

Aesculap[®] TSPACE[®] PEEK

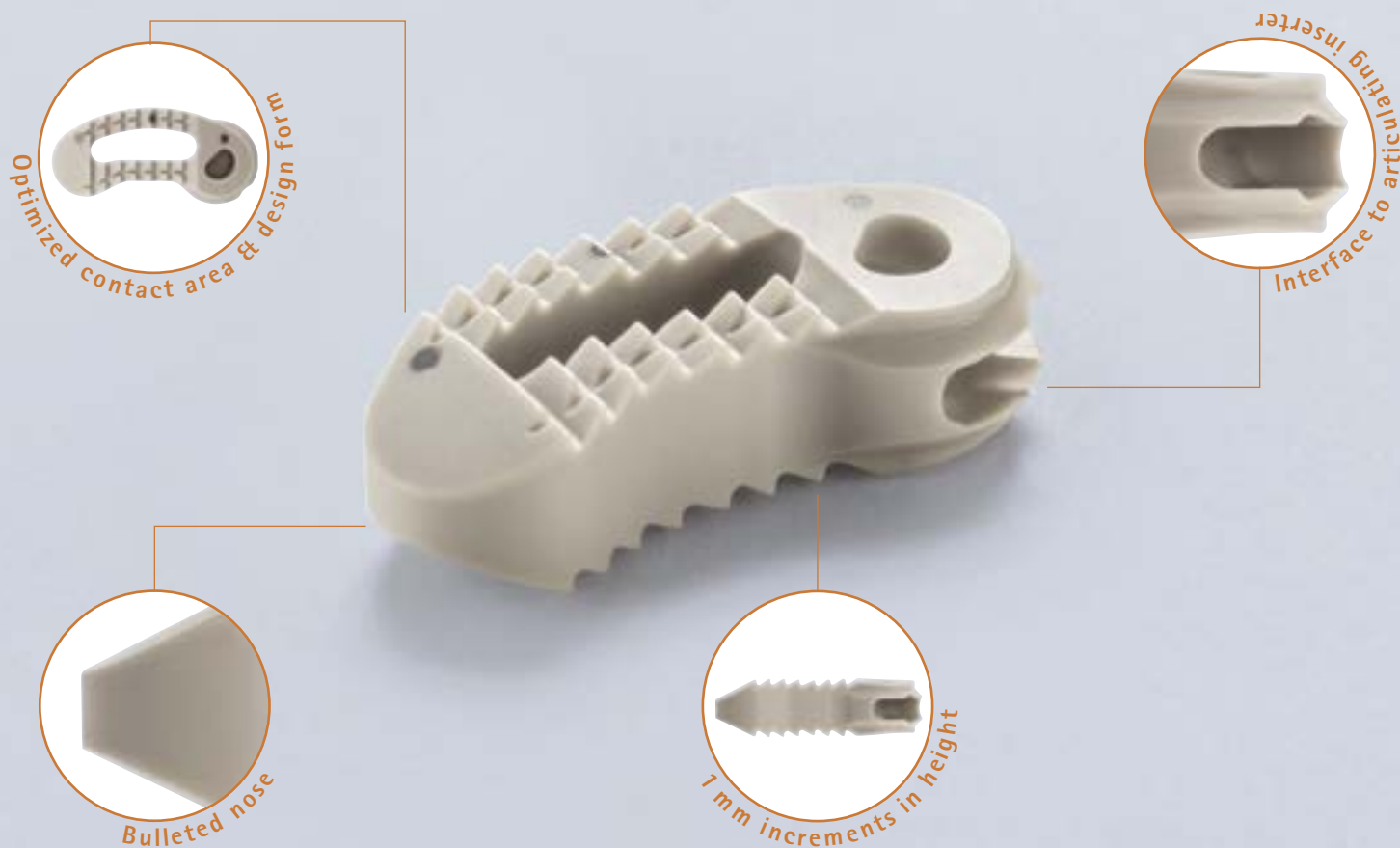
Transforaminal Lumbar Interbody Fusion System



Aesculap Spine

Third Generation
TSPACE[®] PEEK Cages

Aesculap® TSPACE® PEEK



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Foreword

The high incidence of spinal disorders and consecutive symptoms call for optimized diagnostics and therapies. Minimally invasive surgical procedures are of particular interest.

Minimally invasive spine surgery relies on various retractor systems to create small ventral and dorsal access channels to the spine. At the same time innovative implants reducing tissue trauma and new percutaneous surgical techniques are growing in popularity. Accordingly, the S⁴° Element System, the Spine Classics retractor system and the TSPACE® interbody for inter-corporal fusion were designed to meet these new challenges. In this way, minimally invasive mono- and bisegmental fusion surgeries at the lumbar spine can be successfully performed.

The 3rd generation of TSPACE® PEEK interbody device is a further development of the 2011 launched Aesculap transforaminal interbody fusion system. The changes mainly include the introduction of the new, easy-handling inserter which allows for optimized insertion of the implants.

The bulleted nose has been taken from the previous version to ease the implantation of the interbody especially in very degenerated discs. The instrumentation stays focused on the essentials, is clearly arranged and simple in handling. Also new trial implants have been developed to provide improved selection of the implant size.

Spine Classics



S⁴° Spinal System



S⁴° Element Spinal System



Aesculap® TSPACE® PEEK

B

Implant material TSPACE® PEEK

The material used is PEEK-OPTIMA® which was introduced by Invibio 1999. PEEK stands for PolyEtherEtherKetone. PEEK-OPTIMA® polymer comply with ISO10993-1 (ISO norm "Biological Evaluation and Biocompatibility Testing of Medical Devices"), USP Class VI (United States Pharmacopeia Norm for biological plastics evaluation) and ASTM F2026 for use as a medical implant material.

The use of PEEK-OPTIMA® as an orthopedic device material enjoys increased popularity in recent years due to the material's unique combination of characteristics. It's properties include radiolucency, high mechanical strength, biocompatibility and compatibility with standard sterilization methods.¹

The intrinsic radioscopic transparency of the material on X-rays and CT scans allows to view bone growth adjacent to the

implant. This allows quick and simple assessment of the bone structure and progress towards bone fusion. To verify the position of the PEEK implant on radioscopic images, non-radiolucent tantalum marker serve as location marker.

Of particular interest is the modulus of elasticity of PEEK, which is similar to that of cortical bone. This specific stiffness encourages load sharing between implant material and natural bone, thereby stimulating bone healing activity. The material provides excellent strength and rigidity. PEEK-OPTIMA® also exhibits high fatigue resistance and low wear factor.²

Extensive investigations into the biocompatibility of PEEK have proven that the material is suitable for the use as a long-term implant.^{3,4,5}

Lateral view



AP view



¹ Landy BC, VanGordon SB, McFetridge PS, Sikavitsas VI, Jarman-Smith M. Mechanical and in vitro investigation of a porous PEEK foam for medical device implants. *Journal of Applied Biomaterials and Fundamental Materials*. 2013;11(1):35-44.

² Chen Y, Wang X, Lu X, Yang L, Yang H, Yuan W, Chen D. 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;22:1539-46.

³ 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 Feb;8(2):105-11.

⁴ 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 Sep;16(13):987-92.

⁵ Jockisch KA, Brown SA, Bauer TW, Merritt K. Biological response to chopped-carbon-fiber-reinforced peek. *J Biomed Mater Res*. 1992 Feb;26(2):133-46. PubMed PMID: 1569111. 53: Wenz LM, Merritt K, Brown SA, Moet A, Steffee AD. In vitro biocompatibility of polyetheretherketone and polysulfone composites. *J Biomed Mater Res*. 1990 Feb;24(2):207-15.

PEEK-OPTIMA is a registered trademark of Invibio Biomaterial Solutions.

Implant features TSPACE® PEEK



POSITION VERIFICATION DESPITE X-RAY TRANSPARENCY



- PEEK-OPTIMA® is radiolucent and allows for a quick and simple assessment of the bone structure and progress towards bone fusion
- Tantalum markers allow for easy and accurate implant positioning

INTELLIGENT IMPLANT DESIGN



- Bulleted nose for easier implantation especially in very degenerated discs
- Interface for safe and easy connection with articulating inserter
- A wide variety of sizes to better suit patient anatomics
- Enhanced ratio between contact area and opening

THOUGHT-OUT INSTRUMENTS



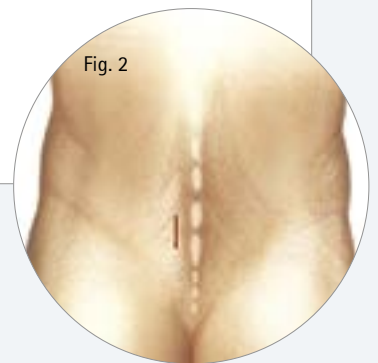
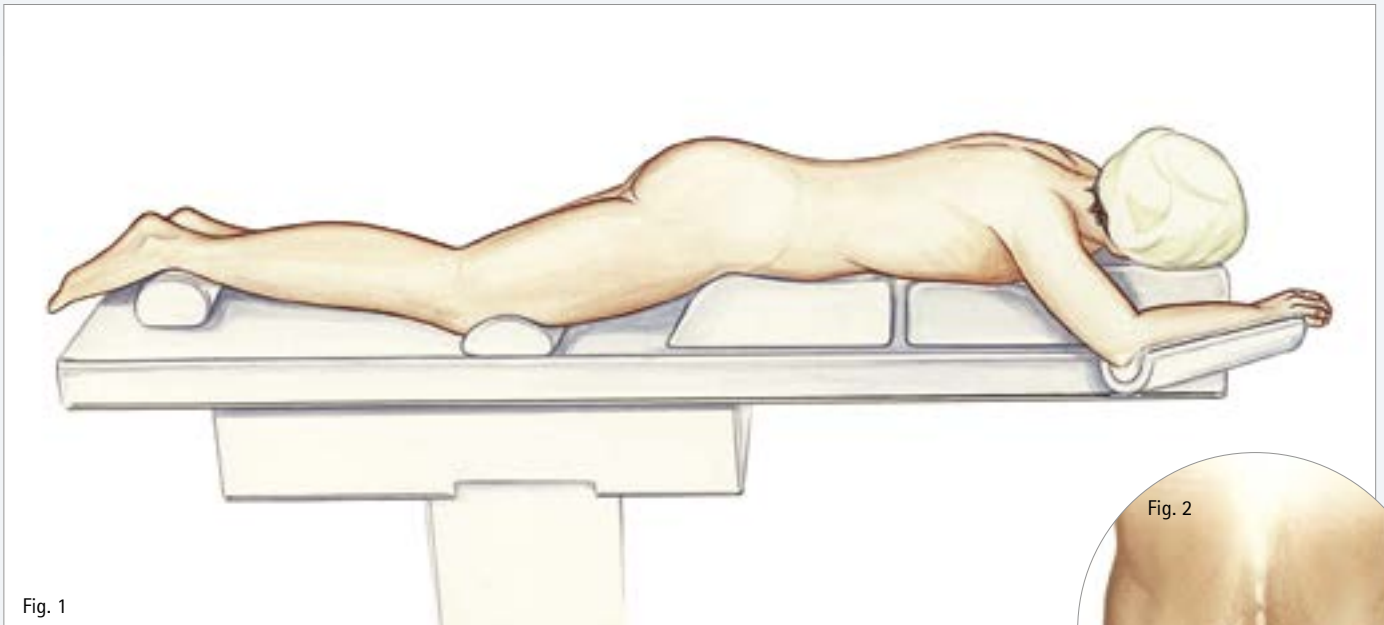
- New articulating interbody inserter for easy interbody positioning
- Easy-handling preparation instruments
- Low-profile and clearly arranged
- Trials available for each implant size

Aesculap® TSPACE® PEEK

Surgical technique

D





Positioning of the patient and incision marking (Fig. 1-2)

- A minimally invasive approach requires the patient to be placed on a radiolucent table which allows for AP views of the various anatomic structures.
- 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.

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Surgical technique

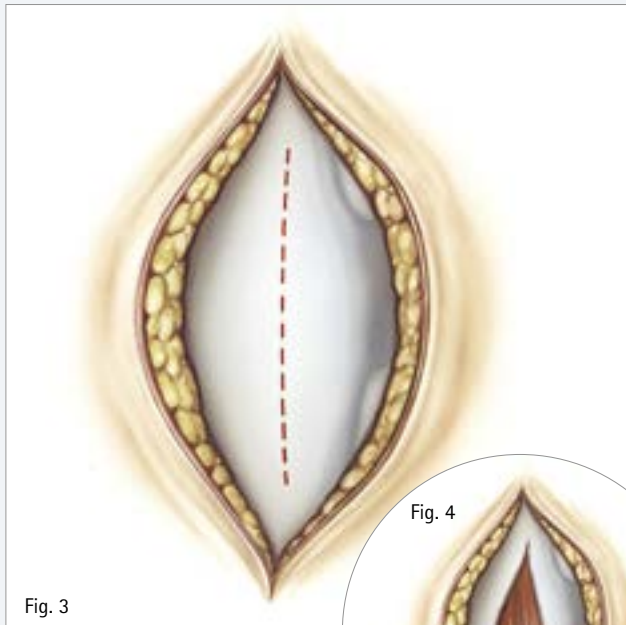


Fig. 3

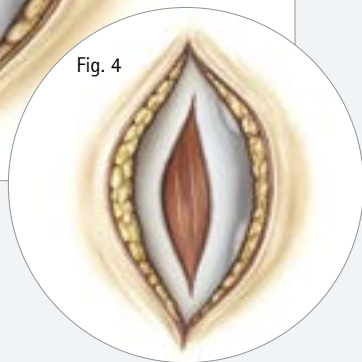


Fig. 4

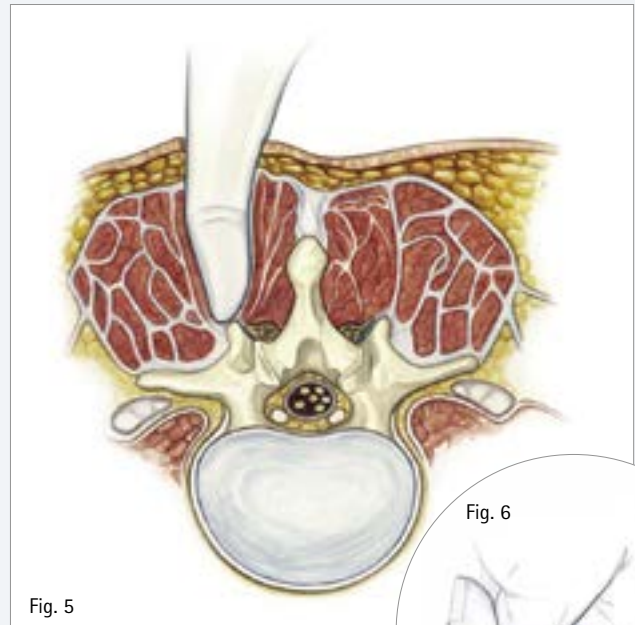


Fig. 5



Fig. 6

Fascial incision (Fig. 3-4)

- A slightly curved fascial incision 1.5 cm from the midline is performed. This allows a firm hold of the speculum and counter retractor, facilitating the exposure of the individual segment.

Exposure and blunt dissection of the paraspinal muscles (Fig. 5-6)

- 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.



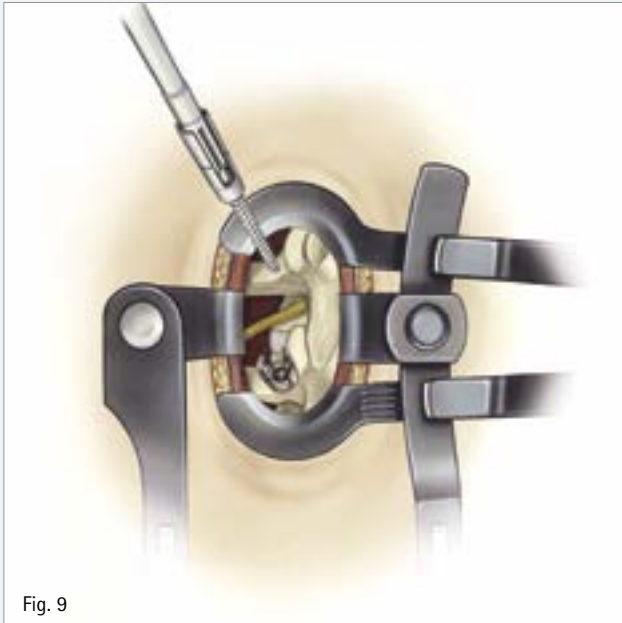
- *Spine Classics retractor system*
 - ▶ *See brochure O11402*

Introduction of the Spine Classics retractor system (Fig. 7-8)

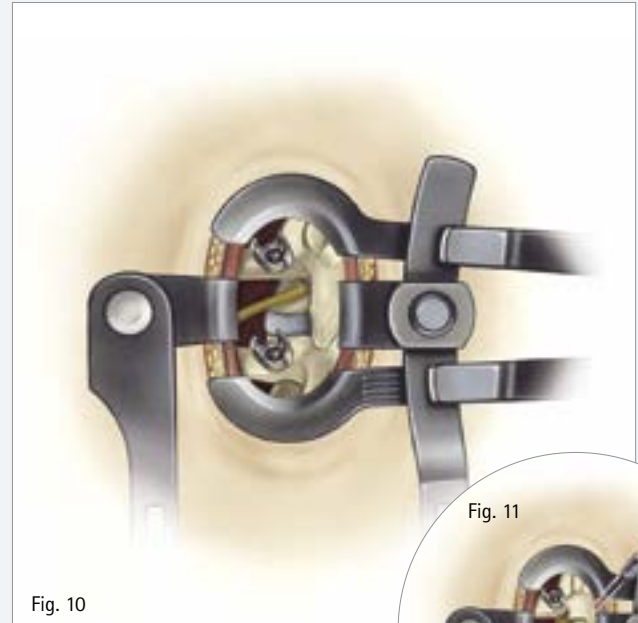
- The muscle retractor is introduced with closed blades and with the handle in the longitudinal direction. It is then turned 90° and expanded.

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Surgical technique



- *S4° Spinal System / S4° Element Spinal System*
 - ▶ See surgical technique 026702 (S4°)



- *Osteotome FJ658R*

Insertion of S4° or S4° Element screws (Fig. 9)

- Using the standard technique the S4°, S4° Element Spinal System or other posterior stabilization system pedicle screws are inserted.

Removal of facet joint (Fig. 10–11)

- A complete unilateral facetectomy should be considered on the side targeted for the implant insertion. The inferior articular process of the facet joint is resected first, then the subjacent superior articular process is resected.

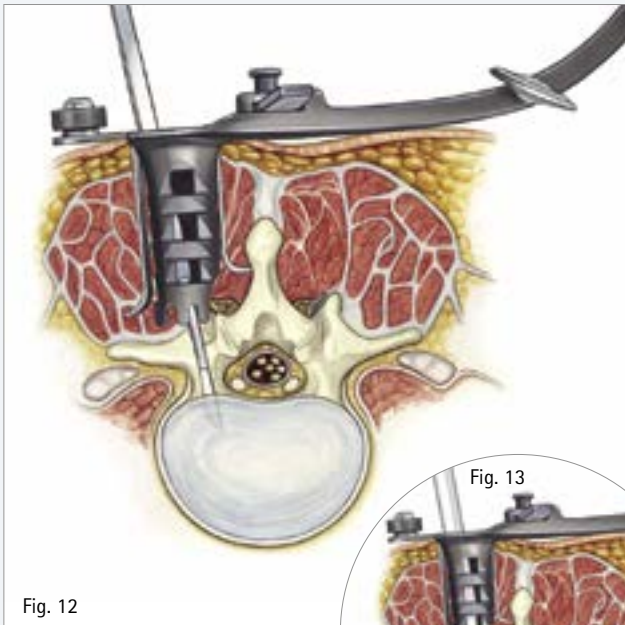


Fig. 12

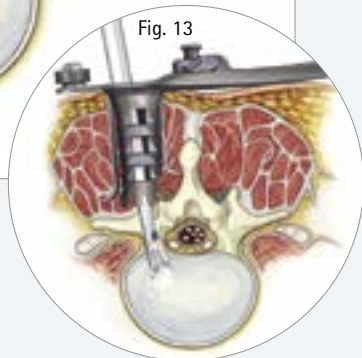


Fig. 13

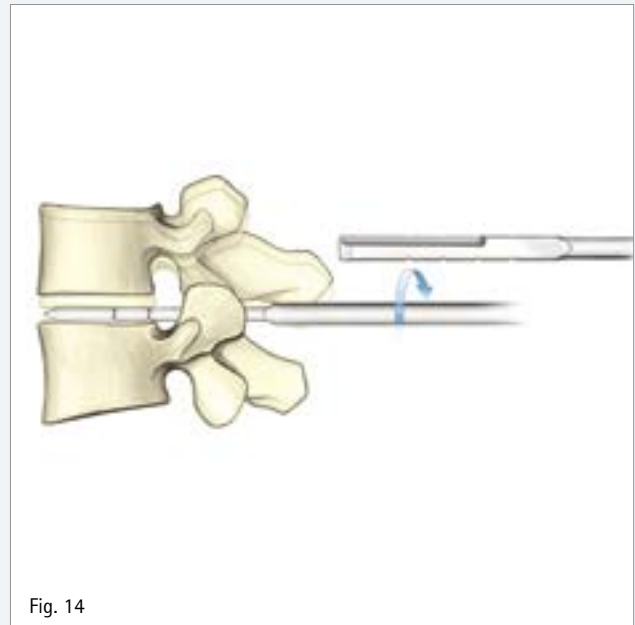


Fig. 14

- *T-handle SJ033R*
- *Distractors FJ647R-FJ657R*

Opening of the disc and removal of disc material (Fig. 12-13)

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

Restoration of disc height (Fig. 14)

- The desired restoration of the natural disc height can be set using the distractors. They are available in heights from 7-17 mm in 1 mm increments.
- The distractor must be inserted horizontally and then rotated. Rotating clockwise the distractors are blunt. A special designed sharp rim allows removal of disc material. If so, the distractor has to be rotated counterclockwise.
- Rotate clockwise for a blunt height restoration maneuver. Rotate counterclockwise to remove disc material with the built-in sharp rim.

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Surgical technique

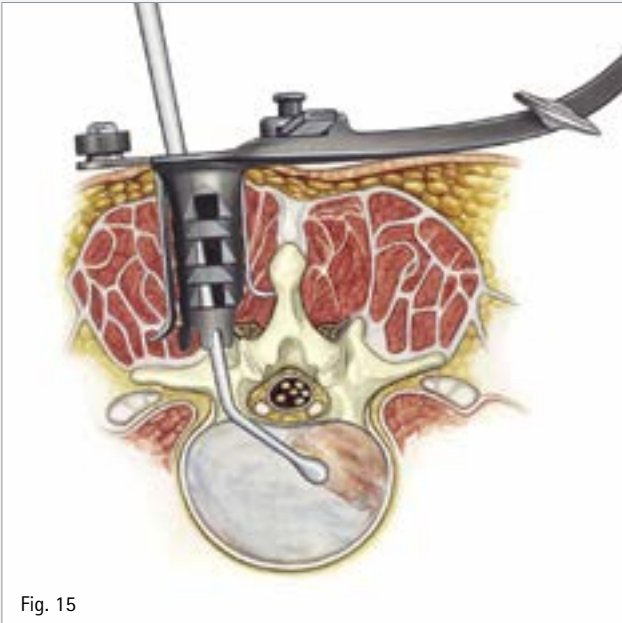


Fig. 15

- Bone curettes, angled FJ679R-FJ680R or FJ698R-FJ699R
- Box curette, straight FJ681R
- Box curettes, angled FJ682R-FJ683R or FJ702R-FJ703R
- Bone rasps, angled FJ685R-FJ686R or FJ704R-FJ705R

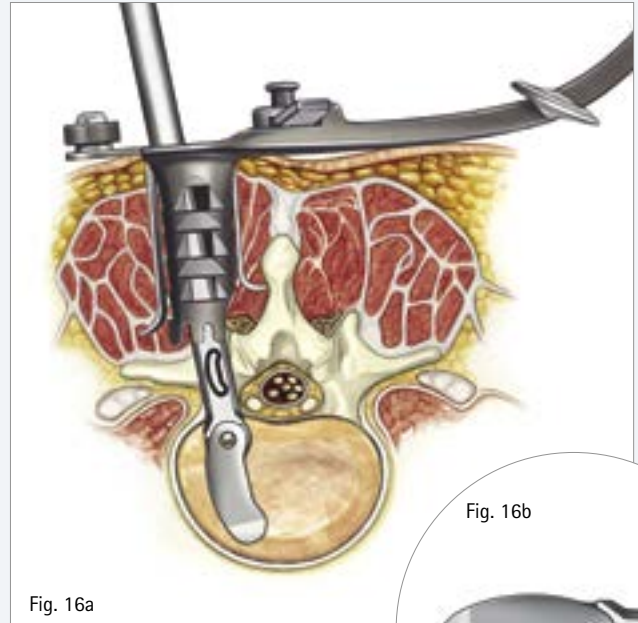


Fig. 16a

- Inserter SN305R
- TSPACE® trials SN322R-SN392R



Fig. 16b

Cleaning of the intervertebral space (Fig. 15)

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

Note:

Excessive preparation of the endplates may weaken the construct which may lead to subsidence of the interbody device.

Note:

Use the nerve retractors FJ051R-FJ054R to protect the dura during insertion.

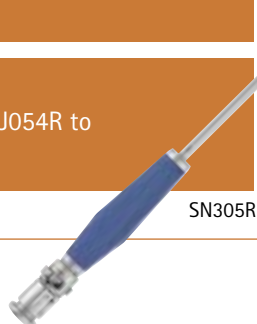
Determination of implant size using trial (Fig. 16a-b)

- Trials are available for each implant size to provide specific selection of the implant size.
- Use the articulating inserter with the TSPACE® trials till the desired position is reached. The trial positioning is done in the same way as the implant positioning. Please refer to pages 14 + 15 for the description of the insertion steps.

Note:

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

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



SN305R



Fig. 17



Fig. 18

- *Inserter SN305R*
- *Slap hammer SN320R*

Removal of the trial using the slap hammer SN320R (Fig. 17-18)

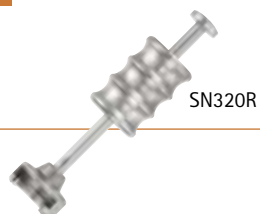
- Connect the slap hammer to the handle of the inserter SN305R.
- Use the slap hammer to back out the trial carefully.

Note:

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

Note:

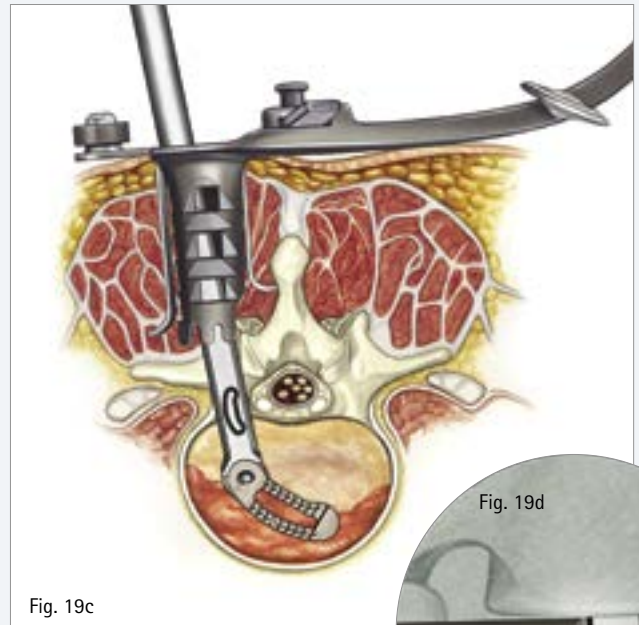
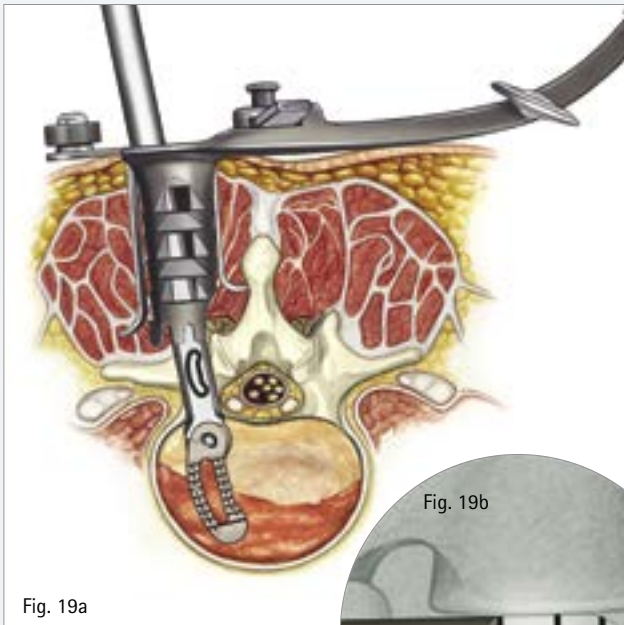
If the inserter knob is more than 1/4 turn counterclockwise loose, the trial may get disengaged from the inserter.



SN320R

Aesculap® TSPACE® PEEK

Surgical technique



- Packing block SN304R
- Inserter SN305R

Implant insertion (Fig. 19a-d)

- Use the packing block to fill the TSPACE® PEEK grafting window with bone or bone substitute.
- It is recommended to place bone graft in the anterior part.
- Insert the TSPACE® PEEK interbody implant partially into the disc space with the articulating inserter.

Note:

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

Note:

Use the nerve retractors FJ051R-FJ054R to protect the dura during insertion.

- After the first insertion step loose the implant to continue the insertion process.
- To use the articulation feature of the inserter release the implant/trial implant by turning the knob slightly counter-clockwise (direction "loosen").
- Use the integrated X-ray markers to verify the implant position during the insertion process.

Note:

Do not loose the implant/trial completely until the end position of the implant is reached.



SN304R



SN305R

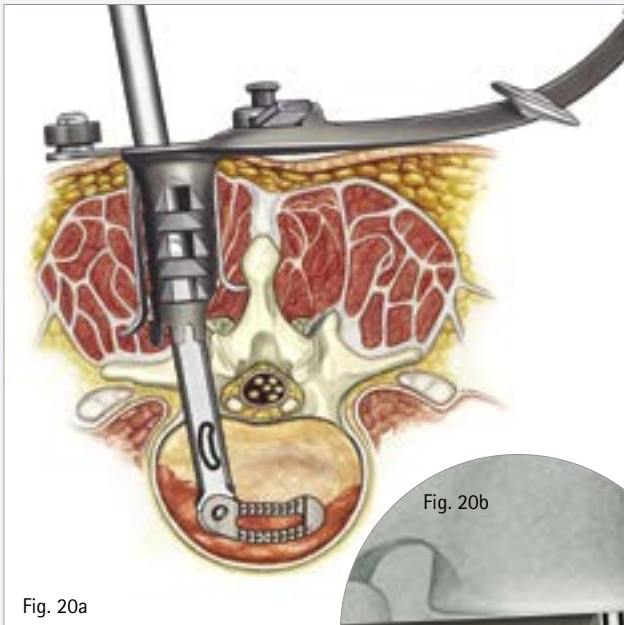


Fig. 20a

■ *Inserter SN305R*

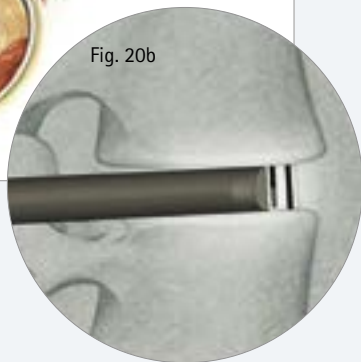


Fig. 20b

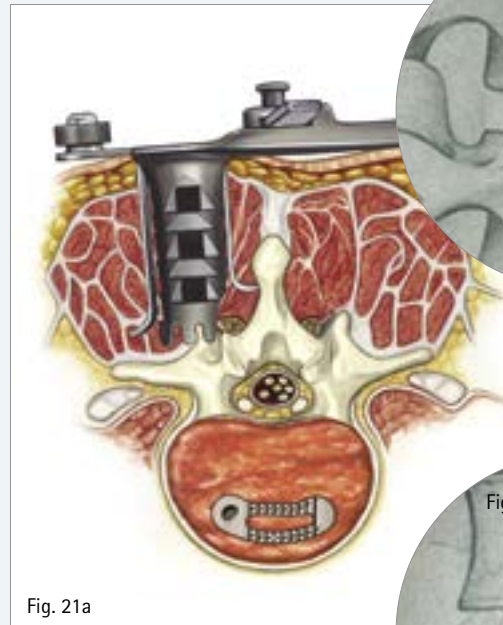


Fig. 21a

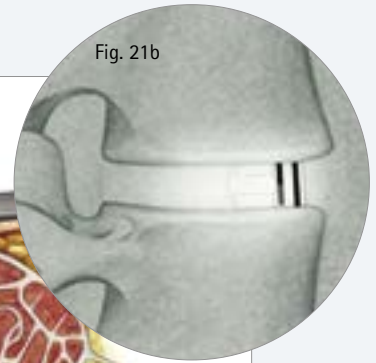


Fig. 21b

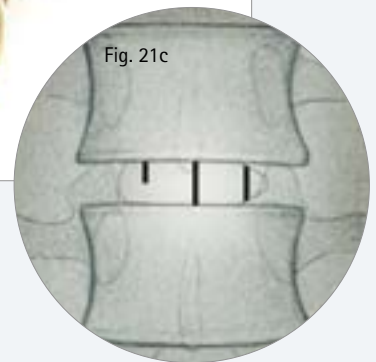


Fig. 21c

**Final implant positioning
(Fig. 20a-b)**

- Use the articulating inserter to rotate the implant up to 90° to achieve the final positioning.
- X-ray control to verify the implant positioning.
- 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 FJ613R could be used.
- It is recommended to put bone material harvested from the facet joint around the TSPACE® implant.

**Final implant position
(Fig. 21a-c)**

- 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 (see Fig. 21b).
- On the AP fluoroscopic image all three markers are visible and the anterior marker should be in the midline (see Fig. 21c).

Note:

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

Aesculap® TSPACE® PEEK

Surgical technique

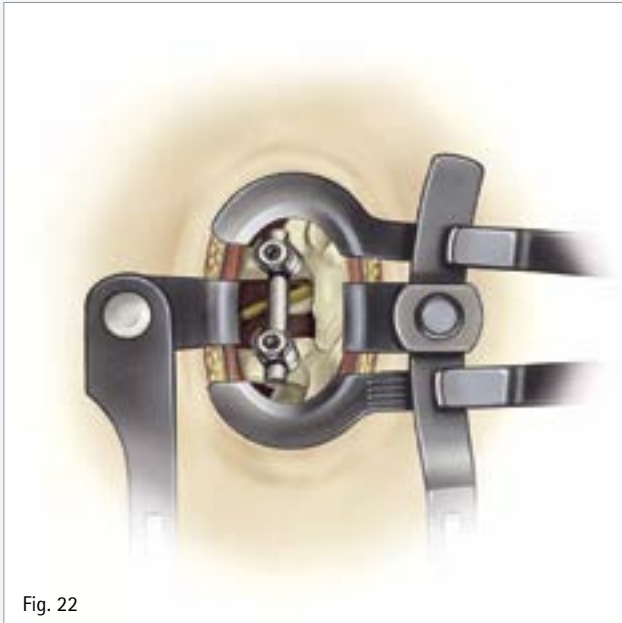


Fig. 22

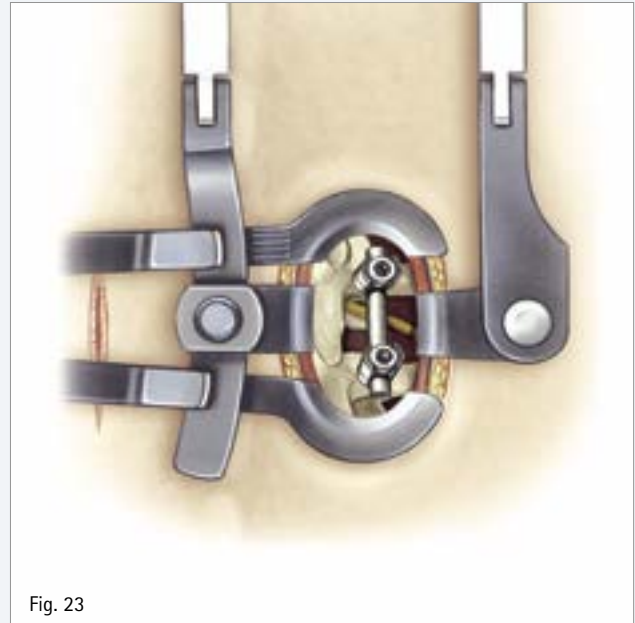


Fig. 23

■ S4® Spinal System

- ▶ See surgical technique 026702
- ▶ See surgical technique 074002 (S4® Element)

Application of rod and set screw (Fig. 22)

- Final assembly of the S4®, S4® Element Spinal System or other posterior stabilization system.
- Compression is applied to the pedicle screws to support the contact area between the TSPACE® implant and the endplates.

Screw positioning on the contra-lateral side (Fig. 23)

- The S4®, S4® Element Spinal System or another posterior stabilization system is applied on the contra-lateral side.

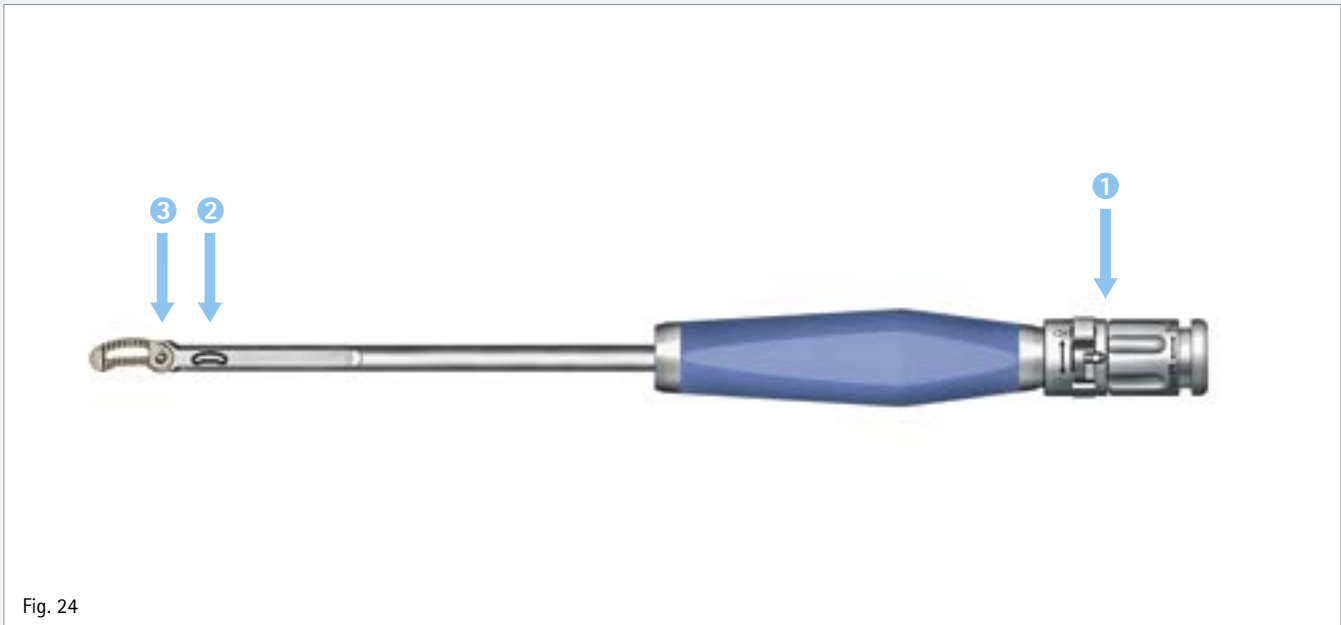


Fig. 24

Overview of the articulating inserter SN305R (Fig. 24)

- The articulating inserter SN305R is used for the trial positioning and removal as well as for the implant insertion.
- The inserter allows continuous articulation for easy interbody positioning of the implant between 0° and up to 90°.
- A controlled insertion is possible because the interbody device is always connected to the inserter during the positioning.
- 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 about the handling of the articulating inserter on the following pages.

Aesculap® TSPACE® PEEK

Surgical technique

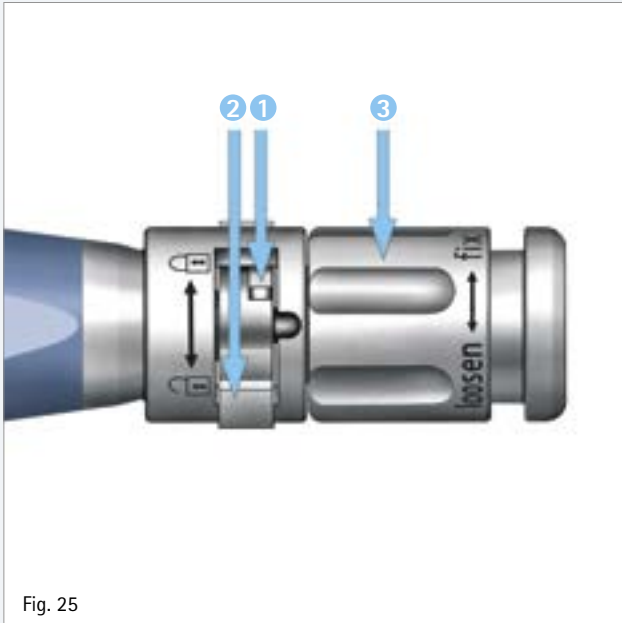




Fig. 25

■ Inserter SN305R

Functionality of the inserter SN305R (Fig. 25)

- 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 (Fig. 25)

- 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 .

Note:

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

Note:

Further information about the handling of the inserter is available in the instructions for use document (TA014389).



Fig. 26

- *Inserter SN305R*
- *Trials SN322R-SN392R*
- *TSPACE® PEEK implants SN307P-SN377P*

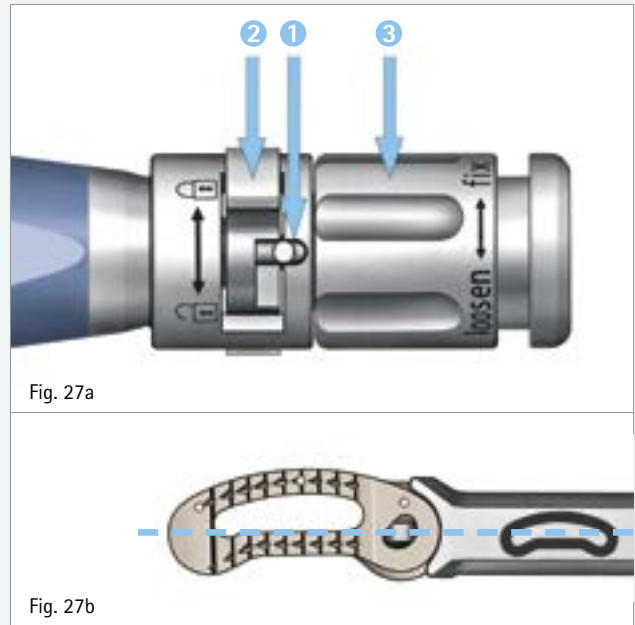



Fig. 27a

Fig. 27b

Loading of the implant/trial (Fig. 26)

- 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.

Locking and fixation of the implant/trial in 0° position (Fig. 27a-b)

- 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® PEEK

Surgical technique



Fig. 28

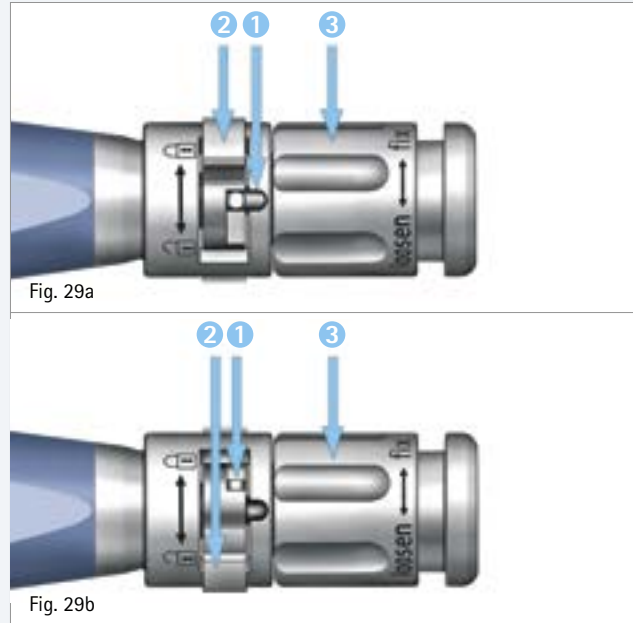


Fig. 29a

Fig. 29b


Use of the articulation feature for implant/trial positioning (Fig. 28)

- 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.
- 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.

Note:

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.

Insert the implant or remove the trial (Fig. 29a-b)

- 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 29a
- Turn the switch ② to the unlocked position . Fig. 29b
- Disconnect the inserter from the implant/trial.

Note:

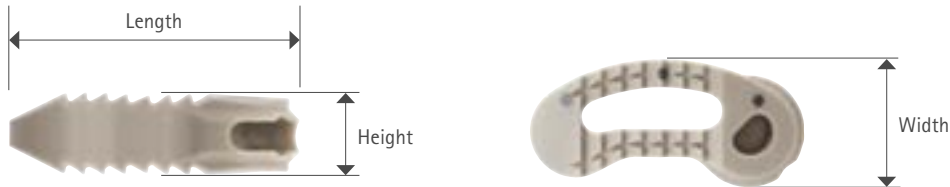
When releasing the implant/trial, ensure that the knob is not over tightened as it may impede the switch changing positions.



Aesculap® TSPACE® PEEK

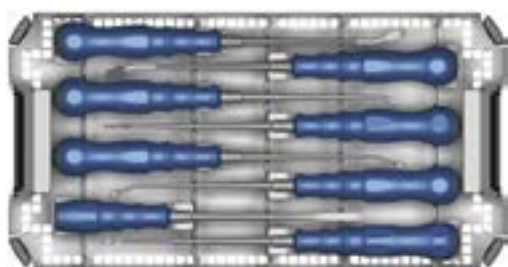
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Ordering information – TSPACE® PEEK implants








Art. no.	Description	Height	Width	Length	Angle
SN307P	TSPACE® PEEK	7 mm	11.5 mm	26 mm	5
SN308P	TSPACE® PEEK	8 mm	11.5 mm	26 mm	5
SN309P	TSPACE® PEEK	9 mm	11.5 mm	26 mm	5
SN310P	TSPACE® PEEK	10 mm	11.5 mm	26 mm	5
SN311P	TSPACE® PEEK	11 mm	11.5 mm	26 mm	5
SN312P	TSPACE® PEEK	12 mm	11.5 mm	26 mm	5
SN313P	TSPACE® PEEK	13 mm	11.5 mm	26 mm	5
SN314P	TSPACE® PEEK	14 mm	11.5 mm	26 mm	5
SN315P	TSPACE® PEEK	15 mm	11.5 mm	26 mm	5
SN317P	TSPACE® PEEK	17 mm	11.5 mm	26 mm	5
SN337P	TSPACE® PEEK	7 mm	11.5 mm	30 mm	5
SN338P	TSPACE® PEEK	8 mm	11.5 mm	30 mm	5
SN339P	TSPACE® PEEK	9 mm	11.5 mm	30 mm	5
SN340P	TSPACE® PEEK	10 mm	11.5 mm	30 mm	5
SN341P	TSPACE® PEEK	11 mm	11.5 mm	30 mm	5
SN342P	TSPACE® PEEK	12 mm	11.5 mm	30 mm	5
SN343P	TSPACE® PEEK	13 mm	11.5 mm	30 mm	5
SN344P	TSPACE® PEEK	14 mm	11.5 mm	30 mm	5
SN345P	TSPACE® PEEK	15 mm	11.5 mm	30 mm	5
SN347P	TSPACE® PEEK	17 mm	11.5 mm	30 mm	5
SN367P	TSPACE® PEEK	7 mm	11.5 mm	34 mm	5
SN368P	TSPACE® PEEK	8 mm	11.5 mm	34 mm	5
SN369P	TSPACE® PEEK	9 mm	11.5 mm	34 mm	5
SN370P	TSPACE® PEEK	10 mm	11.5 mm	34 mm	5
SN371P	TSPACE® PEEK	11 mm	11.5 mm	34 mm	5
SN372P	TSPACE® PEEK	12 mm	11.5 mm	34 mm	5
SN373P	TSPACE® PEEK	13 mm	11.5 mm	34 mm	5
SN374P	TSPACE® PEEK	14 mm	11.5 mm	34 mm	5
SN375P	TSPACE® PEEK	15 mm	11.5 mm	34 mm	5
SN377P	TSPACE® PEEK	17 mm	11.5 mm	34 mm	5

Ordering information – Preparation instruments



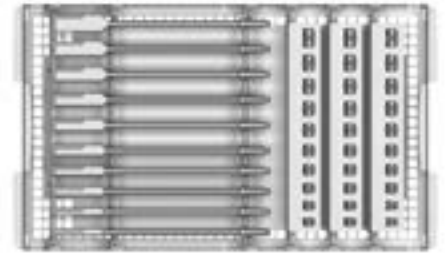
SN300 TSPACE® PEEK instrumentation complete (SN301R and SN302R)

consisting of:

	Art. no.	Description	Recommended	Optional
	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	
	TF239	Graphic template for SN301R	1	

Aesculap® TSPACE® PEEK

Ordering Information – implantation instruments

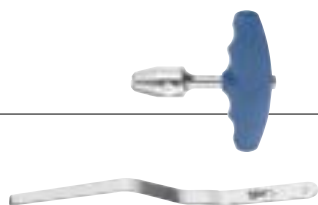
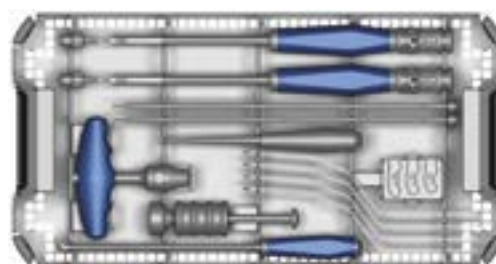


Art. no.	Description	Recommended	Optional
FJ647R	Distractor, 7 mm	1	
FJ648R	Distractor, 8 mm	1	
FJ649R	Distractor, 9 mm	1	
FJ650R	Distractor, 10 mm	1	
FJ651R	Distractor, 11 mm	1	
FJ652R	Distractor, 12 mm	1	
FJ653R	Distractor, 13 mm	1	
FJ654R	Distractor, 14 mm	1	
FJ655R	Distractor, 15 mm	1	
FJ657R	Distractor, 17 mm	1	
SN322R	TSPACE® PEEK/ ^{XP} trial 26 x 7 mm	1	
SN323R	TSPACE® PEEK/ ^{XP} trial 26 x 8 mm	1	
SN324R	TSPACE® PEEK/ ^{XP} trial 26 x 9 mm	1	
SN325R	TSPACE® PEEK/ ^{XP} trial 26 x 10 mm	1	
SN326R	TSPACE® PEEK/ ^{XP} trial 26 x 11 mm	1	
SN327R	TSPACE® PEEK/ ^{XP} trial 26 x 12 mm	1	
SN328R	TSPACE® PEEK/ ^{XP} trial 26 x 13 mm	1	
SN329R	TSPACE® PEEK/ ^{XP} trial 26 x 14 mm	1	
SN330R	TSPACE® PEEK/ ^{XP} trial 26 x 15 mm	1	
SN332R	TSPACE® PEEK/ ^{XP} trial 26 x 17 mm	1	
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	

Art. no.	Description	Recommended	Optional
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	

Aesculap® TSPACE® PEEK

Ordering Information – implantation instruments



Art. no.	Description	Recommended	Optional
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	CASPAR® graft positioning tamp	1	
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SN304R	Packing block	1	
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SN320R	Slap hammer	1	
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SN305R	TSPACE® PEEK/XP inserter	2	
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FJ613R	Impactor	1	
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SN302R	Tray for implantation instruments	1	
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JA455R	Lid for Aesculap® OrthoTray®	1	
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TF240	Graphic template for SN302R	1	
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