



SPINE SURGERY

AESCULAP[®] TSPACE[®] XP

TRANSFORAMINAL LUMBAR INTERBODY FUSION SYSTEM

SURGICAL MANUAL

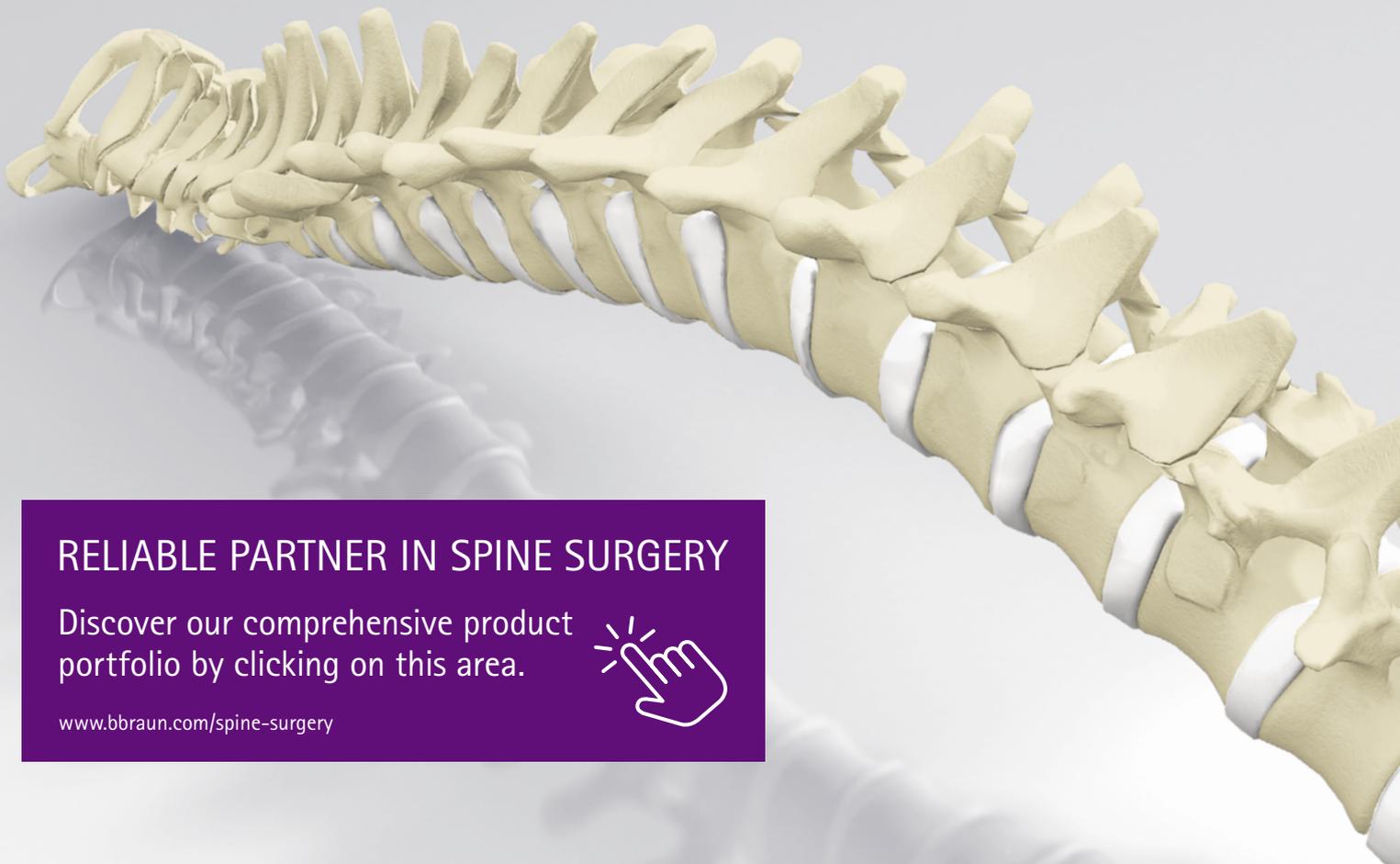
AESCULAP® THORACOLUMBAR SPINE

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

Discover our comprehensive product portfolio by clicking on this area.



www.bbraun.com/spine-surgery

AESCULAP® TSPACE® XP

CONTENT



A GENERAL INFORMATION

B SURGICAL MANUAL

- B.1. POSITIONING OF THE PATIENT AND INCISION MARKING
- B.2. FASCIAL INCISION
- B.3. EXPOSURE AND BLUNT DISSECTION OF THE PARASPINAL MUSCLES
- B.4. INTRODUCTION OF THE SPINE CLASSICS RETRACTOR SYSTEM
- B.5. INSERTION OF PEDICLE SCREW
- B.6. REMOVAL OF FACET JOINT
- B.7. OPENING OF THE DISC AND REMOVAL OF DISC MATERIAL
- B.8. RESTORATION OF DISC HEIGHT
- B.9. CLEANING OF THE INTERVERTEBRAL SPACE
- B.10. DETERMINATION OF IMPLANT SIZE USING TRIAL
- B.11. REMOVAL OF THE TRIAL USING THE SLAP HAMMER SN320R
- B.12. IMPLANT INSERTION
- B.13. FINAL IMPLANT POSITIONING
- B.14. FINAL IMPLANT POSITION
- B.15. APPLICATION OF ROD AND SET SCREW
- B.16. PEDICLE SCREW POSITIONING ON THE CONTRA-LATERAL SIDE
- B.17. OVERVIEW OF THE ARTICULATING INSERTER SN305R

C IMPLANT & INSTRUMENT OVERVIEW

AESCULAP® TSPACE® XP

A | GENERAL INFORMATION

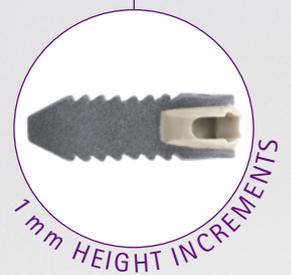
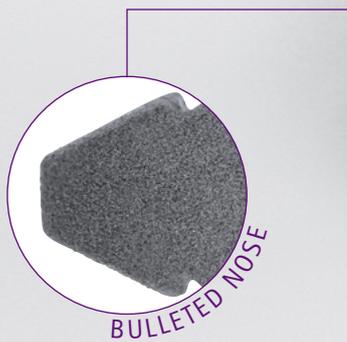
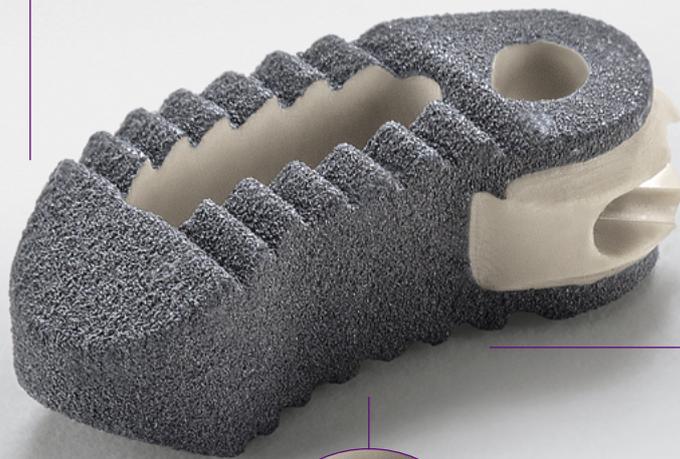
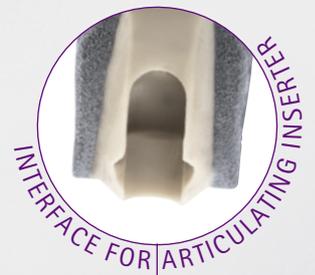
PHILOSOPHY

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

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

> TSPACE® XP IS DESIGNED TO DELIVER

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



AESCULAP[®] XP THE CHOICE OF EXPERTS

AESCULAP® TSPACE® XP

A | GENERAL INFORMATION

IMPLANT MATERIAL

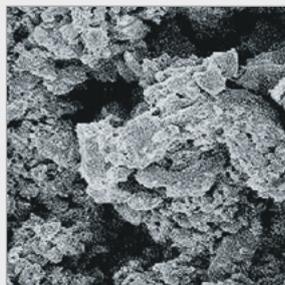


Fig. 1

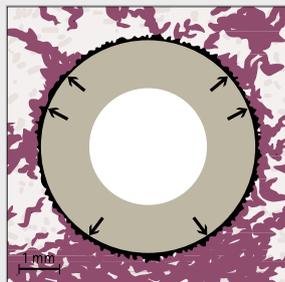


Fig. 2

TSPACE® XP – PLASMAPORE^{XP}

COMBINING MATERIAL ADVANTAGES

The core of the implant 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 the PEEK-OPTIMA® material has several advantages, as its properties include radiolucency, high mechanical strength, high fatigue resistance, a low wear factor and biocompatibility (9-14).

The core is mantled with the proven PLASMAPORE^{XP} coating to increase the contact area between implant and endplate (15). PLASMAPORE^{XP} 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 (15). The coating allows for clear visualization of implant contours during intra and post operative imaging.

AIM OF THE PLASMAPORE^{XP} COATING

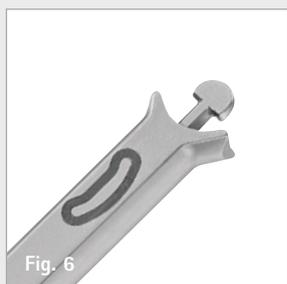
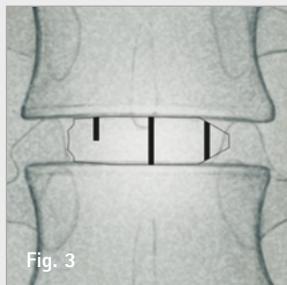
Primary Stability

The increased surface roughness of the PLASMAPORE^{XP} coating contributes to the primary stability of the motion segment (Fig. 1) (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 vertebrae with the implant (15-16) (Fig. 2).

IMPLANT FEATURES



TSPACE® XP - PLASMAPORE^{XP}

IMAGING PROPERTIES

- PLASMAPORE^{XP} allows for clear visualization of implant contours under X-ray (17).
- X-ray pins facilitating implant positioning and localization.
- Allows for assessment of the bone structure and progress towards bone fusion (17).

IMPLANT DESIGN

- Bullet nose to facilitate implant insertion.
- Specially designed interface to allow connection with articulating inserter.
- Option of filling with bone or bone substitute to enhance bone bridging.
- Serrated profile for a high primary stability (Fig. 4) (8).

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.
- Articulating interbody inserter available (Fig. 5).
- Trials available for each implant size.

AESCULAP® TSPACE® XP

B | SURGICAL MANUAL



Fig. 1

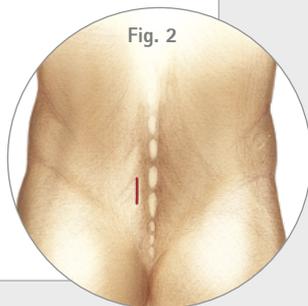


Fig. 2

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).

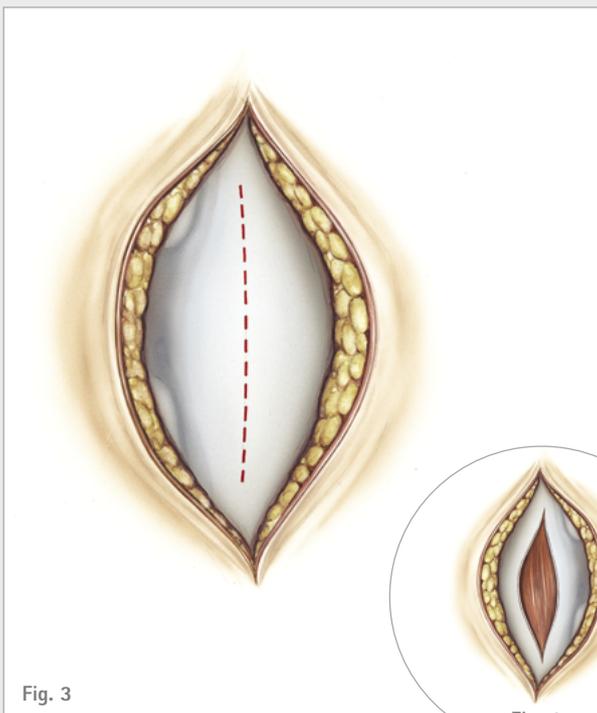


Fig. 3



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).

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).

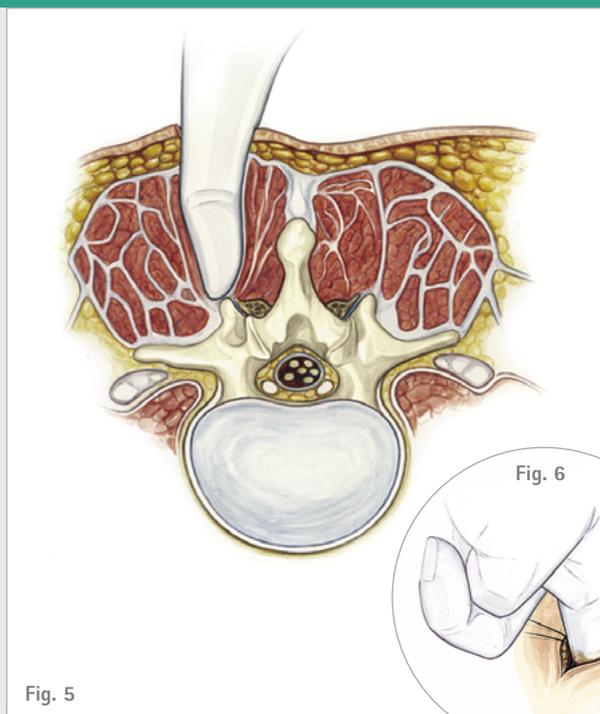


Fig. 5

B.4. INTRODUCTION OF THE SPINE CLASSICS RETRACTOR SYSTEM

- Spine Classics retractor system: see brochure 011402
- 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).

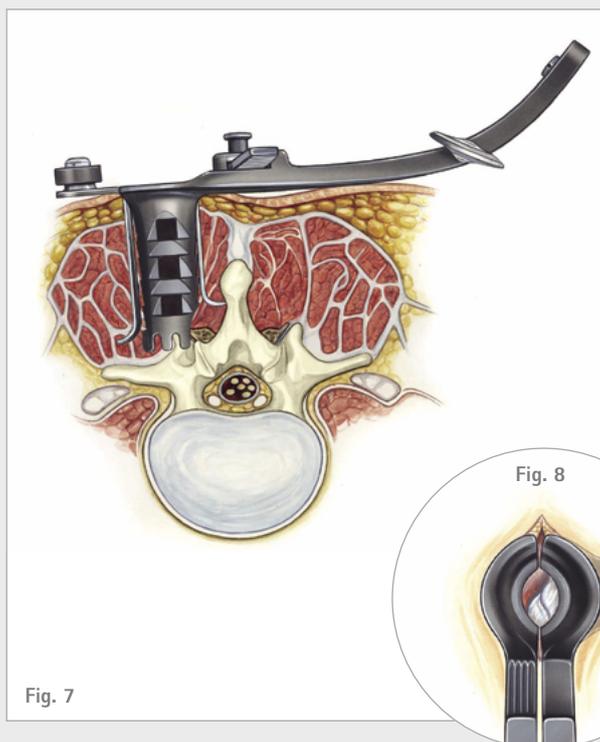


Fig. 7

AESCULAP® TSPACE® XP

B | SURGICAL MANUAL

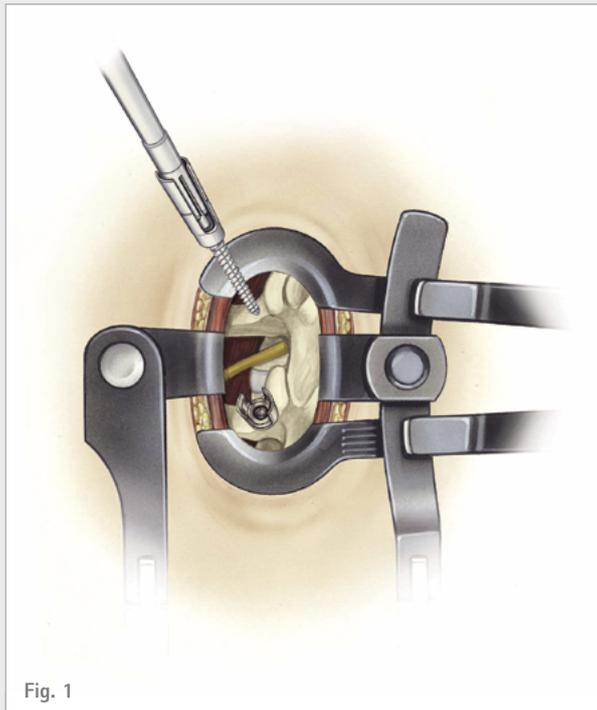


Fig. 1

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

INFORMATION

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

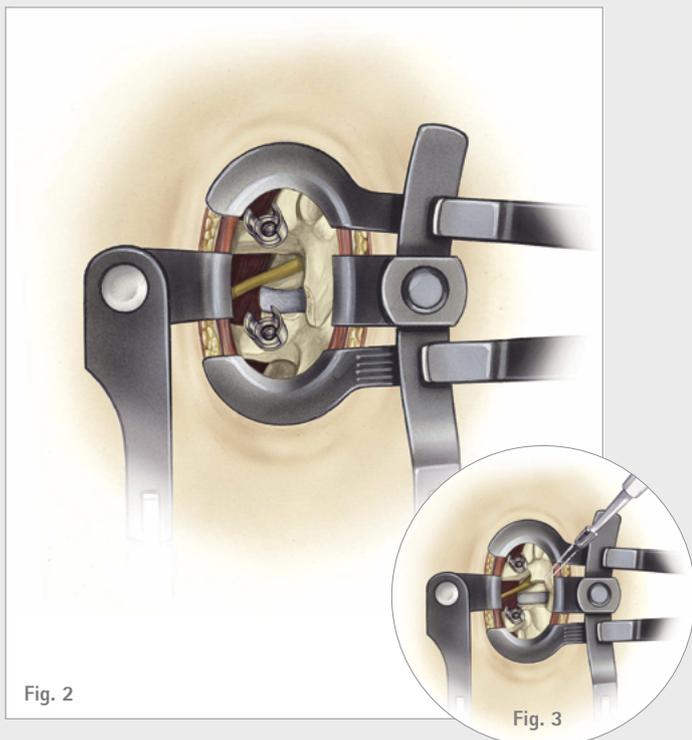


Fig. 2

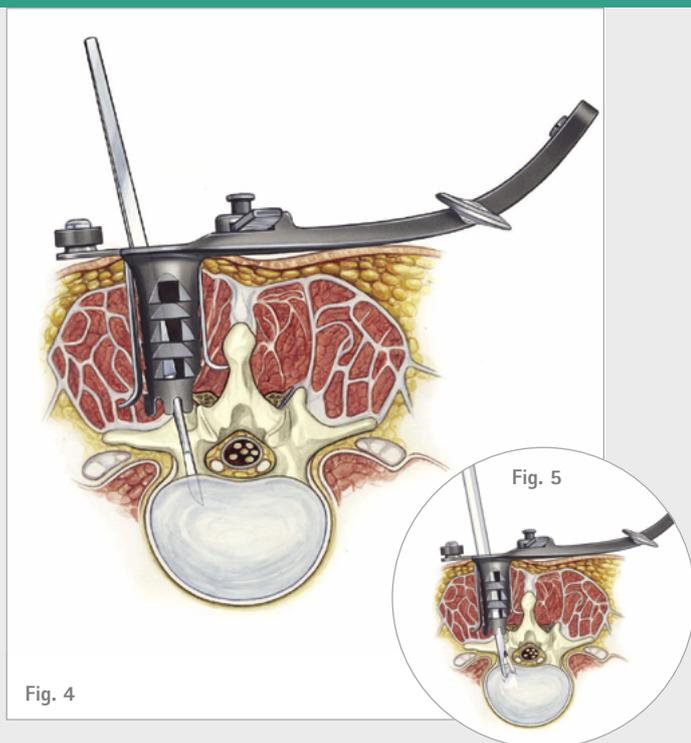
Fig. 3

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).

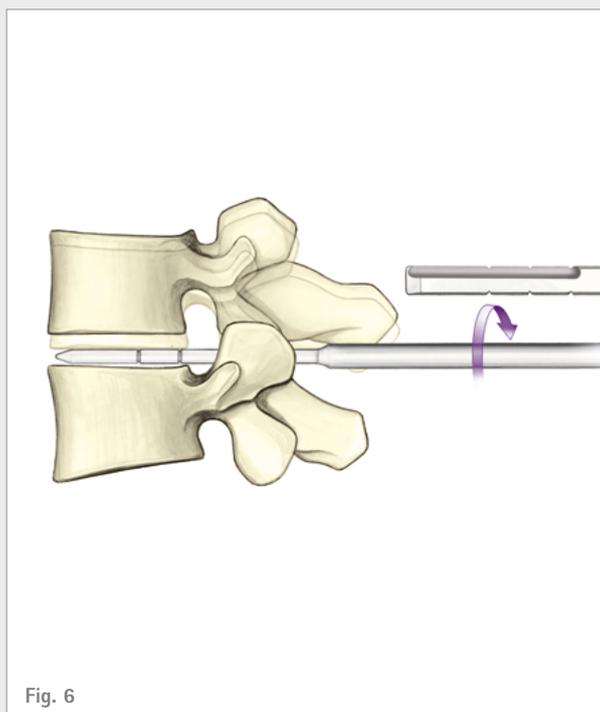
B.7. OPENING OF THE DISC AND REMOVAL OF DISC MATERIAL

- 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.



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).



AESCULAP® TSPACE® XP

B | SURGICAL MANUAL

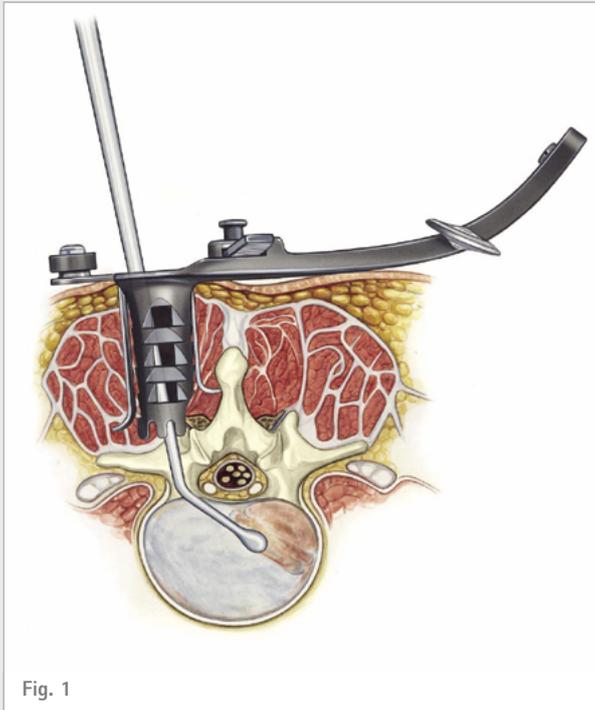


Fig. 1

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.

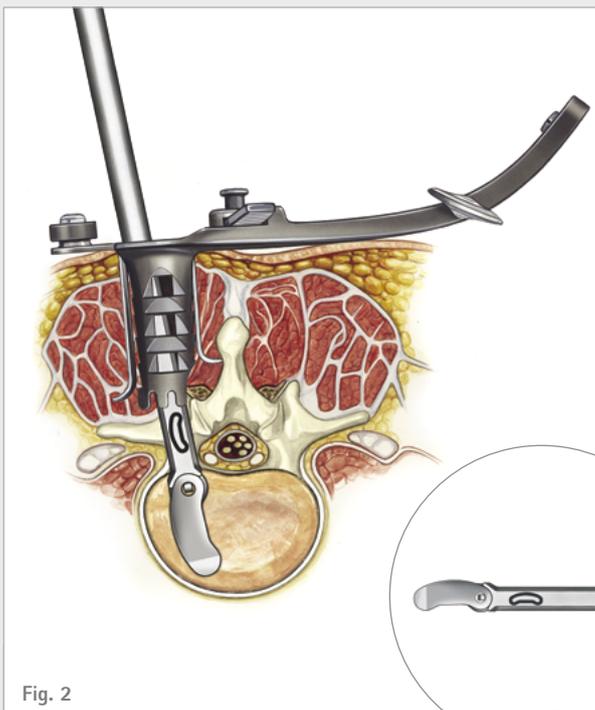


Fig. 2

B.10. DETERMINATION OF IMPLANT SIZE USING TRIAL

- The TSPACE® XP trials are available for each implant size to provide optimized selection of the implant size.
- Use the articulating inserter with the TSPACE® XP trials till the desired position is reached. The trial positioning is done in the same way as the implant positioning (Fig. 2/3).
- Please refer to pages 14 and 15 for the description of the insertion steps.

INFORMATION

Please refer to page 17 for a detailed handling description of the articulating inserter.

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



Fig. 3

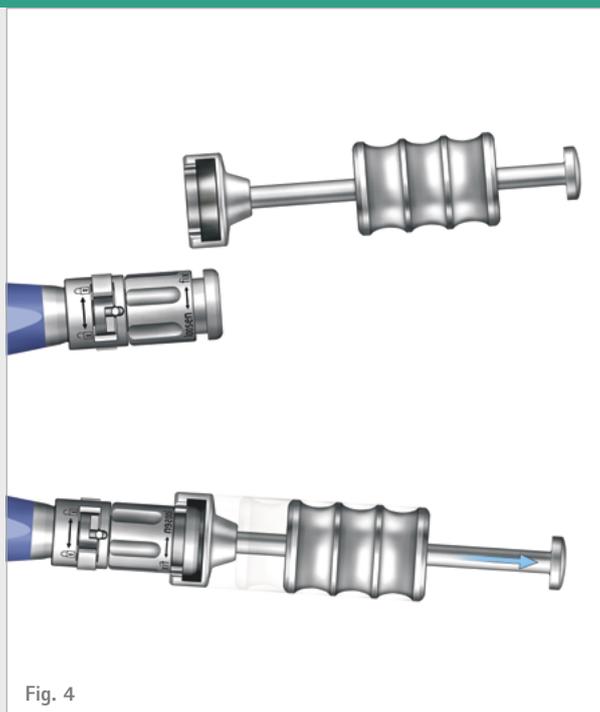
B.11. REMOVAL OF THE TRIAL USING THE SLAP HAMMER SN320R

- Connect the slap hammer to the handle of the articulating inserter by engaging the slap hammer with the interface on the distal end of the articulating inserter.
- Use the slap hammer to back out the trial carefully (Fig. 4).

INFORMATION

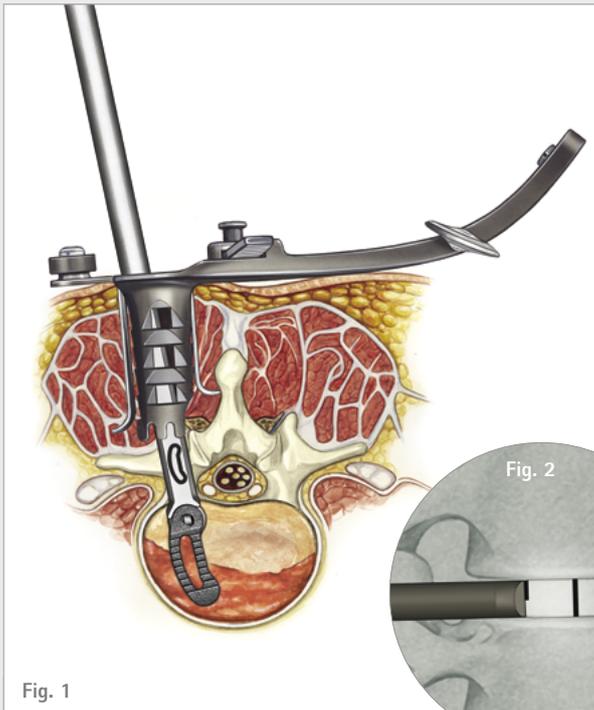
The inserter knob should be loose when backing out the trial.

If the inserter knob is released more than a 1/4 turn counter-clockwise the trial implant may disengage from the inserter.



AESCULAP® TSPACE® XP

B | SURGICAL MANUAL



B.12. IMPLANT INSERTION

- Use the packing block to fill the TSPACE® XP grafting window with bone or bone substitute.
- Using the straight or angled impactor the implant is rotated 90° to achieve the final positioning (Fig. 1).
- X-ray control verify the implant positioning.
- It is recommended to put bone material harvested from the facet joint around the TSPACE® XP implant (Fig. 2).

INFORMATION

Do not use excessive force when filling, mounting or implanting the implant to avoid damaging.

Mount the implant on the insertion instrument hand-tight.

To start the insertion, fix the implant at 0° position to the inserter and recheck the connection between the trial / implant and the inserter.

When inserting the implant into the intervertebral space, avoid canting and levering, and take care to maintain an alignment parallel to the endplate.

- It is recommended to place bone graft in the anterior part.
- Insert the TSPACE® XP interbody implant completely into the disc space with the inserter (Fig. 3 / 4).
- To use the articulation feature of the inserter release the implant / trial implant by turning the knob 1 / 4 turn counterclockwise (direction "loosen") after the interbody implant is completely inside the disc space (Fig. 3).
- Use the integrated X-ray markers to verify the implant position during the insertion process (Fig. 4).

INFORMATION

To avoid premature disengagement of the implant / trial implant from the articulating inserter do not loosen the implant / trial implant completely before the intended end position has been reached.





Fig. 5

B.13. FINAL IMPLANT POSITIONING

- Use the articulating inserter to rotate the implant up to 90° to achieve the final positioning (Fig. 5).
- X-ray control to verify the implant positioning (Fig. 6/7).
- Release the implant after the final position is reached and remove the inserter.
- If there is a need for repositioning of the implant, the impactor could be used.
- It is recommended to place bone material harvested from the facet joint around the TSPACE® XP implant.

INFORMATION

Please refer to page 17 for a detailed handling description of the articulating inserter.

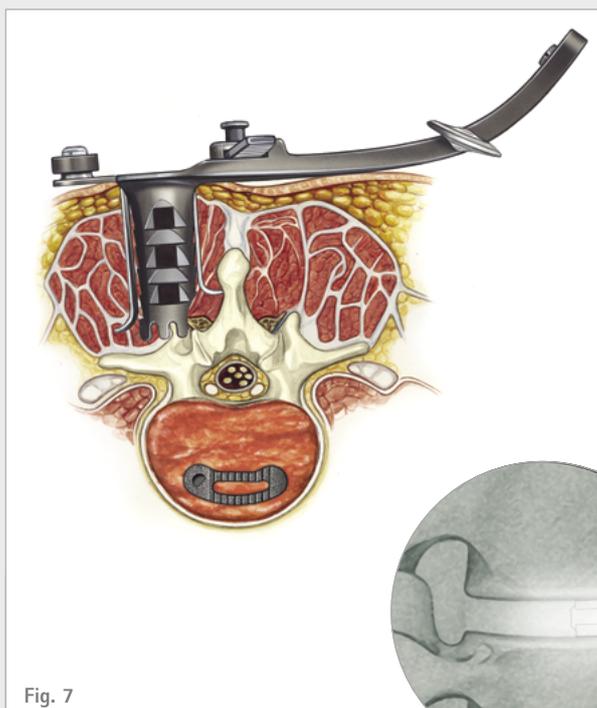


Fig. 7

B.14. FINAL IMPLANT POSITION

- Observe the X-ray markers in both the AP and lateral views to ensure that the implant is placed well within the disc space.
- On the lateral fluoroscopic image the two lateral markers should appear as one line (Fig. 8).
- On the AP fluoroscopic image all three markers are visible and the anterior marker should be in the midline (Fig. 9).

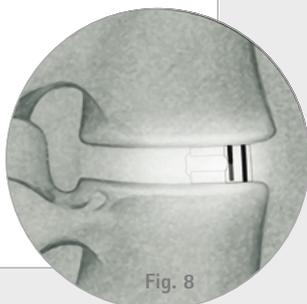


Fig. 8

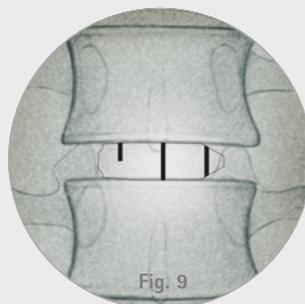
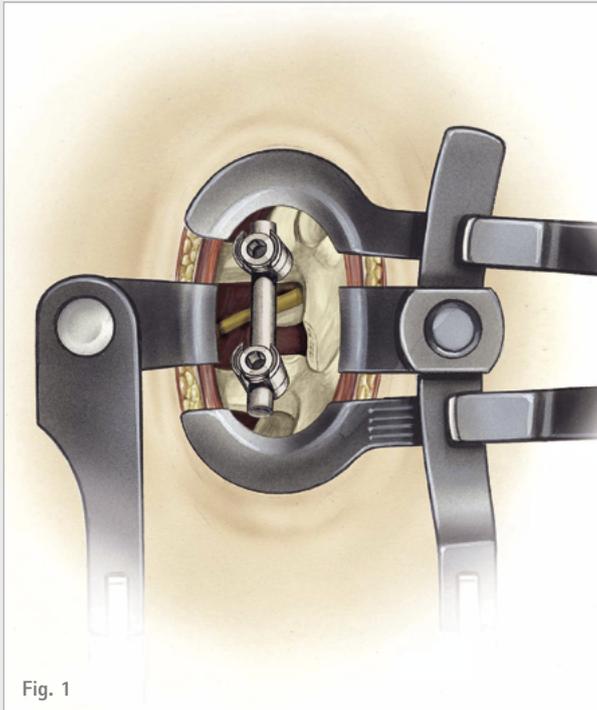


Fig. 9

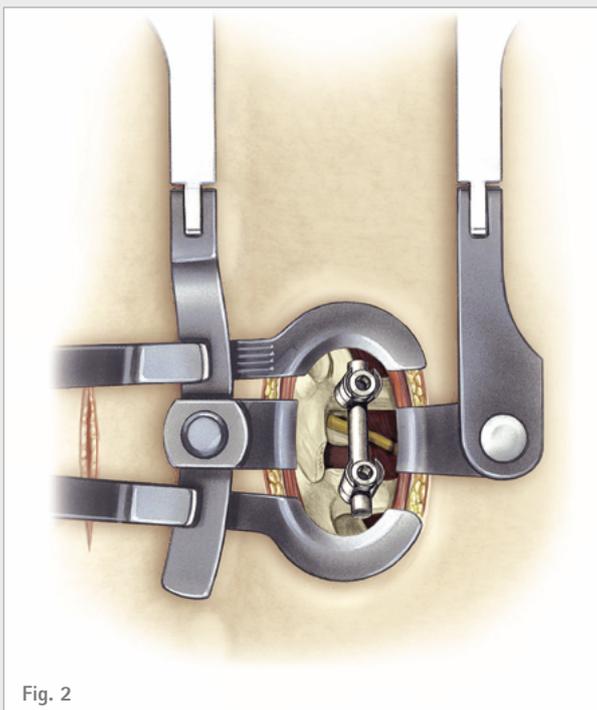
AESCULAP® TSPACE® XP

B | SURGICAL MANUAL



B.15. APPLICATION OF ROD AND SET SCREW

- Final assembly of the thoracolumbar pedicle screw system.
- Compression is applied to the pedicle screws to support the contact area between the TSPACE® XP implant and the endplates.
- Final tightening of the pedicle screws and closure (Fig. 1).



B.16. PEDICLE SCREW POSITIONING ON THE CONTRA-LATERAL SIDE

- Thoracolumbar pedicle screw system is applied on the contra-lateral side (Fig. 2).
- Final X-ray.

To view our full portfolio please visit www.bbraun.com

INFORMATION

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



Fig. 3

B.17. OVERVIEW OF THE ARTICULATING INSERTER SN305R

- The inserter allows continuous articulation enabling an adjustable interbody positioning of the implant between 0° and up to 90°.
- A controlled insertion is possible as the interbody device is always connected to the inserter during the positioning process.
- The most important parts of the inserter are:
 - ① The "control" part consisting of the open/close switch and the rotation knob to handle the trial positioning and implant insertion steps.
 - ② The visual marking on the end of the inserter shaft which determines the loading direction of the trial/implant.
 - ③ The loading part with the tip of the insertion rod where the trial/implant will be connected.
- See a detailed description on the handling of the articulating inserter on the following pages.

INFORMATION

Alternatively, the inserter SN705R can be used for TSPACE® XP. For detailed information see IFU TA015946.

AESCULAP® TSPACE® XP

B | SURGICAL MANUAL

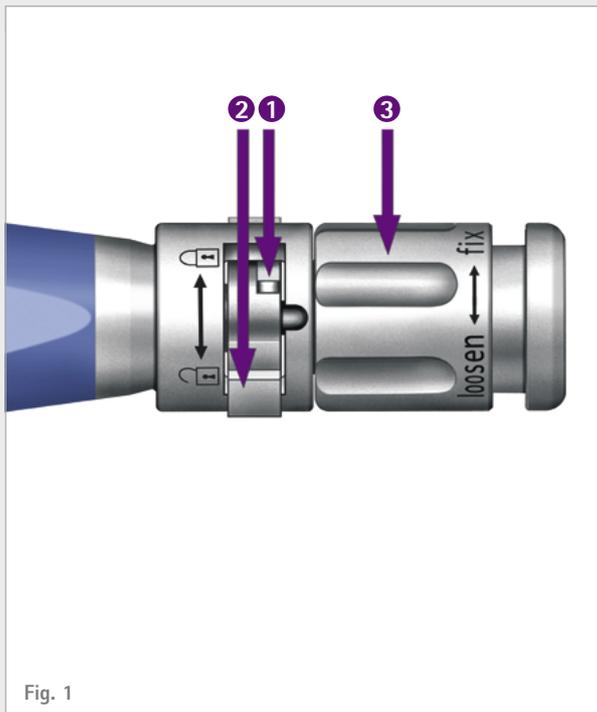


Fig. 1

FUNCTIONALITY OF THE ARTICULATING INSERTER SN305R

- The pin **1** is used to indicate the position of the insertion rod.
- The switch **2** is used to load the implant/trial to the inserter. By turning the switch to the locked position  the implant/trial will be loaded.
- The knob **3** is used to tighten the implant/trial that is loaded. By turning the knob clockwise (direction "fix") the insertion rod protruding out of the shaft tip is moved back in the shaft and tightens the implant/trial.
- Turning the knob counterclockwise (direction "loosen") will do the reverse, loosening the implant/trial implant.

START POSITION FOR IMPLANT CONNECTION

- Rotate the knob **3** counterclockwise to move the insertion rod forward (direction "loosen") until the pin **1** is visible inside of the window.
- Turn the switch **2** to the unlocked position .

INFORMATION

Please check all visual markings on the handle before you start operating the inserter.

Further information about the handling of the inserter is available in the instructions for use document.

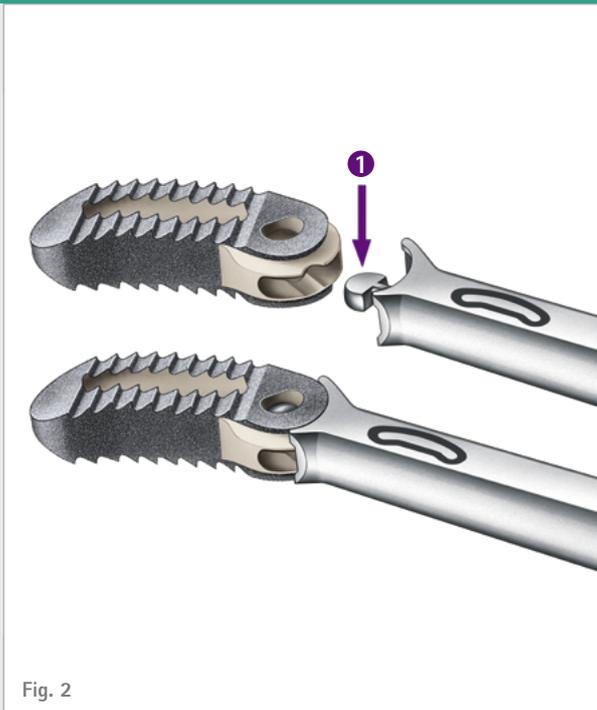


Fig. 2

LOADING OF THE IMPLANT/TRIAL

- Ensure the tip of the insertion rod **1** is fully protruded in its horizontal position.
- Connect the tip of the insertion rod with the implant/trial. The orientation of the implant/trial should match the visual marking on the end of the instrument shaft.

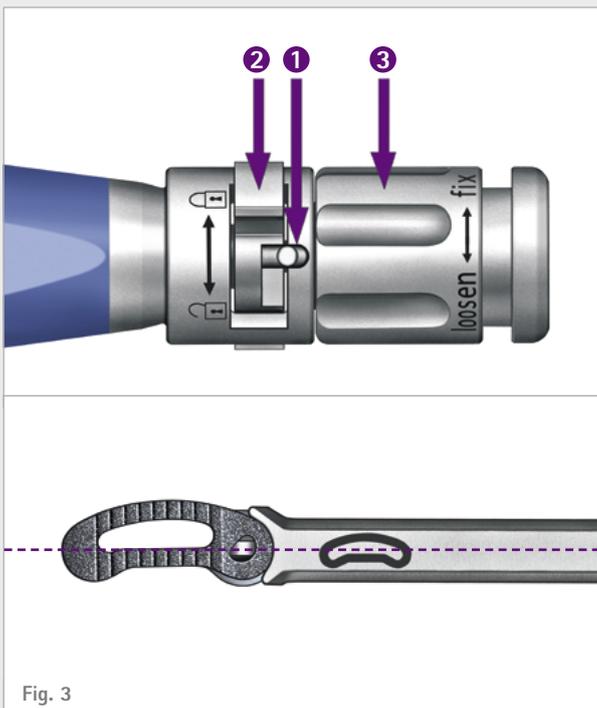


Fig. 3

LOCKING AND FIXATION OF THE IMPLANT/TRIAL IN 0° POSITION

- To lock the implant/trial and fix it at a 0° position place the implant straight and turn the switch **2** to the locked position .
- Rotate the knob **3** clockwise to sink the insertion rod back (direction "fix") into the instrument and fix the implant/trial. The pin **1** should be on the outer side of the window and the knob is tightened completely.
- This is the initial position to start the implantation of the implant/trial.

AESCULAP® TSPACE® XP

B | SURGICAL MANUAL



Fig. 1

USE OF THE ARTICULATION FEATURE FOR IMPLANT/ TRIAL POSITIONING

- To use the articulation feature of the inserter release the implant/trial by turning the knob 1/4 turn counterclockwise (direction "loosen"). This will move the insertion rod forward and loose the implant/trial (Fig. 1).
- To fix the implant in-between rotate the knob clockwise to move the rod backward (direction "fix") into the instrument until the knob is tightened completely.

INFORMATION

Do not loose the implant/trial completely until the end position of the implant is reached or the trial should be removed outside of the patient.

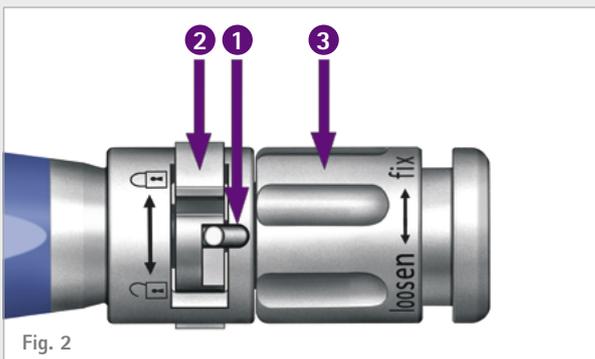


Fig. 2

INSERT THE IMPLANT OR REMOVE THE TRIAL

- To disengage the implant after the final position is reached or to disengage the trial the following steps are necessary.
- Turn the knob **3** counterclockwise to move the insertion rod forward (direction "loosen") until the pin **1** is visible inside of the window (Fig. 2).
- Turn the switch **2** to the unlocked position  (Fig. 3).
- Disconnect the inserter from the implant/trial.

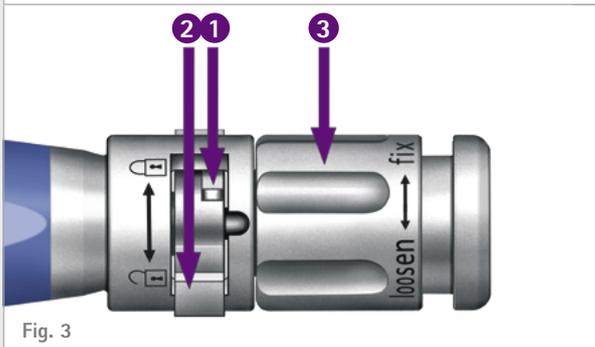
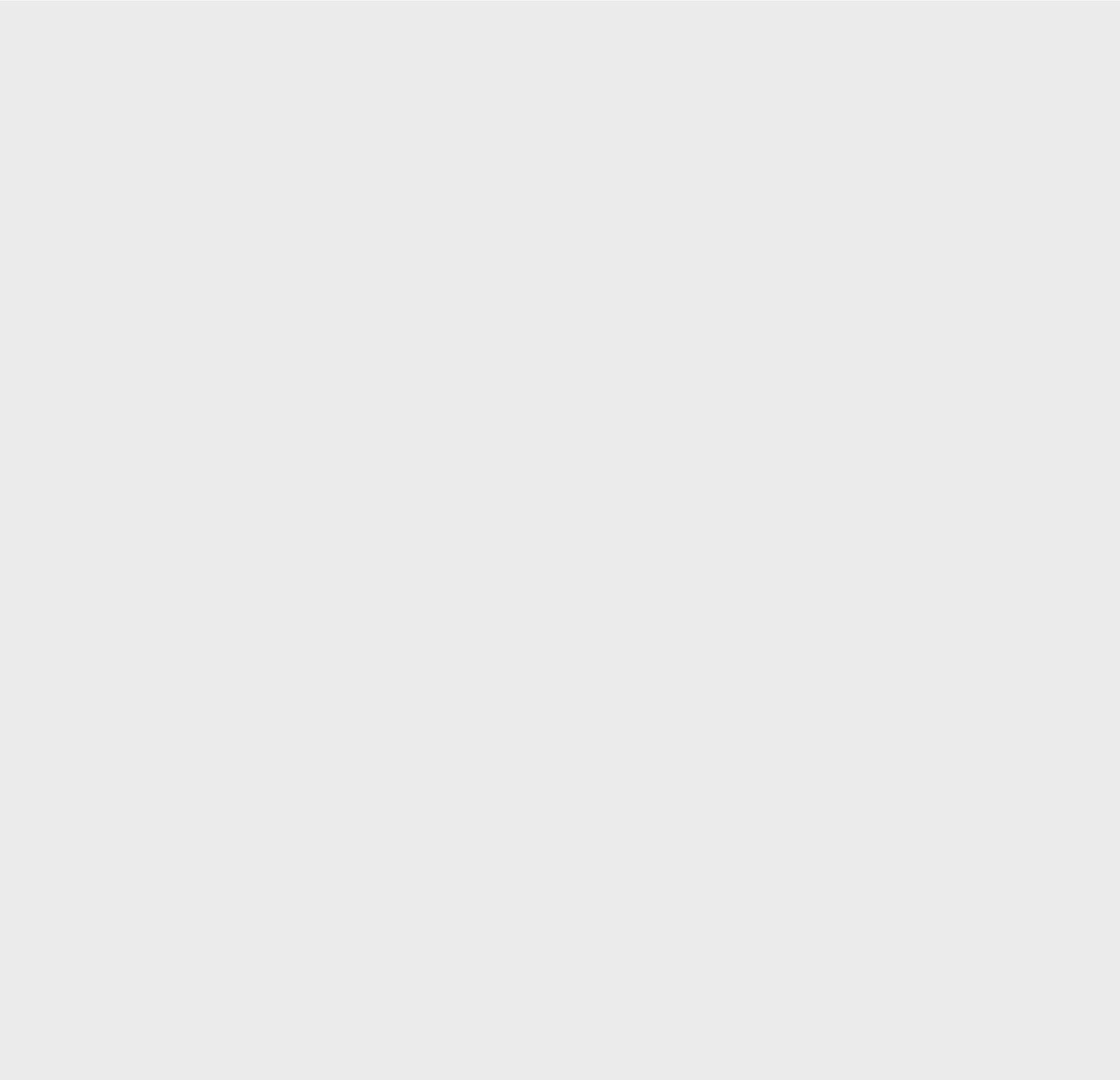


Fig. 3

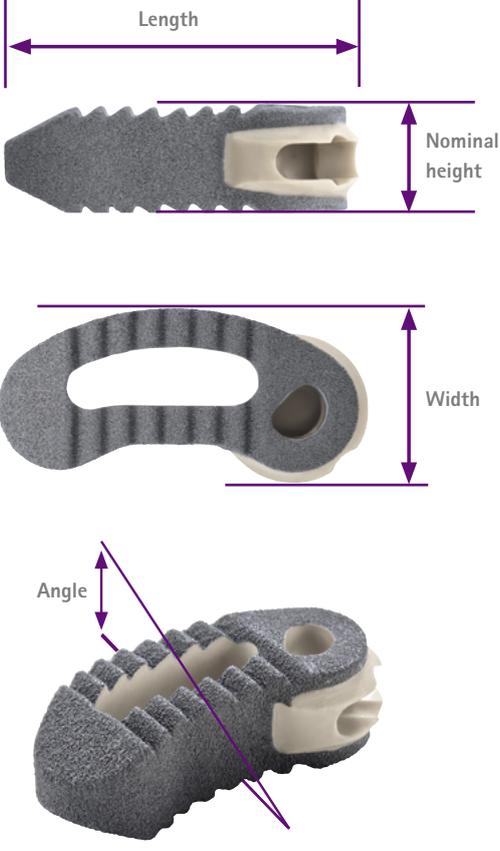
INFORMATION

When releasing the implant/trial, ensure that the knob is not over tightened as it may impede the switch changing positions.



AESCULAP® TSPACE® XP

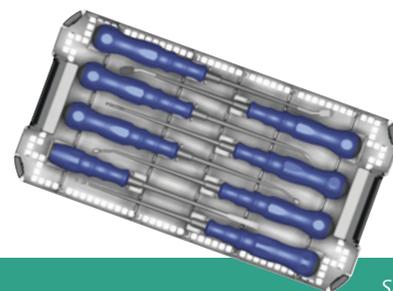
C | IMPLANT & INSTRUMENT OVERVIEW

TSPACE® XP IMPLANTS	Article No.	Size (Length x Width x Height)	Angle
 <p>The diagrams illustrate the dimensions of the TSPACE XP implants. The first diagram shows the 'Length' and 'Nominal height' of a single implant. The second diagram shows the 'Width' of the implant. The third diagram shows the 'Angle' of the implant, which is 5 degrees.</p>	S0907P	26 x 11.5 x 7 mm	5°
	S0908P	26 x 11.5 x 8 mm	5°
	S0909P	26 x 11.5 x 9 mm	5°
	S0910P	26 x 11.5 x 10 mm	5°
	S0911P	26 x 11.5 x 11 mm	5°
	S0912P	26 x 11.5 x 12 mm	5°
	S0913P	26 x 11.5 x 13 mm	5°
	S0914P	26 x 11.5 x 14 mm	5°
	S0915P	26 x 11.5 x 15 mm	5°
	S0917P	26 x 11.5 x 17 mm	5°
	S0937P	30 x 11.5 x 7 mm	5°
	S0938P	30 x 11.5 x 8 mm	5°
	S0939P	30 x 11.5 x 9 mm	5°
	S0940P	30 x 11.5 x 10 mm	5°
	S0941P	30 x 11.5 x 11 mm	5°

Article No.	Size (Length x Width x Height)	Angle
S0942P	30 x 11.5 x 12 mm	5°
S0943P	30 x 11.5 x 13 mm	5°
S0944P	30 x 11.5 x 14 mm	5°
S0945P	30 x 11.5 x 15 mm	5°
S0947P	30 x 11.5 x 17 mm	5°
S0967P	34 x 11.5 x 7 mm	5°
S0968P	34 x 11.5 x 8 mm	5°
S0969P	34 x 11.5 x 9 mm	5°
S0970P	34 x 11.5 x 10 mm	5°
S0971P	34 x 11.5 x 11 mm	5°
S0972P	34 x 11.5 x 12 mm	5°
S0973P	34 x 11.5 x 13 mm	5°
S0974P	34 x 11.5 x 14 mm	5°
S0975P	34 x 11.5 x 15 mm	5°
S0977P	34 x 11.5 x 17 mm	5°

AESCULAP® TSPACE® XP

C | IMPLANT & INSTRUMENT OVERVIEW



SN301R
TSPACE® XP – Preparation Tray

SN300 – TSPACE® XP Instrumentation

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*
	SN301R	Tray for preparation instruments	1
	JA455R	Lid for AESCULAP® OrthoTray®	1
	TF219	Packing stencil for SN301R	1

INSTRUMENTS



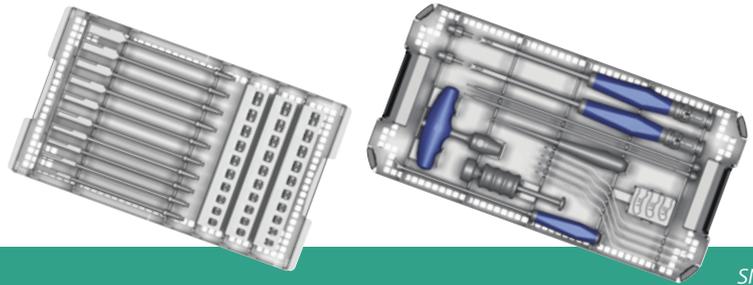
Article No.	Description	Quantity
FJ647R	Distractor, 7 mm	1
FJ648R	Distractor, 8 mm	1
FJ649R	Distractor, 9 mm	1
FJ650R	Distractor, 10 mm	1
FJ651R	Distractor, 11 mm	1
FJ652R	Distractor, 12 mm	1
FJ653R	Distractor, 13 mm	1
FJ654R	Distractor, 14 mm	1
FJ655R	Distractor, 15 mm	1
FJ657R	Distractor, 17 mm	1
SN322R	TSPACE® PEEK/XP/3D trial implant 26 x 7 mm	1
SN323R	TSPACE® PEEK/XP/3D trial implant 26 x 8 mm	1
SN324R	TSPACE® PEEK/XP/3D trial implant 26 x 9 mm	1
SN325R	TSPACE® PEEK/XP/3D trial implant 26 x 10 mm	1
SN326R	TSPACE® PEEK/XP/3D trial implant 26 x 11 mm	1
SN327R	TSPACE® PEEK/XP/3D trial implant 26 x 12 mm	1
SN328R	TSPACE® PEEK/XP/3D trial implant 26 x 13 mm	1
SN329R	TSPACE® PEEK/XP/3D trial implant 26 x 14 mm	1
SN330R	TSPACE® PEEK/XP/3D trial implant 26 x 15 mm	1
SN332R	TSPACE® PEEK/XP/3D trial implant 26 x 17 mm	1

AESCULAP® TSPACE® XP

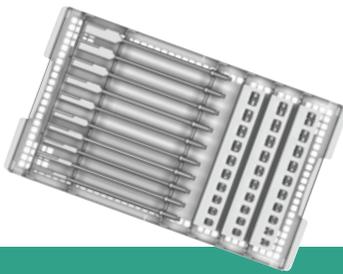
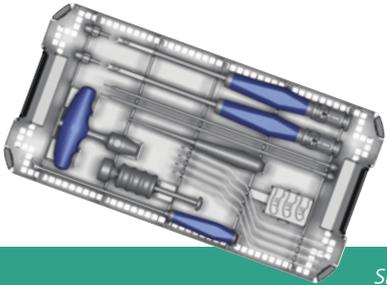
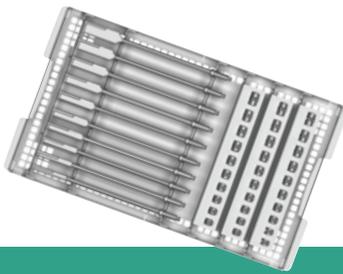
C | IMPLANT & INSTRUMENT OVERVIEW

SN300 – TSPACE® XP Instrumentation

INSTRUMENTS	Article No.	Description	Quantity
	SN352R	TSPACE® PEEK/XP trial 30 x 7 mm	1
	SN353R	TSPACE® PEEK/XP trial 30 x 8 mm	1
	SN354R	TSPACE® PEEK/XP trial 30 x 9 mm	1
	SN355R	TSPACE® PEEK/XP trial 30 x 10 mm	1
	SN356R	TSPACE® PEEK/XP trial 30 x 11 mm	1
	SN357R	TSPACE® PEEK/XP trial 30 x 12 mm	1
	SN358R	TSPACE® PEEK/XP trial 30 x 13 mm	1
	SN359R	TSPACE® PEEK/XP trial 30 x 14 mm	1
	SN360R	TSPACE® PEEK/XP trial 30 x 15 mm	1
	SN362R	TSPACE® PEEK/XP trial 30 x 17 mm	1
	SN382R	TSPACE® PEEK/XP trial 34 x 7 mm	1
	SN383R	TSPACE® PEEK/XP trial 34 x 8 mm	1
	SN384R	TSPACE® PEEK/XP trial 34 x 9 mm	1
	SN385R	TSPACE® PEEK/XP trial 34 x 10 mm	1
	SN386R	TSPACE® PEEK/XP trial 34 x 11 mm	1
	SN387R	TSPACE® PEEK/XP trial 34 x 12 mm	1
	SN388R	TSPACE® PEEK/XP trial 34 x 13 mm	1
	SN389R	TSPACE® PEEK/XP trial 34 x 14 mm	1
	SN390R	TSPACE® PEEK/XP trial 34 x 15 mm	1
	SN392R	TSPACE® PEEK/XP trial 34 x 17 mm	1



SN302R
TSPACE® XP - Implantation Tray

INSTRUMENTS	Article No.	Description	Quantity
	SJ033R	T-handle for distractors and trials	1
	FJ051R	Retractor S	1
	FJ052R	Retractor M	1
	FJ053R	Retractor L	1
	FJ054R	Retractor XL	1
	FF913R	Graft positioning tamp	1
	SN304R	Packing block	1
	SN320R	Slap hammer	1
	SN305R	TSPACE® PEEK/XP inserter	2
	FJ613R	Impactor	1
	SN302R	Tray for implantation instruments	1
	JA455R	Lid for AESCULAP® OrthoTray®	1
	TF220	Packing stencil for SN302R	1

AESFULAP® TSPACE® XP

REFERENCES

- (1) Tropiano P, Bronsard JJ, Louis C, Tallet JM, Sauget Y. Three column stabilisation through a posterior approach 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 AESFULAP® TSPACE XP implant evaluating shear resistance. Tuttlingen, 2013. The AESFULAP® TSPACE® XP 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 AESFULAP® TSPACE XP® implant.
- (9) Kurtz SM, Devine JN. PEEK biomaterials in trauma, orthopedic, and spinal implants. *Biomaterials* 2007; 28(32):4845-69.
- (10) 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.
- (11) Invibio® Biomaterial Solutions. PEEK-OPTIMA® Natural – Typical Material Properties; 2013. Available from: URL: <https://invibio.com/materials/peek-optima-natural>.
- (12) 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.
- (13) 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.
- (14) 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) ensile, 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.

- (15) 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.
- (16) 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).
- (17) Rehnitz, Christoph, PD Dr. med. Radiological image evaluation of AESCULAP® interbody fusion devices, Heidelberg, 2019. CT and X-ray visualization of different AESCULAP® interbody fusion cages (full titanium, porous Ti6Al4V and PLASMAPORE^{XP}® cages) was tested in a cadaver setup. A radiologist evaluated the implant visibility and the presence of artefacts that may limit the visualization of adjacent structures. Visualization and assessment of implant position was achieved in X-ray and CT for all tested cages. Minor artefacts were visible in CT reconstructions in the surrounding of porous Ti6Al4V and full titanium implants. Porous Ti6Al4V implants showed slightly fewer artefacts in CT in comparison to full titanium implants. The minor artefacts observed did not limit the assessment of the surrounding anatomical structures.

AESCULAP[®] – 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 "Ennovate", "OrthoTray", "PLASMAPORE^{XP}" and "PROSPACE" 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.