oyster Inserter Pin protrudes the distal part of the outer Tube. According to surgeon preference the Oyster Inserter with (OI-1010) or without (OI-1020) depth stop can be used. After use the Oyster Inserter shall be disassembled prior to cleaning using the inverse order of the assembly steps.

Implant insertion

Fill the Oyster ACIF Cage with bone grafting material.

Fig. 10: Fill the cage with bone grafting material

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 a 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 implant to the inserter and implant placement), as this may lead to premature failure of the cage. Care must be taken when placing the Oyster ACIF cage to avoid damage.

Implant insertion

Insert the Oyster ACIF Cage. Use fluoroscopy control during insertion to determine proper placement.

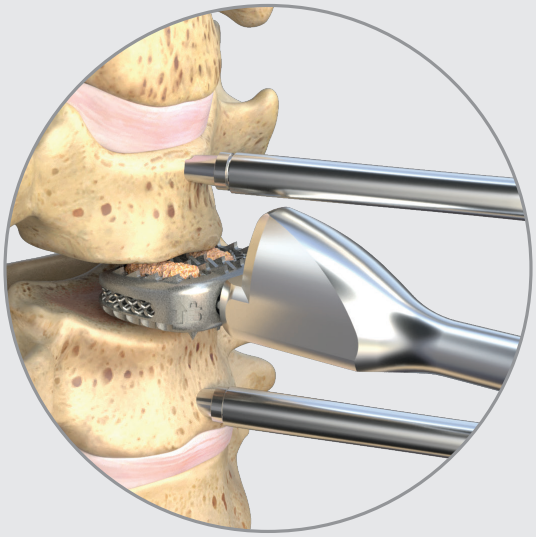


Fig. 11: Insert the cage

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

⚠ **IMPLANT PLACEMENT** The Oyster ACIF Cage has teeth to maximize primary stability, however make sure the soft tissue and oesophagus are adequately retracted when inserting the Oyster ACIF Cage to avoid damage from contact with the Oyster ACIF Cage (in particular the teeth). Adequate Oyster ACIF Cage positioning is critical; an improperly placed Oyster ACIF Cage can adversely affect Oyster ACIF Cage performance or surgical outcome.

Implant insertion

Disconnect inserter from Oyster ACIF Cage
by rotating the inserter knob counterclockwise.

Remove Caspar pins (according to Caspar distractor IFU).

Recommended: insert anterior plate in accordance with plate surgical technique.

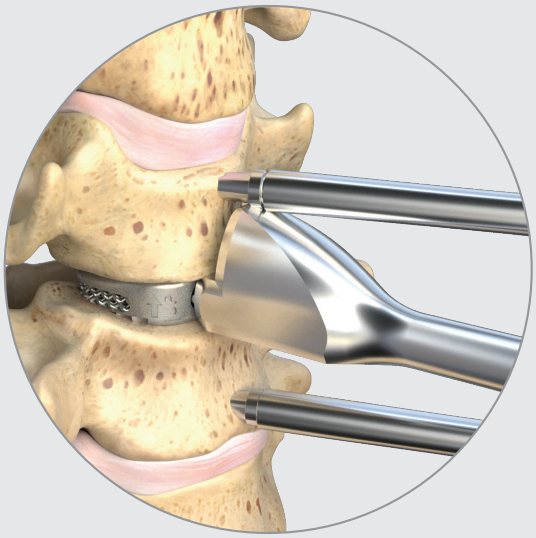


Fig. 12: Disconnect the implant from the inserter

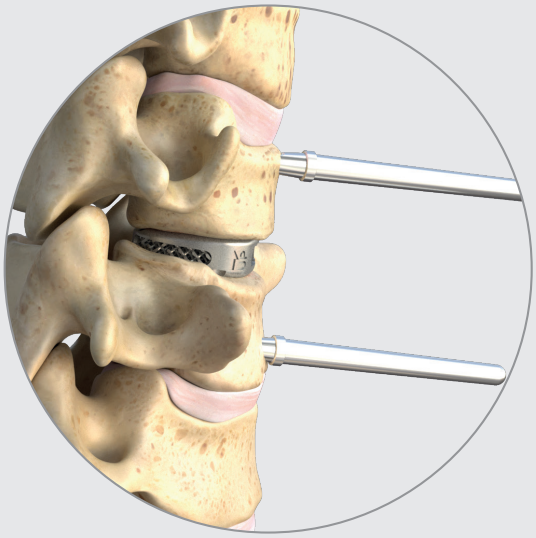


Fig. 13:Remove the Caspar pins

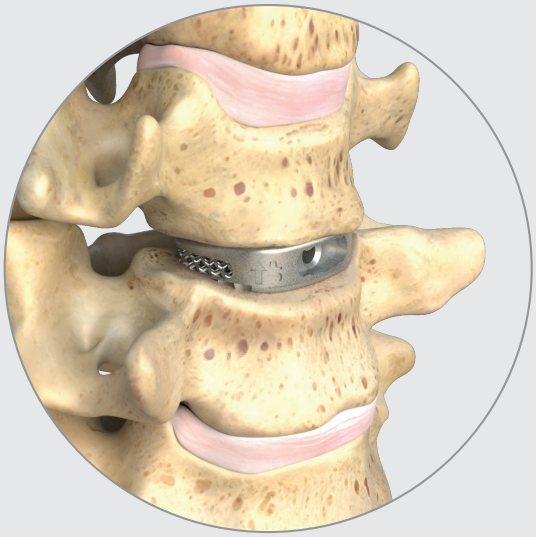


Fig. 14: Oyster ACIF Cage after insertion

Implant removal; Disposal

Implant removal
The Oyster ACIF Cage is intended for permanent implantation, however Oyster ACIF Cage failure or infection might warrant removal of the Oyster ACIF Cage. If it is necessary, expose the Oyster ACIF Cage from the bone by means of dissection and remove it by reattaching the inserter to the Oyster ACIF Cage by use of standard surgical pliers.

Disposal
The disposal 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.

SINGLE USE ONLY The Oyster ACIF Cage is provided as 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.

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.

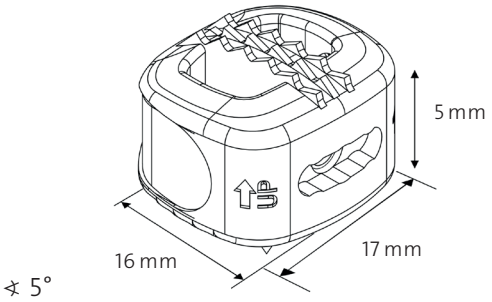
OYSTER® ACIF PRODUCT INFORMATION

Oyster ACIF Implants

Article number explanation for the cage, as an example

Oyster ACIF Cage, 05 x 17 x 16 dome open

S	–	OCT	–	05	17	16	51	–	S
Sterile		System		Height	Width	Length	Type		Property

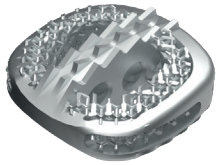


System: Oyster

Implant type: ACIF

Typing: dome open

Material: Ti6Al4VELI

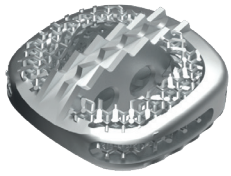
Article number	Description	Illustration
S-OCT-04151451-S	Oyster ACIF Cage, 04 x 15 x 14 mm, anatomic	
S-OCT-05151451-S	Oyster ACIF Cage, 05 x 15 x 14 mm, anatomic	
S-OCT-06151451-S	Oyster ACIF Cage, 06 x 15 x 14 mm, anatomic	
S-OCT-07151451-S	Oyster ACIF Cage, 07 x 15 x 14 mm, anatomic	
S-OCT-08151451-S	Oyster ACIF Cage, 08 x 15 x 14 mm, anatomic	
S-OCT-09151451-S	Oyster ACIF Cage, 09 x 15 x 14 mm, anatomic	
S-OCT-10151451-S	Oyster ACIF Cage, 10 x 15 x 14 mm, anatomic	

System: Oyster

Implant type: ACIF

Typing: dome open

Material: Ti6Al4VELI

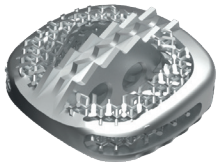
Article number	Description	Illustration
S-OCT-04171651-S	Oyster ACIF Cage, 04 x 17 x 16 mm, anatomic	
S-OCT-05171651-S	Oyster ACIF Cage, 05 x 17 x 16 mm, anatomic	
S-OCT-06171651-S	Oyster ACIF Cage, 06 x 17 x 16 mm, anatomic	
S-OCT-07171651-S	Oyster ACIF Cage, 07 x 17 x 16 mm, anatomic	
S-OCT-08171651-S	Oyster ACIF Cage, 08 x 17 x 16 mm, anatomic	
S-OCT-09171651-S	Oyster ACIF Cage, 09 x 17 x 16 mm, anatomic	
S-OCT-10171651-S	Oyster ACIF Cage, 10 x 17 x 16 mm, anatomic	

System: Oyster

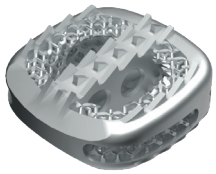
Implant type: ACIF

Typing: dome open

Material: Ti6Al4VELI

Article number	Description	Illustration
S-OCT-04171451-S	Oyster ACIF Cage, 04 x 17 x 14 mm, anatomic	
S-OCT-05171451-S	Oyster ACIF Cage, 05 x 17 x 14 mm, anatomic	
S-OCT-06171451-S	Oyster ACIF Cage, 06 x 17 x 14 mm, anatomic	
S-OCT-07171451-S	Oyster ACIF Cage, 07 x 17 x 14 mm, anatomic	
S-OCT-08171451-S	Oyster ACIF Cage, 08 x 17 x 14 mm, anatomic	
S-OCT-09171451-S	Oyster ACIF Cage, 09 x 17 x 14 mm, anatomic	
S-OCT-10171451-S	Oyster ACIF Cage, 10 x 17 x 14 mm, anatomic	

Oyster® ACIF Implants

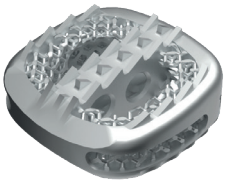
Article number	Description	Illustration
S-OCT-04151405-S	Oyster ACIF Cage, 04 x 15 x 14 mm, wedge shape	
S-OCT-05151405-S	Oyster ACIF Cage, 05 x 15 x 14 mm, wedge shape	
S-OCT-06151405-S	Oyster ACIF Cage, 06 x 15 x 14 mm, wedge shape	
S-OCT-07151405-S	Oyster ACIF Cage, 07 x 15 x 14 mm, wedge shape	
S-OCT-08151405-S	Oyster ACIF Cage, 08 x 15 x 14 mm, wedge shape	
S-OCT-09151405-S	Oyster ACIF Cage, 09 x 15 x 14 mm, wedge shape	
S-OCT-10151405-S	Oyster ACIF Cage, 10 x 15 x 14 mm, wedge shape	

System:
Oyster

Implant type:
ACIF

Typing:
flat open

Material:
Ti6Al4VELI

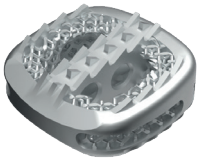
Article number	Description	Illustration
S-OCT-04171605-S	Oyster ACIF Cage, 04 x 17 x 16 mm, wedge shape	
S-OCT-05171605-S	Oyster ACIF Cage, 05 x 17 x 16 mm, wedge shape	
S-OCT-06171605-S	Oyster ACIF Cage, 06 x 17 x 16 mm, wedge shape	
S-OCT-07171605-S	Oyster ACIF Cage, 07 x 17 x 16 mm, wedge shape	
S-OCT-08171605-S	Oyster ACIF Cage, 08x17x16mm, wedge shape	
S-OCT-09171605-S	Oyster ACIF Cage, 09x17x16mm, wedge shape	
S-OCT-10171605-S	Oyster ACIF Cage, 10x17x16mm, wedge shape	

System:
Oyster

Implant type:
ACIF

Typing:
flat open

Material:
Ti6Al4VELI

Article number	Description	Illustration
S-OCT-04171405-S	Oyster ACIF Cage, 04 x 17 x 14 mm, wedge shape	
S-OCT-05171405-S	Oyster ACIF Cage, 05 x 17 x 14 mm, wedge shape	
S-OCT-06171405-S	Oyster ACIF Cage, 06 x 17 x 14 mm, wedge shape	
S-OCT-07171405-S	Oyster ACIF Cage, 07 x 17 x 14 mm, wedge shape	
S-OCT-08171405-S	Oyster ACIF Cage, 08 x 17 x 14 mm, wedge shape	
S-OCT-09171405-S	Oyster ACIF Cage, 09 x 17 x 14 mm, wedge shape	
S-OCT-10171405-S	Oyster ACIF Cage, 10 x 17 x 14 mm, wedge shape	

System:
Oyster

Implant type:
ACIF

Typing:
flat open

Material:
Ti6Al4VELI

Oyster® ACIF Trial Implants

System:
Oyster

Instrument type:
Trial implant

Typing:
dome

Material:
Stainless Steel (17-4PH)

Article number	Description	Illustration
OI-T04151451	Oyster ACIF Trial 04 x 15 x 14 mm, anatomic	
OI-T05151451	Oyster ACIF Trial 05 x 15 x 14 mm, anatomic	
OI-T06151451	Oyster ACIF Trial 06 x 15 x 14 mm, anatomic	
OI-T07151451	Oyster ACIF Trial 07 x 15 x 14 mm, anatomic	
OI-T08151451	Oyster ACIF Trial 08 x 15 x 14 mm, anatomic	
OI-T09151451	Oyster ACIF Trial 09 x 15 x 14 mm, anatomic	
OI-T10151451	Oyster ACIF Trial 10 x 15 x 14 mm, anatomic	

System:
Oyster

Instrument type:
Trial implant

Typing:
dome

Material:
Stainless Steel (17-4PH)
)

Article number	Description	Illustration
OI-T04171651	Oyster ACIF Trial 04 x 17 x 16 mm, anatomic	
OI-T05171651	Oyster ACIF Trial 05 x 17 x 16 mm, anatomic	
OI-T06171651	Oyster ACIF Trial 06 x 17 x 16 mm, anatomic	
OI-T07171651	Oyster ACIF Trial 07 x 17 x 16 mm, anatomic	
OI-T08171651	Oyster ACIF Trial 08 x 17 x 16 mm, anatomic	
OI-T09171651	Oyster ACIF Trial 09 x 17 x 16 mm, anatomic	
OI-T10171651	Oyster ACIF Trial 10 x 17 x 16 mm, anatomic	

System:
Oyster

Instrument type:
Trial implant

Typing:
dome

Material:
Stainless Steel (17-4PH)

Article number	Description	Illustration
OI-T04171451	Oyster ACIF Trial 04 x 17 x 14 mm, anatomic	
OI-T05171451	Oyster ACIF Trial 05 x 17 x 14 mm, anatomic	
OI-T06171451	Oyster ACIF Trial 06 x 17 x 14 mm, anatomic	
OI-T07171451	Oyster ACIF Trial 07 x 17 x 14 mm, anatomic	
OI-T08171451	Oyster ACIF Trial 08 x 17 x 14 mm, anatomic	
OI-T09171451	Oyster ACIF Trial 09 x 17 x1 4 mm, anatomic	
OI-T10171451	Oyster ACIF Trial 10 x 17 x 14 mm, anatomic	

System:
Oyster

Instrument type:
Trial implant

Typing:
flat

Material:
Stainless Steel (17-4PH)

Article number	Description	Illustration
OI-T04151405	Oyster ACIF Trial 04 x 15 x 14 mm, wedge shape	
OI-T05151405	Oyster ACIF Trial 05 x 15 x 14 mm, wedge shape	
OI-T06151405	Oyster ACIF Trial 06 x 15 x 14 mm, wedge shape	
OI-T07151405	Oyster ACIF Trial 07 x 15 x 14 mm, wedge shape	
OI-T08151405	Oyster ACIF Trial 08 x 15 x 14 mm, wedge shape	
OI-T09151405	Oyster ACIF Trial 09 x 15 x 14 mm, wedge shape	
OI-T10151405	Oyster ACIF Trial 10 x 15 x 14 mm, wedge shape	

Oyster® ACIF Trial Implants

Article number	Description	Illustration
OI-T04171605	Oyster ACIF Trial 04 x 17 x 16 mm, wedge shape	
OI-T05171605	Oyster ACIF Trial 05 x 17 x 16 mm, wedge shape	
OI-T06171605	Oyster ACIF Trial 06 x 17 x 16 mm, wedge shape	
OI-T07171605	Oyster ACIF Trial 07 x 17 x 16 mm, wedge shape	
OI-T08171605	Oyster ACIF Trial 08 x 17 x 16 mm, wedge shape	
OI-T09171605	Oyster ACIF Trial 09 x 17 x 16 mm, wedge shape	
OI-T10171605	Oyster ACIF Trial 10 x 17 x 16 mm, wedge shape	

System:
Oyster

Instrument type:
Trial implant

Typing:
flat

Material:
Stainless Steel (17-4PH)

Article number	Description	Illustration
OI-T04171405	Oyster ACIF Trial 04 x 17 x 14 mm, wedge shape	
OI-T05171405	Oyster ACIF Trial 05 x 17 x 14 mm, wedge shape	
OI-T06171405	Oyster ACIF Trial 06 x 17 x 14 mm, wedge shape	
OI-T07171405	Oyster ACIF Trial 07 x 17 x 14 mm, wedge shape	
OI-T08171405	Oyster ACIF Trial 08 x 17 x 14 mm, wedge shape	
OI-T09171405	Oyster ACIF Trial 09 x 17 x 14 mm, wedge shape	
OI-T10171405	Oyster ACIF Trial 10 x 17 x 14 mm, wedge shape	

System:
Oyster

Instrument type:
Trial implant

Typing:
flat

Material:
Stainless Steel (17-4PH)

Oyster® Instruments

The Oyster ACIF Cage will be used in combination with:
- Dedicated instruments
- Standard spinal instruments (including Caspar distractor and Curettes)
- Cervical plate system (optional)

Article number	Description	Illustration
OI-1010	Oyster Inserter, with Stop	
OI-1015	Oyster Inserter, Tube, with Stop	
OI-1005	Oyster Inserter, Pin	
OI-1020	Oyster Inserter, without Stop	
OI-1025	Oyster Inserter, Tube, without Stop	

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