B BRAUN
SHARING EXPERTISE

SPINE SURGERY

AESCULAP® PROSPACE® PEEK

POSTERIOR LUMBAR INTERBODY FUSION SYSTEM

SURGICAL MANUAL

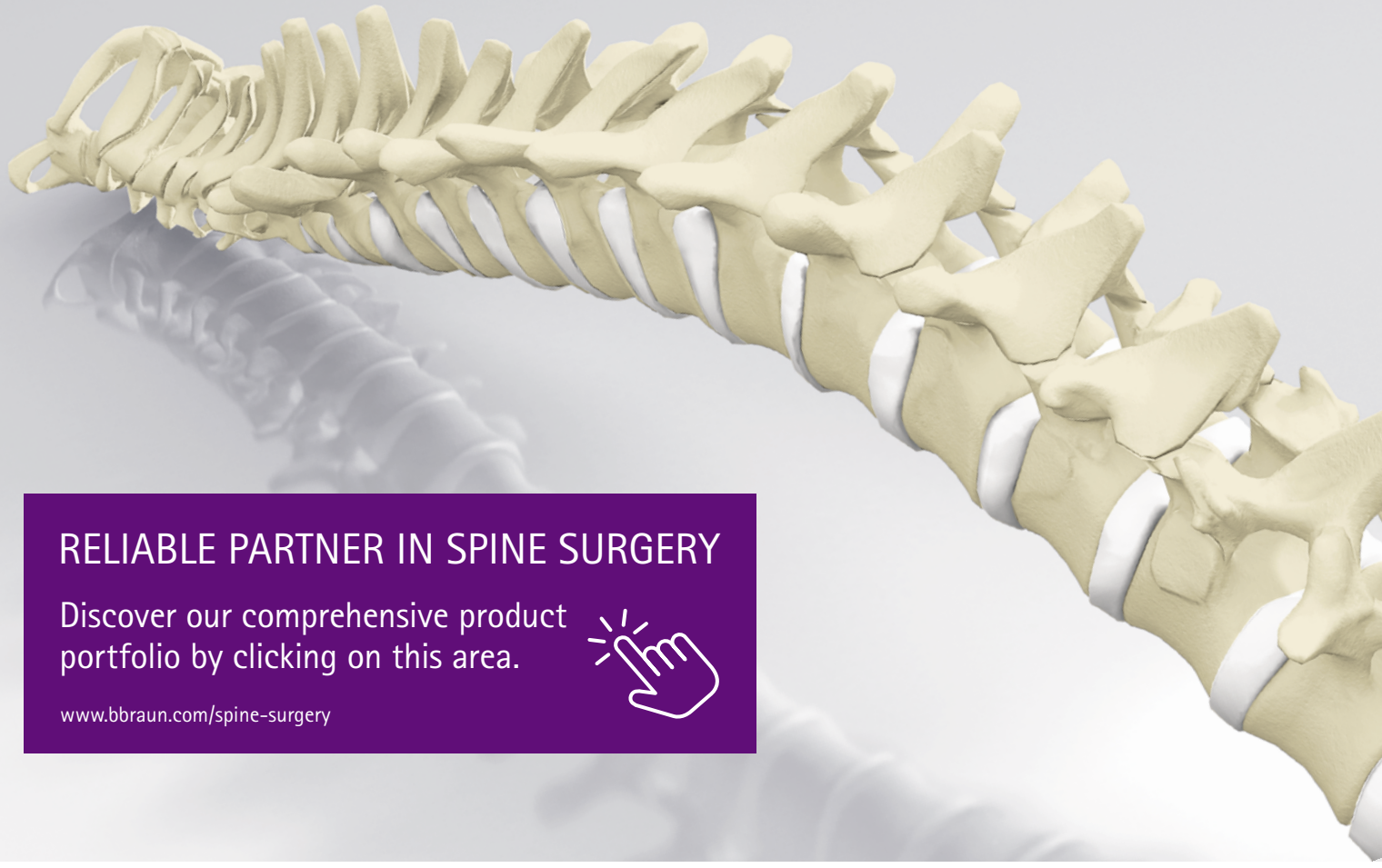
AESCULAP® THORACOLUMBAR SPINE

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 reliable procedures and good clinical outcomes (1-7).

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® PROSPACE® PEEK

CONTENT

AESCULAP® PROSPACE® PEEK

PHILOSOPHY

PROSPACE® PEEK implants are used for the stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental.

Always implant two implants per layer (PLIF technique). Always use PROSPACE® PEEK implants in conjunction with an internal fixator.

PROSPACE® PEEK IS DESIGNED TO DELIVER

- PRIMARY STABILITY (8).
- RESTORATION OF THE NATURAL DISC HEIGHT AND LORDOSIS (9).

IMPLANT MATERIAL

Fig. 1

Fig. 2

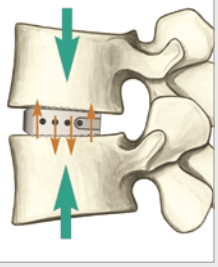


Fig. 3

The material used is biocompatible PEEK-OPTIMA®. PEEK stands for PolyEtherEtherKetone. PEEK-OPTIMA® polymer complies with ISO, ASTM and USP standards for use as a medical implant material.

The use of PEEK-OPTIMA® as an orthopaedic device material enjoys increased popularity due to the material's special combination of characteristics (10). Its properties include radiolucency, high mechanical strength, high fatigue resistance, a low wear factor and biocompatibility (11-15).

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 (12). 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 (12, 16).

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 (11, 12).

*Based on biomechanical, chemical and cytotoxicity testing after 40 days at 70°C, 5 bar oxygen pressure.

IMPLANT FEATURES

Fig. 4

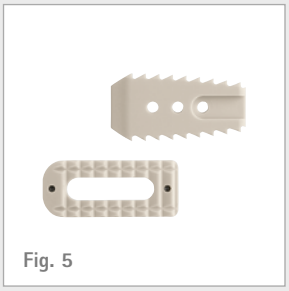


Fig. 5

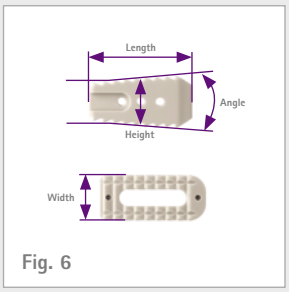


Fig. 6

Fig. 7

POSITION VERIFICATION DESPITE X-RAY TRANSPARENCY

- The radiolucency of PEEK-OPTIMA® enables assessment of the bone structure and progress towards bone fusion (12).
- X-ray pins facilitating implant positioning and localization.

IMPLANT DESIGN

- Anatomical shape and serrated profile aim for an implant fit and high primary stability (8, 9).
- 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.
- Inserter is attached to implant via a clamping mechanism.

AESCULAP® PROSPACE® PEEK

B | SURGICAL MANUAL

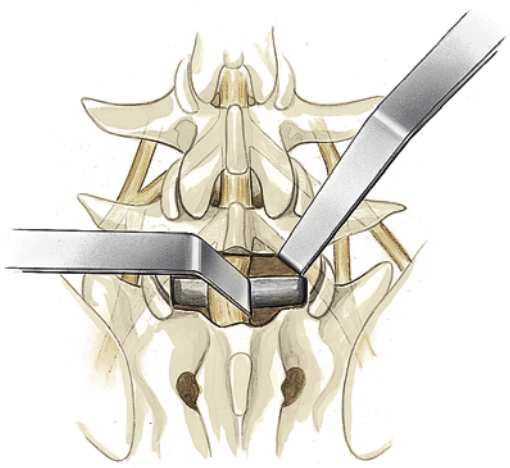


Fig. 1

B.1. BONE RESECTION

- Using an osteotome and a Kerrison bone punch the bone resection is performed to get access to the intervertebral space.

B.2. REVEALING THE DISC SPACE

- The dura and upper nerve root are carefully retracted in the desired direction using the nerve root retractors (Fig. 1).
- In order to make room for the insertion of the distractor, resection of disc material is now carried out using rongeurs and forceps.

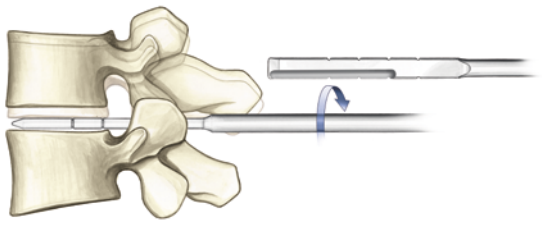


Fig. 2

B.3. RESTORATION OF DISC HEIGHT

- The desired distraction can be set using the distractors, available in heights from 7-17 mm in 1 mm increments (Fig. 2). The distractors are inserted one after the other alternating the side of the disc until the desired distraction is obtained.

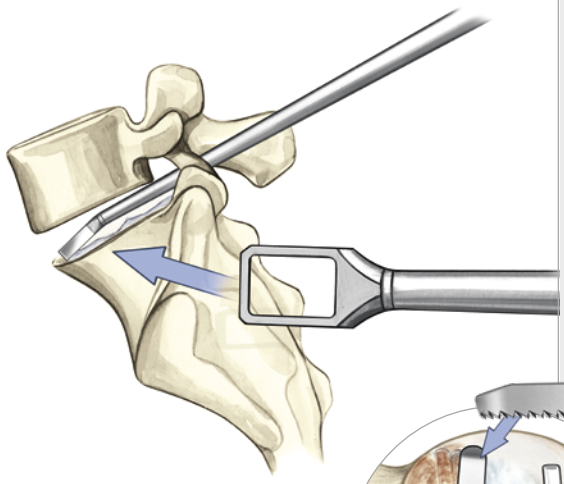


Fig. 3

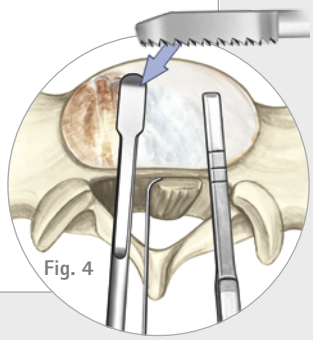


Fig. 4

B.4. CLEANING OF THE INTERVERTEBRAL SPACE

- The disc space is cleared using rongeurs, bone curettes and rectangular curettes (Fig. 3). The bone rasps are used to refresh the cartilaginous endplates. (Fig. 4).

INFORMATION

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.

Use the nerve root retractors to protect the dura during insertion.

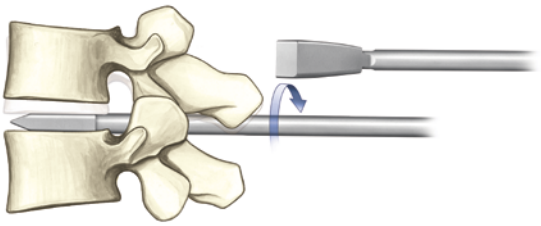


Fig. 5

B.5. DETERMINATION OF IMPLANT SIZE USING TRIAL IMPLANTS

- Trial implants are available in 0°, 5°and 8° corresponding to the sizes of the implants. Starting with the smallest size the trial implants are inserted horizontally and rotated clockwise (Fig. 5). Stepwise the next heights are inserted until the required distraction has been achieved. The adequate trial implant indicates now the height, the angle and length of the implant to be inserted.

INFORMATION

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

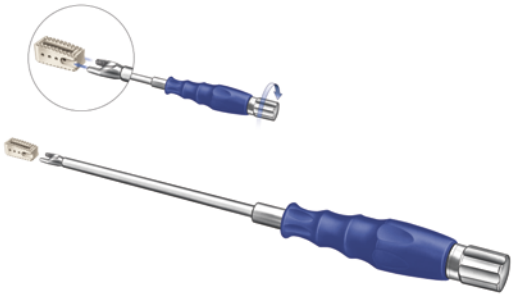


Fig. 1

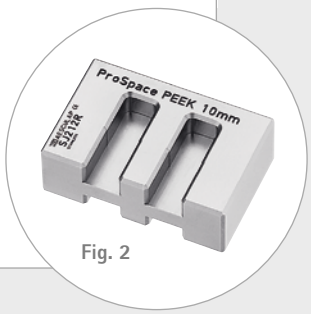


Fig. 2

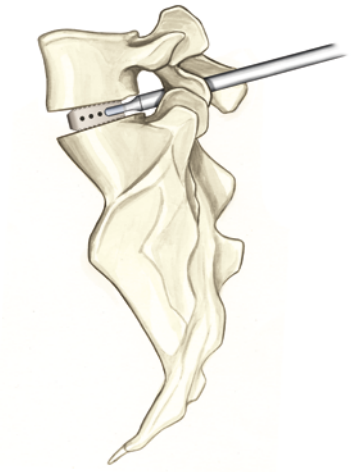


Fig. 3

B.6. INSERTION OF PROSPACE® PEEK

- After filling the PROSPACE® PEEK implant with bone graft or artificial bone substitute (Fig. 2) the implant is clamped to the PROSPACE® PEEK insertion instrument (Fig. 1).

INFORMATION

- Do not use force during filling to avoid implant damaging.
- Mount the implant on the insertion instrument hand-tight as far as it will go.
- When inserting the implant into the intervertebral space, avoid canting and levering, and take care to maintain an alignment parallel to the endplate.
- Do not use excessive force when mounting or implanting the implant.

B.7. INSERTION ON THE CONTRA-LATERAL SIDE

- The described operative steps are now repeated for the contra-lateral side. Bone material can be packed between both implants (Fig. 3).
- The implants get jammed by release of distraction as well as by compression with the posterior instrumentation.
- X-ray control to verify the position of the implants.

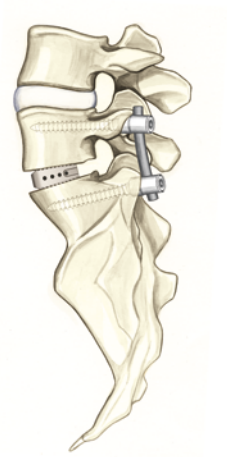


Fig. 4

B.8. POSTERIOR STABILIZATION

- Additional posterior stabilization of the motion segment (e. g. using AESCULAP® Ennovate®) should be performed (Fig. 4).
- Subsequent segmental compression with posterior instrumentation allows loading of the anterior column and restoration of sagittal alignment.
- Final X-ray.

For more information visit www.bbraun.com/ennovate

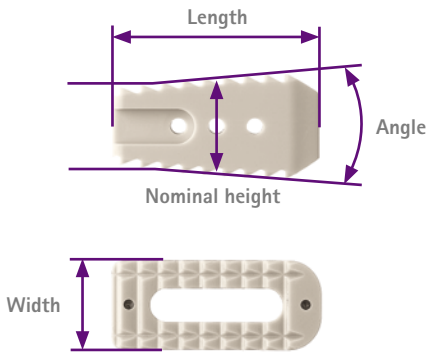
INFORMATION

Thoracolumbar pedicle screw system shown in images is the AESCULAP® S4® Spinal System.

AESCULAP® PROSPACE® PEEK

C | IMPLANT & INSTRUMENT OVERVIEW

PROSPACE® PEEK IMPLANTS



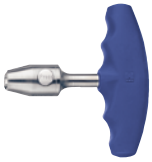
Article No.	Size (Height x Width x Length)	Angle
SJ232P	7 x 8 x 19 mm	0°
SJ234P	7 x 8 x 22 mm	0°
SJ231P	8 x 8 x 22 mm	0°
SJ233P	9 x 8 x 19 mm	0°
SJ235P	9 x 8 x 22 mm	0°
SJ236P	9 x 10 x 22 mm	0°
SJ237P	10 x 8 x 22 mm	0°
SJ238P	11 x 10 x 25 mm	0°
SJ239P	13 x 10 x 25 mm	0°
SJ252P	7 x 8 x 19 mm	5°
SJ254P	7 x 8 x 22 mm	5°
SJ251P	8 x 8 x 22 mm	5°
SJ253P	9 x 8 x 19 mm	5°
SJ255P	9 x 8 x 22 mm	5°
SJ256P	9 x 10 x 22 mm	5°
SJ257P	10 x 8 x 22 mm	5°
SJ258P	11 x 10 x 25 mm	5°
SJ259P	13 x 10 x 25 mm	5°
SJ282P	7 x 8 x 19 mm	8°
SJ283P	9 x 8 x 19 mm	8°
SJ285P	9 x 8 x 22 mm	8°
SJ286P	9 x 10 x 22 mm	8°
SJ288P	11 x 10 x 25 mm	8°
SJ289P	13 x 10 x 25 mm	8°

Implant material
PEEK-OPTIMA® PolyEtherEtherKeton

All PROSPACE® PEEK implants are single sterile packed.

FJ025 – PROSPACE® PEEK Instrumentation

FJ643P
PROSPACE® PEEK - Preparation Tray

PREPARATION INSTRUMENTS	Article No.	Description	Quantity
	**FJ051R**	Retractor S	1
	FJ052R	Retractor M	1
	FJ053R	Retractor L	1
	FJ054R	Retractor XL	1
	**FJ646R**	T-Handle for Distractors	2
	**FJ647R**	Distractor, 7 mm	1
	FJ648R	Distractor, 8 mm	1
	FJ649R	Distractor, 9 mm	1
	FJ650R	Distractor, 10 mm	1
	FJ651R	Distractor, 11 mm	1
	FJ653R	Distractor, 13 mm	1
	**FJ678R**	Bone Curette, Straight	1
	**FJ681R**	Curette, Straight	1
	**FJ658R**	Straight Osteotome, 8 mm	1
	**FJ684R**	Bone Rasp, Straight	1
	FJ643P	Tray for Prep. Instr. PROSPACE® PEEK	1

Recommended container for FJ643P: JK442 and lid JK489.

AESCULAP® PROSPACE® PEEK

C | IMPLANT & INSTRUMENT OVERVIEW

FJ025 – PROSPACE® PEEK INSTRUMENTATION

IMPLANTATION INSTRUMENTS

Article No.	Description	Quantity
SJ242R	PROSPACE® PEEK Trial Implant, 0°, 7 x 19 mm	1
SJ243R	PROSPACE® PEEK Trial Implant, 0°, 9 x 19 mm	1
SJ244R	PROSPACE® PEEK Trial Implant, 0°, 7 x 22 mm	1
SJ245R	PROSPACE® PEEK Trial Implant, 0°, 9 x 22 mm	1
SJ248R	PROSPACE® PEEK Trial Implant, 0°, 11 x 25 mm	1
SJ249R	PROSPACE® PEEK Trial Implant, 0°, 13 x 25 mm	1
SJ262R	PROSPACE® PEEK Trial Implant, 5°, 7 x 19 mm	1
SJ263R	PROSPACE® PEEK Trial Implant, 5°, 9 x 19 mm	1
SJ264R	PROSPACE® PEEK Trial Implant, 5°, 7 x 22 mm	1
SJ265R	PROSPACE® PEEK Trial Implant, 5°, 9 x 22 mm	1
SJ268R	PROSPACE® PEEK Trial Implant, 5°, 11 x 25 mm	1
SJ269R	PROSPACE® PEEK Trial Implant, 5°, 13 x 25 mm	1
SJ292R	PROSPACE® PEEK Trial Implant, 8°, 7 x 19 mm	1
SJ293R	PROSPACE® PEEK Trial Implant, 8°, 9 x 19 mm	1
SJ295R	PROSPACE® PEEK Trial Implant, 8°, 9 x 22 mm	1
SJ298R	PROSPACE® PEEK Trial Implant, 8°, 11 x 25 mm	1
SJ299R	PROSPACE® PEEK Trial Implant, 8°, 13 x 25 mm	1

FJ640P
PROSPACE® PEEK - Implantation Tray

IMPLANTATION INSTRUMENTS	Article No.	Description	Quantity
	**SJ212R**	Packing Block	1
	**FF913R**	Punch	1
	**SJ210R**	Insertion Instrument	1
	**SJ211R**	Impactor	1
	FJ640P	Tray for Implantation Instrument PROSPACE® PEEK	1

Recommended container for FJ640P: JK442 and lid JK489.

AESCULAP® PROSPACE® PEEK

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flex and impact specimens in PEEK-OPTIMA® were tested according to appropriate ISO standards (ISO 527, ISO 178 and ISO 180). A comparison was made between control PEEK-OPTIMA® and aged PEEK-OPTIMA® 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 intense ageing cycle demonstrates that PEEK-OPTIMA® is very resistant to oxygen ageing.

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