Aesculap Spine

CeSpace® Titanium / PEEK

Anterior Cervical Interbody Fusion System

B BRAUN
SHARING EXPERTISE

CeSpace®

Implant Design

Philosophy

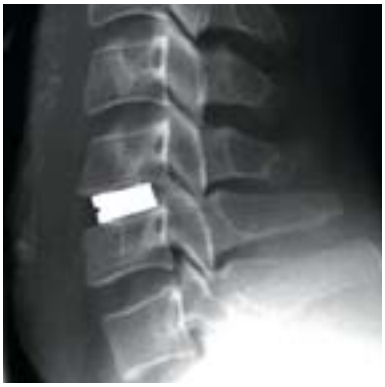
CeSpace® is a spacer used for cervical interbody fusion. It is indicated for the treatment of degenerative diseases of the cervical disc and instabilities in the C3 to C7 region.
The design of the CeSpace® implant allows a maximum contact area between implant and vertebral endplates. CeSpace® implants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

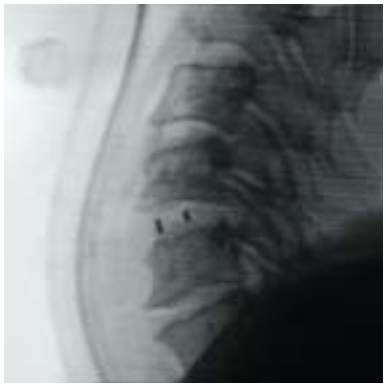
CeSpace® stands for

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

Combined with reliable instrumentation, CeSpace® is the solution for cervical interbody fusion.

Stabilization with CeSpace® Titanium.





Stabilization with CeSpace® PEEK.

CeSpace®

CeSpace® – Titanium

The heart of this implant is a solid titanium core.
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 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 raw material 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 prothetics, has now become a new standard in spinal surgery.

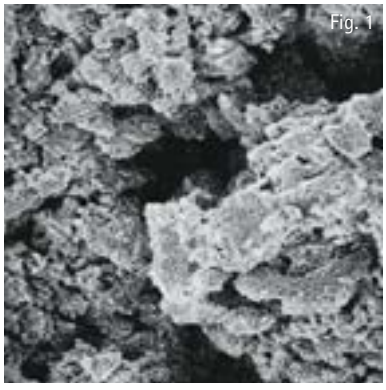


Fig. 1


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 comply 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 gives it permeability on x-rays and CT scans, making it possible 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 our PEEK-implants on radioscopic images, we have enclosed non-radiolucent pins which serve as location markers (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 into the bio-compatibility of PEEK-OPTIMA® have proven that the material is suitable for the use as a long-term implant.

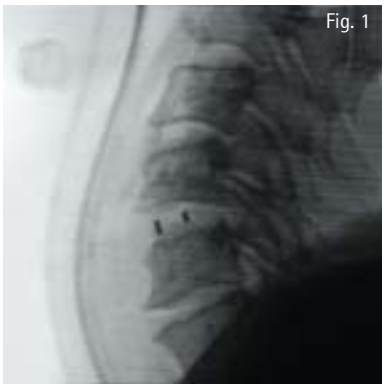


Fig. 1

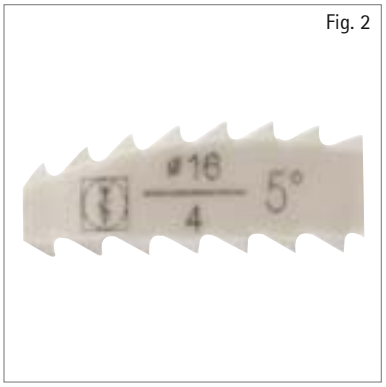
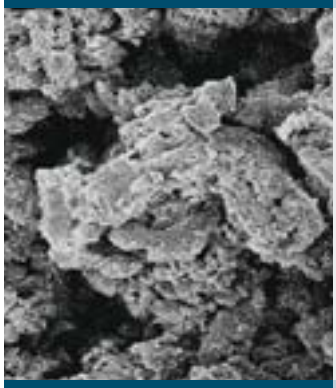


Fig. 2

CeSpace® Titanium

Plasmapore® Coating: Rapid Osteointegration



- High frictional resistance due to the rough surface
- Solid osteointegration due to a fast migration of bone cells into the Plasmapore® structure
- High primary stability
- High secondary stability

Implant Design

- Fixation crown
- Optimized ratio between contact area and opening
- Option of filling with bone or bone substitute to enhance bone bridging
- Exact implant fit ensures primary stability
- Subsidence of the implant is kept to a minimum
- Secondary stability is assured through fusion

Implant Variety

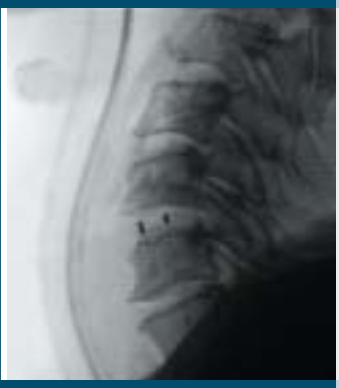
- Wide range of implant sizes
- Minimum 4 mm height
- Adequate selection of sizes presenting the right implant to fit the patient

Thought-Out Instruments

- Simple in handling
- Clearly arranged
- Safe

CeSpace® PEEK

Position Verification despite X-ray Transparency



- PEEK-OPTIMA® is transparent to X-rays
- Artifact-free
- Tantal markers
- Quick and simple assessment of the bone structure and progress towards bone fusion
- Easy, exact implant positioning and localization

Implant Design

- Anatomical shape and serrated profile
- Optimized ratio between contact area and opening
- Option of filling with bone or bone substitute to enhance bone bridging
- Exact implant fit ensures primary stability
- Subsidence of the implant is kept to a minimum
- Secondary stability is assured through fusion

Implant Variety

- Wide range of implant sizes
- Minimum 4 mm height
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Thought-Out Instruments

- Simple in handling
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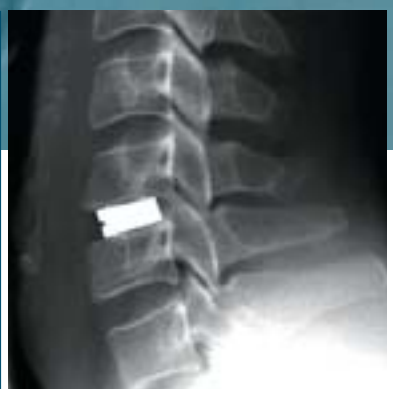
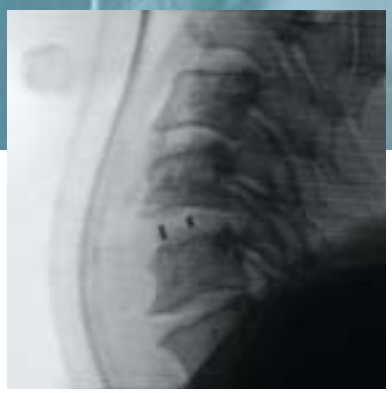
CeSpace®

Surgical Technique





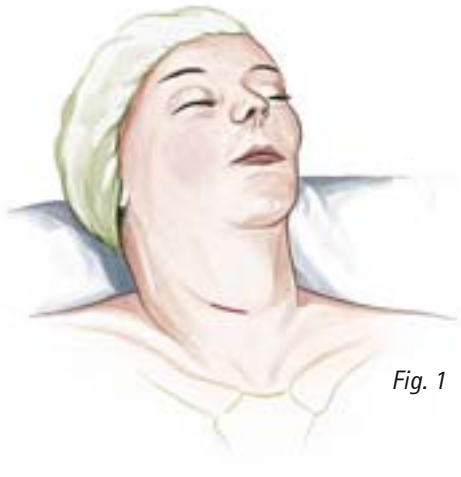


Fig. 1

Patient Positioning

- The patient is placed in the supine position with the head slightly reclined and resting in a head trough or ring.
  Once the lordotic cervical spine has been supported, the thorax may be placed on a pillow to emphasize the reclination of the cervical spine (Fig. 1).

- The arms are fixed along the sides of the body. Using the arm fixations, draw the shoulders down far enough to remove them from the radiation path of the segment to be fused.

■ CASPAR Cervical Retractor System

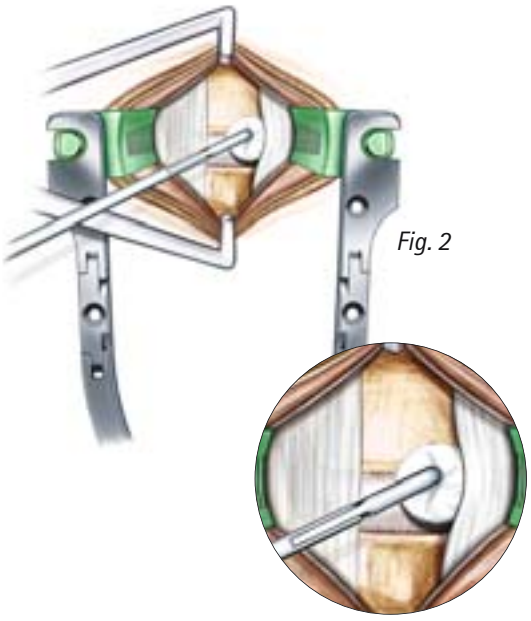


Fig. 2

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®

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.

NB:

✪ **Excessive preparation of the endplates may weaken the construct and cause subsidence of the CeSpace® implant.**

■ CASPAR Vertebral Body Distractor
■ CASPAR Distraction Screws

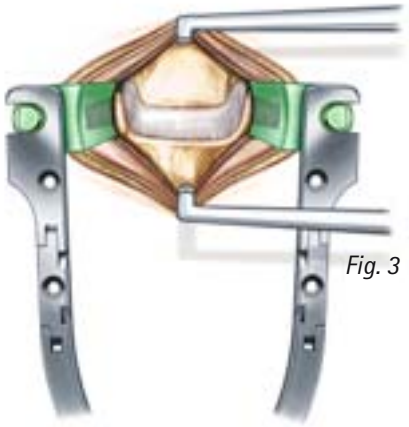


Fig. 3

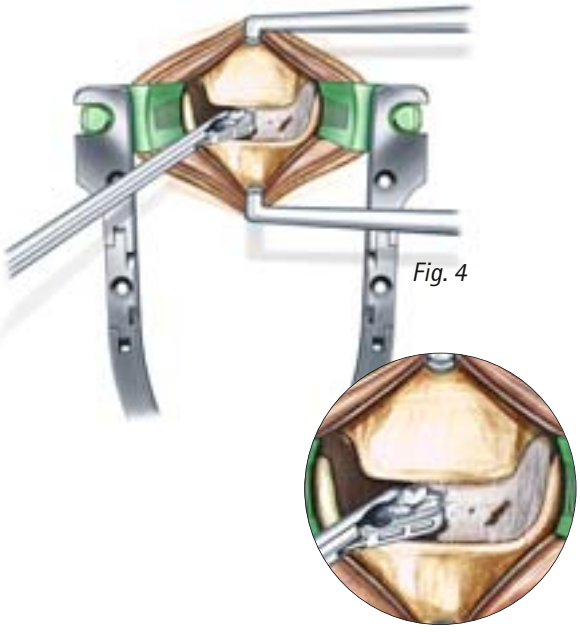


Fig. 4

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

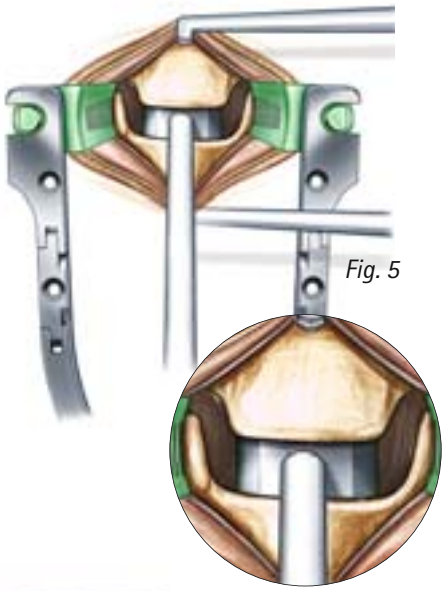


Fig. 5

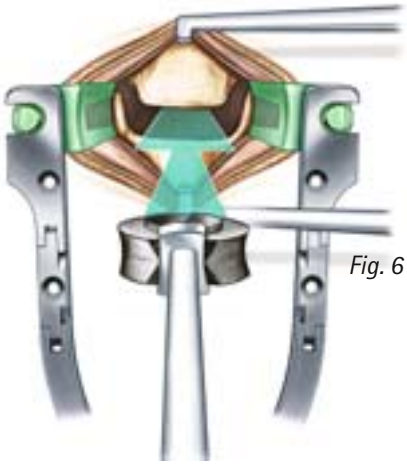


Fig. 6

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

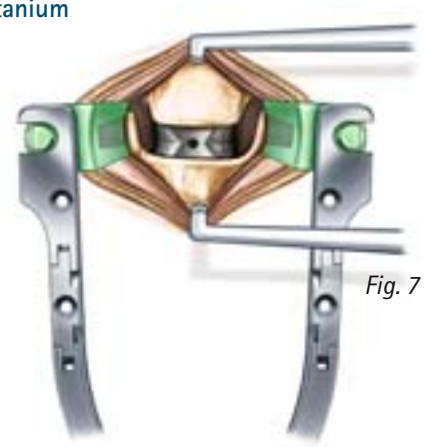


Fig. 7

Implant Selection

✪ The correct implant size can be established using the trial implants (Fig. 5).

✪ Due to the different shape of the implants we offer a comprehensive range of different sizes for both the CeSpace® Titanium and CeSpace® PEEK systems. Laser markings on the handle as well as 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 corresponds exactly with the height of the final implant and 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.

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.

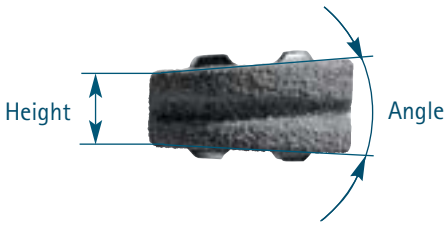
✪ The CeSpace® PEEK inserter has a clamp mechanism and is available with or without safety stop. Laser markings indicate the cranial and caudal side of the instrument.

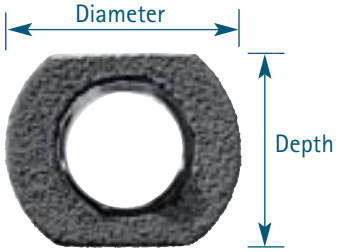
✪ Once CeSpace® is attached to the inserter, it can be introduced into the intervertebral space using image converter monitoring (Fig. 6).

✪ 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).

CeSpace® Titanium

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°

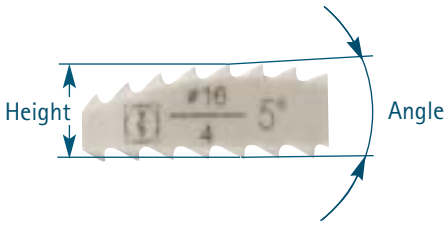
Implant materials

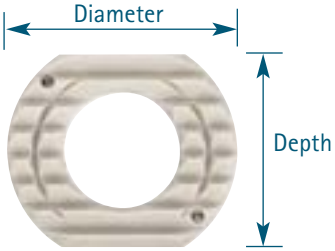
ISOTAN® F	Titanium forged alloy	(Ti6Al4V / ISO 5832-3)
Plasmapore®	Pure titanium	(Ti / ISO 5832-2)

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

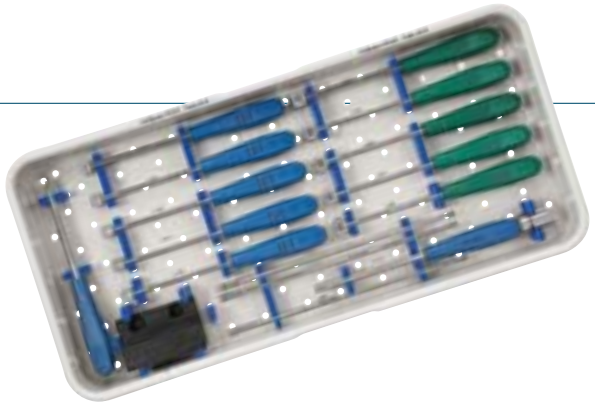
Ordering Information – Implantation Instruments

	Art. no.	Description	Handle Colour	Recommended
	FJ164R	Trial implant, 5°, 14x4 mm	blue	1
	FJ165R	Trial implant, 5°, 14x5 mm	blue	1
	FJ166R	Trial implant, 5°, 14x6 mm	blue	1
	FJ167R	Trial implant, 5°, 14x7 mm	blue	1
	FJ174R	Trial implant, 5°, 16x4 mm	green	1
	FJ175R	Trial implant, 5°, 16x5 mm	green	1
	FJ176R	Trial implant, 5°, 16x6 mm	green	1
	FJ177R	Trial implant, 5°, 16x7 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: JP001

CeSpace® PEEK

Ordering Information – Implantation Instruments



CeSpace® PEEK – Implantation

Art. no.	Description	Handle Colour	Recommended
FJ474R	Trial implant, 5°, 14x4 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: JP001

AESCULAP®

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