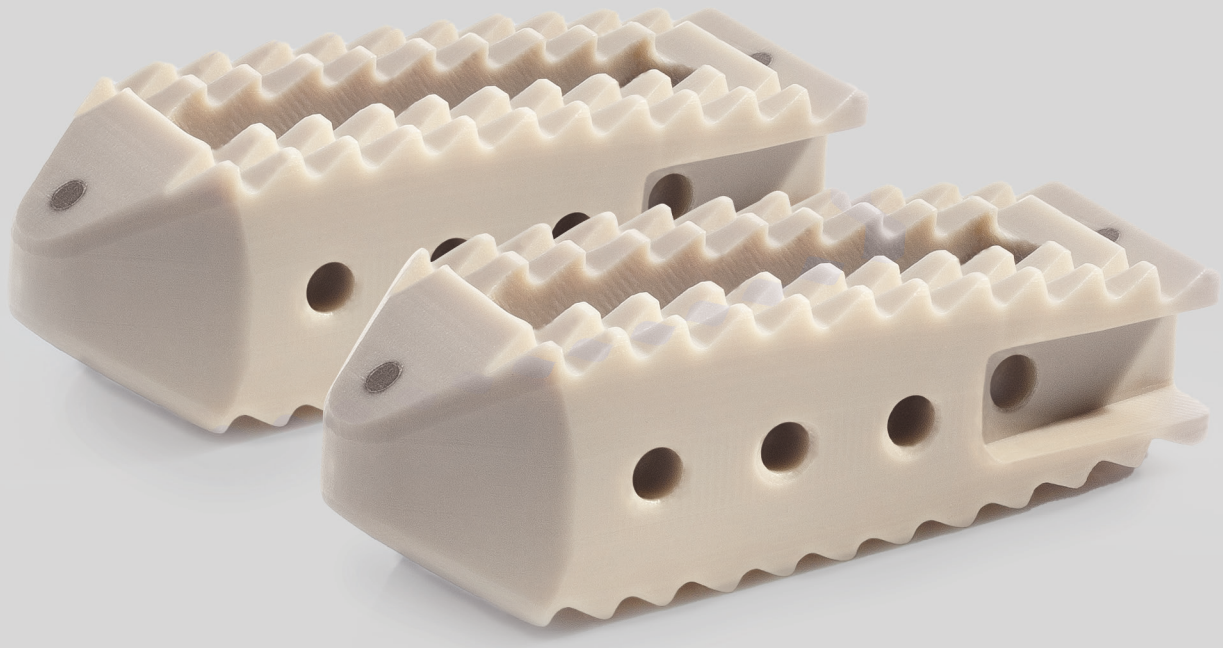


AESCULAP® PROSPACE® PEEK

Posterior Lumbar Interbody Fusion System

B|BRAUN
SHARING EXPERTISE

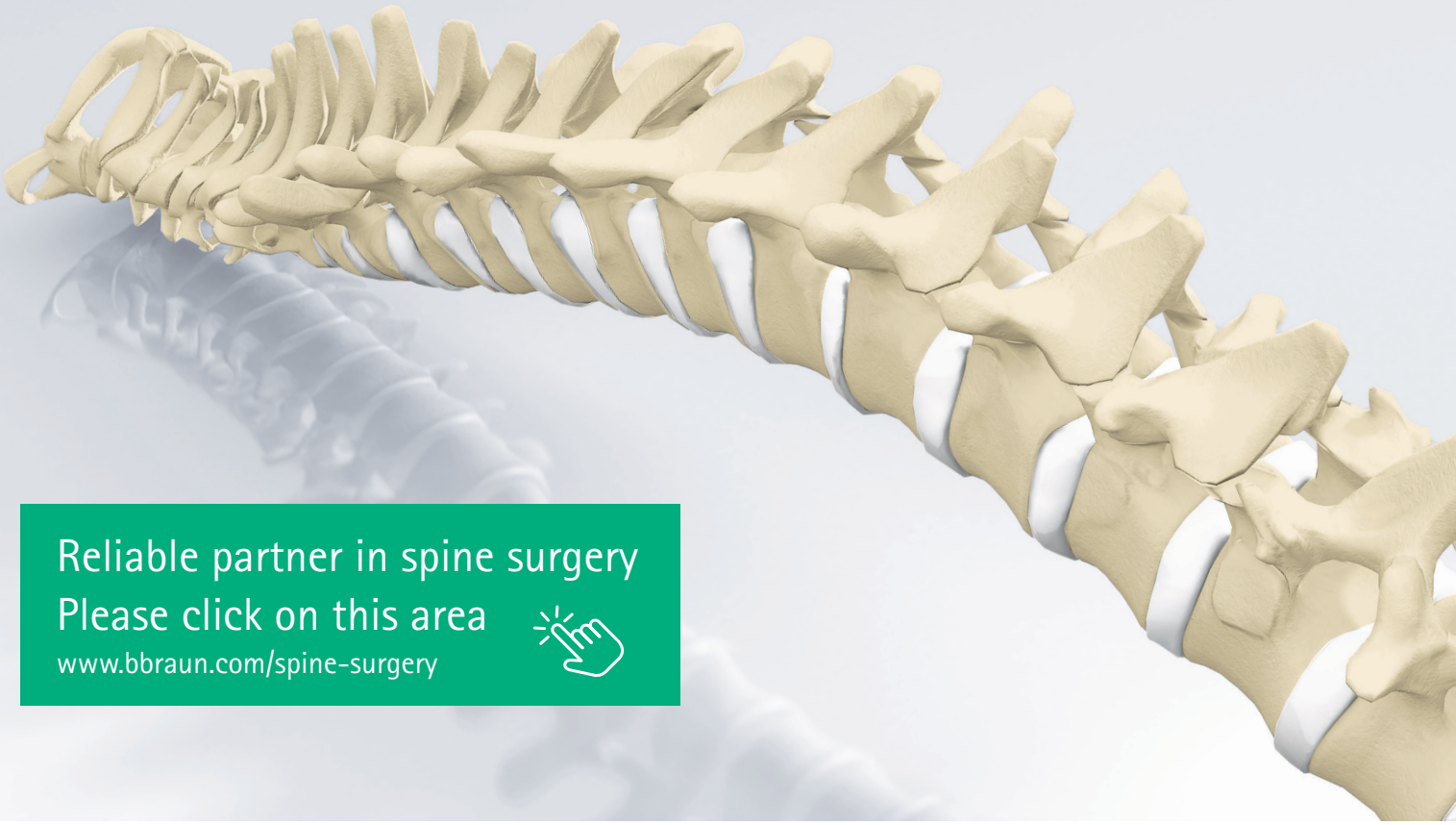
AESCULAP® Thoracolumbar Spine

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.



Reliable partner in spine surgery
Please click on this area
www.bbraun.com/spine-surgery

AESCULAP® PROSPACE® PEEK

Content

A	General information	3
B	Surgical manual	8
	B.1 Bone resection	8
	B.2 Revealing the disc space	8
	B.3 Restoration of disc height	8
	B.4 Cleaning of the intervertebral space	9
	B.5 Determination of implant size using trial implants	9
	B.6 Insertion of PROSPACE® PEEK	10
	B.7 Insertion on the contra-lateral side	10
	B.8 Posterior stabilization	11
C	Implant & instrument overview	12
D	References	16

AESCULAP® PROSPACE® PEEK

A | General information

Philosophy

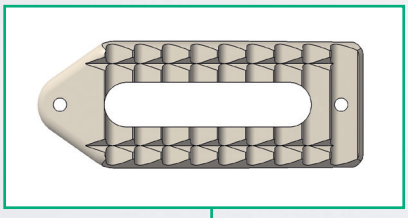
PROSPACE® PEEK implants are used for the stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental.

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

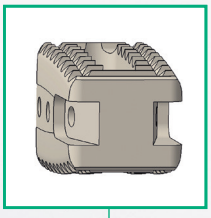
PROSPACE® PEEK is designed to deliver

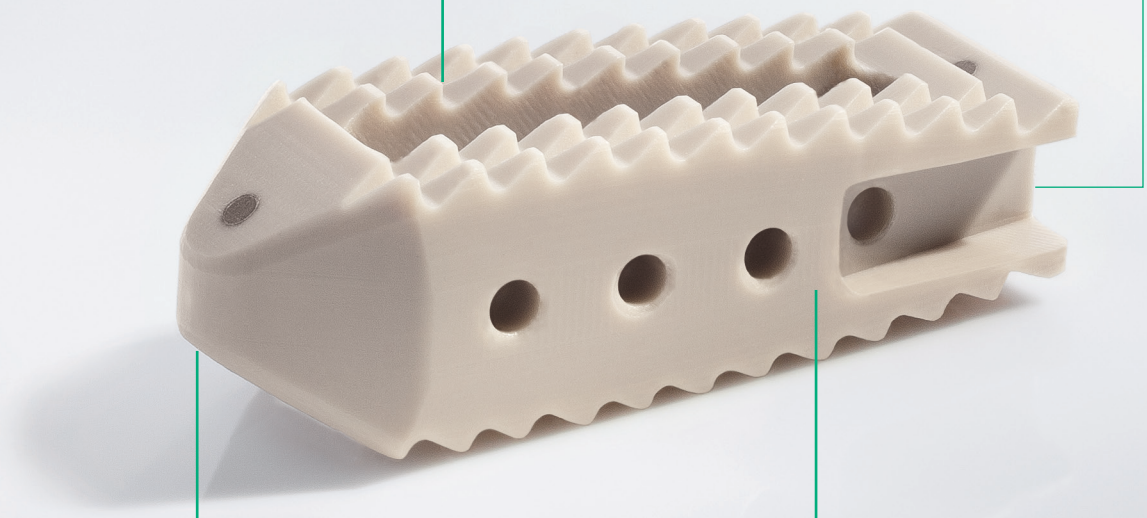
- Primary stability (8).
- Restoration of the natural disc hight and lordosis (9).

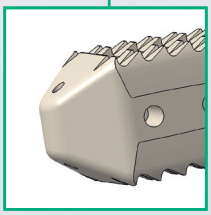
Enhanced contact area & design



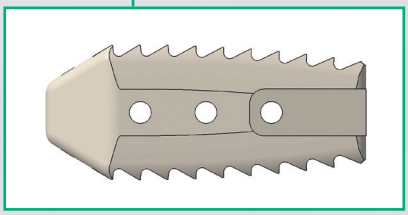
Clamping mechanism with undercut







Bullet nose



1mm height increments

Implant material

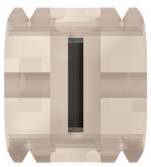


Fig. 1

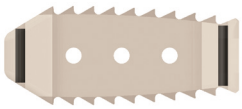


Fig. 2

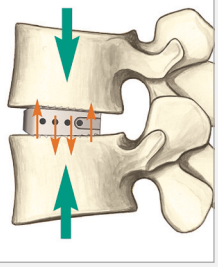


Fig. 3

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, radio-opaque 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

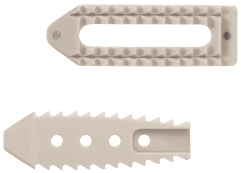


Fig. 5

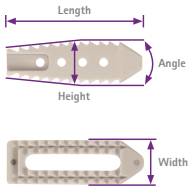


Fig. 6

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

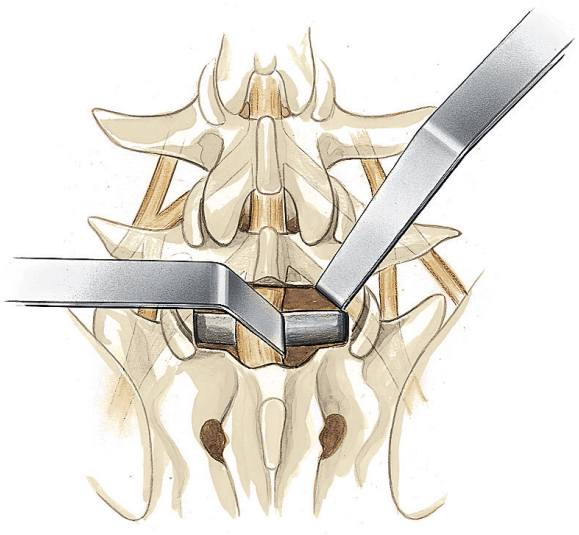


Fig. 1

B.1 Bone resection

- Using an osteotome and a 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.

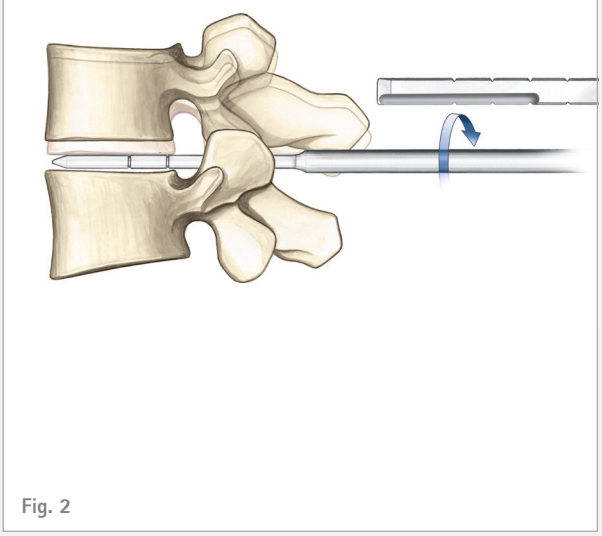


Fig. 2

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.

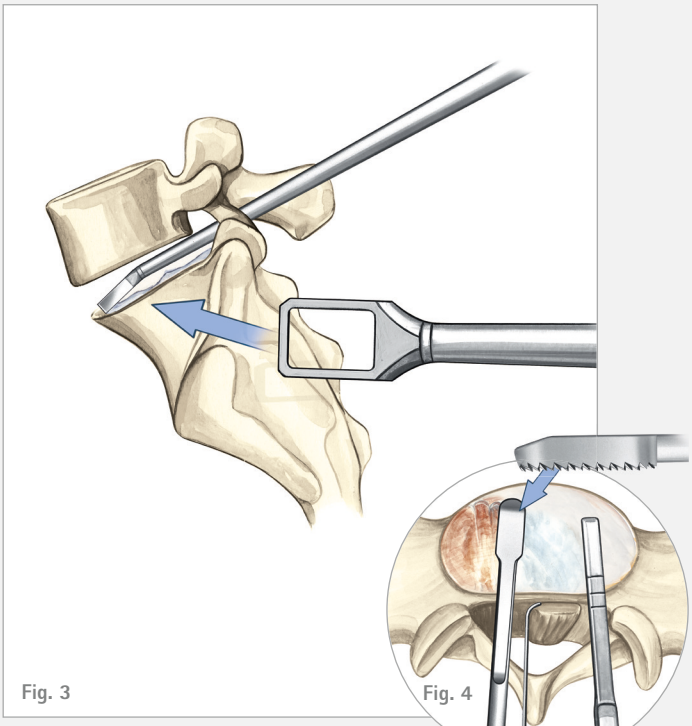


Fig. 3

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.

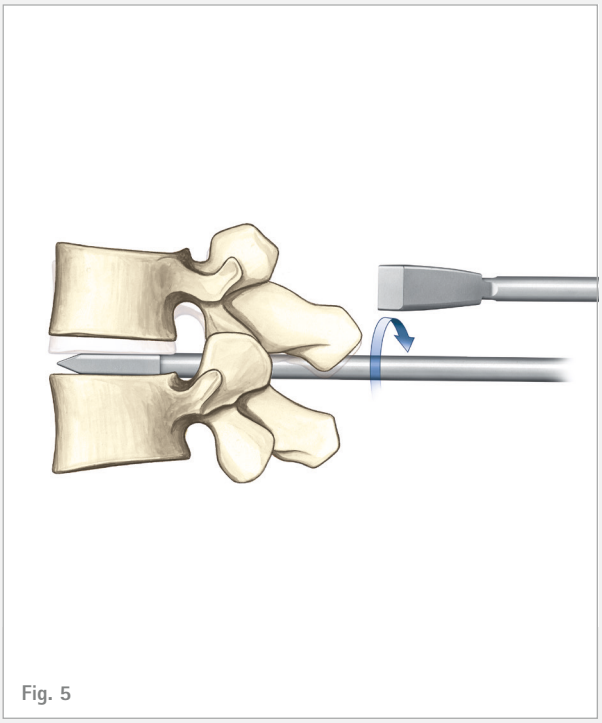


Fig. 5

B.5 Determination of implant size using trial implants

- Trials are available in 5° and corresponding to the implant height. The trials measure 26 mm in length and indicate the length 22 mm by a laser marking. Starting with the smallest size the trials are inserted horizontally and rotated clockwise. Stepwise the next heights are inserted until the required distraction has been achieved (Fig. 5)

Information

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

AESCULAP® PROSPACE® PEEK

B | Surgical manual

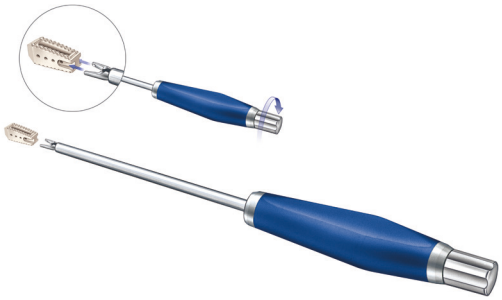


Fig. 1

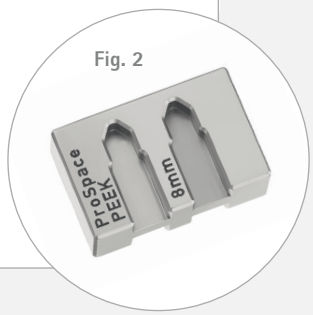


Fig. 2

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.

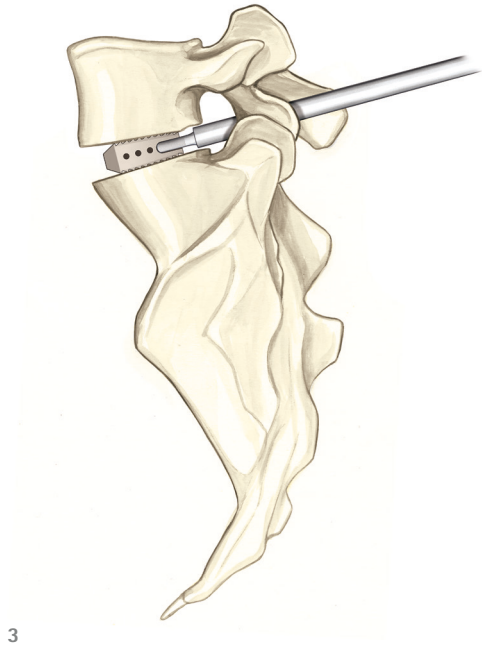


Fig. 3

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.

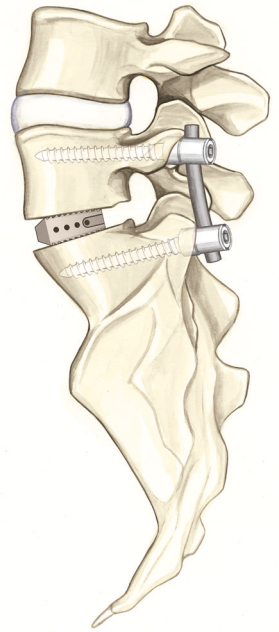


Fig. 4

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

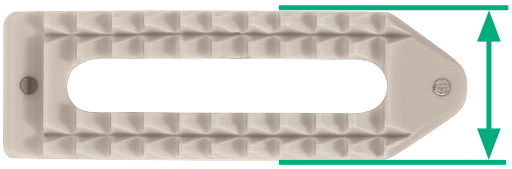
C | Implant & instrument overview

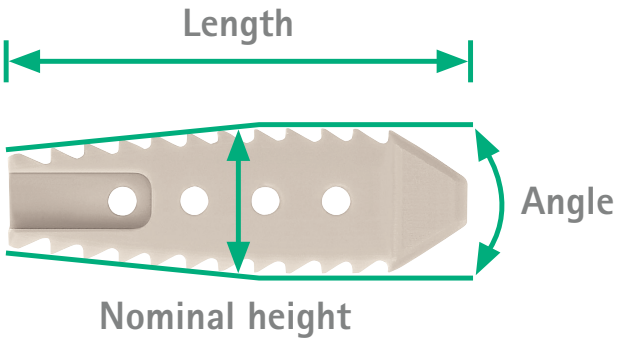
PROSPACE® PEEK implants

Article No.	Size (Height x Width x Length)	Angle
SN007P	7 x 8.5 x 22 mm	0°
SN008P	8 x 8.5 x 22 mm	0°
SN009P	9 x 8.5 x 22 mm	0°
SN010P	10 x 8.5 x 22 mm	0°
SN011P	11 x 8.5 x 22 mm	0°
SN012P	12 x 8.5 x 22 mm	0°
SN013P	13 x 8.5 x 26 mm	0°
SN015P	15 x 8.5 x 26 mm	0°
SN017P	17 x 8.5 x 26 mm	0°
SN022P	7 x 8.5 x 26 mm	0°
SN023P	8 x 8.5 x 26 mm	0°
SN024P	9 x 8.5 x 26 mm	0°
SN025P	10 x 8.5 x 26 mm	0°
SN026P	11 x 8.5 x 26 mm	0°
SN027P	12 x 8.5 x 26 mm	0°
SN028P	13 x 8.5 x 26 mm	0°
SN030P	15 x 8.5 x 26 mm	0°
SN032P	17 x 8.5 x 26 mm	0°
SN037P	7 x 8.5 x 22 mm	5°
SN038P	8 x 8.5 x 22 mm	5°
SN039P	9 x 8.5 x 22 mm	5°
SN040P	10 x 8.5 x 22 mm	5°
SN041P	11 x 8.5 x 22 mm	5°
SN042P	12 x 8.5 x 22 mm	5°
SN043P	13 x 8.5 x 22 mm	5°
SN045P	15 x 8.5 x 22 mm	5°

Article No.	Size (Height x Width x Length)	Angle
SN047P	17 x 8.5 x 22 mm	5°
SN052P	7 x 8.5 x 26 mm	5°
SN053P	8 x 8.5 x 26 mm	5°
SN054P	9 x 8.5 x 26 mm	5°
SN055P	10 x 8.5 x 26 mm	5°
SN056P	11 x 8.5 x 26 mm	5°
SN057P	12 x 8.5 x 26 mm	5°
SN058P	13 x 8.5 x 26 mm	5°
SN060P	15 x 8.5 x 26 mm	5°
SN062P	17 x 8.5 x 26 mm	5°
SN068P	8 x 8.5 x 22 mm	8°
SN069P	9 x 8.5 x 22 mm	8°
SN070P	10 x 8.5 x 22 mm	8°
SN071P	11 x 8.5 x 22 mm	8°
SN072P	12 x 8.5 x 22 mm	8°
SN073P	13 x 8.5 x 22 mm	8°
SN075P	15 x 8.5 x 22 mm	8°
SN077P	17 x 8.5 x 22 mm	8°
SN083P	8 x 8.5 x 26 mm	8°
SN084P	9 x 8.5 x 26 mm	8°
SN085P	10 x 8.5 x 26 mm	8°
SN086P	11 x 8.5 x 26 mm	8°
SN087P	12 x 8.5 x 26 mm	8°
SN088P	13 x 8.5 x 26 mm	8°
SN090P	15 x 8.5 x 26 mm	8°
SN092P	17 x 8.5 x 26 mm	8°

All PROSPACE® PEEK implants are single sterile packed.





Article No.	Size (Height x Width x Length)	Angle
SN107P	7 x 10.5 x 22 mm	0°
SN108P	8 x 10.5 x 22 mm	0°
SN109P	9 x 10.5 x 22 mm	0°
SN110P	10 x 10.5 x 22 mm	0°
SN111P	11 x 10.5 x 22 mm	0°
SN112P	12 x 10.5 x 22 mm	0°
SN113P	13 x 10.5 x 22 mm	0°
SN115P	15 x 10.5 x 22 mm	0°
SN117P	17 x 10.5 x 22 mm	0°
SN122P	7 x 10.5 x 26 mm	0°
SN123P	8 x 10.5 x 26 mm	0°
SN124P	9 x 10.5 x 26 mm	0°
SN125P	10 x 10.5 x 26 mm	0°
SN126P	11 x 10.5 x 26 mm	0°
SN127P	12 x 10.5 x 26 mm	0°
SN128P	13 x 10.5 x 26 mm	0°
SN130P	15 x 10.5 x 26 mm	0°
SN132P	17 x 10.5 x 26 mm	0°
SN137P	7 x 10.5 x 22 mm	5°
SN138P	8 x 10.5 x 22 mm	5°
SN139P	9 x 10.5 x 22 mm	5°
SN140P	10 x 10.5 x 22 mm	5°
SN141P	11 x 10.5 x 22 mm	5°
SN142P	12 x 10.5 x 22 mm	5°
SN143P	13 x 10.5 x 22 mm	5°
SN145P	15 x 10.5 x 22 mm	5°

Article No.	Size (Height x Width x Length)	Angle
SN147P	17 x 10.5 x 22 mm	5°
SN152P	7 x 10.5 x 26 mm	5°
SN153P	8 x 10.5 x 26 mm	5°
SN154P	9 x 10.5 x 26 mm	5°
SN155P	10 x 10.5 x 26 mm	5°
SN156P	11 x 10.5 x 26 mm	5°
SN157P	12 x 10.5 x 26 mm	5°
SN158P	13 x 10.5 x 26 mm	5°
SN160P	15 x 10.5 x 26 mm	5°
SN162P	17 x 10.5 x 26 mm	5°
SN168P	8 x 10.5 x 22 mm	8°
SN169P	9 x 10.5 x 22 mm	8°
SN170P	10 x 10.5 x 22 mm	8°
SN171P	11 x 10.5 x 22 mm	8°
SN172P	12 x 10.5 x 22 mm	8°
SN173P	13 x 10.5 x 22 mm	8°
SN175P	15 x 10.5 x 22 mm	8°
SN177P	17 x 10.5 x 22 mm	8°
SN183P	8 x 10.5 x 26 mm	8°
SN184P	9 x 10.5 x 26 mm	8°
SN185P	10 x 10.5 x 26 mm	8°
SN186P	11 x 10.5 x 26 mm	8°
SN187P	12 x 10.5 x 26 mm	8°
SN188P	13 x 10.5 x 26 mm	8°
SN190P	15 x 10.5 x 26 mm	8°
SN192P	17 x 10.5 x 26 mm	8°

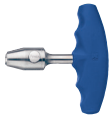
Implant material
PEEK-OPTIMA® PolyEtherKeton

AESCULAP® PROSPACE® PEEK

C | Implant & instrument overview

SJ800 – PROSPACE® PEEK instrumentation

Instruments	Article No.	Description	Quantity
	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
	FJ652R	Distractor, 12 mm	1
	FJ653R	Distractor, 13 mm	1
	FJ655R	Distractor, 15 mm	1
	FJ657R	Distractor, 17 mm	1
	SN252R	PROSPACE® PEEK Trial Implant, 5°, 7 x 26 mm	1
	SN253R	PROSPACE® PEEK Trial Implant, 5°, 8 x 26 mm	1
	SN254R	PROSPACE® PEEK Trial Implant, 5°, 9 x 26 mm	1
	SN255R	PROSPACE® PEEK Trial Implant, 5°, 10 x 26 mm	1
	SN256R	PROSPACE® PEEK Trial Implant, 5°, 11 x 26 mm	1
	SN257R	PROSPACE® PEEK Trial Implant, 5°, 12 x 26 mm	1
	SN258R	PROSPACE® PEEK Trial Implant, 5°, 13 x 26 mm	1
	SN260R	PROSPACE® PEEK Trial Implant, 5°, 15 x 26 mm	1
	SN262R	PROSPACE® PEEK Trial Implant, 5°, 17 x 26 mm	1
	FJ658R	Osteotome, Straight	1
	FJ681R	Curette, Straight	1
	FJ684R	Bone Rasp, Straight	1

Instruments	Article No.	Description	Quantity
	**SJ033R**	T-handle for distractors and trials	2
	SJ804R	T-handle for distractors and trials	2*
	FJ051R	Retractor S	1
	FJ052R	Retractor M	1
	FJ053R	Retractor L	1
	FJ054R	Retractor XL	1
	SN004R	Packing Block	1
	SN002R	PROSPACE® PEEK Insertion Instrument	2
	SN003R	Impactor	1
	FF913R	Punch	1
	SJ801R	PROSPACE® PEEK Tray for Preparation and Implantation	1
	JH217R	Wide perforated basket lid	1
	TF029	Graphic template for SJ801R	1

*article is an alternative for SJ033R

Recommended container for SJ801R: JK442 / JN442 and lid JK489.

AESCULAP® PROSPACE® PEEK

D | References

(1) Tropiano P, Bronsard JJ, Louis C, Tallet JM, Sauget Y. Three column stabilisation through a posterior appraoch with a titanium PLASMAPORE® intervertebral block (PROSPACE®). Radiological and clinical study after 4 years. Rivista di Neuroradiologia. 1999;12(Suppl 1):89-94.

(2) Kroppenstedt S, Gulde M, Schonmayr R. Radiological comparison of instrumented posterior lumbar interbody fusion with one or two closed-box PLASMAPORE® coated titanium cages. Follow-up study over more than seven years. Spine. 2008;33(19):2083-8.

(3) Kreinest M, Schmahl D, Grutzner PA, Matschke S. Radiological Results and Clinical Patient Outcome After Implantation of a Hydraulic Expandable Vertebral Body Replacement following Traumatic Vertebral Fractures in the Thoracic and Lumbar Spine: A 3-Year Follow-Up. Spine (Phila Pa 1976). 2017 Apr 15;42(8):E482-E489.

(4) 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 Neurosurgery. 2014;82(3/4):519-22.

(5) Vanek P, Bradac O, Konopkova R, de Lacy P, Lacman J, Benes V. Treatment of thoracolumbar trauma by short-segment percutaneous transpedicular screw instrumentation: prospective comparative study with a minimum 2-year follow-up. J Neurosurg Spine. 2014;20:150-6.

(6) Beisse R. Endoscopic surgery on the thoracolumbar junction of the spine. Eur Spine J. 2006;15:687-704.

(7) Finger T, Bayerl S, Onken J, Czabanka M, Woitzik J, Vajkoczy P. Sacropelvic fixation versus fusion to the sacrum for spondylodesis in multilevel degenerative spine disease. Eur Spine J. 2014;23:1013-20.

(8) Mechanical testing of the AESCULAP® PROSPACE® PEEK 2nd generation implant evaluating shear resistance. Tuttlingen, 2011. The AESCULAP® PROSPACE® PEEK 2nd generation implant was tested in a shear force test following internal standards to evaluate the risk of implant dislocation related to shear forces occurring in situ. For this test, a synthetic bone-equivalent polyurethane test block was used. A quasi-static shear force was applied to the implant. The implant was axially loaded during the whole test with a constant force to simulate a clinically relevant loading situation. Based on the maximum shear load obtained in the test, the risk of implant dislocation due to shear forces at a physiological load situation is unlikely to occur in the case of the AESCULAP® PROSPACE® PEEK 2nd generation implant.

(9) Aono H, Takenaka S, Nagamoto Y, Tobimatsu H, Yamashita T, Furuya M et al. Fusion Rate and Clinical Outcomes in Two-Level Posterior Lumbar Interbody Fusion. World Neurosurg 2018; 112:e473-e478.

(10) Kurtz SM, Devine JN. PEEK biomaterials in trauma, orthopedic, and spinal implants. Biomaterials 2007; 28(32):4845-69.

(11) Morrison C, Macnair R, MacDonald C, Wykman A, Goldie I, Grant MH. In vitro biocompatibility testing of polymers for orthopaedic implants using cultured fibroblasts and osteoblasts. Biomaterials 1995; 16(13):987-92.

(12) Invibio® Biomaterial Solutions. PEEK-OPTIMA® Natural – Typical Material Properties; 2013. Available from: URL: https://invibio.com/materials/peek-optima-natural.

(13) Chen Y, Wang X, Lu X, Yang L, Yang H, Yuan W et al. 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(7):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) Dr. Stuart Green, Keith Cartwright. An investigation into the effect of accelerated oxygen ageing on the properties of PEEK-OPTIMA®. March 2004. (B.DoCS-ID 21870982) Tensile,

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.

(16) Kuhn JL, Goldstein SA, Choi K, London M, Feldkamp LA, Matthews LS. Comparison of the trabecular and cortical tissue moduli from human iliac crests. J Orthop Res 1989; 7(6):876–84.

AESCULAP® – a B. Braun brand

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

The main product trademark "AESCULAP" and the product trademarks "Ennovate", "PROSPACE" and "S4" are registered trademarks of Aesculap AG. "PEEK-OPTIMA" is a registered trademark of Invibio® 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.

O51702 0525/PDF/2