

Aesculap[®] ProSpace[®] Titanium / PEEK

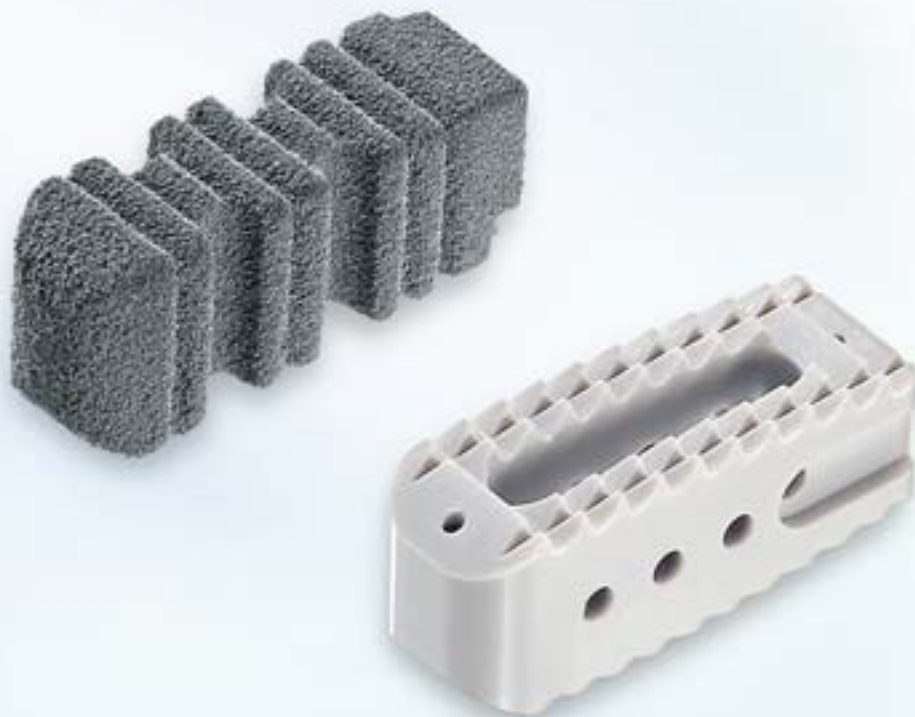
Posterior Lumbar Interbody Fusion System



Aesculap Spine

ProSpace®

Implant Design



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Philosophy

The ProSpace® implant is used for posterior lumbar interbody fusion. The design of the ProSpace® implant allows a maximum contact area between implant and vertebral endplate.

ProSpace® stands for

- Primary stability
- Restoration of the natural lordosis and
- Long-term maintenance of the spinal balance.

3-column stabilization with ProSpace®
PEEK and S® Spinal System.



3-column stabilization with ProSpace®
Titanium and S® Spinal System.



ProSpace® – Titanium

The heart of this implant is a solid titanium alloy core (Ti6Al4V/ISO5832-3). The core is mantled with the proven Plasmapore® coating to increase the area of contact between implant and endplate.

Plasmapore® is a pure titanium coating (Ti/ISO5832-2) which offers an optimal foundation for the ingrowth of bone due to its balanced relationship between pore depth, porosity and roughness.

Using a special manufacturing procedure, the implant surface is sprayed with pure titanium powder. Molten titanium particles settle on the core of the implant where they cool rapidly, building a firm form-lock between coating and core.

In this way, each layer of the coating is built up and an optimal surface for bone ingrowth is created.

Aim of the Plasmapore® coating:

Primary Stability

- The increased surface roughness of the Plasmapore® coating together with a posterior fixation device, ensures immediate stability of the motion segment.

Secondary Stability

- Bone growth into the coating is ensured over a short period due to the optimal features of Plasmapore®. Bone fusion between vertebrae and implant is achieved in this way.

The coating concept, which has been proven as a result of many years of use in the field of hip prosthetics, has now become a new standard in spinal surgery.

The bony integration of Plasmapore® cages has been radiologically proven in lumbar fusion by Kroppenstedt S et al.



ProSpace® – PEEK

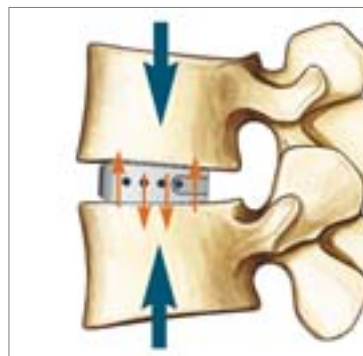
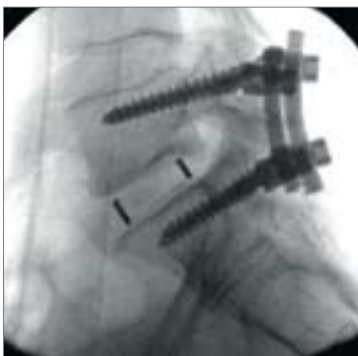
The material used is biocompatible PEEK-Optima, which was introduced by Invivo in 1999. PEEK stands for PolyEtherEther-Ketone. PEEK-OPTIMA polymer complies with ISO 10993-1, USP Class VI and ASTM F2026 for use as a medical implant material.

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.

Its properties include radiolucency, high mechanical strength, biocompatibility and compatibility with standard sterilization methods.

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

Of particular interest is the modulus of elasticity of PEEK-Optima of 3.6 GPa, 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. Extensive investigations of the biocompatibility of PEEK-Optima have proven that the material is suitable for the use as a long-term implant.



AP view



Lateral view



ProSpace[®] Titanium

C

Implant Features – ProSpace[®] Titanium



Plasmapore[®] coating: rapid and safe osteointegration



- High primary stability due to a rough surface
- High secondary stability due to a fast migration of bone cells into the Plasmapore[®] structure

Intelligent implant design



- Straight implant design for minimal retraction of the dura and nerve roots
- Lordotic implant design for restoration of the natural lordosis and spinal balance
- Uniform load sharing on a large contact area
- 16 mm length for not completely reduced Spondylolisthesis cases

Thought-out instruments



- Simple in handling
- Reliable and safe
- Clearly arranged

ProSpace® PEEK

Implant Features – ProSpace® PEEK



Position verification despite X-ray transparency



- PEEK-Optima allows quick and simple assessment of the bone structure and progress towards bone fusion
- Rod style marker for easy and exact localization of the implant

Intelligent implant design



- Anatomical shape for an exact implant fit
- Serrated profile for a high primary stability
- Optimized ratio between contact area and opening
- Adequate size range providing the right implant to fit the patient

Thought-out instruments



- Simple in handling
- Reliable and safe
- Clearly arranged





■ *Nerve root retractor FJ051R-FJ054R*



■ *Distractor FJ061R-FJ075R*
■ *T-Handle FJ059R*

Bone Resection

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

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.

Restoration of Disc Height

- The desired distraction can be set using the distractors, available in heights from 7–14 mm in 1 mm increments (Fig. 2/3/4).
The distractors are inserted one after the other on alternate sides of the disc until the desired distraction is obtained.

ProSpace[®] Titanium

Surgical Technique



- *Curette FK830R*
- *Reamer FJ045R-FJ050R*
- *Rasp FJ029R-FJ044R*
- *T-Handle FJ059R*



- *Broach FJ079R-FJ084R*
- *T-Handle FJ059R*

Cleaning of the Intervertebral Space

- Besides rongeurs and curettes, reamers and rasps are available to prepare the intervertebral space. The reamer is connected to the T-Handle. Turning the instrument will remove disc material (Fig. 5/6). Using the rasps the cartilaginous endplates are refreshed (Fig. 7).

Preparation of the Implant Bed

- The unevenness of the borders of the implant bed can be smoothed using the broach. The sharp leading edge of the instrument enables simple bone resection to the dimensions required. The broach is marked at the length 20, 25 and 30 mm (Fig. 8). The implant bed is now prepared and the implant can be inserted.



Fig. 9



Fig. 10

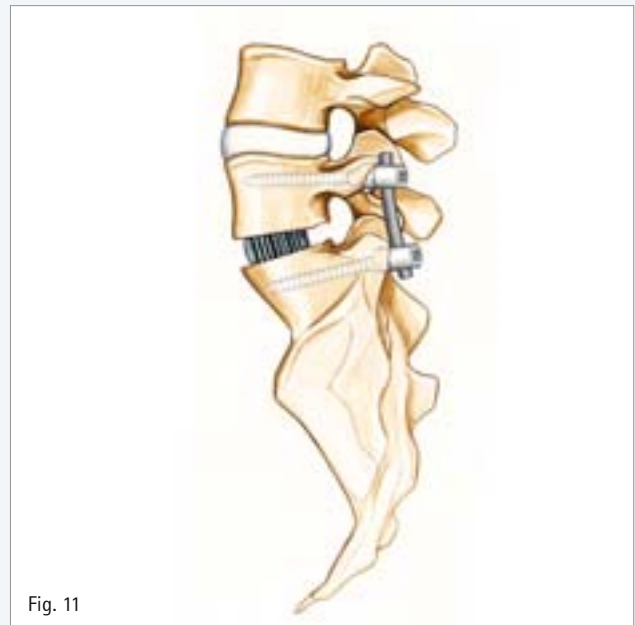


Fig. 11

- *Insertion Instrument ProSpace® Titanium FJ040R*
- *Allen key NF334R*
- *Impactor FJ039R*

Insertion of ProSpace® Titanium

- Depending on the particular level or anatomy, either a straight (0°) or a lordotic (5° or 8°) implant can be inserted.
 - The implant is connected to the inserter by engaging the thread using the allen key connected to the instrument (Fig. 9).
- With the impactor the implant position can be corrected.

Note:

- Please remove the allen key before insertion of the implant with a hammer.
- It is recommended to position ProSpace® 2-3 mm in front of the posterior rim.

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.
- The implants get jammed by release of distraction as well as by compression with the posterior instrumentation.

Posterior Stabilization

- Additional posterior stabilization of the motion segment (e.g. S⁴® Spinal System) should be performed (Fig. 11).
 - Subsequent segmental compression with posterior instrumentation allows loading of the anterior column and restoration of sagittal alignment.
- ▶ Surgical Technique 026702.

Surgical Technique

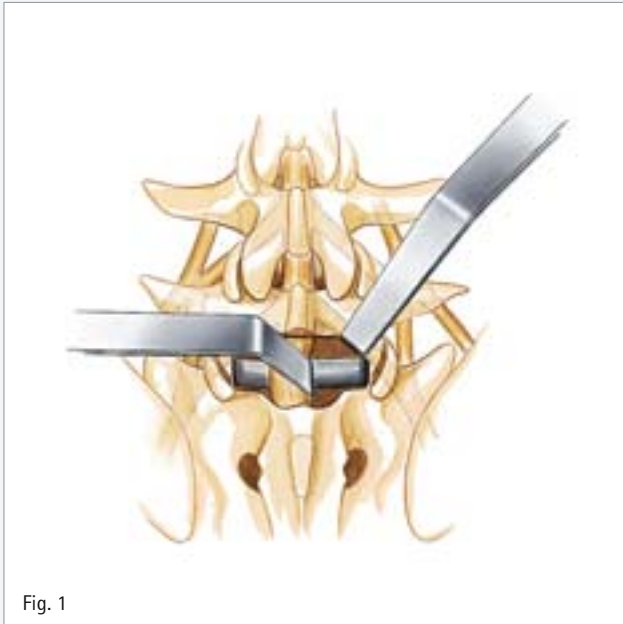


Fig. 1

- Nerve root retractor FJ051R-FJ054R

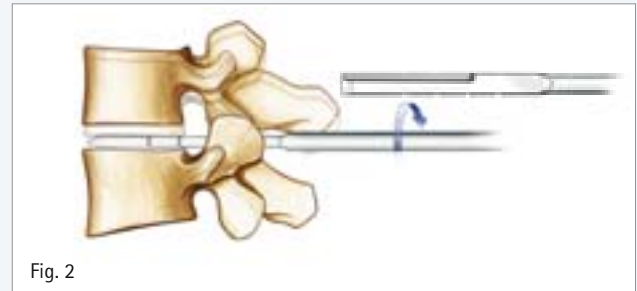


Fig. 2

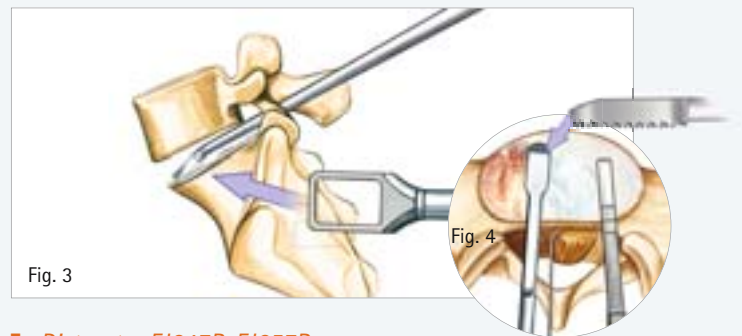


Fig. 3

- Distractor FJ647R-FJ657R
- T-Handle FJ646R
- Bone curette, straight FJ678R
- Rectangular curette, straight FJ681R
- Osteotome FJ658R
- Bone rasp, straight FJ684R

Bone Resection

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

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.

Restoration of Disc Height

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

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 end-plates. (Fig. 4).



Fig. 5



Fig. 7



Fig. 6

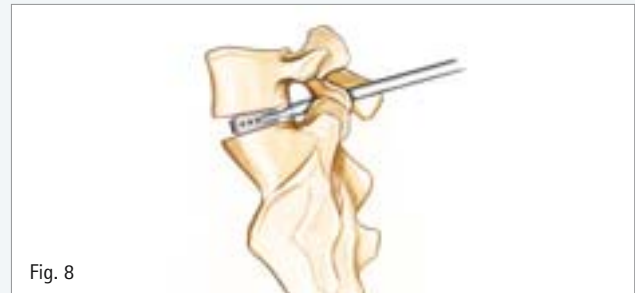


Fig. 8



Fig. 9

- Trial implant SJ242R-SJ299R
- T-Handle FJ646R
- Packing block SJ212R
- Punch FF913R
- Insertion Instrument ProSpace® PEEK SJ210R

- Impactor SJ211R

Determination of Implant Size Using Trial Implants

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

Insertion of ProSpace® PEEK

- After filling the ProSpace® PEEK implant with bone graft or artificial bone substitute (Fig. 6) the implant is clamped to the ProSpace® PEEK insertion instrument (Fig. 7/8).

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.
- The implants get jammed by release of distraction as well as by compression with the posterior instrumentation.

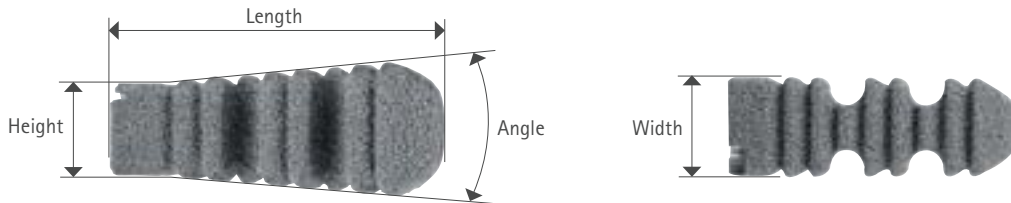
Posterior Stabilization

- Additional posterior stabilization of the motion segment (e.g. S⁴® Spinal System) should be performed (Fig. 9).
- Subsequent segmental compression with posterior instrumentation allows loading of the anterior column and restoration of sagittal alignment.
- ▶ Surgical Technique O26702.

ProSpace® Titanium

E1

Ordering Information – Implants – ProSpace® Titanium

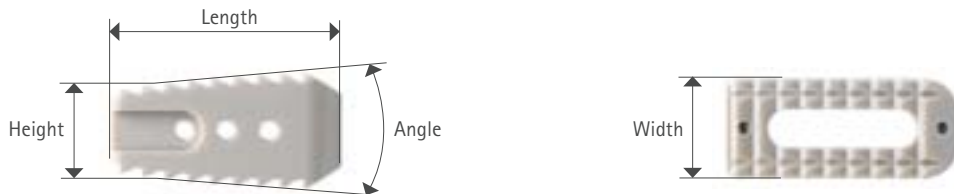


Art. no.	Description	Height	Width	Length	Angle
FJ230T	ProSpace® Titanium	7 mm	7 mm	16 mm	0°
FJ231T	ProSpace® Titanium	9 mm	7 mm	16 mm	0°
FJ232T	ProSpace® Titanium	7 mm	7 mm	19 mm	0°
FJ233T	ProSpace® Titanium	9 mm	7 mm	19 mm	0°
FJ234T	ProSpace® Titanium	7 mm	7 mm	22 mm	0°
FJ236T	ProSpace® Titanium	9 mm	7 mm	22 mm	0°
FJ237T	ProSpace® Titanium	9 mm	9 mm	22 mm	0°
FJ239T	ProSpace® Titanium	11 mm	7 mm	24 mm	0°
FJ240T	ProSpace® Titanium	11 mm	9 mm	24 mm	0°
FJ242T	ProSpace® Titanium	9 mm	7 mm	26 mm	0°
FJ241T	ProSpace® Titanium	13 mm	9 mm	26 mm	0°
FJ252T	ProSpace® Titanium	7 mm	7 mm	19 mm	5°
FJ253T	ProSpace® Titanium	9 mm	7 mm	19 mm	5°
FJ254T	ProSpace® Titanium	7 mm	7 mm	22 mm	5°
FJ256T	ProSpace® Titanium	9 mm	7 mm	22 mm	5°
FJ257T	ProSpace® Titanium	9 mm	9 mm	22 mm	5°
FJ259T	ProSpace® Titanium	11 mm	7 mm	24 mm	5°
FJ260T	ProSpace® Titanium	11 mm	9 mm	24 mm	5°
FJ261T	ProSpace® Titanium	13 mm	9 mm	26 mm	5°
FJ274T	ProSpace® Titanium	7 mm	7 mm	22 mm	8°
FJ276T	ProSpace® Titanium	9 mm	7 mm	22 mm	8°
FJ277T	ProSpace® Titanium	9 mm	9 mm	22 mm	8°
FJ279T	ProSpace® Titanium	11 mm	7 mm	24 mm	8°
FJ280T	ProSpace® Titanium	11 mm	9 mm	24 mm	8°
FJ282T	ProSpace® Titanium	9 mm	7 mm	26 mm	8°
FJ281T	ProSpace® Titanium	13 mm	9 mm	26 mm	8°

The height of the lordotic implant is measured in the middle of the implant.
All ProSpace® Titanium implants are single sterile packed.

ProSpace® PEEK

Ordering Information – Implants – ProSpace® PEEK



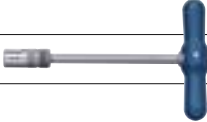



Art. no.	Description	Height	Width	Length	Angle
SJ232P	ProSpace® PEEK	7 mm	8 mm	19 mm	0°
SJ233P	ProSpace® PEEK	9 mm	8 mm	19 mm	0°
SJ234P	ProSpace® PEEK	7 mm	8 mm	22 mm	0°
SJ235P	ProSpace® PEEK	9 mm	8 mm	22 mm	0°
SJ236P	ProSpace® PEEK	9 mm	10 mm	22 mm	0°
SJ238P	ProSpace® PEEK	11 mm	10 mm	25 mm	0°
SJ239P	ProSpace® PEEK	13 mm	10 mm	25 mm	0°
SJ252P	ProSpace® PEEK	7 mm	8 mm	19 mm	5°
SJ253P	ProSpace® PEEK	9 mm	8 mm	19 mm	5°
SJ254P	ProSpace® PEEK	7 mm	8 mm	22 mm	5°
SJ255P	ProSpace® PEEK	9 mm	8 mm	22 mm	5°
SJ256P	ProSpace® PEEK	9 mm	10 mm	22 mm	5°
SJ258P	ProSpace® PEEK	11 mm	10 mm	25 mm	5°
SJ259P	ProSpace® PEEK	13 mm	10 mm	25 mm	5°
SJ282P	ProSpace® PEEK	7 mm	8 mm	19 mm	8°
SJ283P	ProSpace® PEEK	9 mm	8 mm	19 mm	8°
SJ285P	ProSpace® PEEK	9 mm	8 mm	22 mm	8°
SJ286P	ProSpace® PEEK	9 mm	10 mm	22 mm	8°
SJ288P	ProSpace® PEEK	11 mm	10 mm	25 mm	8°
SJ289P	ProSpace® PEEK	13 mm	10 mm	25 mm	8°






ProSpace® Titanium

E2

Ordering Information – Preparation and Implantation Instruments

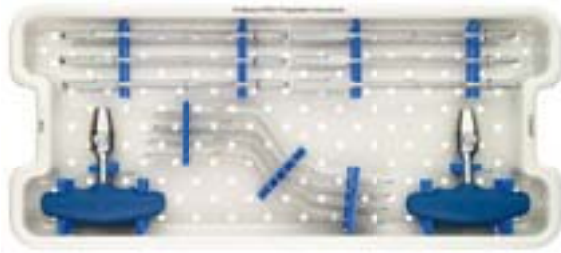


	Art. no.	Description	Recommended	Optional
	FJ051R	Retractor S	1	
	FJ052R	Retractor M	1	
	FJ053R	Retractor L	1	
	FJ054R	Retractor XL	1	
	FJ059R	T-Handle	2	
	FJ061R	Distractor, 7 mm	1	+ 1
	FJ063R	Distractor, 8 mm	1	+ 1
	FJ065R	Distractor, 9 mm	1	+ 1
	FJ067R	Distractor, 10 mm	1	+ 1
	FJ069R	Distractor, 11 mm	1	+ 1
	FJ071R	Distractor, 12 mm	1	+ 1
	FJ073R	Distractor, 13 mm	1	+ 1
	FJ075R	Distractor, 14 mm	1	+ 1
	FK830R	Curette	1	
	FJ045R	Reamer, 7 mm		1
	FJ046R	Reamer, 9 mm		1
	FJ048R	Reamer, 11 mm		1
	FJ050R	Reamer, 13 mm		1

	Art. no.	Description	Recommended	Optional
	FJ029R	Rasp, 7 x 7 mm	1	
	FJ030R	Rasp, 9 x 7 mm	1	
	FJ042R	Rasp, 9 x 9 mm	1	
	FJ031R	Rasp, 11 x 7 mm	1	
	FJ043R	Rasp, 11 x 9 mm	1	
	FJ044R	Rasp, 13 x 9 mm	1	
	FJ079R	Broach, 7 x 7 mm		1
	FJ080R	Broach, 9 x 7 mm		1
	FJ082R	Broach, 9 x 9 mm		1
	FJ081R	Broach, 11 x 7 mm		1
	FJ083R	Broach, 11 x 9 mm		1
	FJ084R	Broach, 13 x 9 mm		1
	FJ040R	Insertion Instrument	1	
	NF334R	Hexagonal Key	1	
	FJ039R	Impactor	1	
	FJ091P	Tray for ProSpace® Titanium instruments	1	

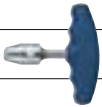





ProSpace® PEEK

Ordering Information – Preparation Instruments



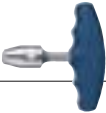





FJ025 ProSpace® PEEK instrumentation

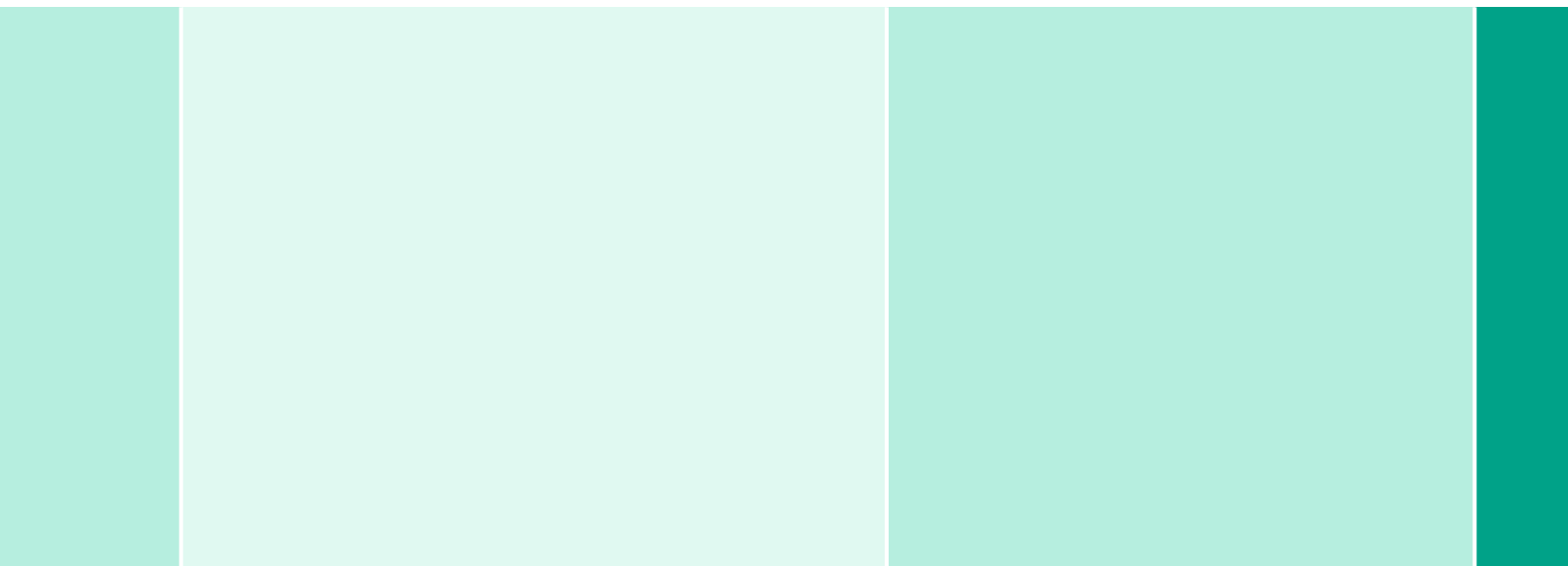
consisting of:

	Art. no.	Description	Recommended
	FJ051R	Retractor S	1
	FJ052R	Retractor M	1
	FJ053R	Retractor L	1
	FJ054R	Retractor XL	1
	FJ646R	T-Handle for distractors	2
	FJ647R	Distractor, 7 mm	1
	FJ648R	Distractor, 8 mm	1
	FJ649R	Distractor, 9 mm	1
	FJ650R	Distractor, 10 mm	1
	FJ651R	Distractor, 11 mm	1
	FJ653R	Distractor, 13 mm	1
	FJ678R	Bone curette, straight	
	FJ681R	Curette, straight	1
	FJ658R	Straight osteotome, 8 mm	1
	FJ684R	Bone rasp, straight	1
	FJ643P	Tray for prep. instr. ProSpace® PEEK	1

Ordering Information – Implantation Instruments



	Art. no.	Description	Recommended
	FJ646R	T-Handle for trial implants	1
	SJ242R	ProSpace® PEEK trial implant, 0°, 7 x 19 mm	1
	SJ243R	ProSpace® PEEK trial implant, 0°, 9 x 19 mm	1
	SJ244R	ProSpace® PEEK trial implant, 0°, 7 x 22 mm	1
	SJ245R	ProSpace® PEEK trial implant, 0°, 9 x 22 mm	1
	SJ248R	ProSpace® PEEK trial implant, 0°, 11 x 25 mm	1
	SJ249R	ProSpace® PEEK trial implant, 0°, 13 x 25 mm	1
	SJ262R	ProSpace® PEEK trial implant, 5°, 7 x 19 mm	1
	SJ263R	ProSpace® PEEK trial implant, 5°, 9 x 19 mm	1
	SJ264R	ProSpace® PEEK trial implant, 5°, 7 x 22 mm	1
	SJ265R	ProSpace® PEEK trial implant, 5°, 9 x 22 mm	1
	SJ268R	ProSpace® PEEK trial implant, 5°, 11 x 25 mm	1
	SJ269R	ProSpace® PEEK trial implant, 5°, 13 x 25 mm	1
	SJ292R	ProSpace® PEEK trial implant, 8°, 7 x 19 mm	1
	SJ293R	ProSpace® PEEK trial implant, 8°, 9 x 19 mm	1
	SJ295R	ProSpace® PEEK trial implant, 8°, 9 x 22 mm	1
	SJ298R	ProSpace® PEEK trial implant, 8°, 11 x 25 mm	1
	SJ299R	ProSpace® PEEK trial implant, 8°, 13 x 25 mm	1
	SJ212R	Packing Block	1
	FF913R	Punch	1
	SJ210R	Insertion instrument	1
	SJ211R	Impactor	1
	FJ640P	Tray for implantation instr. ProSpace® PEEK	1



Aesculap AG | Am Aesculap-Platz | 78532 Tuttlingen | Germany
Phone +49 7461 95-0 | Fax +49 7461 95-26 00 | www.aesculap.com

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