



SPINE SURGERY

### AESCULAP<sup>®</sup> CeSPACE<sup>®</sup> XP

ANTERIOR CERVICAL INTERBODY FUSION SYSTEM

SURGICAL TECHNIQUE

# AESCULAP® CERVICAL SPINE

### PROTECTING AND PRESERVING SPINAL STABILITY

Modern lifestyle has resulted in increasing physical inactivity among people all over the world. Of the many medical problems associated with this, spinal disorders are among the most critical. This is even more significant as the spinal column is one of the most important structures in the human body. It supports and stabilizes the upper body and is the center of our musculoskeletal system, which gives the body movement.

Our work in the field of spine surgery is dedicated to protecting the spinal column and preserving its stability. We support spine surgeons with durable, reliable products and partner services for proven procedures and good clinical outcomes (1-10).

Our philosophy of sharing expertise with healthcare professionals and patients allows us to develop innovative implant and instrument systems that help to preserve stability and stabilize the cervical and thoracolumbar spine.



Please scan QR code or visit www.aesculap.com to view full product portfolio

# AESCULAP® CeSPACE® XP



#### A GENERAL INFORMATION

#### B SURGICAL TECHNIQUE

- **B.1. PATIENT POSITIONING**
- B.2. EXPOSURE OF THE INTERVERTEBRAL SPACE
- B.3. DISTRACTION / DISCECTOMY / PREPARATION OF THE ENDPLATES
- **B.4. IMPLANT SELECTION**
- B.5. FILLING OF CAGE
- B.6. CeSPACE® XP INSERTION
- C IMPLANT & INSTRUMENT OVERVIEW

### AESCULAP® CeSPACE® XP

A | GENERAL INFORMATION

### PHILOSOPHY

CeSPACE<sup>®</sup> XP is a spacer used for cervical interbody fusion.

It is indicated for stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental.

#### CeSPACE® XP IS DESIGNED TO DELIVER

- PRIMARY STABILITY (15).
- **I** RESTORATION OF THE NATURAL DISC HEIGHT (15).
- SEGMENTAL LORDOTIC CORRECTION (15).

## AESCULAP<sup>®</sup> XP THE CHOICE OF EXPERTS



A | GENERAL INFORMATION

### IMPLANT MATERIAL



Fig. 1



Fig. 2

#### COMBINING MATERIAL ADVANTAGES

The core of the implant is biocompatible PEEK-OPTIMA<sup>®</sup>\*. PEEK stands for PolyEtherEtherKetone. PEEK-OPTIMA<sup>®</sup> polymer complies with ISO 10993-1, USP Class VI and ASTM F2026 for use as a medical implant material. The use of the PEEK-OPTIMA<sup>®</sup> material has several advantages, as its properties include radio-lucency, high mechanical strength, high fatigue resistance, a low wear factor and biocompatibility (11-14, 17).

The core is mantled with the proven PLASMAPORE <sup>XP®</sup> coating to increase the contact area between implant and endplate (16). PLASMAPORE <sup>XP®</sup> is an osteoconductive pure titanium coating (Ti/ISO 5832-2) which enables bone ingrowth due to its balanced relationship between pore depth, porosity and roughness (16). The coating allows for clear visualization of implant contours during intra and post operative imaging (Fig. 1).

#### AIM OF THE PLASMAPORE XP® COATING

Primary Stability

The increased surface roughness of the PLASMAPORE  $^{XP^{\otimes}}$  coating contributes to the primary stability of the motion segment (15-16).

Secondary Stability

Bone growth into the coating is enabled due to the supportive features of PLASMAPORE XP®, which leads to bone fusion between the adjacent vertebras with the implant (15-16). (Fig. 2)

### IMPLANT FEATURES



#### IMAGING PROPERTIES

- PLASMAPORE XP® allows for clear visualization of implant contours under X-ray (15).
- Allows for assessment of the bone structure and progress towards bone fusion (15).

#### IMPLANT DESIGN

- Concave anatomical shape and serrated profile for an implant fit and high primary stability
- I Increased ratio between contact area and opening
- Option of filling with bone or bone substitute to enhance bone bridging
- Clamping mechanism allows a firm connection to inserter

#### IMPLANT VARIETY

Adequate range of sizes to enable the choice of implant size to fit the patient.

#### INSTRUMENT DESIGN

Specifically designed and clearly arranged instruments

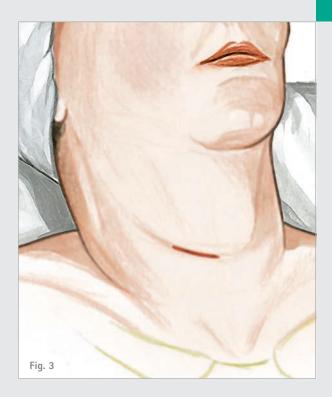


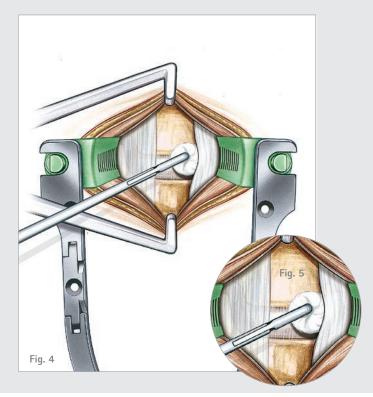






B | SURGICAL TECHNIQUE



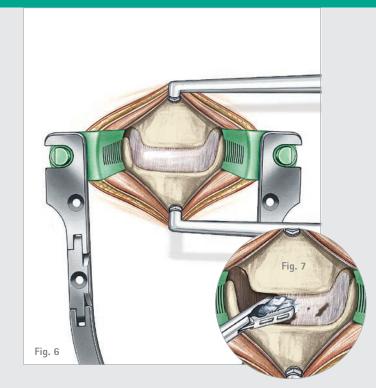


#### B.1. PATIENT POSITIONING

The patient is placed in the supine position with the head slightly reclined (Fig. 3) and stabilized in a head holder. Once the lordotic cervical spine has been supported, the thorax may be placed on a pillow to emphasize the reclination of the cervical spine. The arms are fixed alongside the body.

#### B.2. EXPOSURE OF THE INTERVERTEBRAL SPACE

- After the skin incision and preparation, the CCR retractor is placed. The blades are available in PEEK and titanium. A counter retractor can be used (Fig. 4/5). The subcutaneous tissue is separated from the platysma cranially, caudally and medially, and the platysma is also separated following the direction of its fibres. The margins of the platysma can be held apart with the retractor or with two surgical forceps.
- Now the medial edge of the sternocleidomastoid muscle is located and prepared with the index finger in the connective tissue space over the ventral surface of the cervical spine and under lateralization of the vascular nerve bundle and medialization of the trachea, esophagus and thyroid gland.
- After the Langenbeck hooks have been inserted, the ventral surface of the cervical spine, still covered by a thin prevertebral layer of connective tissue, is revealed. This layer can now be exposed by either a blunt scissor or alternatively through bipolar coagulation, in order to expand the tissue cranially and caudally using a swab. A wire is set under X-ray monitoring to mark the intervertebral disc space.

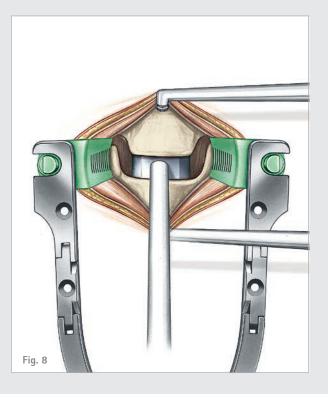


#### B.3. DISTRACTION/DISCECTOMY/PREPARATION OF THE ENDPLATES

- The distraction screws are placed in position and the CASPAR<sup>®</sup> distractor is applied following the CASPAR<sup>®</sup> technique (Fig. 6).
- Complete discectomy is performed using various rongeurs, rectangular curettes and bone curettes (Fig. 7). While using a high speed drill to remove the posterior rim and/or dorsal osteophytes, care must be taken to avoid damaging the vertebral body endplates.

#### PLEASE NOTE

- Make certain that the endplates of the neighboring vertebral bodies are not weakened, in order to minimize the risk of migration.
- Make certain that the implant bed is properly prepared to avoid damage to the implant when it is driven in.



#### **B.4. IMPLANT SELECTION**

- The correct implant size can be established using the trial implants (Fig. 8).
- Laser markings on the handle as well as on the trial itself indicate the cranial and caudal side of the trial.

#### DETERMINATION OF IMPLANT SIZE

■ The CeSPACE<sup>®</sup> XP trials have the anatomical shape of the CeSPACE<sup>®</sup> XP implant.

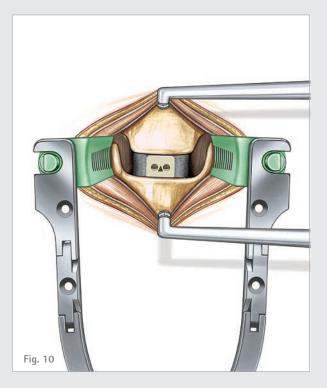
PLEASE NOTE The trials are essential to ensure the correct implant size to be used.

B | SURGICAL TECHNIQUE



#### B.5. FILLING OF CAGE

Use the packing block and the punch for optional filling of the implant with bone or bone substitute.

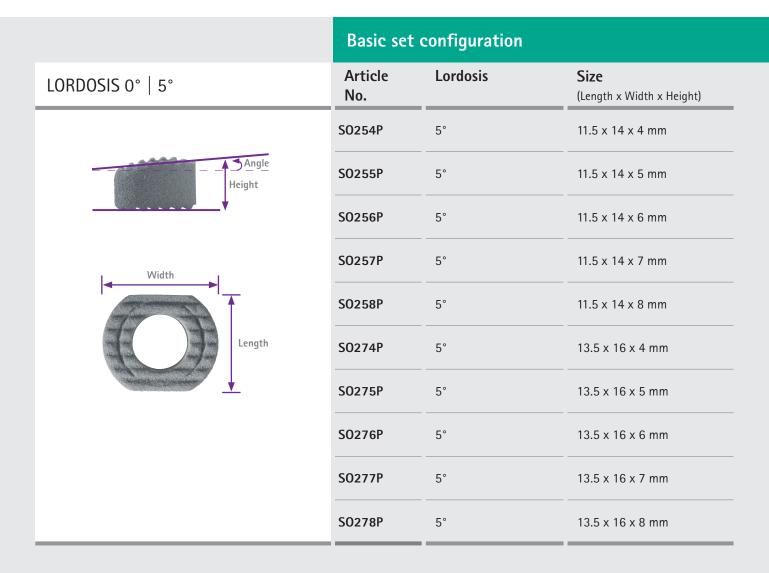


#### B.6. CeSPACE® XP INSERTION

- The CeSPACE<sup>®</sup> XP inserter has a clamp mechanism and is available with or without depth stop. Laser markings indicate the cranial and caudal side of the instrument.
- Once CeSPACE<sup>®</sup> XP is attached to the inserter, it can be introduced into the intervertebral space using image converter monitoring (Fig. 9).
- The implant should be inserted centrally in AP and with a distance of approximately 1-2 mm to both the anterior and posterior rim (Fig. 10).
- For additional stabilization, a cervical plate may be necessary.

PLEASE NOTE Use CeSPACE<sup>®</sup> XP inserter with depth stop.

C | IMPLANT & INSTRUMENT OVERVIEW



Further implants in heights ranging from 9-12 mm are available\*: 5° L 11.5 x W 14 x H 9-12 mm: S0259P-S0262P

5° L 13.5 x W 16 x H 9-12 mm: S0279P-S0282P

\* This article is optional.

12

### Basic set configuration

LORDOSIS 0°   5°	Article No.	Lordosis	<b>Size</b> (Length x Width x Height)
Height	S0245P*	0°	11.5 x 14 x 5 mm
	SO246P*	0°	11.5 x 14 x 6 mm
	S0247P*	0°	11.5 x 14 x 7 mm
Width Length	SO248P*	0°	11.5 x 14 x 8 mm
	SO265P*	0°	13.5 x 16 x 5 mm
	SO266P*	0°	13.5 x 16 x 6 mm
	SO267P*	0°	13.5 x 16 x 7 mm
	SO268P*	0°	13.5 x 16 x 8 mm

Further implants in heights ranging from 4 mm and 9-12 mm are available\*:

0° L 11.5 x W 14 x H 4 mm: S0244P

0° L 13.5 x W 16 x H 4 mm: S0264P

0° L 11.5 x W 14 x H 9-12 mm: S0249P-S0252P

0° L 13.5 x W 16 x H 9-12 mm: S0269P-S0272P

\* This article is optional.

### AESCULAP® CeSPACE® XP

C | IMPLANT & INSTRUMENT OVERVIEW

#### FJ005 - CeSPACE<sup>®</sup> XP Instrumentation



	Basic set configuration CeSPACE" XP Instrumentation		
INSTRUMENTS	Article No.	Description	Quan- tity
152 - 52 (T)	FJ474R	CeSPACE <sup>®</sup> PEEK/XP trial implant 5°, 14 x 4 mm, blue	1
	FJ475R	CeSPACE <sup>®</sup> PEEK/XP trial implant 5°, 14 x 5 mm, blue	1
	FJ476R	CeSPACE <sup>®</sup> PEEK/XP trial implant 5°, 14 x 6 mm, blue	1
	FJ477R	CeSPACE <sup>®</sup> PEEK/XP trial implant 5°, 14 x 7 mm, blue	1
	FJ478R	CeSPACE <sup>®</sup> PEEK/XP trial implant 5°, 14 x 8 mm, blue	1
	FJ484R	CeSPACE <sup>®</sup> PEEK/XP trial implant 5°, 16 x 4 mm, green	1
	FJ485R	CeSPACE <sup>®</sup> PEEK/XP trial implant 5°, 16 x 5 mm, green	1
	FJ486R	CeSPACE <sup>®</sup> PEEK/XP trial implant 5°, 16 x 6 mm, green	1
	FJ487R	CeSPACE <sup>®</sup> PEEK/XP trial implant 5°, 16 x 7 mm, green	1
	FJ488R	CeSPACE <sup>®</sup> PEEK/XP trial implant 5°, 16 x 8 mm, green	1
	FJ308R	CeSPACE <sup>®</sup> PEEK/XP trial implant 0°, 14 x 5 mm, blue	1*
	FJ309R	CeSPACE <sup>®</sup> PEEK/XP trial implant 0°, 14 x 6 mm, blue	1*
	FJ310R	CeSPACE <sup>®</sup> PEEK/XP trial implant 0°, 14 x 7 mm, blue	1*
	FJ311R	CeSPACE <sup>®</sup> PEEK/XP trial implant 0°, 14 x 8 mm, blue	1*
	FJ335R	CeSPACE <sup>®</sup> PEEK/XP trial implant 0°, 16 x 5 mm, green	1*
	FJ336R	CeSPACE <sup>®</sup> PEEK/XP trial implant 0°, 16 x 6 mm, green	1*
	FJ337R	CeSPACE <sup>®</sup> PEEK/XP trial implant 0°, 16 x 7 mm, green	1*
	FJ338R	CeSPACE <sup>®</sup> PEEK/XP trial implant 0°, 16 x 8 mm, green	1*

\* This article is optional.



#### FJ005

CeSPACE<sup>®</sup> XP Instrumentation

#### FJ005 - CeSPACE® XP Instrumentation

INSTRUMENTS	Article No.	Description	Quan- tity
	FJ413P	CeSPACE <sup>®</sup> XP packing block	1
R CO	FF914R	Punch	1
	FJ415R	Inserter	1
	FJ497R	Depth stop	1
	FJ499R	Revision	1
	FJ411P	CeSPACE <sup>®</sup> XP tray	1

Corresponding to the CeSPACE° XP implants 4 mm and 9-12 mm trial implants are available\*:

5° L 11.5 x W 14 x H 9-12 mm: FJ389R-FJ392R

5° L 13.5 x W 16 x H 9-12 mm: FJ399R-FJ402R

0° L 11.5 x W 14 x H 4 mm: FJ434R

0° L 11.5 x W 14 x H 9-12 mm: FJ439R-FJ442R

0° L 13.5 x W 16 x H 4mm: FJ444R

0° L 13.5 x W 16 x H 9-12 mm: FJ449R-FJ452R

The tray FJ411P has storing elements for the standard equipment W 14/16 in H 4-8 mm. Either the 0° or the 5° trials can be stored. If both is needed, two trays are necessary to order.

The marking of the tray only indicates  $5^\circ\!.$ 

\* This article is optional.

### AESCULAP<sup>®</sup> CeSPACE<sup>®</sup> XP REFERENCES

- (1) Suchomel P, Jurák L, Antinheimo J, Pohjola J, Stulik J, Meisel HJ, Čabraja M, Woiciechowsky C, Bruchmann B, Shackleford I, Arregui R, Sola S. Does sagittal position of the CTDR-related centre of rotation influence functional outcome? Prospective 2-year follow-up analysis. Eur Spine J. 2014 May;23(5):1124-34.
- (2) Meisel HJ, Jurák L, Antinheimo J, Arregui R, Bruchmann B, Čabraja M, et al. Four-year results of a prospective singlearm study on 200 semi-constrained total cervical disc prostheses: clinical and radiographic outcome. J Neurosurg Spine. 2016 Jun;3:1-10.
- (3) Boselie TFM, van Santbrink H, de Bie RA, van Mameren H. Pilot Study of Sequence of Segmental Contributions in the Lower Cervical Spine During Active Extension and Flexion: Healthy Controls Versus Cervical Degenerative Disc Disease Patients. Spine (Phila Pa 1976). 2017 Jun 1;42(11):E642-E647.
- (4) Epstein NE. Anterior cervical dynamic ABC plating with single level corpectomy and fusion in forty-two patients. Spinal Cord. 2003 Mar;41(3):153-8. PubMed PMID:12612617.
- (5) Stulik J, Pitzen TR, Chrobok J, Ruffing S, Drumm J, Sova L, et al. Fusion and failure following anterior cervical plating with dynamic or rigid plates: 6-months results of a multicentric, prospective, randomized, controlled study. Euro Spine J. 2007;16:1689-94.
- (6) Krayenbühl N, Schneider C, Landolt H, Fandino J. Use of an empty, PLASMAPORE-covered titanium cage for interbody fusion after anterior cervical microdiscectomy. J Clin Neurosci. 2008;15(1):11-7.
- (7) Takeuchi M, Yasuda M, Niwa A, Wakao N, Nakura T, Osuka K, et al. PLASMAPORE-coated titanium cervical cages induce more rapid and complete bone fusion after anterior cervical discectomy and fusion as compared to noncoated titanium cage. World Neurosurg. 2014;82(3-4):519-22.

- (8) Stulik J, Vyskocil T, Sebesta P, Kryl J. Atlantoaxial fixation using the polyaxial screw-rod system. Eur Spine J. 2007 Apr; 16(4):479-84. PubMed PMID: 17051397; PubMed Central PMCID: PMC2229812.
- (9) Tippets RH, Apfelbaum RI. Anterior cervical fusion with the Caspar instrumentation system. Neurosurgery. 1988 Jun; 22(6 Pt 1):1008-13. PubMed PMID: 3419561.
- (10) Stulik J, Nesnidal P, Kryl J, Vyskocil T, Barna M. Kyphotic deformities of the cervical spine. 28th Annual Meeting of the AANS/CNS Section on Disorders of the cervical Spine and peripheral Nerves. March 2012 Orlando, Florida.
- (11) Morrison C, Macnair R, MacDonald C, Wykman A, Goldie I, Grant MH. In vitro bio-compatibility testing of polymers for ortho-paedic implants using cultured fibroblasts and osteoblasts. Biomaterials. 1995 Sep;16(13):987-92.
- (12) Invibio<sup>®</sup> Biomaterial Solutions. PEEK-OPTIMA<sup>®</sup> Natural Typical Material Properties. https://invibio.com/spine/ materials/peek-optima-natural (03/2019).
- (13) Chen Y, Wang X, Lu X, Yang L, Yang H, Yuan W, Chen D. Comparison of titanium and polyetheretherketone (PEEK) cages in the surgical treatment of multilevel cervical spondylotic myelopathy: a prospective, randomized, control study with over 7-year follow-up. Eur Spine J. 2013;22:1539-46.
- (14) Macnair R, Rodgers EH, MacDonald C, Wykman A, Goldie I, Grant MH. The response of primary rat and human osteoblasts and an immortalized rat osteoblast cell line to orthopaedic materials: comparative sensitivity of several toxicity indices. J Mater Sci Mater Med. 1997;8(2):105–11.

- (15) Arregui R, Aso J, Martínez Quiñones J-V, Sebastián C, Consolini F, Aso Vizan A. Follow-up of a new titaniumcoated polyetheretherketone cage for the cervical spine. Orthop Rev (Pavia) 2020; 12(1).
- (16) Cheng BC, Koduri S, Wing CA, Woolery N, Cook DJ, Spiro RC. Porous titanium-coated polyetheretherketone implants exhibit an improved bone-implant interface: an in vitro and in vivo biochemical, biomechanical, and histological study. MDER 2018; 11:391–402.
- (17) Dr. Stuart Green, Keith Cartwright. An investigation into the effect of accelerated oxygen ageing on the properties of PEEK-OPTIMA<sup>®</sup>. March 2004.

Tensile, flex and impact specimens in PEEK-OPTIMA<sup>®</sup> were tested according to appropiate ISO standards (ISO 527, ISO 178 and ISO 180). A comparison was made between control PEEK-OPTIMA<sup>®</sup> and aged PEEK-OPTIMA<sup>®</sup> to investigate the effect of accelerated oxygen ageing on the material properties. Accelerated ageing was conducted exposing the specimens 40 days to 70°C oxygen at 5 bars pressure. The results show no significant effect on the mechanical properties of the PEEK polymer with the aged and control specimens showing similar values. The retention of good mechanical properties after the instense ageing cycle demonstrates that PEEK-OPTIMA<sup>®</sup> is very resistant to oxygen ageing.

### AESCULAP<sup>®</sup> – a B. Braun brand

Aesculap AG | Am Aesculap-Platz | 78532 Tuttlingen | Germany Phone +49 7461 95-0 | Fax +49 7461 95-2600 | www.aesculap.com

The main product trademark "AESCULAP" and the product trademarks "CASPAR", "CeSPACE", "PLASMAPORE" and "PLASMAPORE<sup>xp</sup>" are registered trademarks of Aesculap AG. "PEEK-OPTIMA" is a registered trademark of Invibio<sup>®</sup> Biomaterial Solutions.

Subject to technical changes. All rights reserved. This brochure may only be used for the exclusive purpose of obtaining information about our products. Reproduction in any form partial or otherwise is not permitted.