



SPINE SURGERY

AESCULAP[®] CeSPACE[®] PEEK

ANTERIOR CERVICAL INTERBODY FUSION SYSTEM

SURGICAL TECHNIQUE

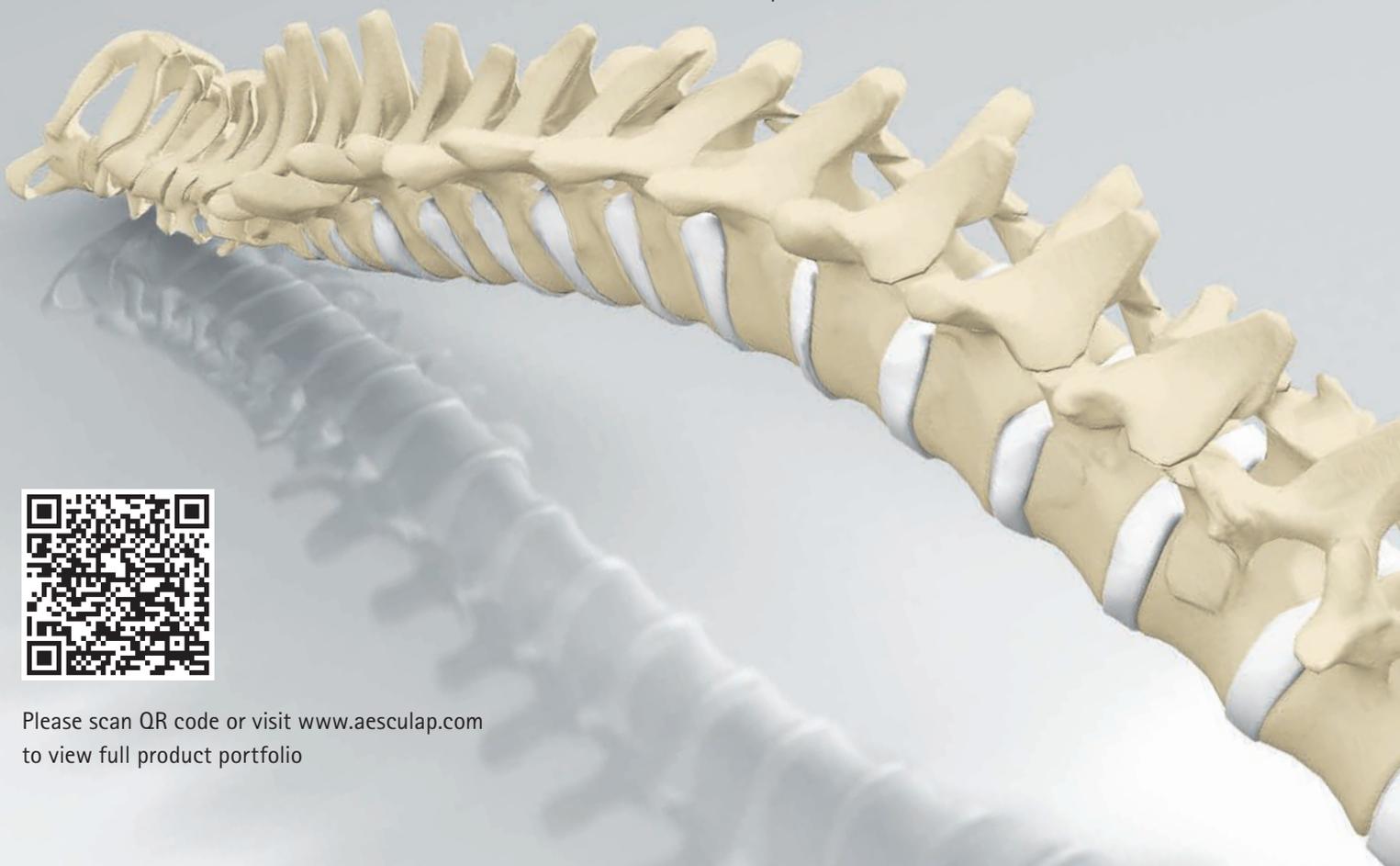
AESCULAP® CERVICAL SPINE

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.



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AESCULAP® CeSPACE® PEEK

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AESCULAP® CeSPACE® PEEK

A | GENERAL INFORMATION

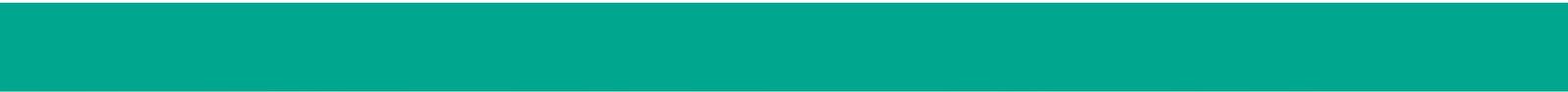
PHILOSOPHY

CeSPACE® PEEK 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® PEEK IS DESIGNED TO DELIVER

- PRIMARY STABILITY (11).
- RESTORATION OF THE NATURAL DISC HEIGHT AND LORDOSIS (12, 13).



AESCULAP® CeSPACE® PEEK

A | GENERAL INFORMATION

IMPLANT MATERIAL



Fig. 1



Fig. 2

➤ The material used is biocompatible PEEK-OPTIMA®. PEEK stands for PolyEtherEtherKetone. PEEK-OPTIMA® polymer complies with ISO 10993-1, USP Class VI and ASTM F2026 for use as a medical implant material.

The use of PEEK-OPTIMA® as an orthopedic device material enjoys increased popularity due to the material's special combination of characteristics (14). Its properties include radiolucency, high mechanical strength, high fatigue resistance, a low wear factor and biocompatibility (15-17, 19-20).

The intrinsic radioscopic transparency of the material provides permeability on X-rays and CT scans, allowing to visualize bone growth adjacent to the implant. This enables a quick and simple assessment of the bone structure and progress towards bone fusion. To verify the position of PEEK implants on radioscopic images, non-radiolucent tantalum markers were integrated serving as location indicators (Fig. 1 / 2).

Of particular interest is the modulus of elasticity of PEEK-OPTIMA®, which is similar to that of cortical bone. This modulus of elasticity may reduce implant subsidence and allow for improved bone growth (16, 18).

In vitro results of PEEK-OPTIMA® test specimens show a high long-term material stability after oxygen aging.* These results correspond with extensive biocompatibility investigations for PEEK-OPTIMA® proving the material suitable for use as a long-term implant (15, 16).

IMPLANT FEATURES



➤ POSITION VERIFICATION DESPITE X-RAY TRANSPARENCY

- The radiolucency of PEEK-OPTIMA® enables assessment of the bone structure and progress towards bone fusion (16).
- X-ray pins facilitating assessment of implant positioning and localization.



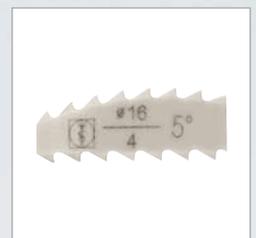
➤ IMPLANT DESIGN

- Concave anatomical shape and serrated profile aims for an implant fit and high primary stability.
- Option of filling with bone or bone substitute to enhance bone bridging.



➤ IMPLANT VARIETY

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



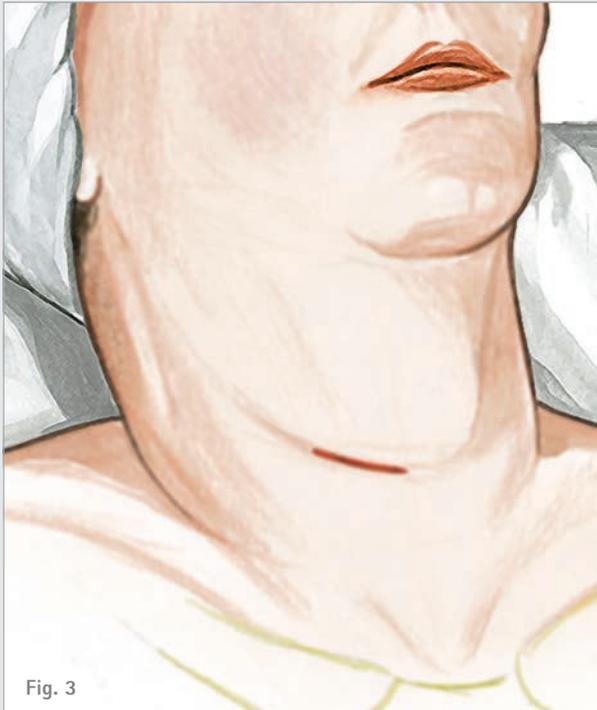
➤ INSTRUMENT DESIGN

- Specifically designed and clearly arranged instruments.



AESCULAP® CeSPACE® PEEK

B | SURGICAL TECHNIQUE

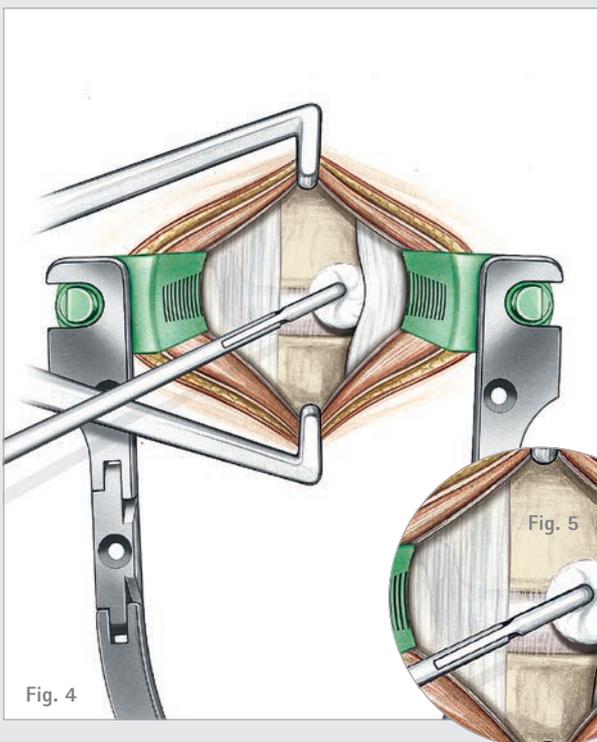


B.1. PATIENT POSITIONING

- 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® distractor is applied following the CASPAR® 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).
- Specific trials respecting the implant geometry are available for the CeSPACE® PEEK implants. 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 OF CeSPACE® PEEK

- The CeSPACE® PEEK trials regard the concave anatomical shape and serrated profile of the CeSPACE® PEEK implant.

PLEASE NOTE

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

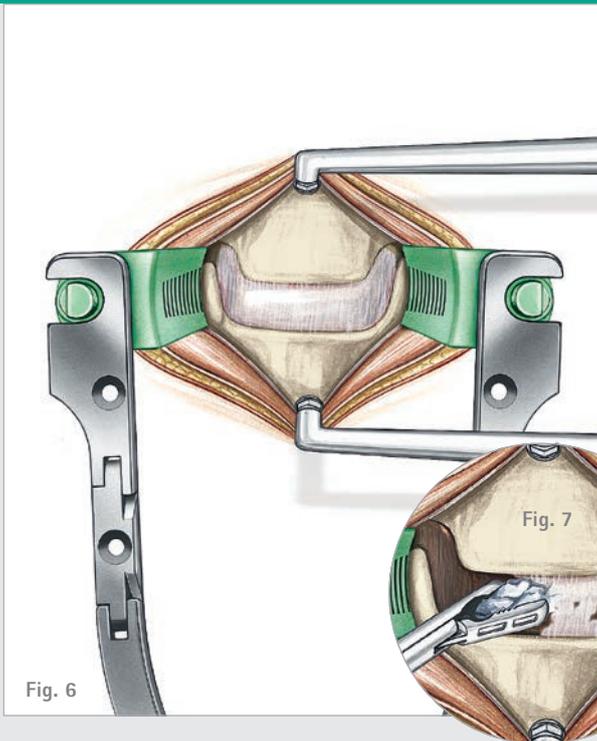


Fig. 6

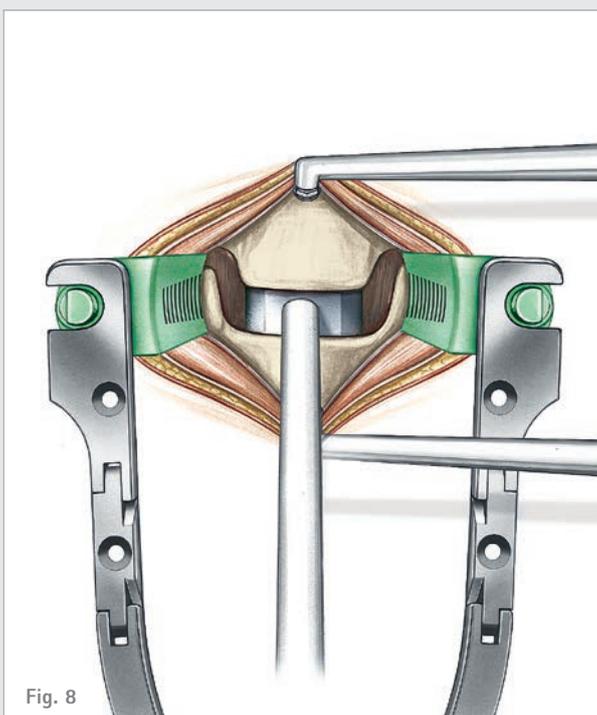
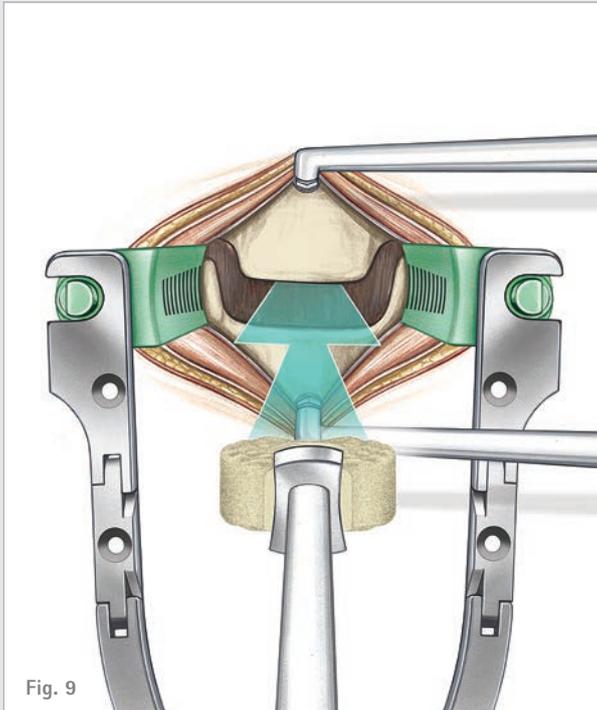


Fig. 8

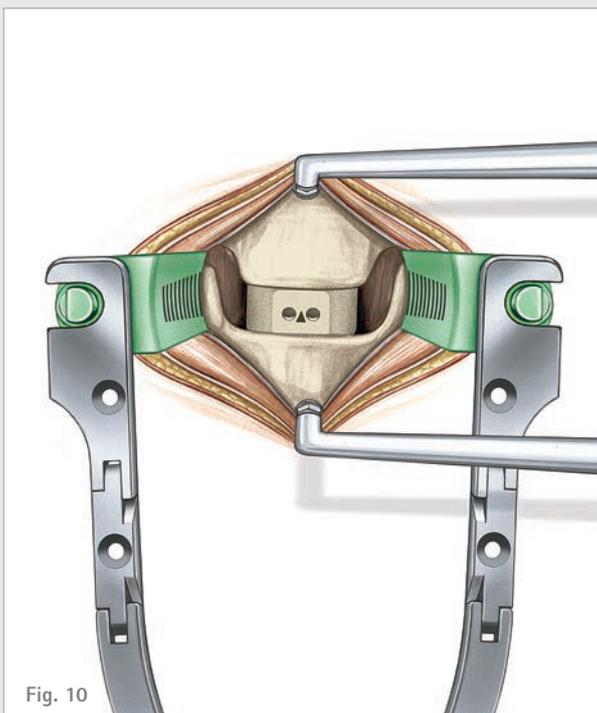
AESCULAP® CeSPACE® PEEK

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.

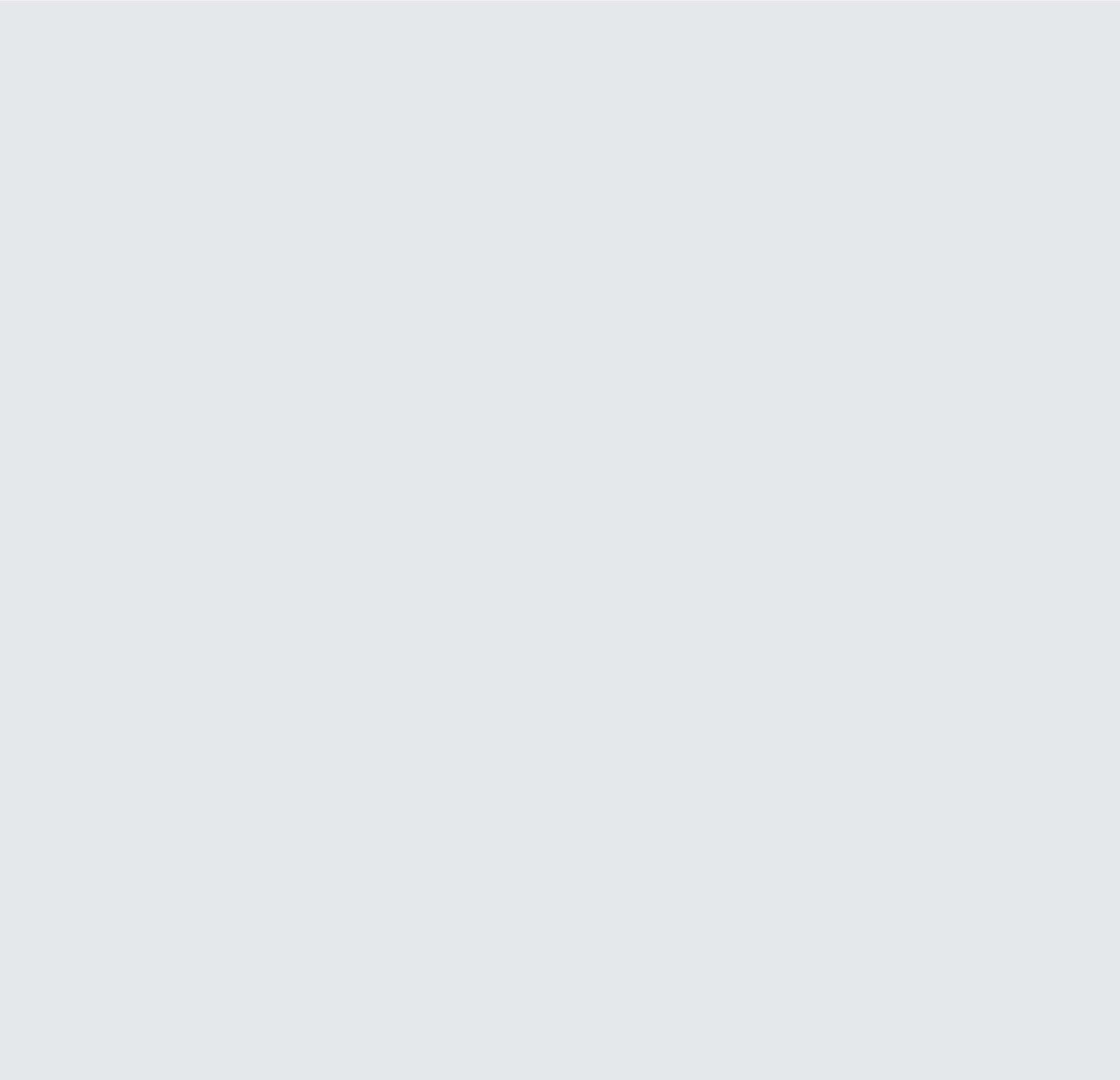


B.6. CeSPACE® PEEK INSERTION

- The CeSPACE® PEEK 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® PEEK 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® PEEK inserter with depth stop.
- Implant marking points in the cranial direction.

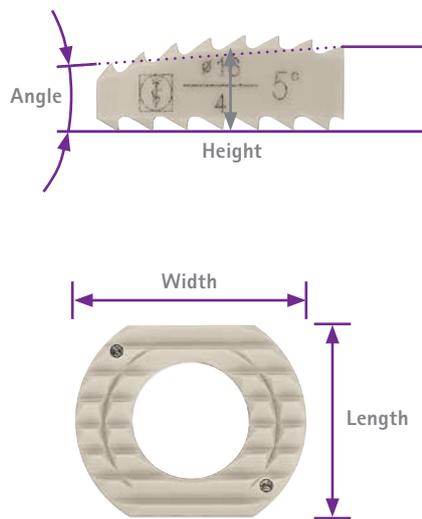


AESCALAP® CeSPACE® PEEK

C | IMPLANT & INSTRUMENT OVERVIEW

Basic set configuration

LORDOSIS 0° | 5°



Article No.	Lordosis	Size (Length x Width x Height)
FJ404P	5°	11.5 x 14 x 4 mm
FJ405P		11.5 x 14 x 5 mm
FJ406P		11.5 x 14 x 6 mm
FJ407P		11.5 x 14 x 7 mm
FJ408P		11.5 x 14 x 8 mm
FJ424P		13.5 x 16 x 4 mm
FJ425P		13.5 x 16 x 5 mm
FJ426P		13.5 x 16 x 6 mm
FJ427P	0°	13.5 x 16 x 7 mm
FJ428P		13.5 x 16 x 8 mm
FJ455P*		11.5 x 14 x 5 mm
FJ456P*		11.5 x 14 x 6 mm
FJ457P*		11.5 x 14 x 7 mm
FJ458P*		11.5 x 14 x 8 mm
FJ465P*		13.5 x 16 x 5 mm
FJ466P*		13.5 x 16 x 6 mm
FJ467P*	13.5 x 16 x 7 mm	
FJ468P*	13.5 x 16 x 8 mm	

Implant material

PEEK-OPTIMA® (PolyEtherEtherKeton)

Further implants in heights ranging from 9–12 mm are available*:

5° L 11.5 x W 14 x H 9–12 mm: FJ409P–FJ410P, FJ421P–FJ422P

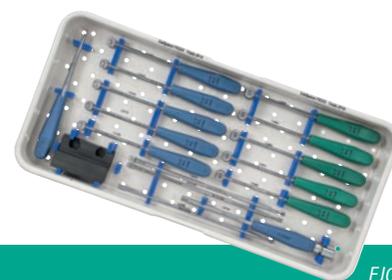
5° L 13.5 x W 16 x H 9–12mm: FJ429P–FJ432P

0° L 11.5 x W 14 x H 9–12mm: FJ459P–FJ462P

0° L 13.5 x W 16 x H 9–12mm: FJ469P–FJ472P

* This article is optional.

FJ005 – CeSPACE® PEEK Instrumentation



FJ005
CeSPACE® PEEK Instrumentation

Basic set configuration

INSTRUMENTS	Article No.	Description	Quantity
	FJ474R	CeSPACE® PEEK trial implant 5°, 14 x 4 mm, blue	1
	FJ475R	CeSPACE® PEEK trial implant 5°, 14 x 5 mm, blue	1
	FJ476R	CeSPACE® PEEK trial implant 5°, 14 x 6 mm, blue	1
	FJ477R	CeSPACE® PEEK trial implant 5°, 14 x 7 mm, blue	1
	FJ478R	CeSPACE® PEEK trial implant 5°, 14 x 8 mm, blue	1
	FJ484R	CeSPACE® PEEK trial implant 5°, 16 x 4 mm, green	1
	FJ485R	CeSPACE® PEEK trial implant 5°, 16 x 5 mm, green	1
	FJ486R	CeSPACE® PEEK trial implant 5°, 16 x 6 mm, green	1
	FJ487R	CeSPACE® PEEK trial implant 5°, 16 x 7 mm, green	1
	FJ488R	CeSPACE® PEEK trial implant 5°, 16 x 8 mm, green	1
	FJ308R	CeSPACE® PEEK trial implant 0°, 14 x 5 mm, blue	1*
	FJ309R	CeSPACE® PEEK trial implant 0°, 14 x 6 mm, blue	1*
	FJ310R	CeSPACE® PEEK trial implant 0°, 14 x 7 mm, blue	1*
	FJ311R	CeSPACE® PEEK trial implant 0°, 14 x 8 mm, blue	1*
	FJ335R	CeSPACE® PEEK trial implant 0°, 16 x 5 mm, green	1*
	FJ336R	CeSPACE® PEEK trial implant 0°, 16 x 6 mm, green	1*
	FJ337R	CeSPACE® PEEK trial implant 0°, 16 x 7 mm, green	1*
	FJ338R	CeSPACE® PEEK trial implant 0°, 16 x 8 mm, green	1*

Corresponding to the CeSPACE® PEEK implants 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 9–12 mm: FJ439R–FJ442R

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

Tray has storing elements for standard equipment W 14/16 5° trials in H 4–8 mm.

* This article is optional.

AESCULAP® CeSPACE® PEEK

C | IMPLANT & INSTRUMENT OVERVIEW

FJ005 – CeSPACE® PEEK Instrumentation

INSTRUMENTS	Basic set configuration		
	Article No.	Description	Quantity
	FJ413P	Packing Block	1
	FF914R	Punch	1
	FJ415R	Inserter	1
	FJ497R	Depth stop	1
	FJ499R	Revision	1
	FJ411P	Storage Tray	1

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AESFULAP[®] – a B. Braun brand

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