B BRAUN
SHARING EXPERTISE

SPINE SURGERY

AESCULAP® TSPACE® PEEK

BULLETED NOSE
TRANSFORAMINAL LUMBAR INTERBODY FUSION SYSTEM

SURGICAL MANUAL

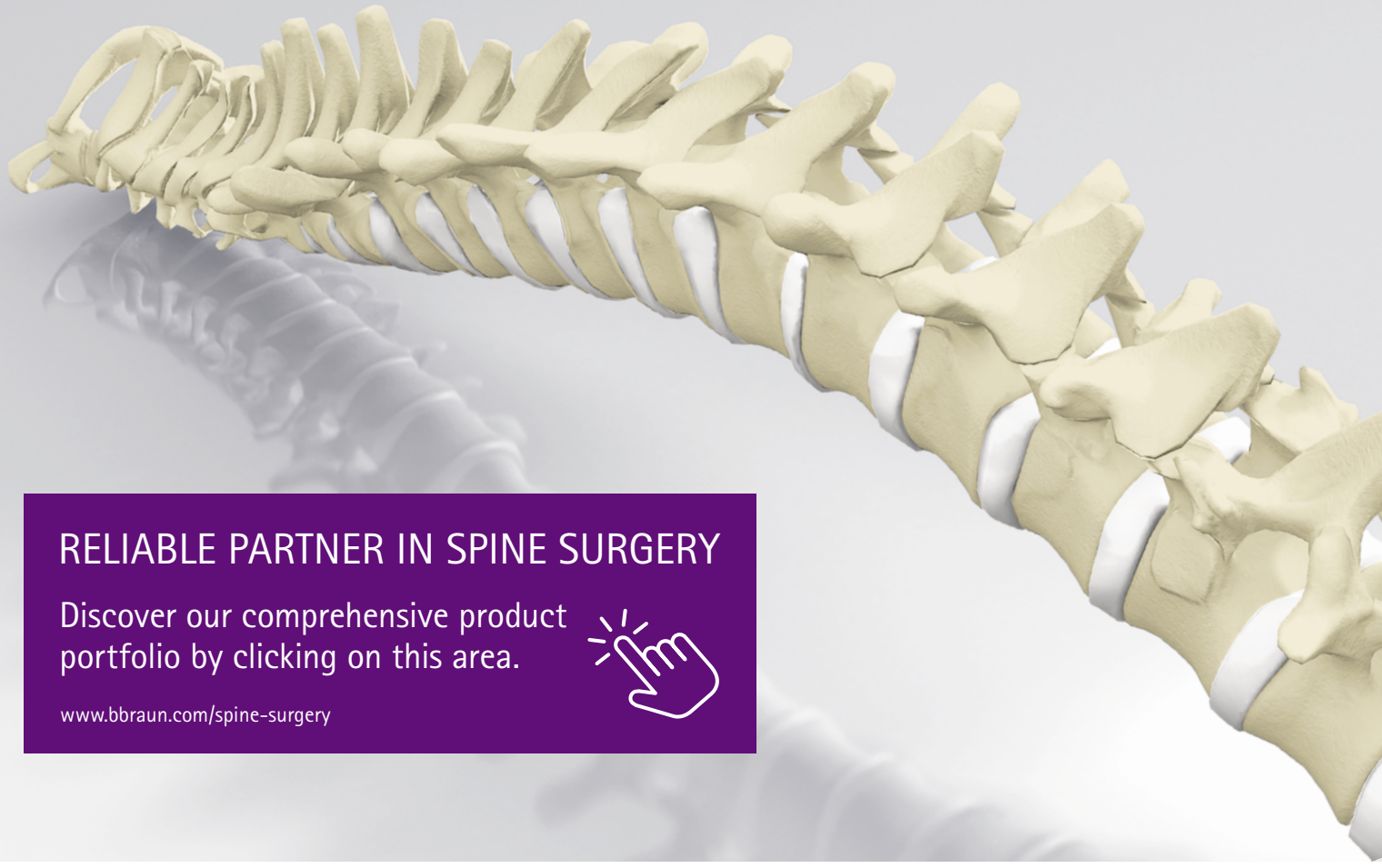
AESCULAP® THORACOLUMBAR SPINE

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.



RELIABLE PARTNER IN SPINE SURGERY

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AESCULAP® TSPACE® PEEK

CONTENT

AESCULAP® TSPACE® PEEK

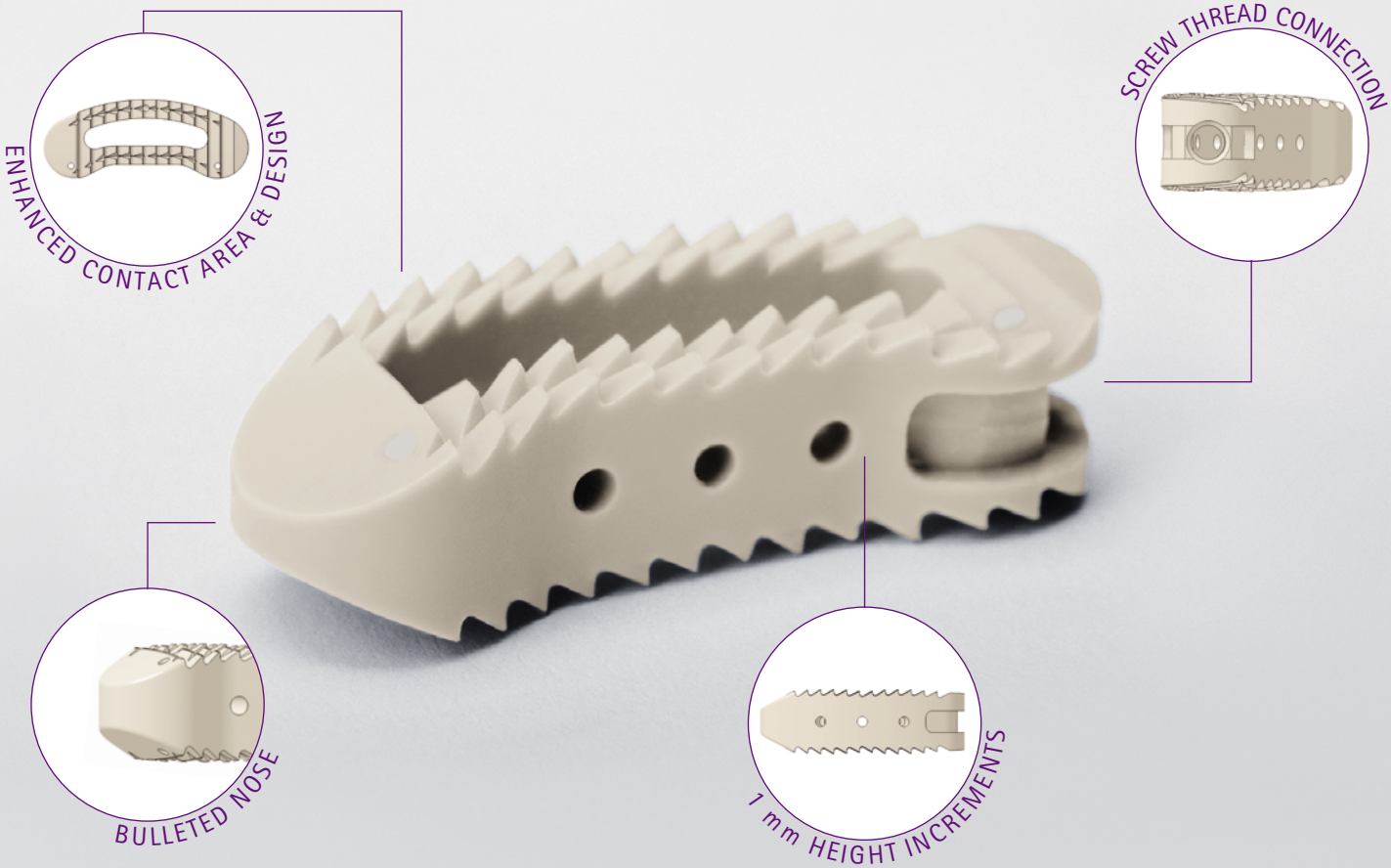
PHILOSOPHY

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

Always use TSPACE® PEEK implants in conjunction with an internal fixator.

TSPACE® PEEK IS DESIGNED TO DELIVER

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


ENHANCED CONTACT AREA & DESIGN
SCREW THREAD CONNECTION
BULLETED NOSE
1 mm HEIGHT INCREMENTS

IMPLANT MATERIAL

Fig. 1 AP view

Fig. 2 Lateral view

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 (9). Its properties include radiolucency, high mechanical strength, high fatigue resistance, a low wear factor and biocompatibility (10-14).

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 (11). 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 (11, 15).

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 (10, 11).

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

IMPLANT FEATURES

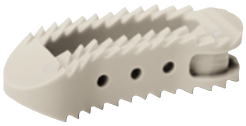


Fig. 3

Fig. 4

Fig. 5

Fig. 6

POSITION VERIFICATION DESPITE X-RAY TRANSPARENCY

- The radiolucency of PEEK-OPTIMA® enables assessment of the bone structure and progress towards bone fusion (11).
- 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).
- 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.
- Straight, curved and offset inserter available.
- Inserters attach with implant via screw thread connection.

AESCULAP® TSPACE® PEEK

B | SURGICAL MANUAL

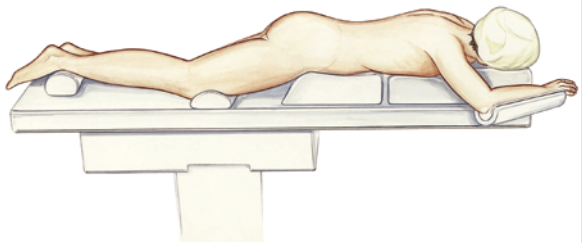


Fig. 1

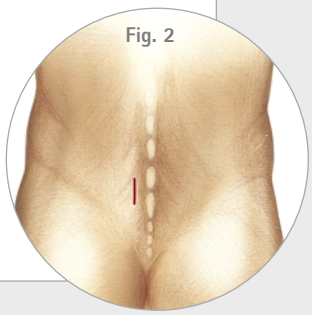


Fig. 2

B.1. POSITIONING OF THE PATIENT AND INCISION MARKING

- A minimally invasive approach requires the patient to be placed on a radiolucent table which allows for AP views of the various anatomic structures (Fig. 1).
- The appropriate position of the longitudinal incision (4 - 5 cm in length) is determined by using a C-arm. The intended skin incision is marked paraspinally on the right and respectively on the left side (Fig. 2).

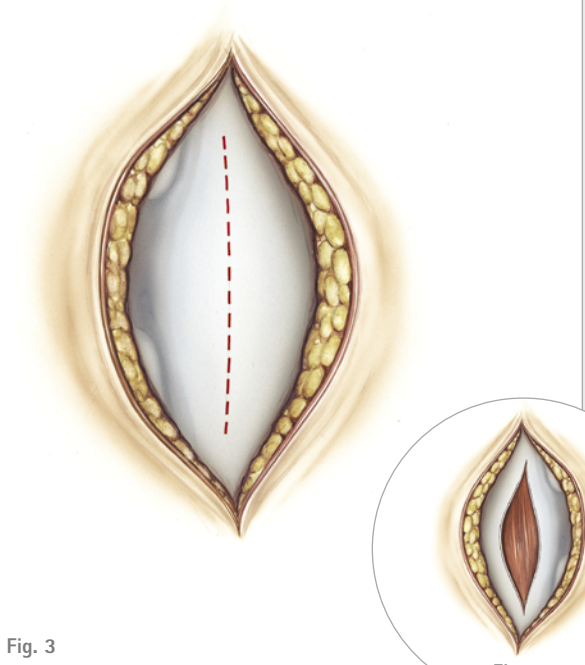


Fig. 3

Fig. 4

B.2. FASCIAL INCISION

- A slightly curved fascial incision 1.5 cm from the mid-line is performed. This allows a firm hold of the speculum and counter retractor, facilitating the exposure of the individual segment (Fig. 3 / 4).

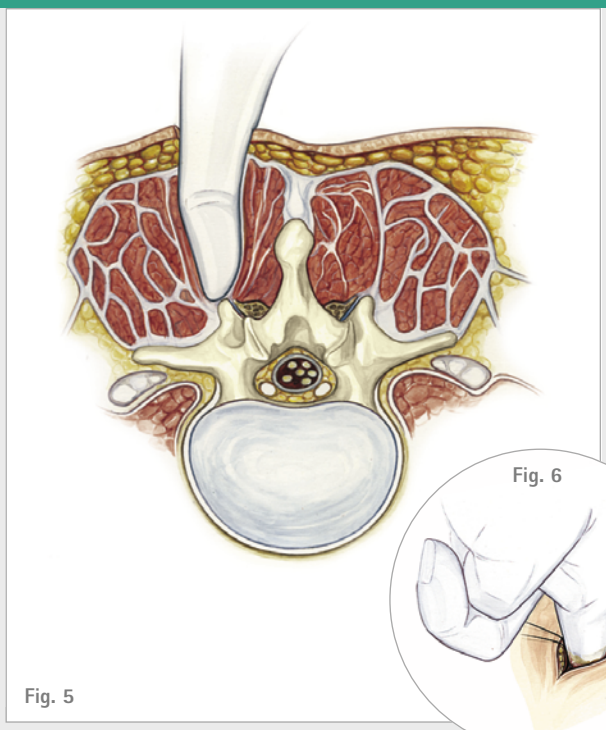


Fig. 5

Fig. 6

B.3. EXPOSURE AND BLUNT DISSECTION OF THE PARASPINAL MUSCLES

- After splitting of the thoracolumbar fascia a blunt dissection of the paraspinal muscles is performed with the fingertip. In accordance with the palpatory finding, a correction of the skin incision is still possible, as the muscle retractor should be introduced as vertically as possible and in the direction of the interlaminar space. The length of the retractor is selected by using the index finger (Fig. 5/6).

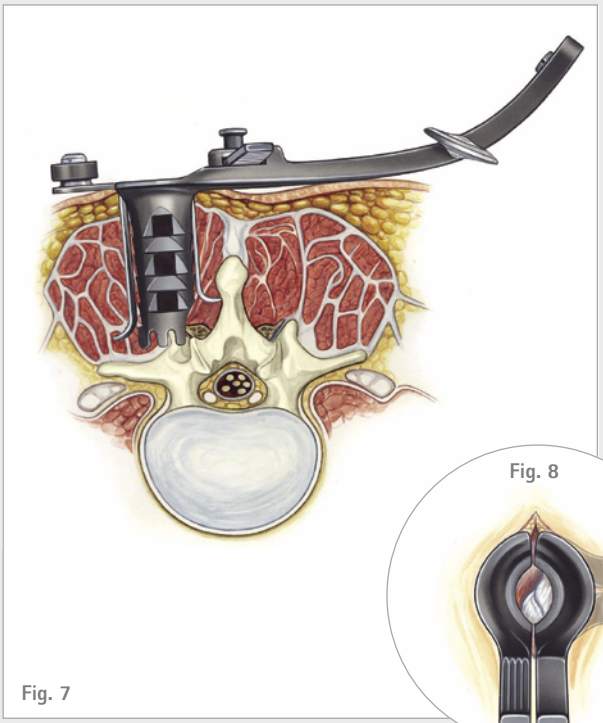


Fig. 7

Fig. 8

B.4. INTRODUCTION OF THE SPINE CLASSICS RETRACTOR SYSTEM

- Spine Classics retractor system: see brochure O11402

- The muscle retractor is introduced with closed blades and with the handle in the longitudinal direction. It is then turned 90° and expanded (Fig. 7/8).

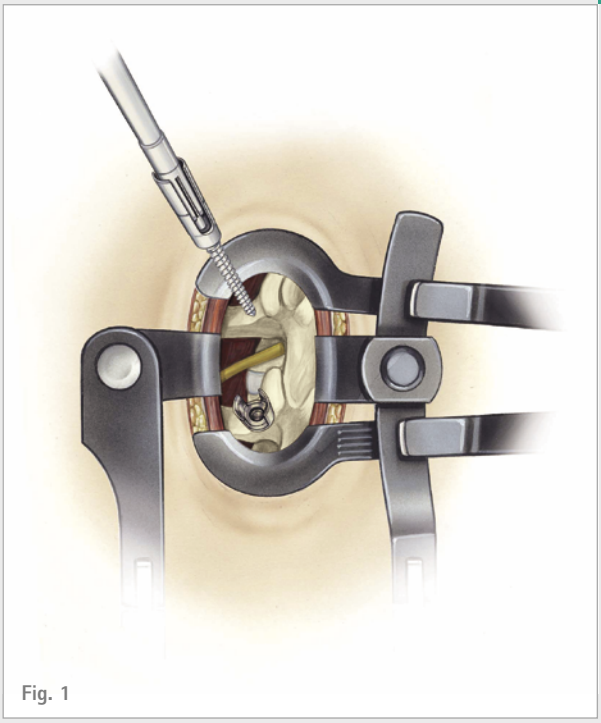


Fig. 1

B.5. INSERTION OF PEDICLE SCREW

- Using the standard technique, the pedicle screws are inserted, e. g. AESCULAP® Ennovate® (Fig. 1).

For more information please visit www.bbraun.com/ennovate

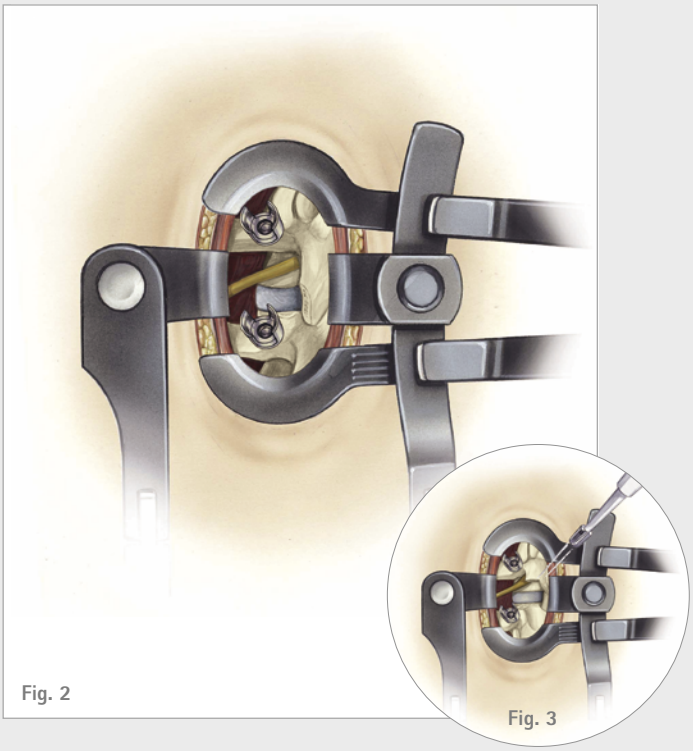


Fig. 2

Fig. 3

B.6. REMOVAL OF FACET JOINT

- A complete unilateral facetectomy should be considered on the side targeted for the implant insertion, for which an osteotome may be used. The inferior articular process of the facet joint is resected first, then the subjacent superior articular process is resected (Fig 2 / 3).

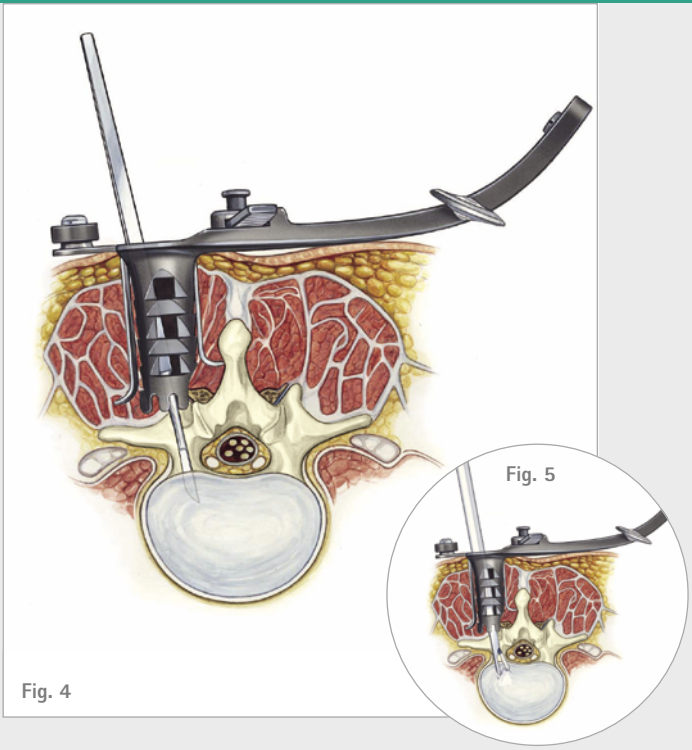


Fig. 4

Fig. 5

B.7. OPENING OF THE DISC AND REMOVAL OF DISC MATERIAL

- To open the disc a small window is cut into the annulus (Fig. 4).
- Rongeurs are used to remove the opened annulus (Fig. 5).
- Posterior osteophytes are removed by using Kerrisons.

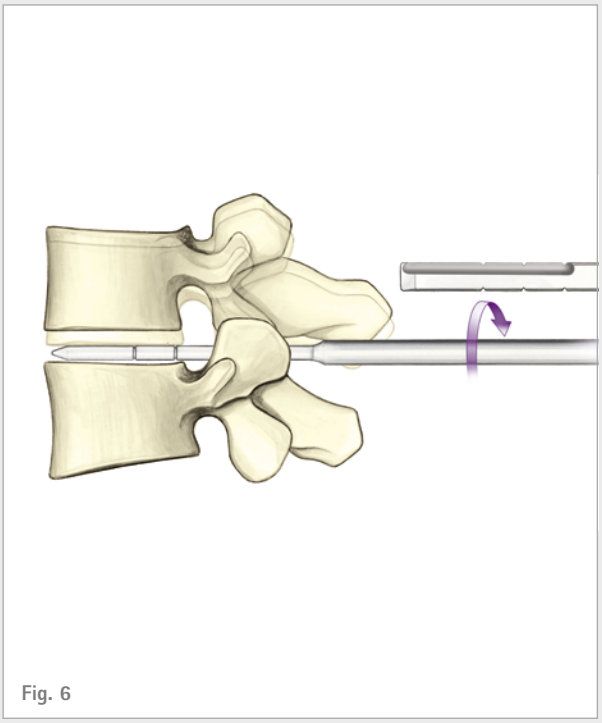


Fig. 6

B.8. RESTORATION OF DISC HEIGHT

- The desired restoration of the natural disc height can be set using the distractors. They are available in heights from 7 - 17 mm in 2 mm increments and can be attached to the t-handle in the set.
- The distractor must be inserted horizontally and then rotated. Rotating clockwise the distractors are blunt and allow for a blunt height restoration maneuver. Rotating counterclockwise the distractors have a specially designed sharp rim to allow for removal of disc material (Fig. 6).

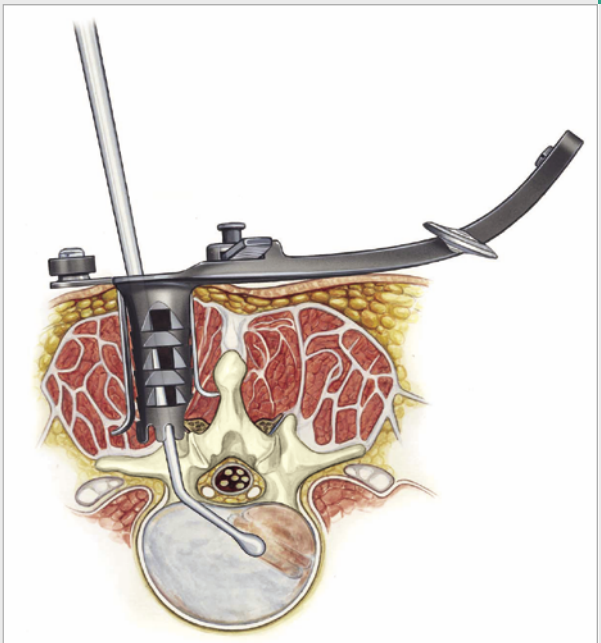


Fig. 1

B.9. CLEANING OF THE INTERVERTEBRAL SPACE

- The disc space is cleared using rongeurs, bone curettes and box curettes (Fig. 1).
- The bone rasps are used for endplate preparation.
- Alternatively, the box curettes can be used.

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. 2

B.10. DETERMINATION OF IMPLANT SIZE USING TRIAL IMPLANTS

- The TSPACE® PEEK trial implants are available in heights from 7 - 17 mm in 2 mm increments.
- Using the slap hammer the desired trial implant is inserted (Fig. 2).

INFORMATION

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

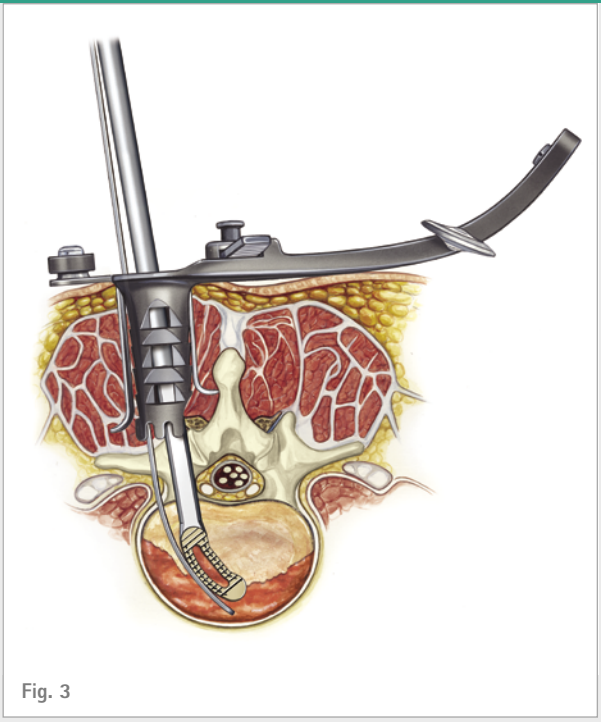


Fig. 3

Fig. 4

B.11. IMPLANT INSERTION

- The TSPACE® PEEK implant should be filled with bone or bone substitutes by using the packing block.

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.

- It is recommended to place bone material harvested from the facet joint around the TSPACE® PEEK implant.
- The insertion guide supports the implantation of the TSPACE® PEEK implant (Fig. 3).
- The TSPACE® PEEK implant is inserted gradually into the disc space using one of the three implant inserters (Fig. 4).
- The TSPACE® PEEK inserters connect to the implant via a screw thread.
- Three inserter options are available for TSPACE® PEEK: a straight, a curved and an offset inserter.

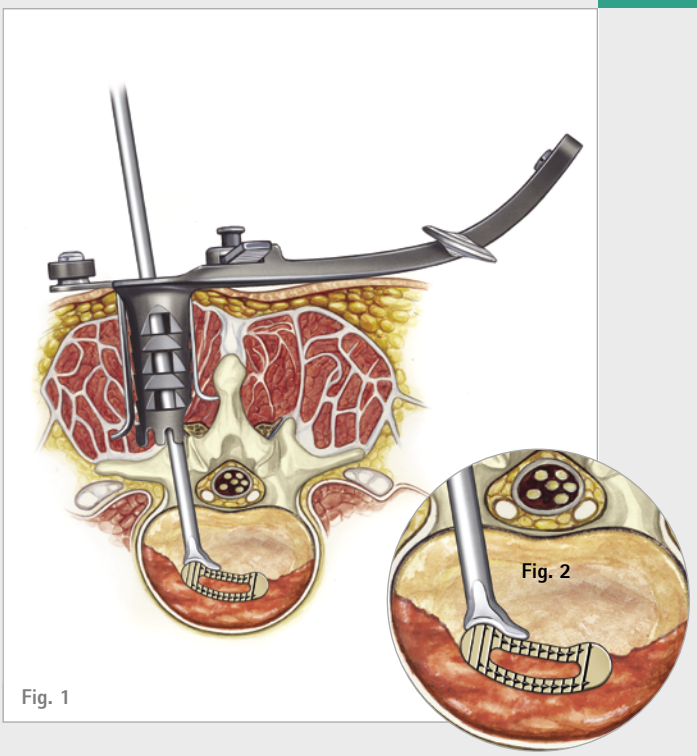


Fig. 1

Fig. 3

B.12. FINAL IMPLANT POSITIONING

- Using the straight or angled impactor the implant is rotated 90° to achieve the final positioning (Fig. 1/2/3).
- X-ray control to verify the implant positioning.
- It is recommended to put bone material harvested from the facet joint around the TSPACE® PEEK implant.

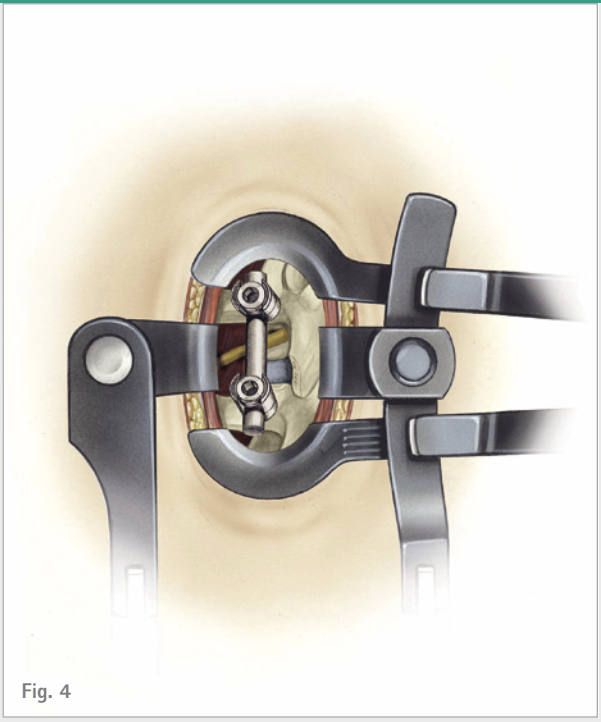


Fig. 4

B.13. APPLICATION OF ROD AND SET SCREW

- Final assembly of the thoracolumbar pedicle screw system (Fig. 4).
- Compression is applied to the pedicle screws to support the contact area between the TSPACE® PEEK implant and the endplates.
- Final tightening of the pedicle screws and closure.

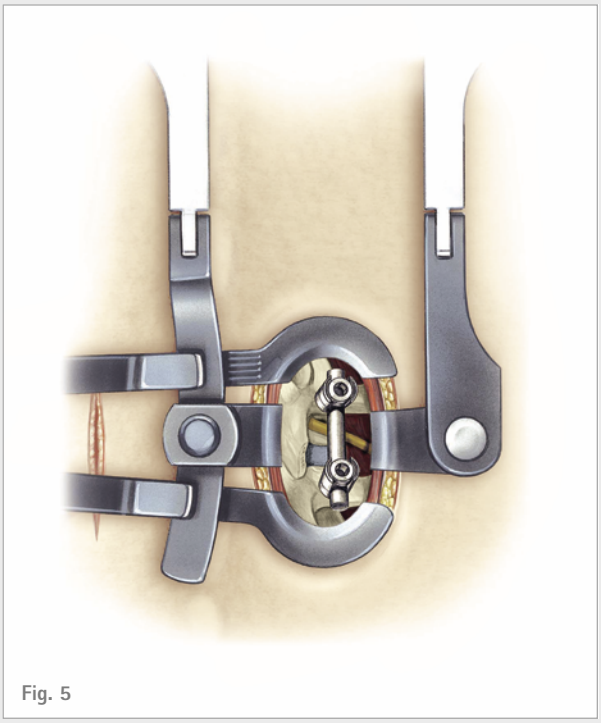


Fig. 5

B.14. PEDICLE SCREW POSITIONING ON THE CONTRA-LATERAL SIDE

- Thoracolumbar pedicle screw system is applied on the contra-lateral side (Fig. 5).

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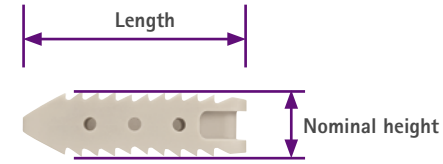
INFORMATION

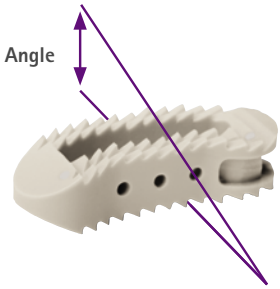
Thoracolumbar pedicle screw system shown in images is the AESCULAP® S4® Spinal System.

AESCULAP® TSPACE® PEEK

C | IMPLANT & INSTRUMENT OVERVIEW

TSPACE® PEEK IMPLANTS





Article No.	Size (Length x Width x Height)	Angle
SJ907P	26 x 11.5 x 7 mm	5°
SJ908P	26 x 11.5 x 8 mm	5°
SJ909P	26 x 11.5 x 9 mm	5°
SJ910P	26 x 11.5 x 10 mm	5°
SJ911P	26 x 11.5 x 11 mm	5°
SJ912P	26 x 11.5 x 12 mm	5°
SJ913P	26 x 11.5 x 13 mm	5°
SJ915P	26 x 11.5 x 15 mm	5°
SJ917P	26 x 11.5 x 17 mm	5°
SJ937P	30 x 11.5 x 7 mm	5°
SJ938P	30 x 11.5 x 8 mm	5°
SJ939P	30 x 11.5 x 9 mm	5°
SJ940P	30 x 11.5 x 10 mm	5°
SJ941P	30 x 11.5 x 11 mm	5°
SJ942P	30 x 11.5 x 12 mm	5°
SJ943P	30 x 11.5 x 13 mm	5°
SJ945P	30 x 11.5 x 15 mm	5°
SJ947P	30 x 11.5 x 17 mm	5°
SJ967P	34 x 11.5 x 7 mm	5°
SJ968P	34 x 11.5 x 8 mm	5°
SJ969P	34 x 11.5 x 9 mm	5°
SJ970P	34 x 11.5 x 10 mm	5°
SJ971P	34 x 11.5 x 11 mm	5°
SJ972P	34 x 11.5 x 12 mm	5°
SJ973P	34 x 11.5 x 13 mm	5°
SJ975P	34 x 11.5 x 15 mm	5°
SJ977P	34 x 11.5 x 17 mm	5°

All TSPACE® PEEK implants are single sterile packed.

FJ610 – TSPACE® PEEK INSTRUMENTATION

FJ633R
TSPACE® PEEK – Preparation Tray

INSTRUMENTS	Article No.	Description	Quantity
	FJ679R	Left angled bone curette, 45°	1
	FJ680R	Right angled bone curette, 45°	1
	FJ698R	Left angled bone curette, 20°	1*
	FJ699R	Right angled bone curette, 20°	1*
	FJ681R	Straight curette	1
	FJ682R	Left angled curette, 45°	1
	FJ683R	Right angled curette, 45°	1
	FJ702R	Left angled curette, 20°	1*
	FJ703R	Right angled curette, 20°	1*
	FJ658R	Straight osteotome, 8 mm	1
	FJ685R	Left angled bone rasp, 45°	1
	FJ686R	Right angled bone rasp, 45°	1
	FJ704R	Left angled bone rasp, 20°	1*
	FJ705R	Right angled bone rasp, 20°	1*
	FJ633R	Tray for preparation instruments	1
	JH217R	Wide perforated basket lid	1

*This article is optional.
Recommended container for FJ633R: JK441 / JN441 and lid JK489.

AESCULAP® TSPACE® PEEK

C | IMPLANT & INSTRUMENT OVERVIEW

FJ610 – TSPACE® 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
	FJ667R	TSPACE® trial, 7 mm	1
	FJ668R	TSPACE® trial, 8 mm	1
	FJ669R	TSPACE® trial, 9 mm	1
	FJ670R	TSPACE® trial, 10 mm	1
	FJ671R	TSPACE® trial, 11 mm	1
	FJ672R	TSPACE® trial, 12 mm	1
	FJ673R	TSPACE® trial, 13 mm	1
	FJ675R	TSPACE® trial, 15 mm	1
	FJ677R	TSPACE® trial, 17 mm	1
	FJ619R	TSPACE® curved trial, 7 mm	1*
	FJ620R	TSPACE® curved trial, 8 mm	1*
	FJ621R	TSPACE® curved trial, 9 mm	1*
	FJ622R	TSPACE® curved trial, 10 mm	1*
	FJ623R	TSPACE® curved trial, 11 mm	1*
	FJ624R	TSPACE® curved trial, 12 mm	1*
	FJ625R	TSPACE® curved trial, 13 mm	1*
	FJ627R	TSPACE® curved trial, 15 mm	1*
	FJ629R	TSPACE® curved trial, 17 mm	1*

*This article is optional.

INSTRUMENTS	Article No.	Description	Quantity
	SJ033R	T-handle for distractors and trials	2
	FJ051R	Retractor S	1
	FJ052R	Retractor M	1
	FJ053R	Retractor L	1
	FJ054R	Retractor XL	1
	FJ615R	Packing block	1
	FJ603R	Offset inserter	1
	FJ604R	Straight inserter	1
	FJ605R	Curved inserter	1
	FJ613R	Impactor	1
	FJ611R	Tray for implantation instruments	1
	JH217R	Wide perforated basket lid	1

Recommended container for FJ611R: JK442/JN442 and lid JK489.

AESCULAP® TSPACE® PEEK

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

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