Aesculap® CeSpace® Titanium / PEEK

Anterior Cervical Interbody Fusion System

Aesculap Spine

B BRAUN
SHARING EXPERTISE

CeSpace®

Content

Foreword

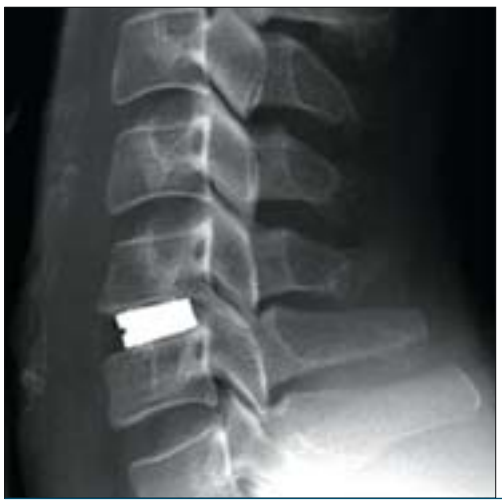
A

CeSpace is a spacer used for cervical interbody fusion. It is indicated for the treatment of degenerative diseases of the cervical disc and instabilities in the C3 to C7 region.
The design of the CeSpace implant allows a maximum contact area between implant and vertebral endplates. CeSpace implants are available in PEEK and Titanium, depending on the preference of the surgeon.

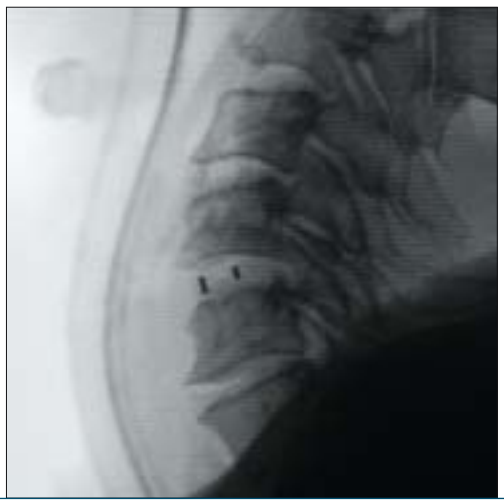
CeSpace stands for

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

Combined with reliable instrumentation, CeSpace – a solution for cervical interbody fusion.



Stabilization with CeSpace Titanium.



Stabilization with CeSpace PEEK.

CeSpace®

B

CeSpace – 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 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.

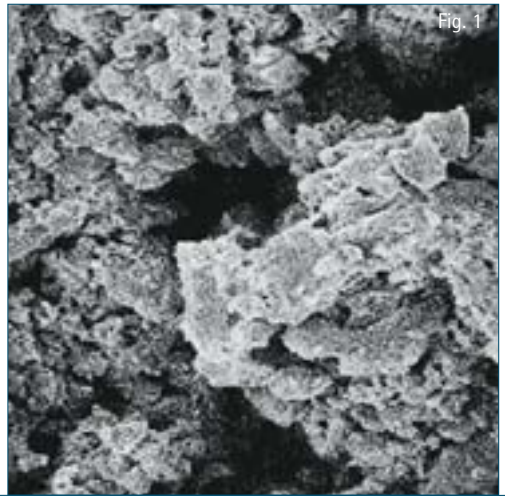


Fig. 1


Fig. 2

CeSpace – PEEK

The material used is biocompatible PEEK-OPTIMA, which was introduced by Invibio in 1999. 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 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.

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 (Fig. 1).

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 a 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.

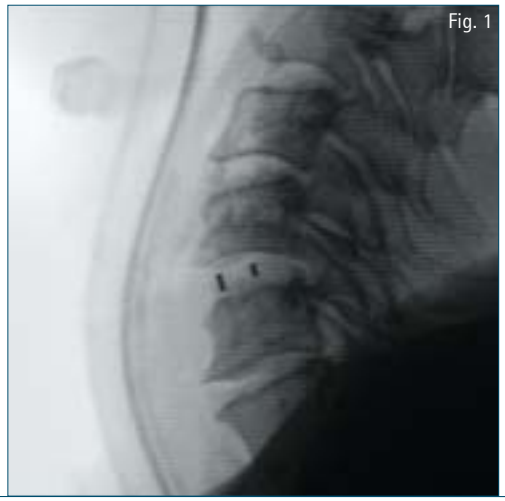


Fig. 1

Lateral view:

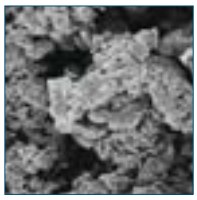
AP view:

CeSpace® Titanium

C

Implant Features – CeSpace 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

- Fixation crown for an exact implant fit and high primary stability
- Optimized ratio between contact area and opening
- Option of filling with bone or bone substitute to enhance bone bridging

Implant variety

- Adequate range of sizes providing the right implant to fit the patient
- Minimum 4 mm height

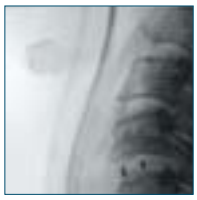
Thought-out instruments

- Simple in handling
- Reliable and safe
- Clearly arranged

CeSpace® PEEK

Implant Features – CeSpace 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 implant positioning and localization

Intelligent implant design

- Anatomical shape and serrated profile for an exact implant fit and high primary stability
- Optimized ratio between contact area and opening
- Option of filling with bone or bone substitute to enhance bone bridging

Implant variety

- Adequate range of sizes providing the right implant to fit the patient
- Minimum 4 mm height

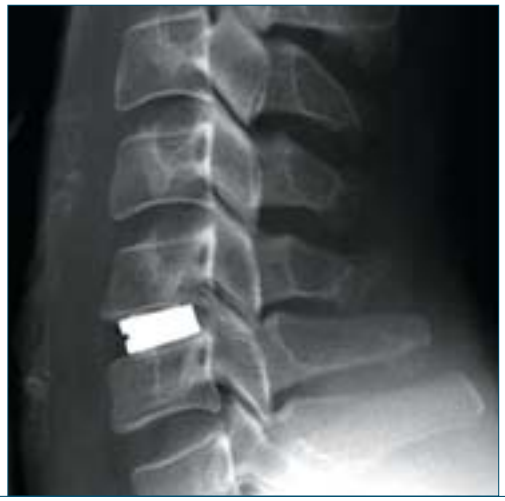
Thought-out instruments

- Simple in handling
- Reliable and safe
- Clearly arranged

CeSpace®

D

Surgical Technique



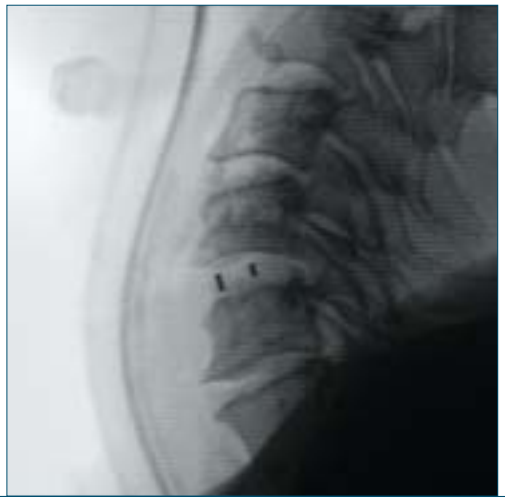


Fig. 1

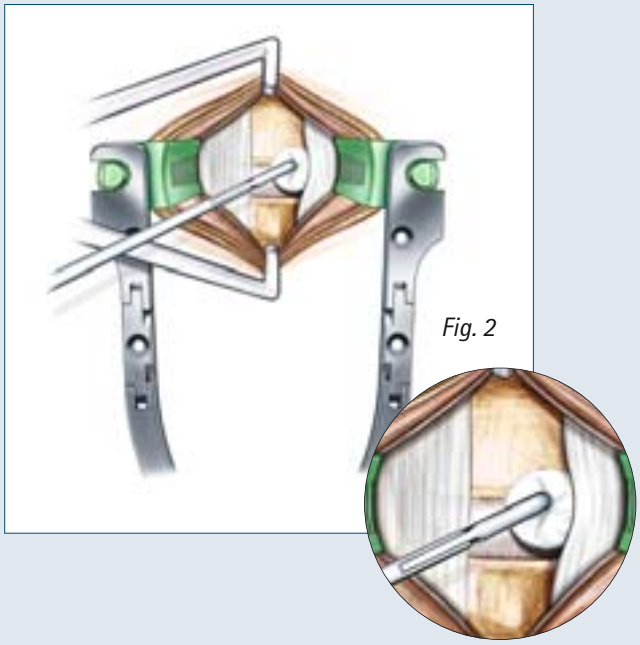


Fig. 2

CASPAR Cervical Retractor System

Patient Positioning

- The patient is placed in the supine position with the head slightly reclined (Fig. 1) and stabilized in a head holder. Once the lordotic cervical spine has been supported, the thorax may be placed on a pillow to emphasize the reclination of the cervical spine. The arms are fixed along the sides of the body.

Exposure of the Intervertebral Space

- After the skin incision and preparation, the CCR retractor is applied. The blades are available in PEEK and Titanium. A counter retractor can be used (Fig. 2). The subcutaneous tissue is separated from the platysma cranially, caudally and medially, and the platysma is also separated following the direction of its fibres. The margins of the platysma can be held apart with the retractor or with two surgical forceps.

- Now the medial edge of the sternocleidomastoid muscle is located and prepared with the index finger in the connective tissue space over the ventral surface of the cervical spine and under lateralization of the vascular nerve bundle and medialization of the trachea, esophagus and thyroid gland.

- After the Langenbeck hooks have been inserted, the ventral surface of the cervical spine, still covered by a thin prevertebral layer of connective tissue, is revealed. This layer can now be exposed by either a blunt scissor or alternatively through bipolar coagulation in order to expand the tissue cranially and caudally using a swab. A wire is set under X-ray monitoring to mark the intervertebral disc space.

CeSpace®

Surgical Technique

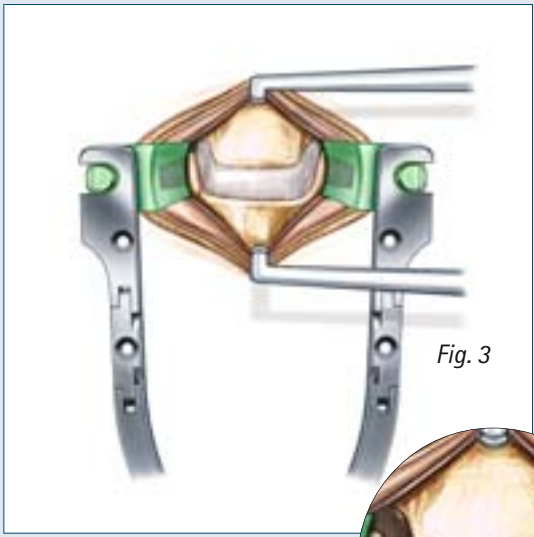


Fig. 3

- CASPAR Vertebral Body Distractor
- CASPAR Distraction Screws

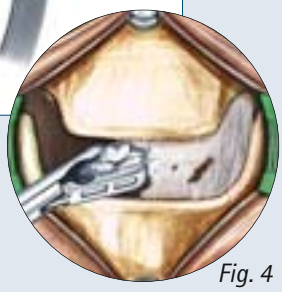


Fig. 4

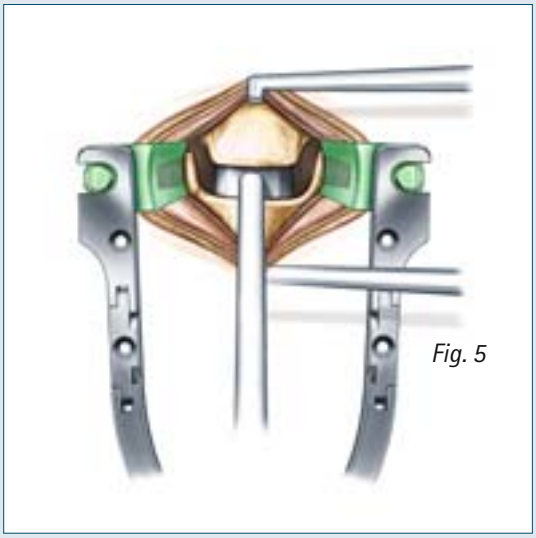


Fig. 5

- Trial Implants CeSpace Titanium *FJ164R-FJ167R/ FJ174R-FJ177R*
- Trial Implants CeSpace PEEK: *FJ474R-FJ478R/ FJ484R-FJ488R*

Distraction / Discectomy / Preparation of the Endplates

- The distraction screws are placed in position and the CASPAR distractor is applied following the CASPAR technique (Fig. 3).
- Complete discectomy is performed using various rongeurs, rectangular curettes and bone curettes (Fig. 4). While using a high speed drill to remove the posterior rim and/or dorsal osteophytes, care must be taken to avoid damaging the vertebral body endplates.

Please note:
Excessive preparation of the endplates may weaken the construct and cause subsidence of the CeSpace implant.

Implant Selection

- The correct implant size can be established using the trial implants (Fig. 5).
- Due to the different geometry of the CeSpace Titanium and CeSpace PEEK implants specific trials for the respective system are needed. Laser markings on the handle as well as on the trial itself indicate the cranial and caudal side of the trial.

Determination of Implant Size of CeSpace Titanium

The height of the CeSpace Titanium trials is inclusive of the fixation crown.

Determination of Implant Size of CeSpace PEEK

The CeSpace PEEK trials regard the anatomical shape and serrated profile of the CeSpace PEEK implant.

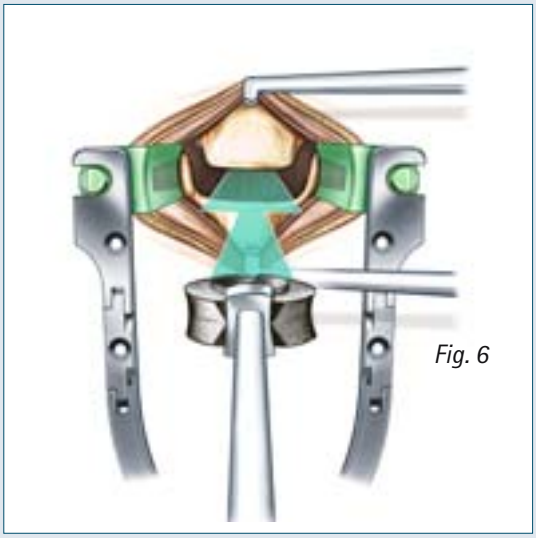


Fig. 6

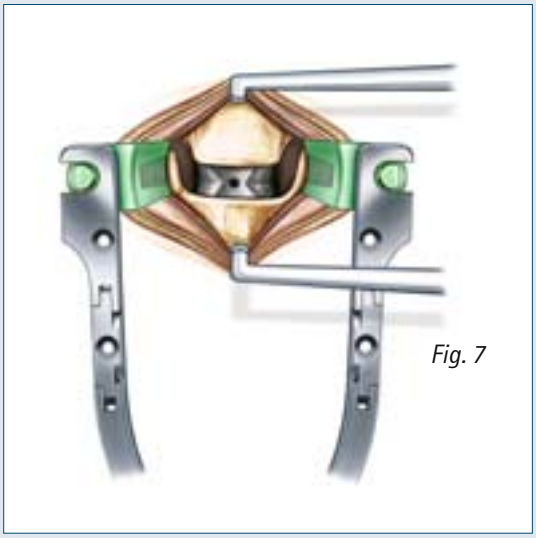


Fig. 7

- **Inserter CeSpace Titanium**
  FJ100R
- **Inserter CeSpace PEEK**
  FJ415R/FJ497R
- **CeSpace PEEK**
  Packing Block / Punch
  FJ413P/FF914R

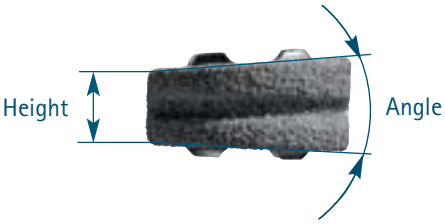
CeSpace Insertion

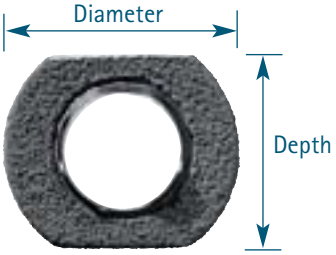
- The Titanium implant is held securely and firmly onto the CeSpace inserter by means of a screw joint. The flexible sheath on the inserter has a stop at the front end which prevents the implant from being inserted too deeply into the intervertebral disc compartment.
- The CeSpace PEEK inserter has a clamp mechanism and is available with or without safety stop. Laser markings indicate the cranial and caudal side of the instrument.
- Once CeSpace is attached to the inserter, it can be introduced into the intervertebral space using image converter monitoring (Fig. 6).
- The implant should be inserted centrally in AP and with a distance of approximately 1-2 mm to both the anterior and posterior rim (Fig. 7).
- If indicated an Aesculap cervical plate should be used for additional stabilization.

CeSpace® Titanium

E1

Ordering Information – Implants





Art. no.	Description	Height	Diameter	Depth	Angle
FJ134T	CeSpace Titanium	4 mm	14 mm	11.5 mm	5°
FJ135T	CeSpace Titanium	5 mm	14 mm	11.5 mm	5°
FJ136T	CeSpace Titanium	6 mm	14 mm	11.5 mm	5°
FJ137T	CeSpace Titanium	7 mm	14 mm	11.5 mm	5°
FJ144T	CeSpace Titanium	4 mm	16 mm	13.5 mm	5°
FJ145T	CeSpace Titanium	5 mm	16 mm	13.5 mm	5°
FJ146T	CeSpace Titanium	6 mm	16 mm	13.5 mm	5°
FJ147T	CeSpace Titanium	7 mm	16 mm	13.5 mm	5°

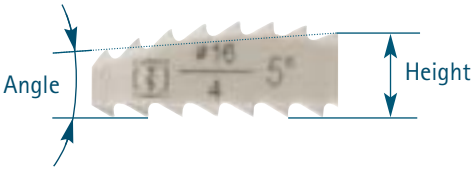
Implant materials

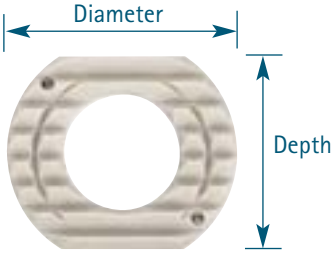
ISOTAN F	Titanium forged alloy	(Ti6Al4V / ISO 5832-3)
Plasmapore	Pure titanium	(Ti / ISO 5832-2)

The specified height for the lordotic implant refers to the average height, which means the anterior section of the implant is higher than the posterior section. All CeSpace implants are individually sterile packed.

CeSpace® PEEK

Ordering Information – Implants





Art. no.	Description	Height	Diameter	Depth	Angle
FJ404P	CeSpace PEEK	4 mm	14 mm	11.5 mm	5°
FJ405P	CeSpace PEEK	5 mm	14 mm	11.5 mm	5°
FJ406P	CeSpace PEEK	6 mm	14 mm	11.5 mm	5°
FJ407P	CeSpace PEEK	7 mm	14 mm	11.5 mm	5°
FJ408P	CeSpace PEEK	8 mm	14 mm	11.5 mm	5°
FJ424P	CeSpace PEEK	4 mm	16 mm	13.5 mm	5°
FJ425P	CeSpace PEEK	5 mm	16 mm	13.5 mm	5°
FJ426P	CeSpace PEEK	6 mm	16 mm	13.5 mm	5°
FJ427P	CeSpace PEEK	7 mm	16 mm	13.5 mm	5°
FJ428P	CeSpace PEEK	8 mm	16 mm	13.5 mm	5°

Implant material
PEEK-OPTIMA (PolyEtherEtherKeton)

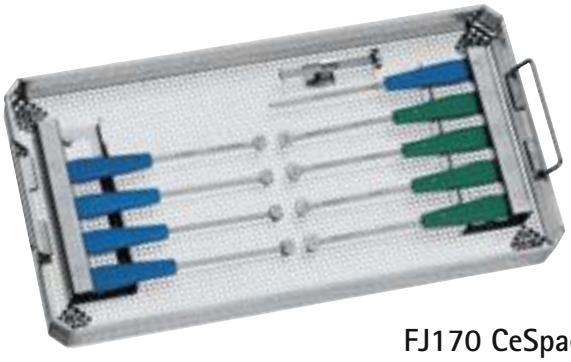
Registered trademark of Invibio Ltd, Lancashire FY5 4QD, UK

The specified height for the lordotic implant refers to the average height, which means the anterior section of the implant is higher than the posterior section. All CeSpace implants are individually sterile packed.

CeSpace® Titanium

Ordering Information – Implantation Instruments

E2



FJ170 CeSpace Titanium instrumentation

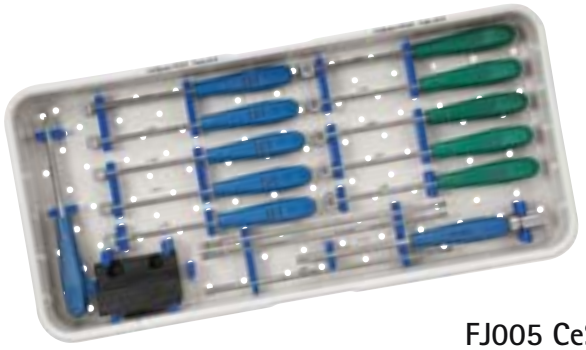
consisting of:

Art. no.	Description	Handle Colour	Recommended
FJ164R	Trial implant, 5°, 14 x 4 mm	blue	1
FJ165R	Trial implant, 5°, 14 x 5 mm	blue	1
FJ166R	Trial implant, 5°, 14 x 6 mm	blue	1
FJ167R	Trial implant, 5°, 14 x 7 mm	blue	1
FJ174R	Trial implant, 5°, 16 x 4 mm	green	1
FJ175R	Trial implant, 5°, 16 x 5 mm	green	1
FJ176R	Trial implant, 5°, 16 x 6 mm	green	1
FJ177R	Trial implant, 5°, 16 x 7 mm	green	1
FJ100R	Inserter		1
FJ171R	Perforated tray with holding and storage elements		1

Recommended container for tray FJ171R: JK440 (without perforation) / JN440 (with perforation)
Recommended lid: JK489

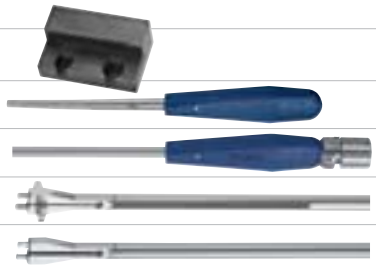
CeSpace® PEEK

Ordering Information – Implantation Instruments



FJ005 CeSpace PEEK instrumentation

consisting of:



Art. no.	Description	Handle Colour	Recommended
FJ474R	Trial implant, 5°, 14 x 4 mm	blue	1
FJ475R	Trial implant, 5°, 14 x 5 mm	blue	1
FJ476R	Trial implant, 5°, 14 x 6 mm	blue	1
FJ477R	Trial implant, 5°, 14 x 7 mm	blue	1
FJ478R	Trial implant, 5°, 14 x 8 mm	blue	1
FJ484R	Trial implant, 5°, 16 x 4 mm	green	1
FJ485R	Trial implant, 5°, 16 x 5 mm	green	1
FJ486R	Trial implant, 5°, 16 x 6 mm	green	1
FJ487R	Trial implant, 5°, 16 x 7 mm	green	1
FJ488R	Trial implant, 5°, 16 x 8 mm	green	1
FJ413P	CeSpace PEEK packing block		1
FF914R	Punch		1
FJ415R	Inserter		1
FJ497R	Safety stop		1
FJ499R	Revision		1
FJ411P	CeSpace PEEK tray		1

Recommended container for tray FJ411P: JK440 (without perforation) / JN440 (with perforation)
Recommended lid: JK489

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