Aesculap® CeSPACE® XP

Anterior Cervical Interbody Fusion System
with Innovative Surface Technology

Aesculap Spine

B BRAUN
SHARING EXPERTISE

Aesculap® CeSPACE® XP

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 an enhanced contact area between implant and vertebral endplates.

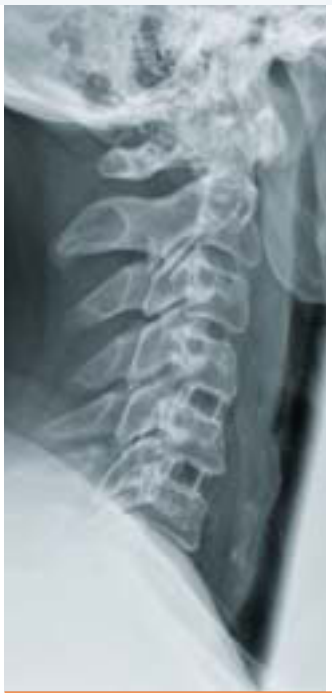
CeSPACE® stands for
- Stability
- Restoration of the natural disc height and lordosis and
- Maintenance of the spinal balance.

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

CeSPACE®XP Interbody System brings an innovative surface enhancing technology, Plasmapore XP®, to ACDF procedures. The combination of a PEEK-OPTIMA® core with osteoconductive Plasmapore XP® coating delivers enhanced stability, artifact free visualization, and biocompatibility.

Plasmapore XP® is the result of 30 years of experience in spinal treatment technology and 20 years of success in applying Plasmapore® coating to Titanium orthopedic and spinal implants.

Aesculap has developed a way to complement the PEEK interbodys with a surface-enhancing technology.
The resulting Plasmapore XP®:
- Combines a PEEK implant core with a porous Titanium coating
- Allows a greater surface area of the implant to be in direct contact with bone
- Offers an enhanced foundation for the ingrowth of bone
- Allows for clear delineation of implant contours during intra and post operative imaging.



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

Aesculap® CeSPACE® XP

B

Implant material

Plasmapore XP® – a further development of our interbody fusion implants.

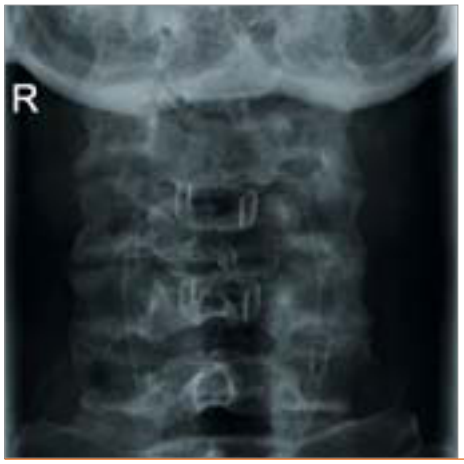
- Combines material advantages
- Consists of two materials, PEEK-OPTIMA® and pure Titanium
- Results in a superior interbody device for your patients

The core of the implant is biocompatible PEEK-OPTIMA®, which was introduced by Invibio in 1999. PEEK stands for PolyEther-EtherKetone. The PEEK-OPTIMA® polymer complies with ISO 10993-1, USP Class VI and ASTM F2026 for use as a medical implant material. PEEK-OPTIMA® offers several advantages, involves compatibility with imaging techniques, high mechanical strength, high fatigue resistance, good buffer function to distribute load and biocompatibility for long-term implantation.

Plasmapore XP® is the result of 30 years of experience in spinal technology and 20 years of success in applying Plasmapore® coating to Titanium orthopedic and spinal implants.[1,2]
Aesculap has developed a way to complement the PEEK interbodys with a surface-enhancing technology.
The resulting Plasmapore XP® is a pure titanium porous coating on PEEK, which allows a greater surface area of the implant to be in direct contact with bone which offers a foundation for the ingrowth of bone. At the same time the combination of a PEEK implant core with a porous Titanium coating allows for clear delineation of implant contours during intra and post operative imaging.

The intrinsic radioscopic transparency of the material provides permeability on X-rays and CT scans, which allows for visualization of bone growth adjacent to the implant.

- Quick and simple assessment of the bone structure and progress towards bone fusion
- Verification of the implant position on radioscopic images – X-ray markers are integrated in the implant
- Plasmapore XP® coating allows for clear delineation of implant contours during imaging (Fig. 1)



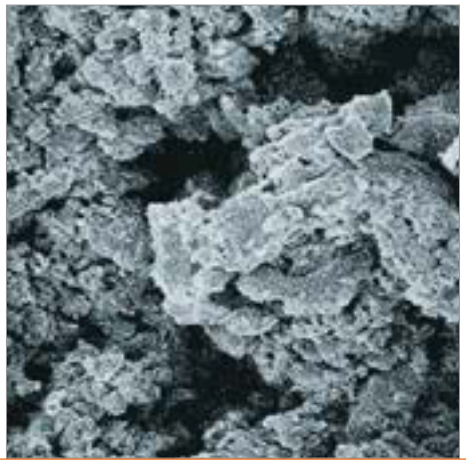


Fig. 1

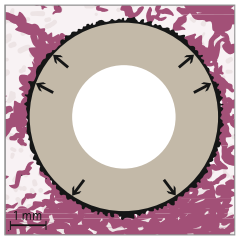
PEEK-OPTIMA® is a registered trademark of Invibio Biomaterial Solutions.

[1] Fink U. Plasmapore: A plasma-sprayed microporous titanium coating to improve the long-term stability. Acutalités en Biomatériaux. 1996;III:97-104.
[2] C. Eingartner, T. Heigele, J. Dieter, E. Winter, K. Weise. Long termn results with the Bicontact system - aspects to investigate and to learn from. 2003.

Implant features

C

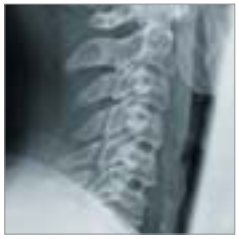
Innovative Surface Enhancing Technology



Plasmapore XP® is an osteoconductive pure Titanium porous coating with proven biocompatibility.[3]

- Porosity of up to 60 % creates a good surface-to-bone contact
- Normal tissue reaction
- No toxic reaction
- Bone ingrowth can be seen at the bone-implant interface of the coated PEEK implant

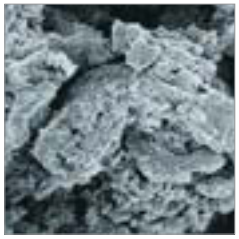
Excellent Imaging Properties



Plasmapore XP® coating and X-ray marker pins allow for improved visibility during imaging.

- Plasmapore XP® delineates the contours of the implant under X-ray to allow for excellent visualization during insertion
- Allows for assessment of the bone structure and progress towards bone fusion
- Does not create artifacts under CT control
- Does not create artifacts in MRI

Enhanced Stability



The roughened surface area provided by the osteoconductive Plasmapore XP® coating deliver enhanced implant stability.

- High primary stability due to roughened surface which increases migration resistance and mechanical strength
- High secondary stability due to fast migration of bone cells into the Plasmapore XP® structure

Intelligent Implant Design

- Anatomical shape and serrated profile for an ideal implant fit
- Enhanced ratio between contact area and opening
- Option of filling with bone or bone substitute to enhance bone bridging

Thought-out Instruments

- Simple in handling
- Reliable
- Clearly arranged

[3] Aesculap AG, BTC Biological Test Center. Evaluation of the local and systemic reaction to a Plasmapore XP coated implant in the distal femora of new zealand white rabbits. Final Report 2011.

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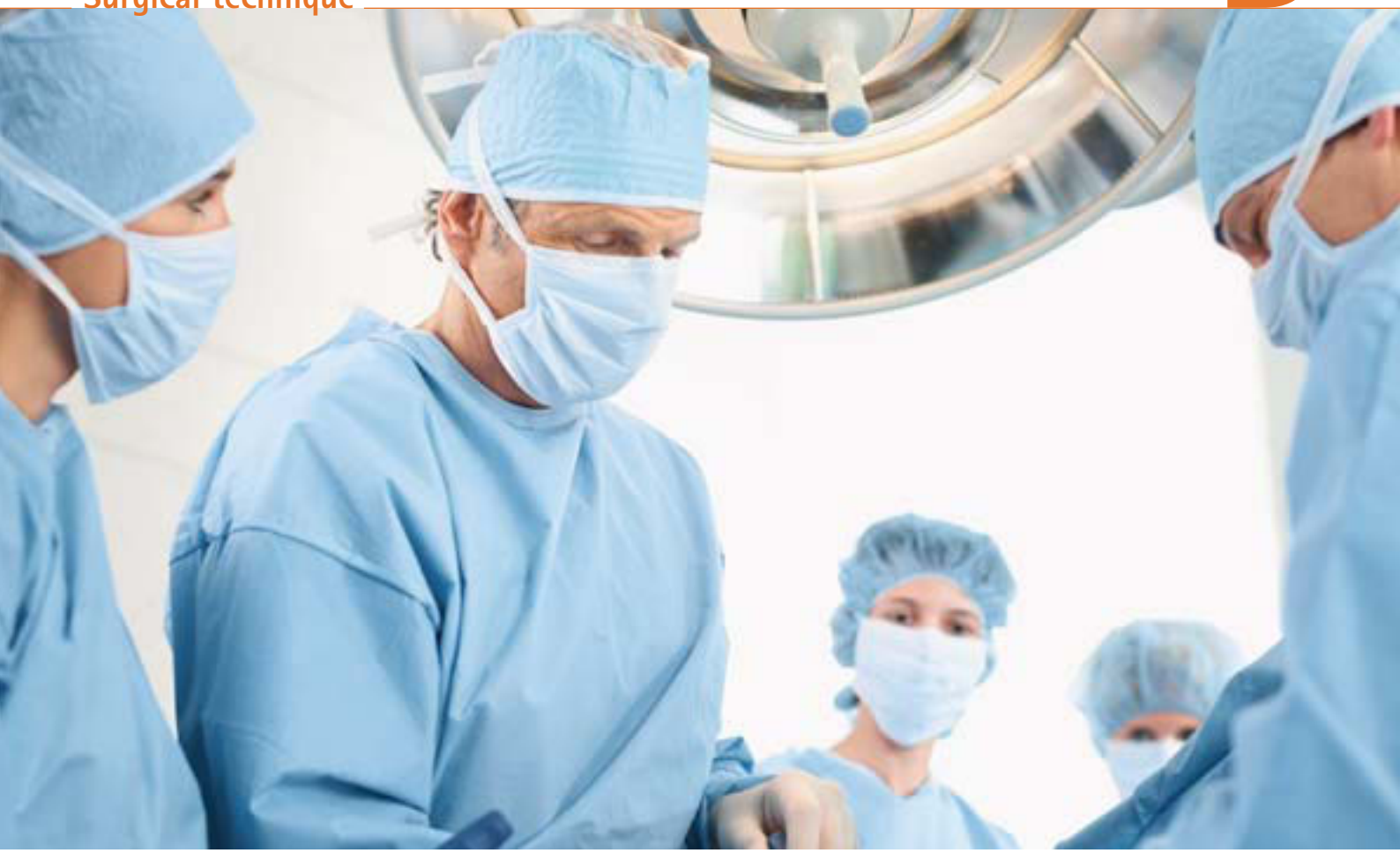
D

Surgical technique



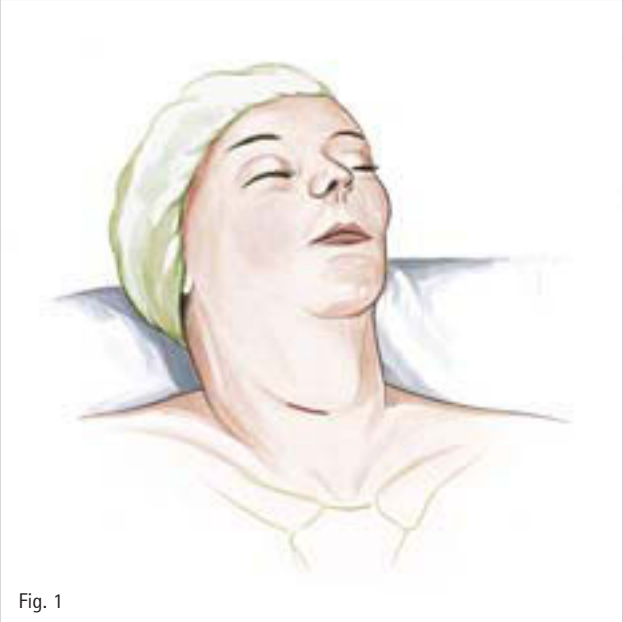


Fig. 1

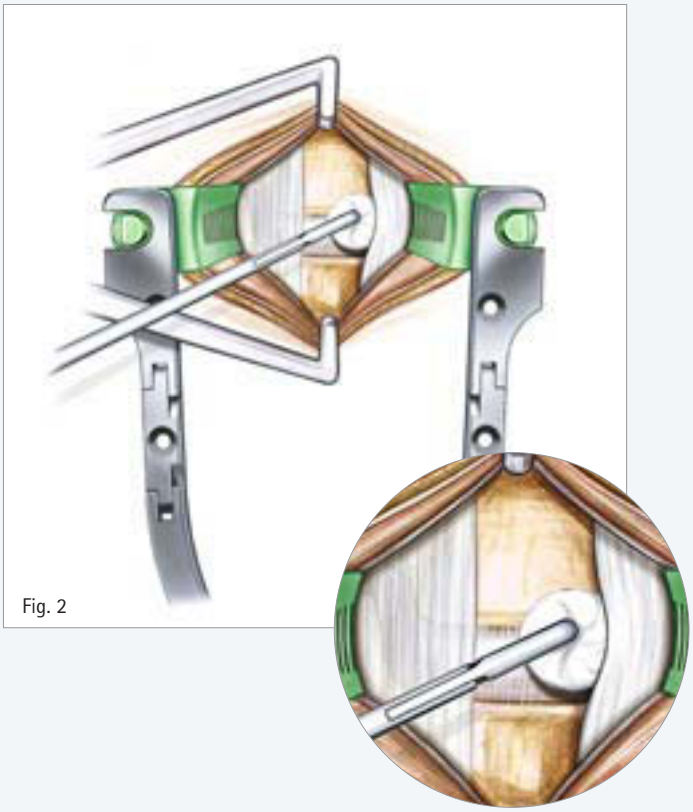


Fig. 2

- 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.

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D

Surgical technique

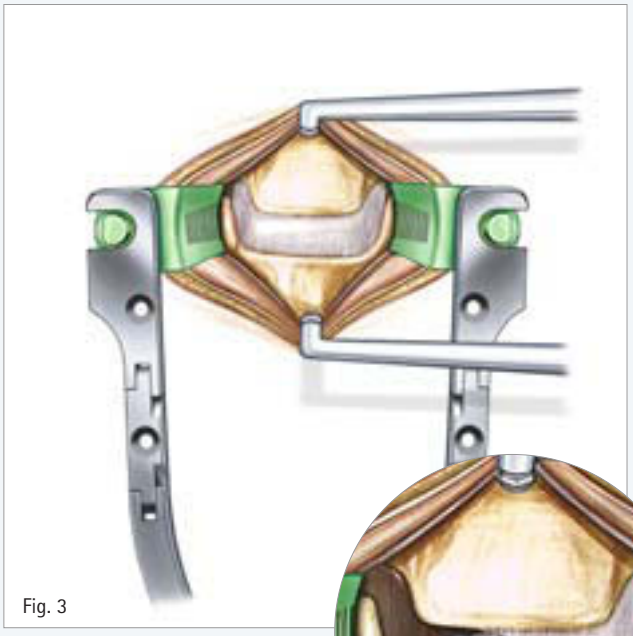


Fig. 3

- CASPAR Vertebral Body Distractor
- CASPAR Distraction Screws

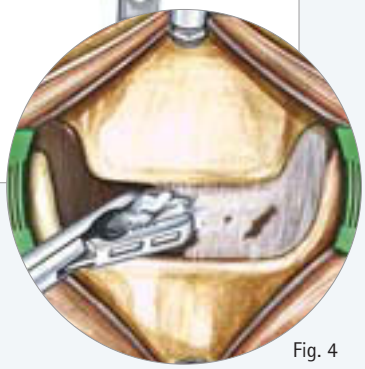


Fig. 4

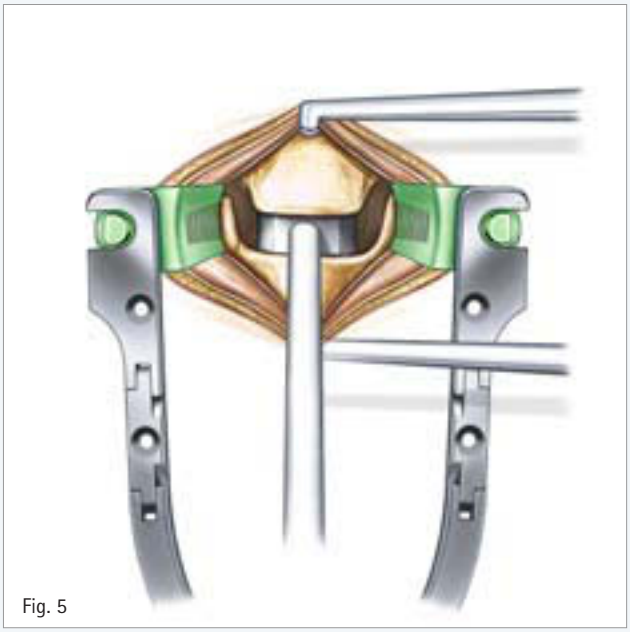


Fig. 5

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®XP implant.

Implant Selection

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

The CeSPACE®XP trials have the anatomical shape of the CeSPACE®XP implant.

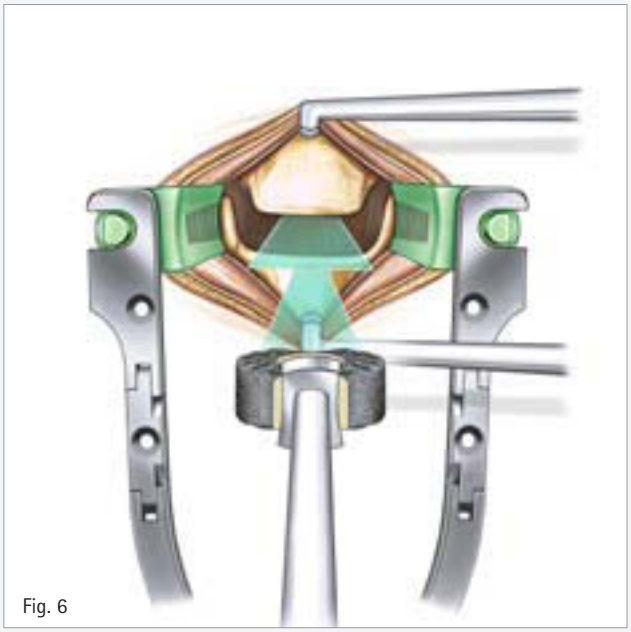


Fig. 6

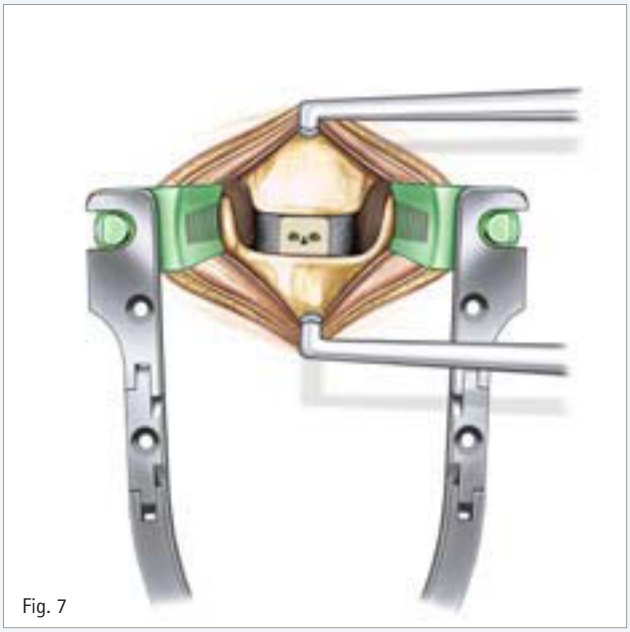


Fig. 7

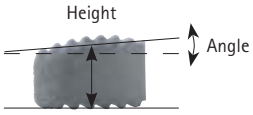
CeSPACE®XP Insertion

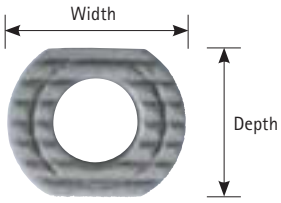
- The CeSPACE®XP inserter has a clamp mechanism and is available with or without safety stop. Laser markings indicate the cranial and caudal side of the instrument.
- Once CeSPACE®XP is attached to the inserter, it can be introduced into the intervertebral space using image converter monitoring (Fig. 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.

Aesculap® CeSPACE®XP

E1

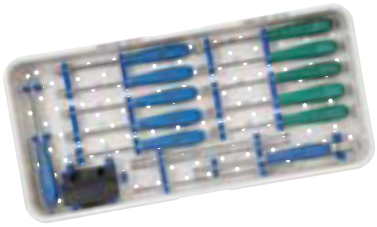
Ordering information – Implants





Art. no.	Description	Height	Width	Depth	Angle
SO254P	CeSPACE®XP	4 mm	14 mm	11.5 mm	5°
SO255P	CeSPACE®XP	5 mm	14 mm	11.5 mm	5°
SO256P	CeSPACE®XP	6 mm	14 mm	11.5 mm	5°
SO257P	CeSPACE®XP	7 mm	14 mm	11.5 mm	5°
SO258P	CeSPACE®XP	8 mm	14 mm	11.5 mm	5°
SO274P	CeSPACE®XP	4 mm	16 mm	13.5 mm	5°
SO275P	CeSPACE®XP	5 mm	16 mm	13.5 mm	5°
SO276P	CeSPACE®XP	6 mm	16 mm	13.5 mm	5°
SO277P	CeSPACE®XP	7 mm	16 mm	13.5 mm	5°
SO278P	CeSPACE®XP	8 mm	16 mm	13.5 mm	5°

Ordering information – Implantation instruments



FJ005 CeSPACE®XP 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 & CeSPACE®XP packing block		1
FF914R	Punch		1
FJ415R	Inserter		1
FJ497R	Safety stop		1
FJ499R	Revision		1
FJ411P	CeSPACE® PEEK & CeSPACE®XP tray		1

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