

Aesculap[®] ProSpace[®] Titanium / PEEK

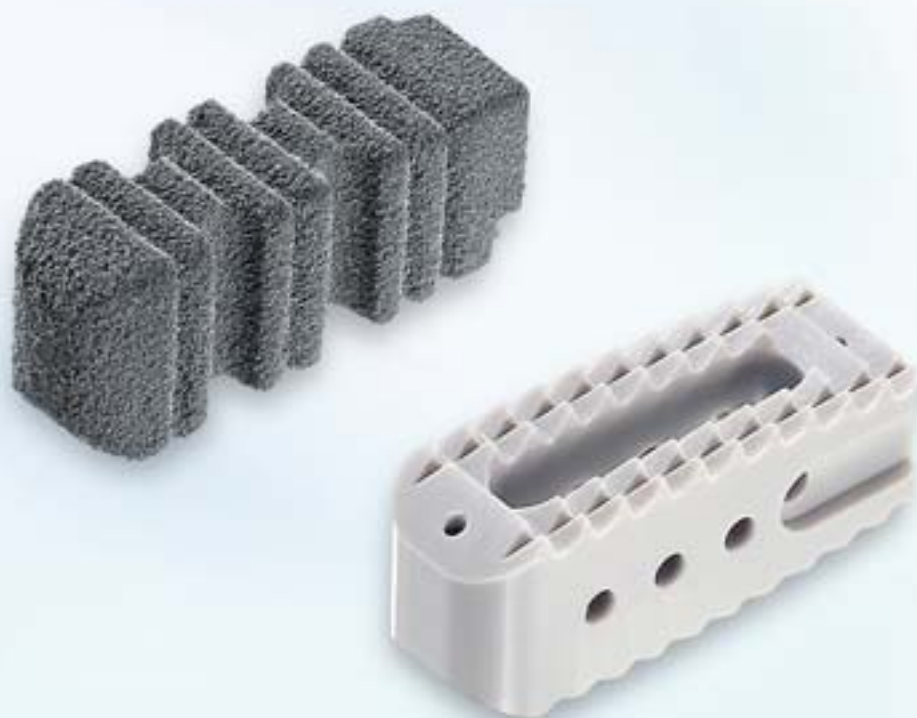
Posterior Lumbar Interbody Fusion System



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

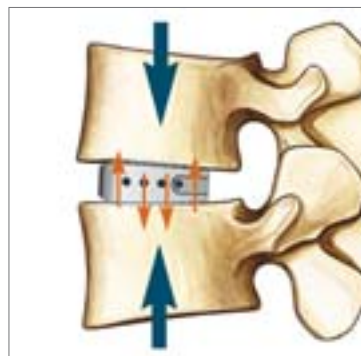
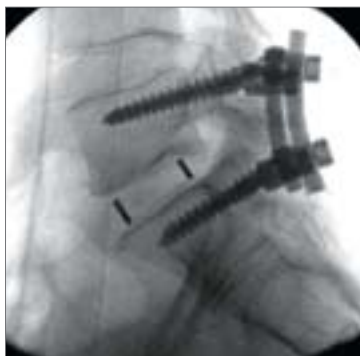
The material used is biocompatible PEEK-Optima, which was introduced by Invivo in 1999. PEEK stands for PolyEtherEther-Ketone. PEEK-OPTIMA polymer complies with ISO 10993-1, USP Class VI and ASTM F2026 for use as a medical implant material.

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

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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

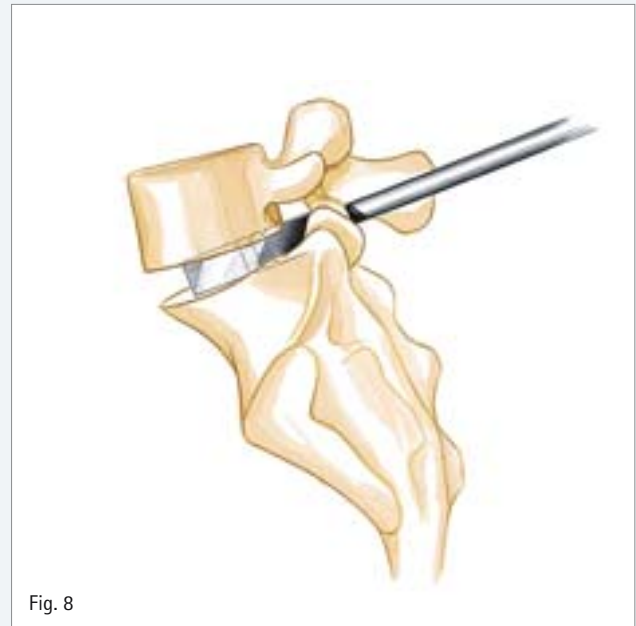
- The desired distraction can be set using the distractors, available in heights from 7–14 mm in 1 mm increments (Fig. 2/3/4).
The distractors are inserted one after the other on alternate sides of the disc until the desired distraction is obtained.

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

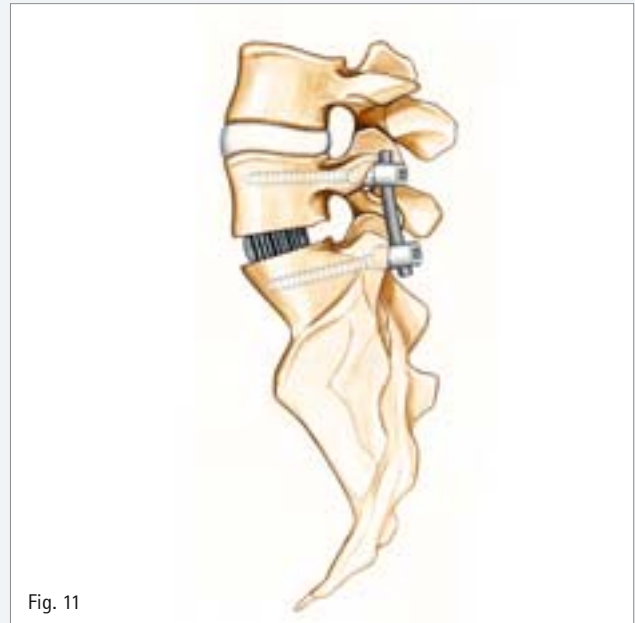


Fig. 11

- *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



■ *Nerve root retractor FJ051R-FJ054R*

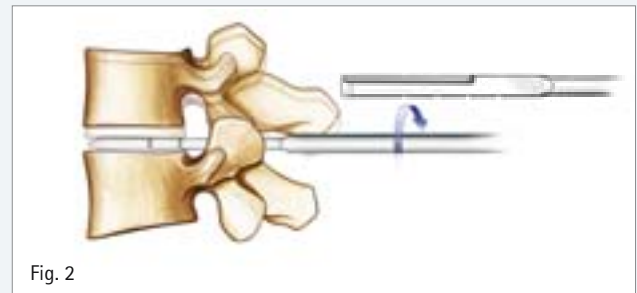


Fig. 2

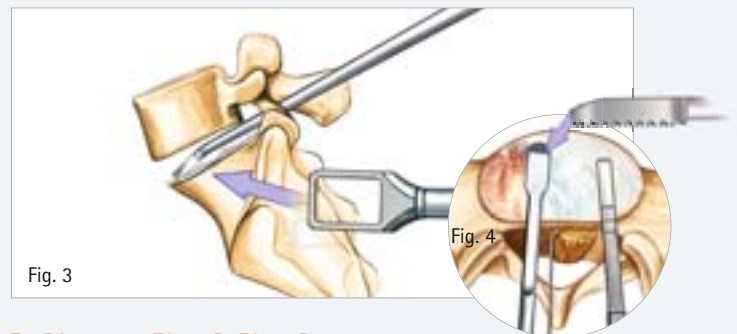


Fig. 3

- *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 currettes and rectangular currettes (Fig.3).
The bone rasps are used to refresh the cartilaginous end-plates. (Fig. 4).

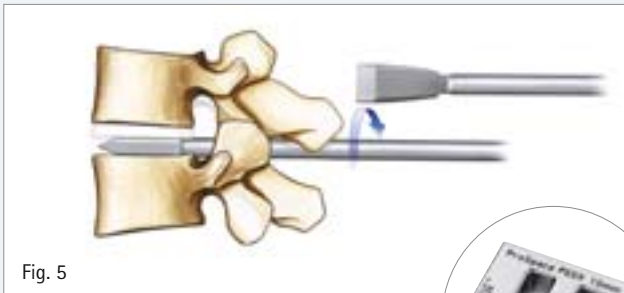


Fig. 5



Fig. 7

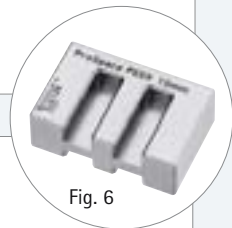


Fig. 6



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.

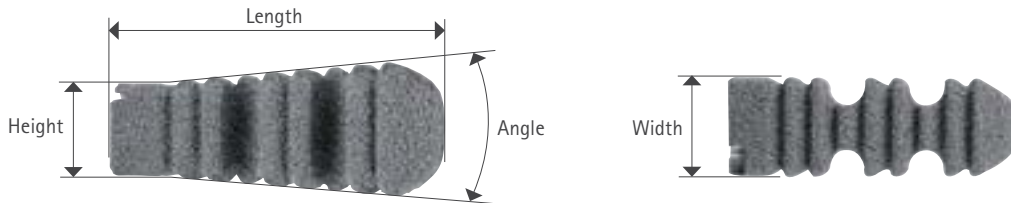
Posterior Stabilization

- 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 026702.

ProSpace[®] Titanium

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Ordering Information – Implants – ProSpace Titanium

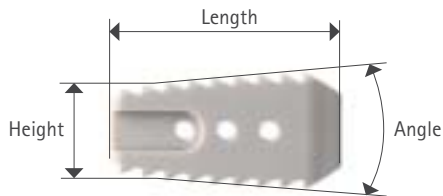


| Art. no. | Description | Height | Width | Length | Angle |
|----------|-------------------|--------|-------|--------|-------|
| FJ230T | ProSpace Titanium | 7 mm | 7 mm | 16 mm | 0° |
| FJ231T | ProSpace Titanium | 9 mm | 7 mm | 16 mm | 0° |
| FJ232T | ProSpace Titanium | 7 mm | 7 mm | 19 mm | 0° |
| 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




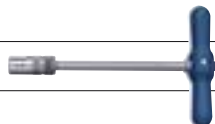



| Art. no. | Description | Height | Width | Length | Angle |
|----------|---------------|--------|-------|--------|-------|
| SJ232P | ProSpace PEEK | 7 mm | 8 mm | 19 mm | 0° |
| SJ233P | ProSpace PEEK | 9 mm | 8 mm | 19 mm | 0° |
| SJ234P | ProSpace PEEK | 7 mm | 8 mm | 22 mm | 0° |
| SJ235P | ProSpace 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



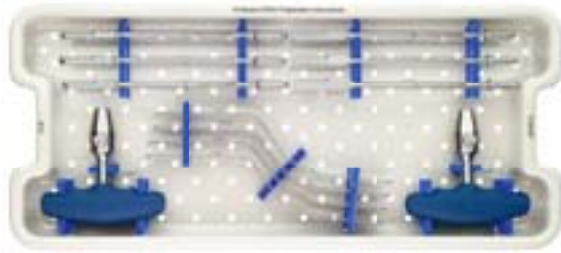
| | Art. no. | Description | Recommended | Optional |
|---|----------|-------------------|-------------|----------|
| | FJ051R | Retractor S | 1 | |
| | FJ052R | Retractor M | 1 | |
| | FJ053R | Retractor L | 1 | |
| | FJ054R | Retractor XL | 1 | |
|  | FJ059R | T-Handle | 2 | |
|  | FJ061R | Distractor, 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 | |

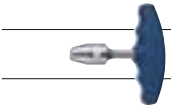





ProSpace® PEEK

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°, 7x19 mm | 1 |
| | SJ243R | ProSpace PEEK trial implant, 0°, 9x19 mm | 1 |
| | SJ244R | ProSpace PEEK trial implant, 0°, 7x22 mm | 1 |
| | SJ245R | ProSpace PEEK trial implant, 0°, 9x22 mm | 1 |
| | SJ248R | ProSpace PEEK trial implant, 0°, 11x25 mm | 1 |
| | SJ249R | ProSpace PEEK trial implant, 0°, 13x25 mm | 1 |
| | SJ262R | ProSpace PEEK trial implant, 5°, 7x19 mm | 1 |
| | SJ263R | ProSpace PEEK trial implant, 5°, 9x19 mm | 1 |
|  | SJ264R | ProSpace PEEK trial implant, 5°, 7x22 mm | 1 |
| | SJ265R | ProSpace PEEK trial implant, 5°, 9x22 mm | 1 |
| | SJ268R | ProSpace PEEK trial implant, 5°, 11x25 mm | 1 |
| | SJ269R | ProSpace PEEK trial implant, 5°, 13x25 mm | 1 |
| | SJ292R | ProSpace PEEK trial implant, 8°, 7x19 mm | 1 |
| | SJ293R | ProSpace PEEK trial implant, 8°, 9x19 mm | 1 |
| | SJ295R | ProSpace PEEK trial implant, 8°, 9x22 mm | 1 |
| | SJ298R | ProSpace PEEK trial implant, 8°, 11x25 mm | 1 |
| | SJ299R | ProSpace PEEK trial implant, 8°, 13x25 mm | 1 |
|  | SJ212R | Packing Block | 1 |
|  | FF913R | Punch | 1 |
|  | SJ210R | Insertion instrument | 1 |
|  | SJ211R | Impactor | 1 |
| | FJ640P | Tray for implantation instr. ProSpace PEEK | 1 |

