silony SPINE

OYSTER® ACIF

SURGICAL TECHNIQUE & PRODUCT GUIDE

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PREFACE

This guide provides guidelines for the use of Oyster ACIF for anterior, cervical instrumentation – it does not replace briefing by a surgeon experienced in surgical instrumentation of the spinal column.
Refer to latest version of IFU D30287 for indications and contraindications for Oyster ACIF and other important information related to patient selection and safety.

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

Positioning and approach: decompression and trialing

The patient is positioned for an anterior cervical decompression and fusion. Retractors are commonly used. Adequate distraction is one of the preconditions for the primary stability of the implant; however, it is critical to ensure that the segment is not over distracted to avoid damage of ligaments and/or endplates. The cervical intervertebral disc must be removed completely. The cartilages on the endplates should be removed thoroughly until the endplates start to bleed slightly. When doing this, care should be taken that the endplates are not weakened to ensure sufficient supporting surface and stability for the implantation of the Oyster ACIF Cage. Damage of the bony inferior and superior endplate can lead to sinking of the implant into the vertebral body.

In order to achieve good access to the target segment for the implantation, anterior osteophytes or other bony changes must also be removed if necessary. Neural structures have to be decompressed.

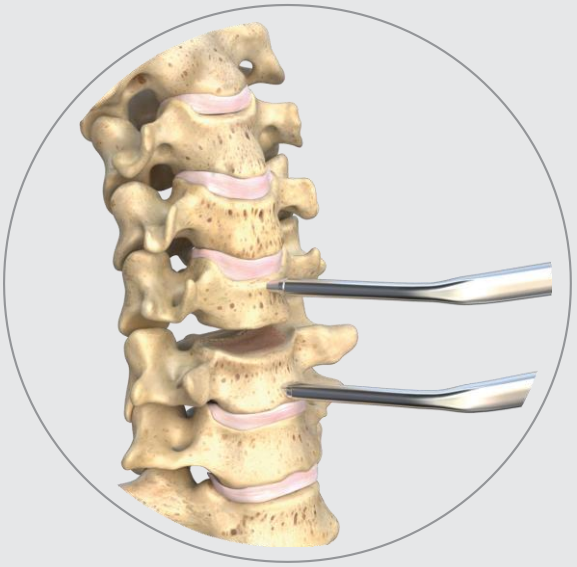


Fig. 1 Distraction and complete removal of the cervical intervertebral disc using standard retractor and preparation instruments

The Oyster ACIF Cage system offers a broad selection of different lengths, widths and anatomic shapes to determine appropriate implant length, width and height and anatomic shape.

Assemble inserter OI-1080 (short) or OI-1180 (long) (Fig. 2) by inserting the shaft completely into the sleeve and secure it by fully tightening the connection. The RI-8050 ROCCIA ACIF depth stop can optionally be attached if required. The depth stop can be removed and re-attached without removing the trial implant.

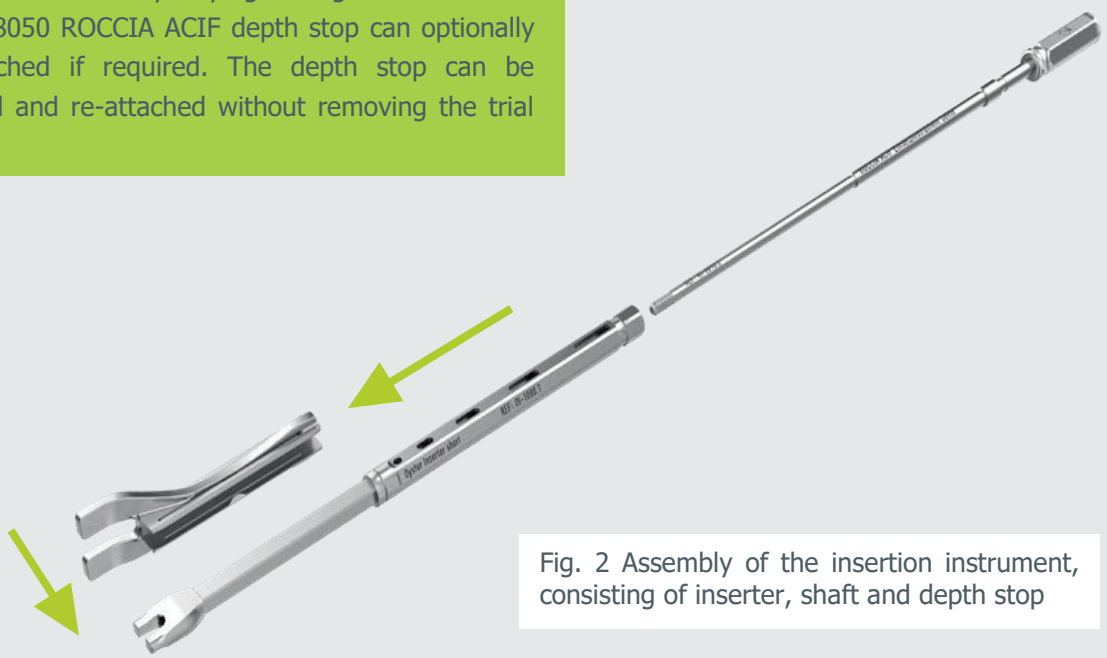


Fig. 2 Assembly of the insertion instrument, consisting of inserter, shaft and depth stop

Attach the desired trial implant onto the inserter (Fig. 3). Align the front of the trial implant with the tip of the inserter and make sure the tip slides into the openings of the interface. The label 'TOP' on the trial implant must be aligned cranially when inserting the trial. Rotate the knob at the back of the instrument clockwise until the trial implant is securely seated at the tip of the inserter.

Fig. 3 Fixing the trial implant onto the inserter

The trial implant also serves to simulate the insertion of the implant into its final position. Use fluoroscopy during insertion of the trial implant to reduce risk of spinal cord injury by avoiding placement in the spinal canal. A small mallet RI-8060 is available for facilitating the insertion of the trial implant.

Silony recommends selecting an implant that is as wide as possible and safe, to achieve a large contact surface area 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 trial implant is a snug fit, neither too tight or too loose and the nerve roots are decompressed sufficiently. The external dimension of the trial implant corresponds to the core dimension of the implant without the teeth. Correct selection of the cage size has a decisive impact on the success of the instrumentation and fusion.

The distractor can be disengaged in order to get a feeling for the primary stability of the fit of the trial implant in the intervertebral disc space.

Check the final position of the trial implant with fluoroscopy. Remove the trial once appropriate sizing and position are confirmed.

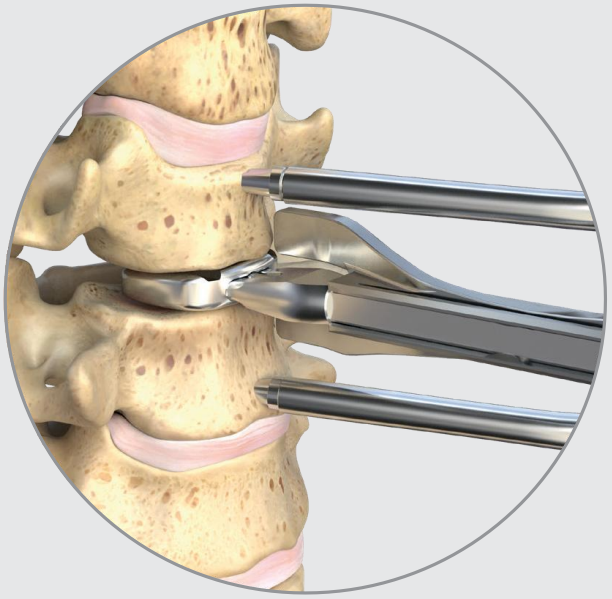


Fig. 4 Inserting the trial implant

Implant insertion

Attach the implant that was determined with the trial implant to the inserter OI-1080 (short) or OI-1180 (long); according to surgeon preference the inserter can be used with or without the depth stop RI-8050. Align the front of the implant with the tip of the inserter and make sure the tip slides into the openings of the implant interface (Fig. 5). Rotate the knob at the back of the instrument clockwise until the implant is securely seated at the tip of the inserter.

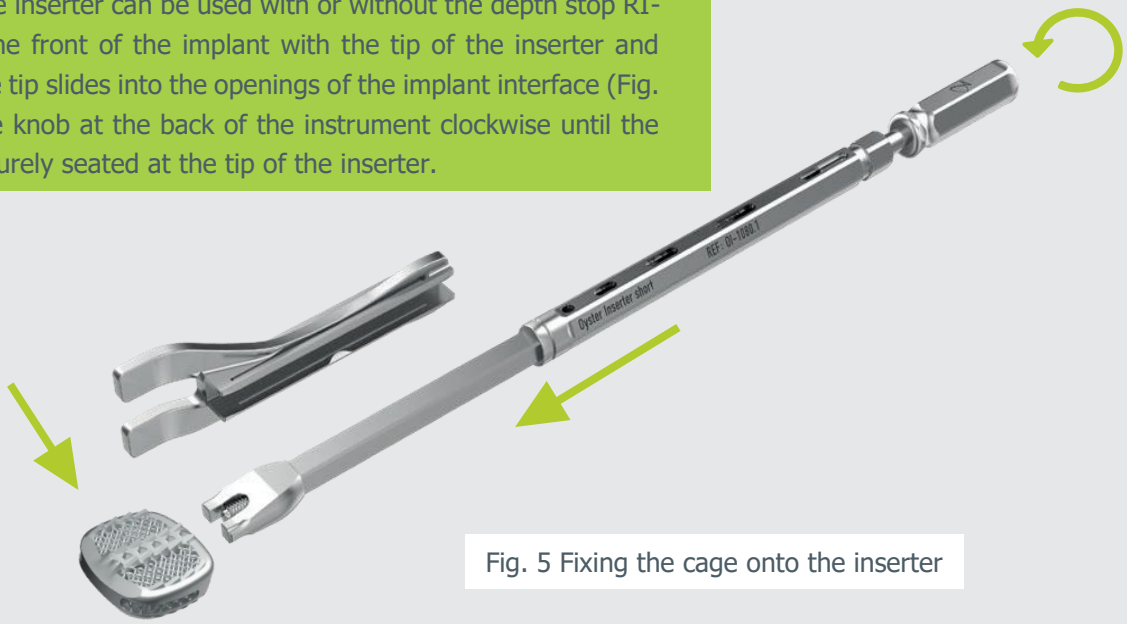


Fig. 5 Fixing the cage onto the inserter

Bone graft material can be added to the cage. Add after attachment of the inserter, to avoid bone graft ingress in the implant-inserter interface. (Fig. 6).
Check the alignment of the cage in cranial and caudal direction. If anatomically shaped cages are used, the convex endplate must always be oriented cranially. The arrow located on the implant must be aligned cranially when inserting the cage.
A small mallet RI-8060 can be used to facilitate the insertion of the implant. The depth stop RI-8050 can be used to prevent the implant from being inserted too deeply.

Fig. 6 Bone material in the Oyster closed implant (left) and Oyster open implant filled with bone material (right).

Insert the implant with gentle taps on the back of the handle of the inserter to the final position in the intervertebral space (Fig. 7).

Insertion should be performed under fluoroscopy control to place the implant safely in the interbody space.

Greater force is required to insert the cage, compared to the trial implant because the implant includes additional teeth for anchoring and the trial implant has a smooth surface.

If the surgical intervention is carried out with the aid of a distractor, then it is advisable to slightly increase the distraction in order to reduce the forces required for inserting the cage. After complete implantation, this distraction should immediately be released again.

The Oyster ACIF Cage has toothing used for anchorage to maximize primary stability, however, make sure the soft tissues are adequately retracted when inserting the implant to avoid damage from contact with the cage (in particular the rough cranial and caudal surfaces). Adequate implant positioning is critical; an improperly placed implant can adversely affect device performance or surgical outcome.

Check the secure fit and final position of the implant with fluoroscopy (Fig. 8). Remove the inserter by rotating the rear inserter knob counterclockwise. No force needs to be exerted to withdraw the inserter from the implant. Should resistance nevertheless be felt, it must be checked whether the inserter has been unscrewed completely. If necessary, this process must be repeated. Make sure that the final position of the implant is not altered when the inserter is removed.

Depending on surgical preference, the disc space can be filled prior to and after cage implantation with remaining bone graft and/or bone graft substitute. Release the distraction and remove the distractor and distraction pins. The Oyster ACIF Cage can be combined with additional stabilization depending on the stability and the sagittal profile.

To remove the implant, the inserter OI-1080 (short) or OI-1180 (long) is attached to the cage and screwed firmly. Revision of a cage requires that the instrument is screwed in until it stops. Now the implant can be removed carefully. To facilitate removal of the implant, distraction of the disc space is recommended.

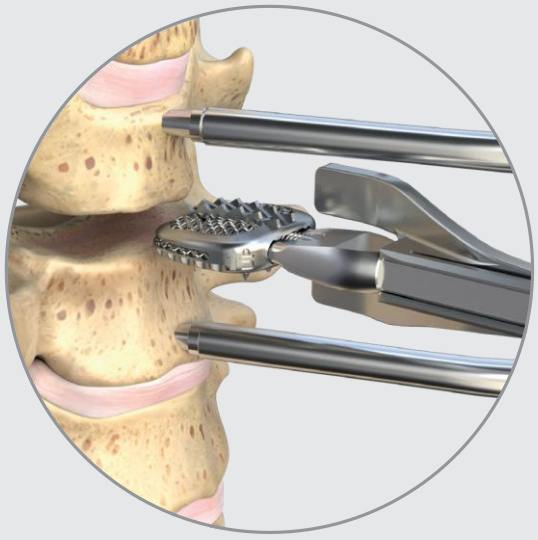


Fig. 7 Inserting the implant

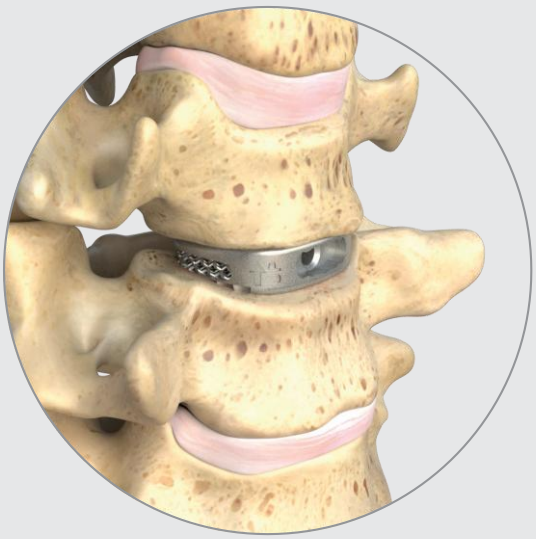


Fig. 8 Final position of implant

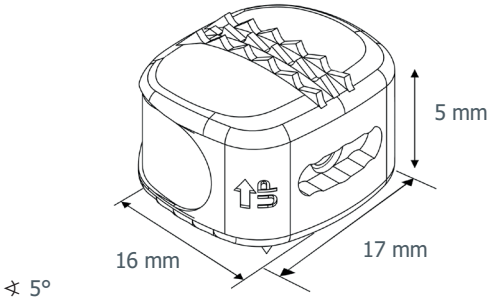
OYSTER ACIF PRODUCT INFORMATION

Oyster ACIF closed implants

Article number explanation for the cage, as an example

Oyster ACIF Cage, 05 x 17 x 16 x 5 dome, closed

S	–	OCT	–	05	17	16	51	–	B
Sterile		System		height	width	length	angle/ shape		Type (open/close)



System:
Oyster

Implant type:
ACIF

Typing:
domed, closed

Material:
Ti6Al4VELI

Article number	Description	Illustration
S-OCT-04151451-B	Oyster ACIF Cage, 04x15x14, dome, closed	
S-OCT-05151451-B	Oyster ACIF Cage, 05x15x14, dome, closed	
S-OCT-06151451-B	Oyster ACIF Cage, 06x15x14, dome, closed	
S-OCT-07151451-B	Oyster ACIF Cage, 07x15x14, dome, closed	
S-OCT-08151451-B	Oyster ACIF Cage, 08x15x14, dome, closed	
S-OCT-09151451-B	Oyster ACIF Cage, 09x15x14, dome, closed	

Article number	Description	Illustration
S-OCT-04171451-B	Oyster ACIF Cage, 04x17x14, dome, closed	
S-OCT-05171451-B	Oyster ACIF Cage, 05x17x14, dome, closed	
S-OCT-06171451-B	Oyster ACIF Cage, 06x17x14, dome, closed	
S-OCT-07171451-B	Oyster ACIF Cage, 07x17x14, dome, closed	
S-OCT-08171451-B	Oyster ACIF Cage, 08x17x14, dome, closed	
S-OCT-09171451-B	Oyster ACIF Cage, 09x17x14, dome, closed	

Article number	Description	Illustration
S-OCT-04171651-B	Oyster ACIF Cage, 04x17x16, dome, closed	
S-OCT-05171651-B	Oyster ACIF Cage, 05x17x16, dome, closed	
S-OCT-06171651-B	Oyster ACIF Cage, 06x17x16, dome, closed	
S-OCT-07171651-B	Oyster ACIF Cage, 07x17x16, dome, closed	
S-OCT-08171651-B	Oyster ACIF Cage, 08x17x16, dome, closed	
S-OCT-09171651-B	Oyster ACIF Cage, 09x17x16, dome, closed	

Oyster ACIF closed implants

Article number	Description	Illustration
S-OCT-04151405-B	Oyster ACIF Cage, 04x15x14, wedge closed	
S-OCT-05151405-B	Oyster ACIF Cage, 05x15x14, wedge closed	
S-OCT-06151405-B	Oyster ACIF Cage, 06x15x14, wedge closed	
S-OCT-07151405-B	Oyster ACIF Cage, 07x15x14, wedge closed	
S-OCT-08151405-B	Oyster ACIF Cage, 08x15x14, wedge closed	
S-OCT-09151405-B	Oyster ACIF Cage, 09x15x14, wedge closed	

System:
Oyster

Implant type:
ACIF

Typing:
wedge, closed

Material:
Ti6Al4V

Article number	Description	Illustration
S-OCT-04171405-B	Oyster ACIF Cage, 04x17x14, wedge closed	
S-OCT-05171405-B	Oyster ACIF Cage, 05x17x14, wedge closed	
S-OCT-06171405-B	Oyster ACIF Cage, 06x17x14, wedge closed	
S-OCT-07171405-B	Oyster ACIF Cage, 07x17x14, wedge closed	
S-OCT-08171405-B	Oyster ACIF Cage, 08x17x14, wedge closed	
S-OCT-09171405-B	Oyster ACIF Cage, 09x17x14, wedge closed	

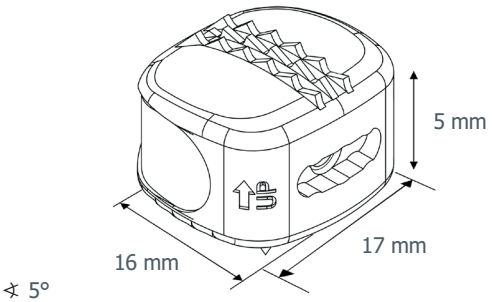
Article number	Description	Illustration
S-OCT-04171605-B	Oyster ACIF Cage, 04x17x16, wedge closed	
S-OCT-05171605-B	Oyster ACIF Cage, 05x17x16, wedge closed	
S-OCT-06171605-B	Oyster ACIF Cage, 06x17x16, wedge closed	
S-OCT-07171605-B	Oyster ACIF Cage, 07x17x16, wedge closed	
S-OCT-08171605-B	Oyster ACIF Cage, 08x17x16, wedge closed	
S-OCT-09171605-B	Oyster ACIF Cage, 09x17x16, wedge closed	

Oyster ACIF open implants

Article number explanation for the cage, as an example

Oyster ACIF Cage, 05 x 17 x 16 anatomic

S	–	OCT	–	05	17	16	51	–	S
Sterile		System		height	width	length	angle/ shape		Type (open/close)



System:
Oyster

Implant type:
ACIF

Typing:
anat., open

Material:
Ti6Al4VELI

Article number	Description	Illustration
S-OCT-04151451-S	oyster ACIF Cage, 04x15x14mm, anatomic	
S-OCT-05151451-S	oyster ACIF Cage, 05x15x14mm, anatomic	
S-OCT-06151451-S	oyster ACIF Cage, 06x15x14mm, anatomic	
S-OCT-07151451-S	oyster ACIF Cage, 07x15x14mm, anatomic	
S-OCT-08151451-S	oyster ACIF Cage, 08x15x14mm, anatomic	
S-OCT-09151451-S	oyster ACIF Cage, 09x15x14mm, anatomic	

Article number	Description	Illustration
S-OCT-04171451-S	oyster ACIF Cage, 04x17x14mm, anatomic	
S-OCT-05171451-S	oyster ACIF Cage, 05x17x14mm, anatomic	
S-OCT-06171451-S	oyster ACIF Cage, 06x17x14mm, anatomic	
S-OCT-07171451-S	oyster ACIF Cage, 07x17x14mm, anatomic	
S-OCT-08171451-S	oyster ACIF Cage, 08x17x14mm, anatomic	
S-OCT-09171451-S	oyster ACIF Cage, 09x17x14mm, anatomic	

Article number	Description	Illustration
S-OCT-04171651-S	oyster ACIF Cage, 04x17x16mm, anatomic	
S-OCT-05171651-S	oyster ACIF Cage, 05x17x16mm, anatomic	
S-OCT-06171651-S	oyster ACIF Cage, 06x17x16mm, anatomic	
S-OCT-07171651-S	oyster ACIF Cage, 07x17x16mm, anatomic	
S-OCT-08171651-S	oyster ACIF Cage, 08x17x16mm, anatomic	
S-OCT-09171651-S	oyster ACIF Cage, 09x17x16mm, anatomic	

Oyster ACIF open implants

System:
Oyster

Implant type:
ACIF

Typing:
wedge, open

Material:
Ti6Al4VELI

Article number	Description	Illustration
S-OCT-04151405-S	oyster ACIF Cage, 04x15x14mm, wedge shape	
S-OCT-05151405-S	oyster ACIF Cage, 05x15x14mm, wedge shape	
S-OCT-06151405-S	oyster ACIF Cage, 06x15x14mm, wedge shape	
S-OCT-07151405-S	oyster ACIF Cage, 07x15x14mm, wedge shape	
S-OCT-08151405-S	oyster ACIF Cage, 08x15x14mm, wedge shape	
S-OCT-09151405-S	oyster ACIF Cage, 09x15x14mm, wedge shape	

Article number	Description	Illustration
S-OCT-04171405-S	oyster ACIF Cage, 04x17x14mm, wedge shape	
S-OCT-05171405-S	oyster ACIF Cage, 05x17x14mm, wedge shape	
S-OCT-06171405-S	oyster ACIF Cage, 06x17x14mm, wedge shape	
S-OCT-07171405-S	oyster ACIF Cage, 07x17x14mm, wedge shape	
S-OCT-08171405-S	oyster ACIF Cage, 08x17x14mm, wedge shape	
S-OCT-09171405-S	oyster ACIF Cage, 09x17x14mm, wedge shape	

Article number	Description	Illustration
S-OCT-04171605-S	oyster ACIF Cage, 04x17x16mm, wedge shape	
S-OCT-05171605-S	oyster ACIF Cage, 05x17x16mm, wedge shape	
S-OCT-06171605-S	oyster ACIF Cage, 06x17x16mm, wedge shape	
S-OCT-07171605-S	oyster ACIF Cage, 07x17x16mm, wedge shape	
S-OCT-08171605-S	oyster ACIF Cage, 08x17x16mm, wedge shape	
S-OCT-09171605-S	oyster ACIF Cage, 09x17x16mm, wedge shape	

Oyster ACIF Trial Implants

System:
Oyster

Implant type:
ACIF

Typing:
anatomic

Material:
Stainless Steel (1.4542)

Article number	Description	Illustration
OI-T04151451	oyster ACIF Trial 04x15x14mm, anatomic	
OI-T05151451	oyster ACIF Trial 05x15x14mm, anatomic	
OI-T06151451	oyster ACIF Trial 06x15x14mm, anatomic	
OI-T07151451	oyster ACIF Trial 07x15x14mm, anatomic	
OI-T08151451	oyster ACIF Trial 08x15x14mm, anatomic	
OI-T09151451	oyster ACIF Trial 09x15x14mm, anatomic	

Article number	Description	Illustration
OI-T04171451	oyster ACIF Trial 04x17x14mm, anatomic	
OI-T05171451	oyster ACIF Trial 05x17x14mm, anatomic	
OI-T06171451	oyster ACIF Trial 06x17x14mm, anatomic	
OI-T07171451	oyster ACIF Trial 07x17x14mm, anatomic	
OI-T08171451	oyster ACIF Trial 08x17x14mm, anatomic	
OI-T09171451	oyster ACIF Trial 09x17x14mm, anatomic	

Article number	Description	Illustration
OI-T04171651	oyster ACIF Trial 04x17x16mm, anatomic	
OI-T05171651	oyster ACIF Trial 05x17x16mm, anatomic	
OI-T06171651	oyster ACIF Trial 06x17x16mm, anatomic	
OI-T07171651	oyster ACIF Trial 07x17x16mm, anatomic	
OI-T08171651	oyster ACIF Trial 08x17x16mm, anatomic	
OI-T09171651	oyster ACIF Trial 09x17x16mm, anatomic	

System:
Oyster

Implant type:
ACIF

Typing:
wedge shape

Material:
Stainless Steel (1.4542)

Article number	Description	Illustration
OI-T04151405	oyster ACIF Trial 04x15x14mm, wedge shape	
OI-T05151405	oyster ACIF Trial 05x15x14mm, wedge shape	
OI-T06151405	oyster ACIF Trial 06x15x14mm, wedge shape	
OI-T07151405	oyster ACIF Trial 07x15x14mm, wedge shape	
OI-T08151405	oyster ACIF Trial 08x15x14mm, wedge shape	
OI-T09151405	oyster ACIF Trial 09x15x14mm, wedge shape	

Oyster ACIF Trial Implants

Article number	Description	Illustration
OI-T04171405	oyster ACIF Trial 04x17x14mm, wedge shape	
OI-T05171405	oyster ACIF Trial 05x17x14mm, wedge shape	
OI-T06171405	oyster ACIF Trial 06x17x14mm, wedge shape	
OI-T07171405	oyster ACIF Trial 07x17x14mm, wedge shape	
OI-T08171405	oyster ACIF Trial 08x17x14mm, wedge shape	
OI-T09171405	oyster ACIF Trial 09x17x14mm, wedge shape	

System:
Oyster

Implant type:
ACIF

Typing:
wedge shape

Material:
Stainless Steel (1.4542)

Article number	Description	Illustration
OI-T04171605	oyster ACIF Trial 04x17x16mm, wedge shape	
OI-T05171605	oyster ACIF Trial 05x17x16mm, wedge shape	
OI-T06171605	oyster ACIF Trial 06x17x16mm, wedge shape	
OI-T07171605	oyster ACIF Trial 07x17x16mm, wedge shape	
OI-T08171605	oyster ACIF Trial 08x17x16mm, wedge shape	
OI-T09171605	oyster ACIF Trial 09x17x16mm, wedge shape	

Oyster Instruments

Article number	Description	Illustration
OI-1080	Oyster Inserter short, dismountable	
OI-1180	Oyster Inserter long, dismountable	
RI-8050	ROCCIA ACIF Depth Stop lat. large	
RI-8060	ROCCIA Mallet small	

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