Plasmapore®XP Surface Enhancing Technology

Stability Starts on the Surface™
Since 1986, Plasmapore surface technology has been implanted in more than a half million patients.\(^1\)

**APPOSITION**
Osteoconductive surface properties provide high secondary stability.\(^2,3,4\)

**STRENGTH**
Demonstrated delamination-resistant surface with a shear force exceeding that of PEEK.\(^1,5\)

**STABILITY**
Optimized surface structure for high initial stability and long-term migration resistance.\(^2\)

**ELASTICITY**
Mimics the natural dynamic loading of cortical bone to reduce the risk of subsidence.\(^3\)

**VISUALIZATION**
Radiolucent PEEK-OPTIMA\(^®\) core allows for clearly defined intra- and post-operative imaging.\(^10\)

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1 Data on file, Aesculap AG.
4 Aesculap AG, BTC Biological Test Center. Evaluation of the local and systemic reaction to a Plasmapore\(^®\) coated implant in the distal femoral of a New Zealand white rabbit model. Final Report 2011.
Built on eXperience

Plasmapore® 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® 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® 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® 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® devices to address a variety of indications and approaches.

1 Data on file, Aesculap AG.

PEEK-OPTIMA is a registered trademark of Invibio Biomaterials Solutions.
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.
Aesculap designs Plasmapore μ-CaP treated activL® Artificial Disc and launches in Europe

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

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

#1 in eXPerience for more than 30 straight years.

"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

*Not available in the U.S.
Osteoconductive surface properties provide high secondary stability\textsuperscript{1,2,3}

The unique, biocompatible surface of the Plasmapore\textsuperscript{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 Plasmapore\textsuperscript{XP} enhanced interbody when compared to uncoated PEEK at 12 weeks (p=0.002).\textsuperscript{1}

![Percentage of bone apposition by time and implant type.](image)

The histological data shows significant bone ingrowth and adhesion with the implants with the Plasmapore\textsuperscript{XP} surface after 24 weeks. In comparison, increased fibrous tissue was observed at the contact points of the uncoated PEEK implants.\textsuperscript{1}

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


\textsuperscript{3} Aesculap AG, BTC Biological Test Center. Evaluation of the local and systemic reaction to a Plasmapore XP coated implant in the distal femur\textsuperscript{1} of a New Zealand white rabbit model. Final Report 2011.

Demonstrated delamination-resistant surface with a shear force exceeding that of PEEK\textsuperscript{1,2}

Studied in over 1,050 patients with no reported incidence of delamination in any peer-reviewed publication\textsuperscript{1}

Plasmapore\textsuperscript{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 Plasmapore\textsuperscript{XP} coating were substantially higher than these industry requirements\textsuperscript{1}.

Aesculap’s proven clinical experience and proprietary surface enhancement process means surgeons can implant Plasmapore\textsuperscript{XP} 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 Plasmapore\textsuperscript{XP} delaminates.

Comparison of mean shear strength of Plasmapore\textsuperscript{XP} treated samples to the industry recommended requirement

1 Data on file, Aesculap AG.
Optimized surface structure for high initial stability and long-term migration resistance¹

Unique titanium surface enhancing technology extends the surface area, providing a biomechanical advantage²

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

¹ Data on file, Aesculap AG.
The ideal balance of PEEK and Plasmapore\textsuperscript{XP} maintains the modulus of elasticity necessary to prevent stress shielding which causes a reduction in bone density\textsuperscript{2,3,4}. The PEEK-OPTIMA\textsuperscript{®} core gives Plasmapore\textsuperscript{XP} implants a low modulus of elasticity that is close to that of cortical bone.\textsuperscript{3} A low modulus of elasticity means that Plasmapore\textsuperscript{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.\textsuperscript{1}

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

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3 Invibio\textsuperscript{®} Biomaterial Solutions. PEEK-OPTIMA\textsuperscript{®} Natural Typical Material Properties. www.invibio.com (10/2013).
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™ implants for additional intra- and post-operative support.
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
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®

**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
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

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