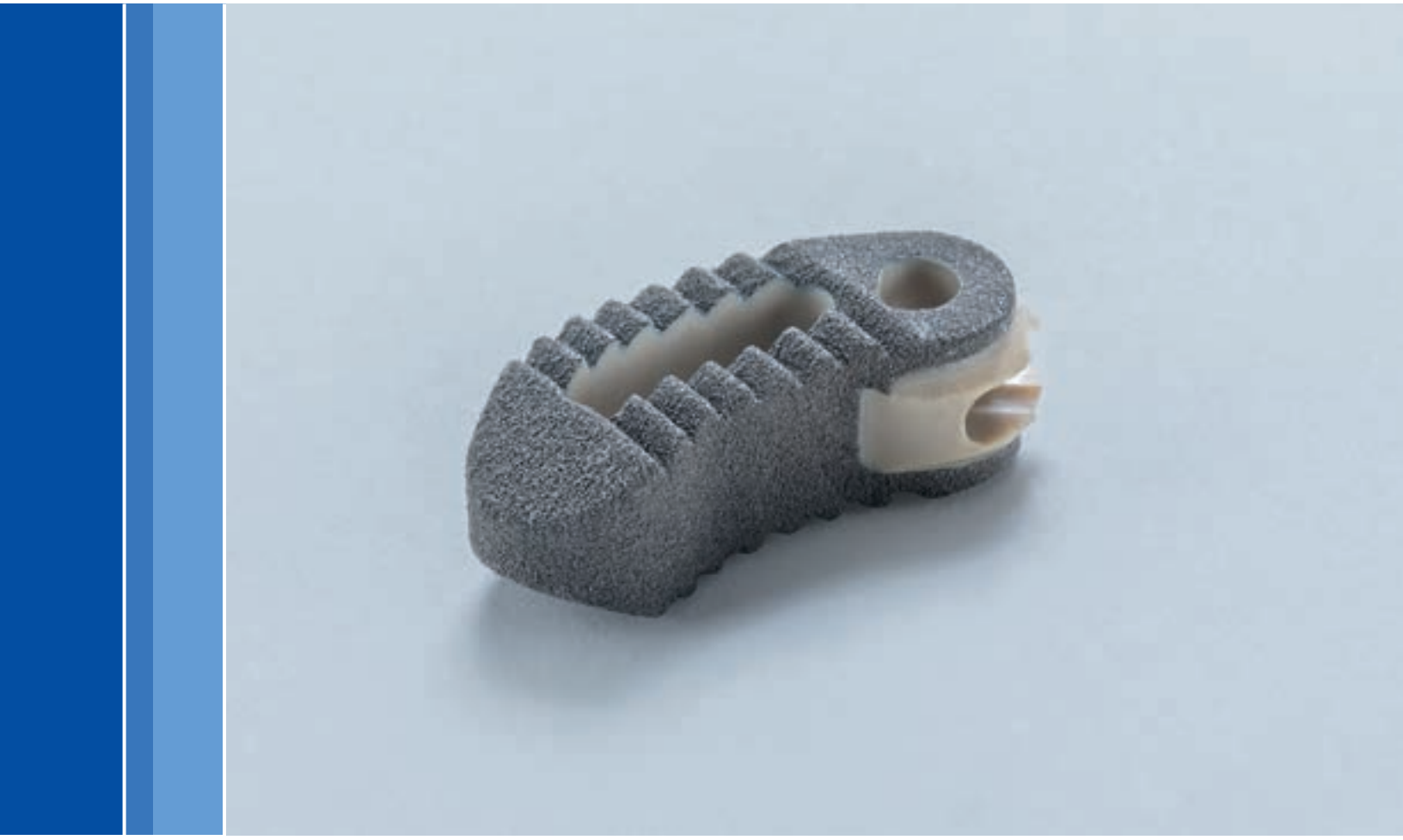
TSpace®XP Ordering Guide



Aesculap Spine

AESCULAP®
Implant Systems

Plasmapore®XP Treated TLIF Interbody

From the company with 30 years of clinical experience in porous titanium coatings

Indications for Use

When used as an Intervertebral Body Fusion System:

The TSpace®XP Spinal Implant System is indicated for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at involved levels. These patients may have had previous non-fusion spinal surgery at the involved spinal level(s). The TSpaceXP Spinal Implant System is intended for use with supplemental spinal fixation systems that have been cleared for use in the lumbrosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The TSpaceXP Spinal Implant System implants can be used individually or in pairs. The TSpaceXP Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the Aesculap device.

Contraindications, Warnings and Precautions

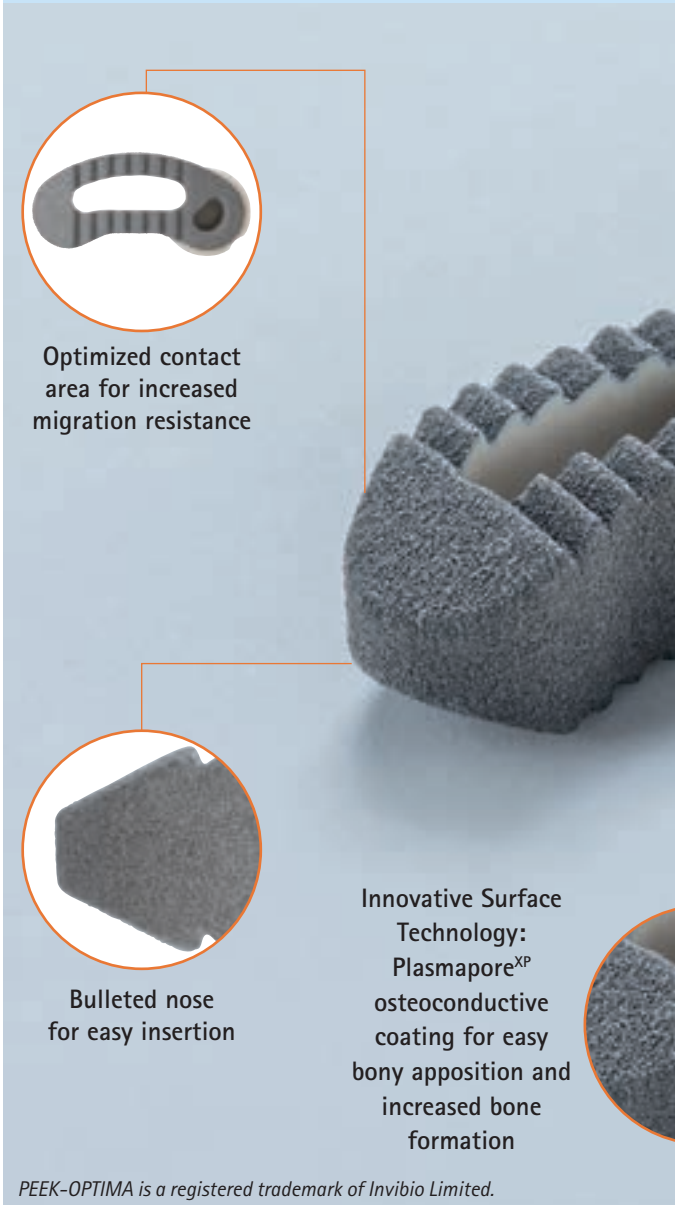
The operation should not be carried out against the following contraindications:

- Acute or chronic infections or severe defects of the osseous structures of the vertebral bodies, which need to be sound for the stable implantation of the PEEK devices
- Bone tumors in the region of the implant anchoring
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar bone density loss
- Systemic or metabolic illnesses
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Adiposity
- Psychosocial issues; lack of cooperation by the patient
- All cases that are not listed under indications

For a complete list of Warnings, Precautions and Risks, please visit our website at www.aesculapimplantsystems.com.

Features

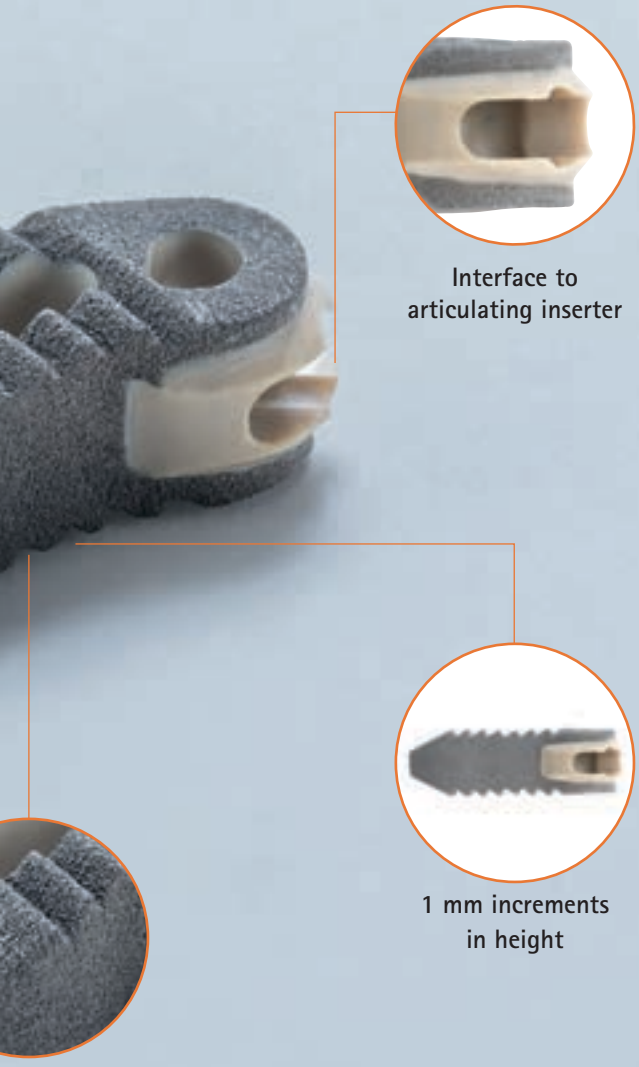
- Radiolucent PEEK-OPTIMA® core treated with osteoconductive PlasmaporeXP pure porous titanium
- Chamfered leading edge and aggressive teeth to resist migration



PEEK-OPTIMA is a registered trademark of Invibio Limited.

- Uniform curve-shaped width that follows the anatomical curvature of the end plate
- Tantalum markers for easy identification of implant orientation
- Inserter that allows for controlled articulation of implant within the disc space

> “At 24 weeks post-implantation, Plasmapore®XP treated implants have *nine times the pullout strength* compared to PEEK.”
>
> **– Cheng, Boyle. Biomechanical pullout strength and histology of Plasmapore®XP Coated Implants: Ovine multi time point survival study. Aesculap Implant Systems, Whitepaper, 2013 (ART129)**



Ordering Information

Implants are delivered sterile packed.

Set Numbers	
ST0622	TSpace®XP Instrument Set
ST0623	TSpaceXP Implant Set

Implant Bank Configuration

The TSpaceXP Implant Set has been optimized to include the following quantities of each implant footprint (Height x Length in mm):

Implant Bank Configuration (ST0623)				
Height	**Quantity**	**26**	**30**	**34**
7	2	S0907P	S0937P	S0967P
8	3	S0908P	S0938P	S0968P
9	3	S0909P	S0939P	S0969P
10	3	S0910P	S0940P	S0970P
11	3	S0911P	S0941P	S0971P
12	2	S0912P	S0942P	S0972P
13	2	S0913P	S0943P	S0973P
14	1	S0914P	S0944P	S0974P
15	1	S0915P	S0945P	S0975P
17	1	S0917P	S0947P	S0977P

*All implants come with 5° lordosis and 11.5 mm width

Lateral and AP View of three Tantalum X-Ray Markers:

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