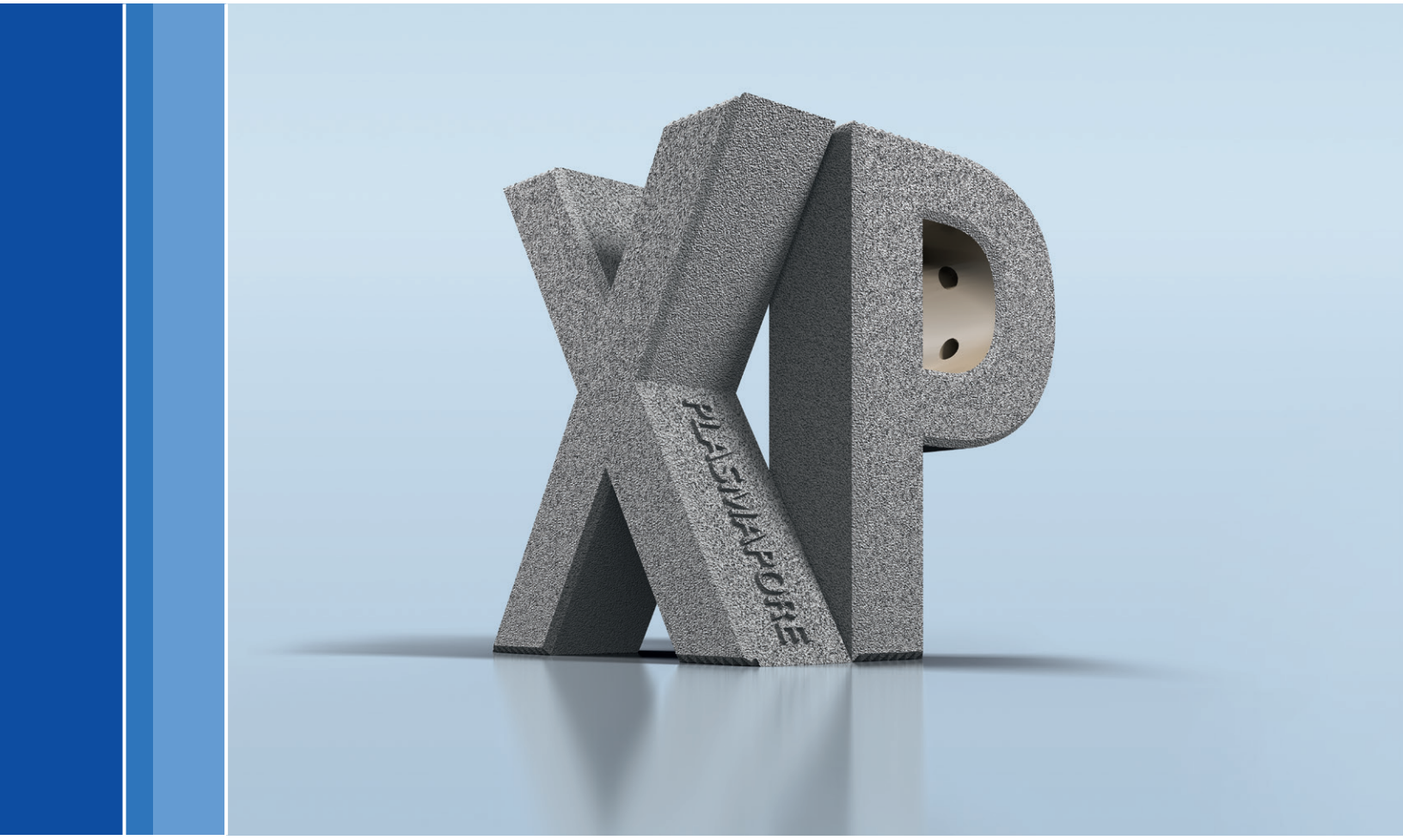
Plasmapore®XP Surface Enhancing Technology

Stability Starts on the Surface™

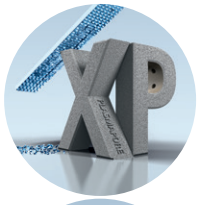


Aesculap Spine

AESCULAP®
Implant Systems

PLASMAPORE®XP

Stability Starts on the Surface™



1 Data on file, Aesculap AG.

2 Cheng, Boyle. Biomechanical pullout strength and histology of PlasmaporeXP Coated Implants: Ovine multi-time point survival study. Aesculap Implant Systems, Whitepaper. 2013

3 Chen, Y, Wang X, Lu X, Yang H, Yuan W, Chen D. Comparison of titanium and polyetheretherketone (PEEK) cages in the surgical treatment of multilevel cervical spondylotic myelopathy: A prospective, randomized, control study with over 7-year follow-up, Eur Spine J (2013) 22:1539-1546.

4 Aesculap AG, BTC Biological Test Center. Evaluation of the local and systemic reaction to a Plasmapore^{XP} coated implant in the distal femoral of a New Zealand white rabbit model. Final Report 2011.

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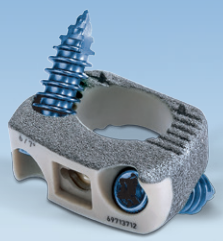
PEEK + TITANIUM

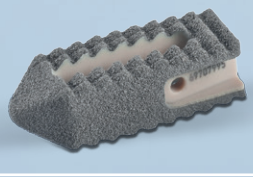


Arcadius®XP C

Arcadius®XP L

CeSpace™XP

TSpace®XP



ProSpace™XP

Built on eXPerience

Plasmapore^{XP} is the culmination of 20 years of innovation in spinal technology and 30 years of experience with porous titanium coatings. In 1986, Aesculap introduced the first Plasmapore® titanium coating on the BiContact™ hip prosthesis, and later in 1995, launched the first Plasmapore coated spinal fusion implant with Plasmapore technology – ProSpace.

eXPanding Possibilities

Aesculap's solid experience applying surface enhancing technology on titanium implants and results from over 20 clinical studies provided the foundation to explore new material compositions.[1,2] Combining the trusted Plasmapore surface with a PEEK-OPTIMA®[3] core was a big technical challenge undertaken to bring together the advantages of both technologies in a single product. The result was the launch of the first Plasmapore^{XP} interbody (titanium-coated PEEK-OPTIMA) in 2012.

As a forerunner in surface enhancing technology, Aesculap's proprietary application process coats the core of each Plasmapore^{XP} implant on the top, bottom and lateral surfaces with a pure titanium surface that is porous, osteoconductive and biocompatible.[2,3] Based on the global success of this surface enhancing technology, Aesculap has developed a full portfolio of Plasmapore^{XP} devices to address a variety of indications and approaches.

1 Data on file, Aesculap AG.

2 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.

3 Cheng B. Biomechanical pullout strength and histology of Plasmapore^{XP} Coated Implants: Ovine multi time point survival study. Aesculap Implant Systems, Whitepaper. 2013. (ART 129)

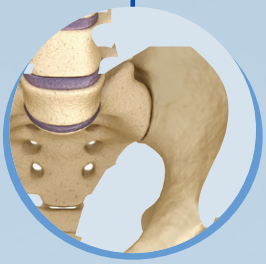
PEEK-OPTIMA is a registered trademark of Invibio Biomaterials Solutions.

The Evolution of Spinal Technology

Plasmapore®XP is the culmination of 20 years of innovation in spinal technology and 30 years of experience with porous titanium surface enhancements.

And, we're still innovating today.

1911

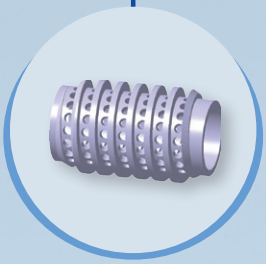


First spinal fusion performed using autograft

1986

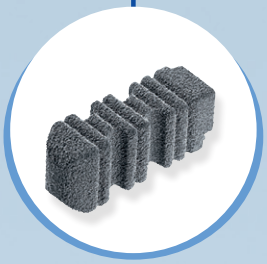
First application of Aesculap's Plasmapore® treatment done on BiContact™ Universal Hip System*

1988



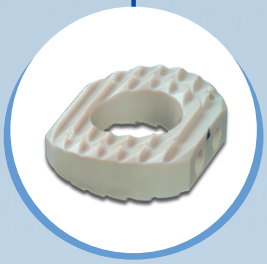
Titanium barrel cages developed to capitalize on high pull-out and strength

1995



Aesculap launches first Plasmapore treated spinal implant - ProSpace™ Titanium*

2005



Aesculap releases PEEK-OPTIMA® cages to **address subsidence of solid titanium cages** with a material that mimics the natural modulus of elasticity of bone

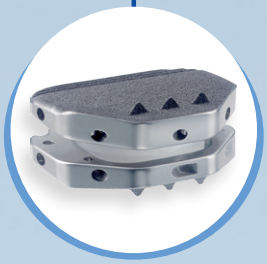
"I've used cementless hip implant components with Plasmapore Surface Technology for more than 25 years and still recommend them for my patients today."

– Professor Christoph Eingartner, M.D., Bad Mergentheim, Germany"

"I've relied on Plasmapore for primary and secondary stability for my ALIF patients since 2012."

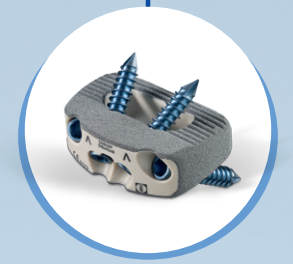
– Richard Guyer, MD, Plano, Texas

2005



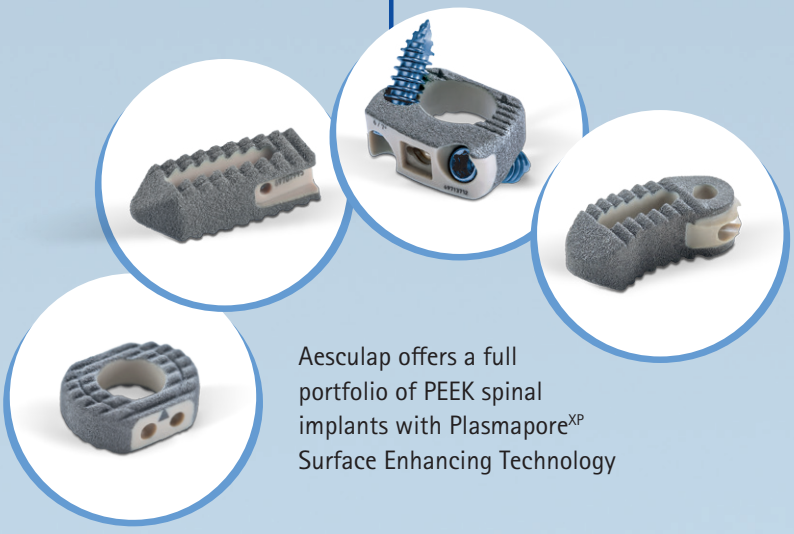
Aesculap designs Plasmapore µ-CaP treated activL® Artificial Disc and launches in Europe

2012



Aesculap launches first **Plasmapore**XP implant for the global market - Arcadius®XP L Spinal System

TODAY



Aesculap offers a full portfolio of PEEK spinal implants with Plasmapore XP Surface Enhancing Technology

#1 in eXPerience for more than 30 straight years.

**Not available in the U.S.*

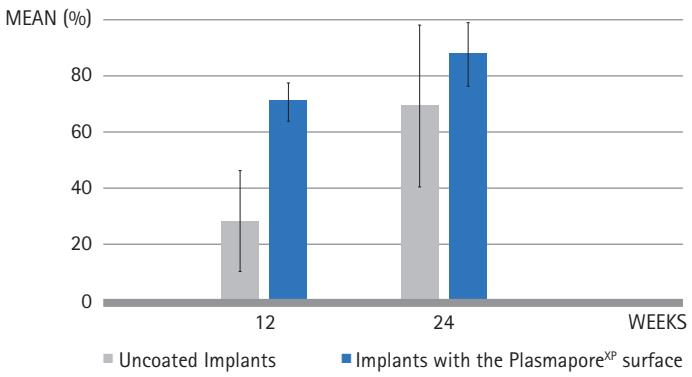
APPOSITION

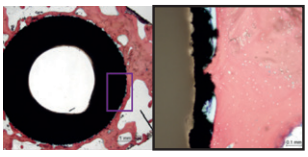
Osteoconductive surface properties provide high secondary stability[1,2,3]

Falls within the ideal range of porosity and pore size for bone ingrowth[4]

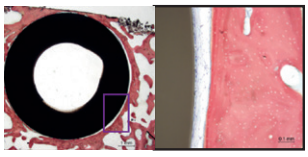
The unique, biocompatible surface of the Plasmapore®XP implant reduces the fibrous tissue response, creating an osteoconductive environment that leads to early and long-term stability. In a sheep study, there was significantly greater boney apposition into the PlasmaporeXP enhanced interbody when compared to uncoated PEEK at 12 weeks (p=0.002).[1]

Percentage of bone apposition by time and implant type.[1]





Implant with the PlasmaporeXP surface



Uncoated PEEK implant

The histological data shows significant bone ingrowth and adhesion with the implants with the PlasmaporeXP surface after 24 weeks. In comparison, increased fibrous tissue was observed at the contact points of the uncoated PEEK implants.[1]

1 Cheng B. Biomechanical pullout strength and histology of PlasmaporeXP Coated Implants: Ovine multi time point survival study. Aesculap Implant Systems, Whitepaper. 2013. (ART 129)

2 Chen, Y, Wang X, Lu X, Yang H, Yuan W, Chen D. Comparison of titanium and polyetheretherketone (PEEK) cages in the surgical treatment of multilevel cervical spondylotic myelopathy: A prospective, randomized, control study with over 7-year follow-up, Eur Spine J (2013) 22:1539-1546.

3 Aesculap AG, BTC Biological Test Center. Evaluation of the local and systemic reaction to a Plasmapore XP coated implant in the distal femora1 of a New Zealand white rabbit model. Final Report 2011.

4 Klawitter J. An evaluation of bone growth into porous high density polyethylene. Journal of Biomedical Materials Research. 1976;10(2):311-323.

S T R E N G T H

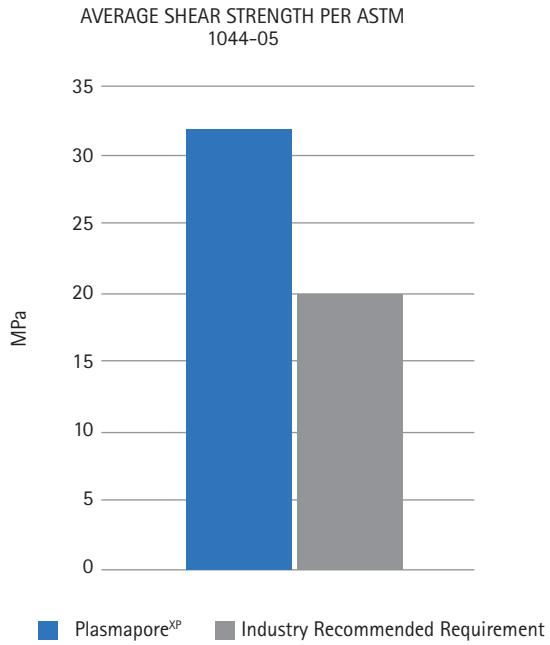
Demonstrated delamination-resistant surface with a shear force exceeding that of PEEK[1,2]

Studied in over 1,050 patients with no reported incidence of delamination in any peer-reviewed publication[1]

Plasmapore®XP Surface Enhancing Technology has proven adhesion strength to the radiolucent PEEK core. Mechanical testing was performed according to recognized industry standards to evaluate this adhesion strength. The tensile strength and static shear strength results for the PlasmaporeXP coating were substantially higher than these industry requirements.[1]

Aesculap's proven clinical experience and proprietary surface enhancement process means surgeons can implant PlasmaporeXP devices and be confident in the integrity of the surface. In fact, the adhesion strength of the coating is so strong, the PEEK implant will actually fracture before the PlasmaporeXP delaminates.

Comparison of mean shear strength of PlasmaporeXP treated samples to the industry recommended requirement



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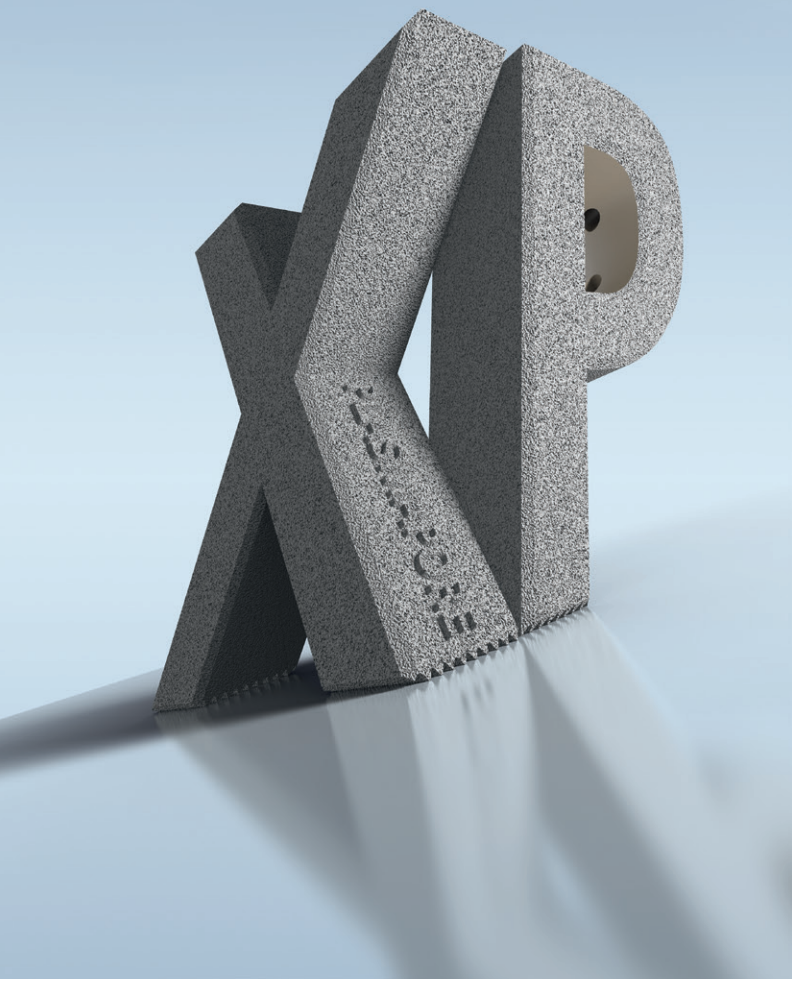
S T A B I L I T Y

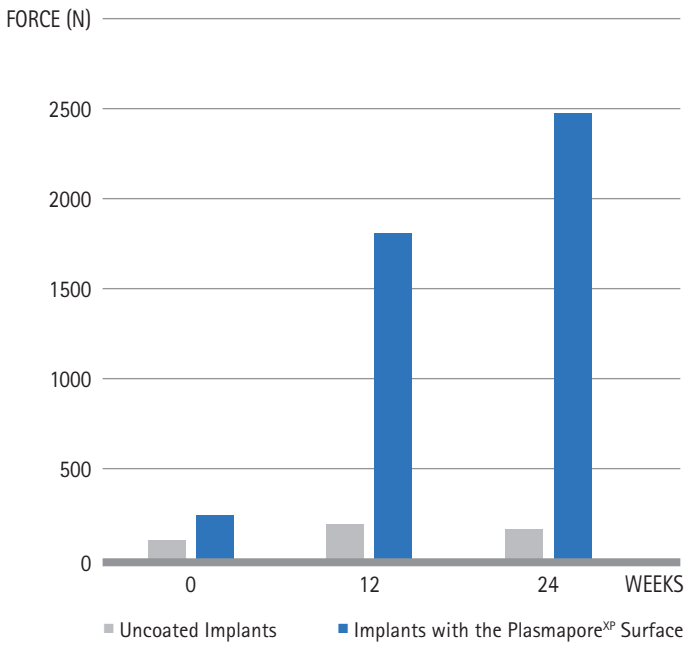
Optimized surface structure for high initial stability and long-term migration resistance[1]



Unique titanium surface enhancing technology extends the surface area, providing a biomechanical advantage[1]

A sheep study demonstrated six times greater pull-out strength at 12 weeks post-implantation and nine times greater pull-out strength at 24 weeks post-implantation with Plasmapore®XP devices in comparison to uncoated PEEK.[2]

Biomechanical pullout strength and histology of implants with Plasmapore^{XP} surface[2]



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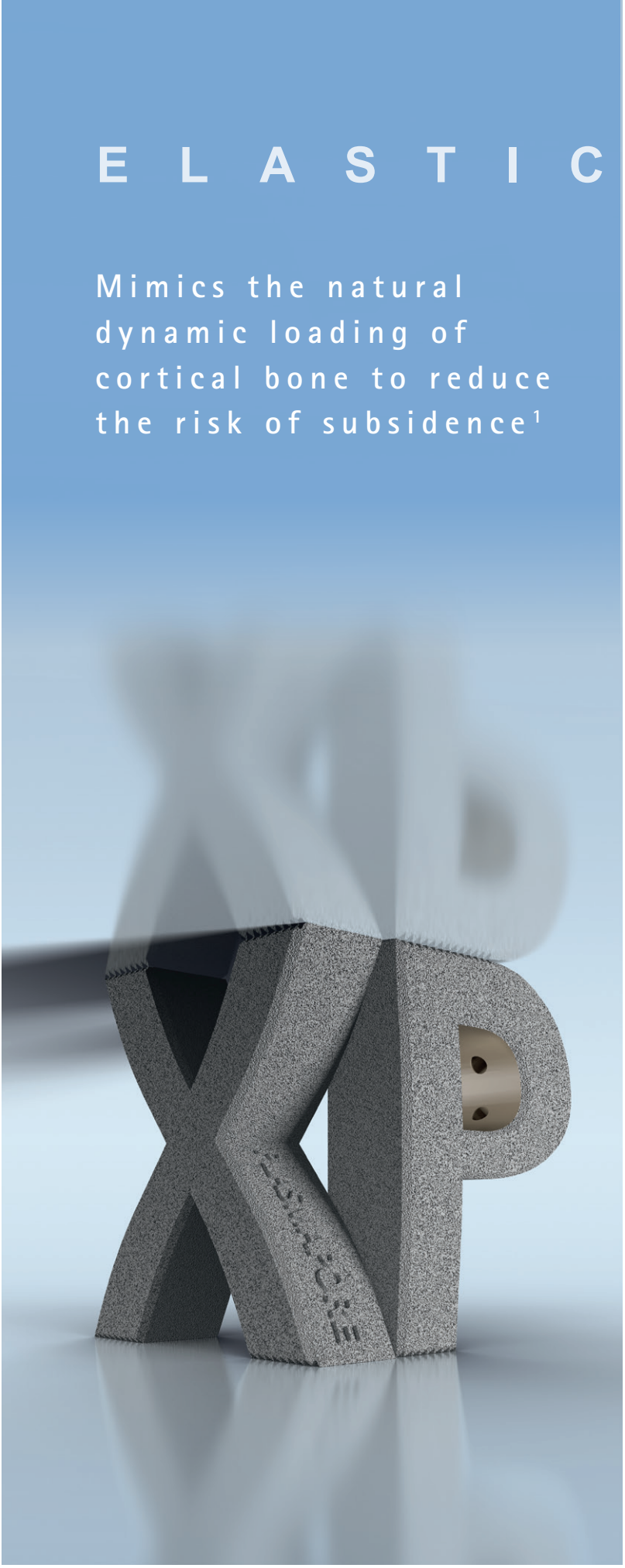
ELASTICITY

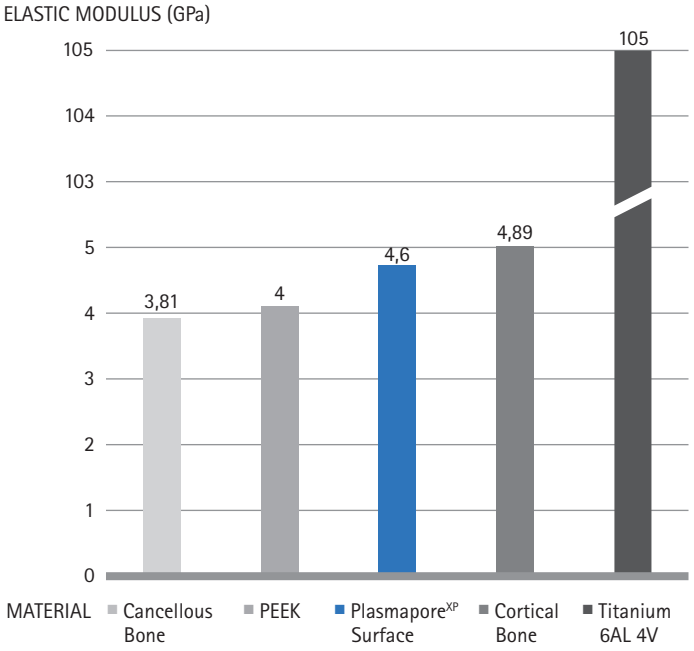
Mimics the natural dynamic loading of cortical bone to reduce the risk of subsidence[1]



The ideal balance of PEEK and Plasmapore®XP maintains the modulus of elasticity necessary to prevent stress shielding which causes a reduction in bone density[2,3,4]

The PEEK-OPTIMA® core gives Plasmapore^{XP} implants a low modulus of elasticity that is close to that of cortical bone.[3] A low modulus of elasticity means that Plasmapore^{XP} implants can be dynamically loaded, allowing the newly formed bone to remain strong. Conversely, implants with a high modulus of elasticity—such as solid titanium interbodies—have an increased chance of subsidence.[1]

The modulus of elasticity of implants with the Plasmapore^{XP} surface is close to the modulus of elasticity of cortical and cancellous bone.



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2 Kuhn JL, Goldstein SA, Choi K, London M, Feldkamp LA, Matthews LS. Comparison of the trabecular and cortical tissue moduli from human iliac crests. J Orthop Res. 1989;7(6):876-84.

3 Invibio® Biomaterial Solutions. PEEK-OPTIMA® Natural Typical Material Properties. www.invibio.com (10/2013).

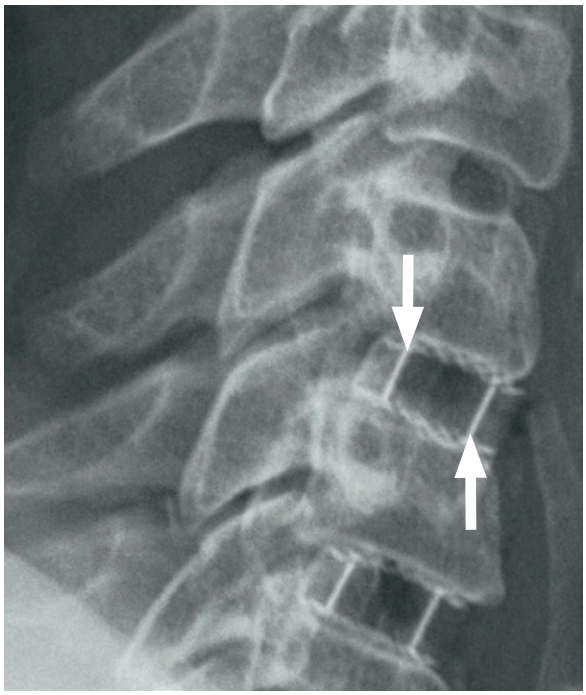
4 Ratner BD, Hoffmann AS, Schoen FJ, Lemons JE. An Introduction to Materials in Medicine. Academic Press. 1996.

VISUALIZATION

Radiolucent PEEK-OPTIMA® core allows for clearly defined intra- and postoperative imaging

Intraoperative implant margin definition and X-ray pins allow for optimal placement of the interbody

All surface-enhanced Plasmapore®XP implants have excellent imaging properties due to the radiolucent PEEK-OPTIMA core. The optimized Plasmapore™XP surface thickness means implant contours can be clearly seen in X-rays, with low artifact formation in CT and MRI scans.



Radiograph of CeSpace™XP: X-ray markers are integrated into all Plasmapore™XP implants for additional intra- and post-operative support.

THE PLASMAPORE®XP SURFACE ENHANCING TECHNOLOGY PORTFOLIO

The Plasmapore^{XP} portfolio includes cervical and lumbar interbodies for multiple approaches.

In addition to the outstanding properties resulting from the combination of the Plasmapore^{XP} and a PEEK-OPTIMA® core, each of the products also offers:

- Anatomical implant design maximizing Plasmapore^{XP} surface area to increase opportunity for bone apposition
- Sophisticated instrumentation to streamline procedural steps
- Comprehensive sizes and configurations to provide individualized patient care

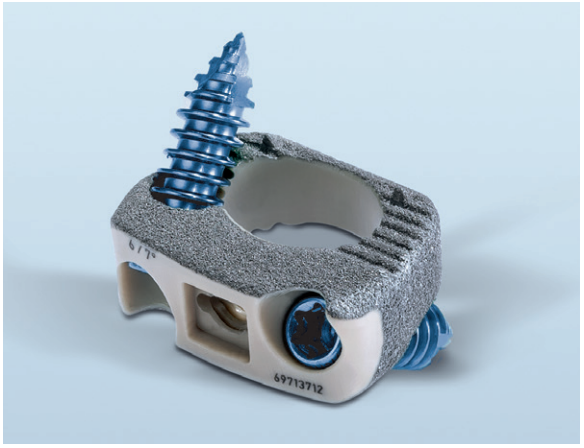
THE CHOICE OF EXPERTS

CeSpace™XP Cervical Interbody System

For anterior cervical fusion with Plasmapore®XP

KEY FEATURES

- Anatomical shape and serrated profile for a well-adapted implant fit
- Increased ratio between contact area and opening
- Option of filling with bone or bone substitute to enhance bone bridging
- Clearly arranged instrument set with simple handling

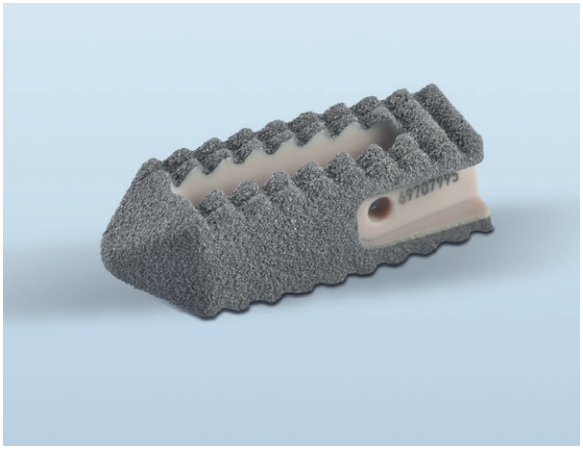


Arcadius®XP C Stand-Alone Interbody System

For anterior cervical fusion with Plasmapore^XP

KEY FEATURES

- Stand-alone system avoids supplementary fixation
- Zero-Profile design
- Dual locking mechanism with single step activation
- Integrated posterior spikes that double as X-ray markers

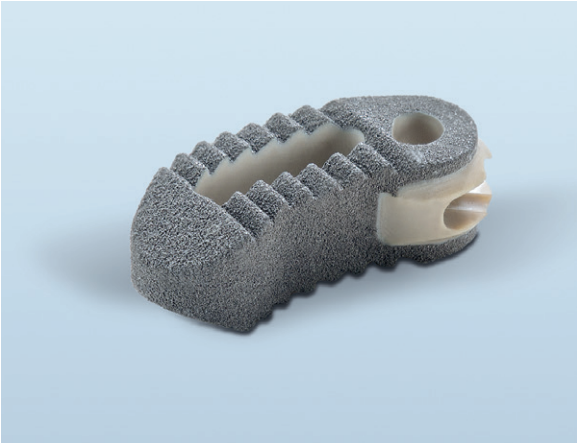


ProSpace™XP Interbody System

For posterior lumbar interbody fusion (PLIF) with Plasmapore^XP

KEY FEATURES

- Bulleted nose for easier implantation, especially in strongly degenerated segments
- Clamping mechanism with undercut for easy connection with the inserter
- Wide range of sizes to accommodate different anatomies, i.e., 1 mm increments in height
- Enhanced ratio between contact area and opening



TSpace® XP Interbody System

For transforaminal lumbar interbody fusion (TLIF) with Plasmapore®XP

KEY FEATURES

- Intelligent implant design with bullet-shaped nose for easier implantation
- Intuitive articulating interbody inserter for easy positioning
- A wide variety of sizes to better suit patient anatomies
- Increased ratio between contact area and opening

Arcadius®XP L Stand-Alone Interbody System

For anterior lumbar fusion with Plasmapore®XP

KEY FEATURES

- Surface texturing
- Midline accessibility for screw insertion
- Diverging screw design
- Dual locking mechanism
- Self-centering, self-drilling and self-tapping bone screws
- New compression screw to maximize contact between the implant and the vertebral endplate

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