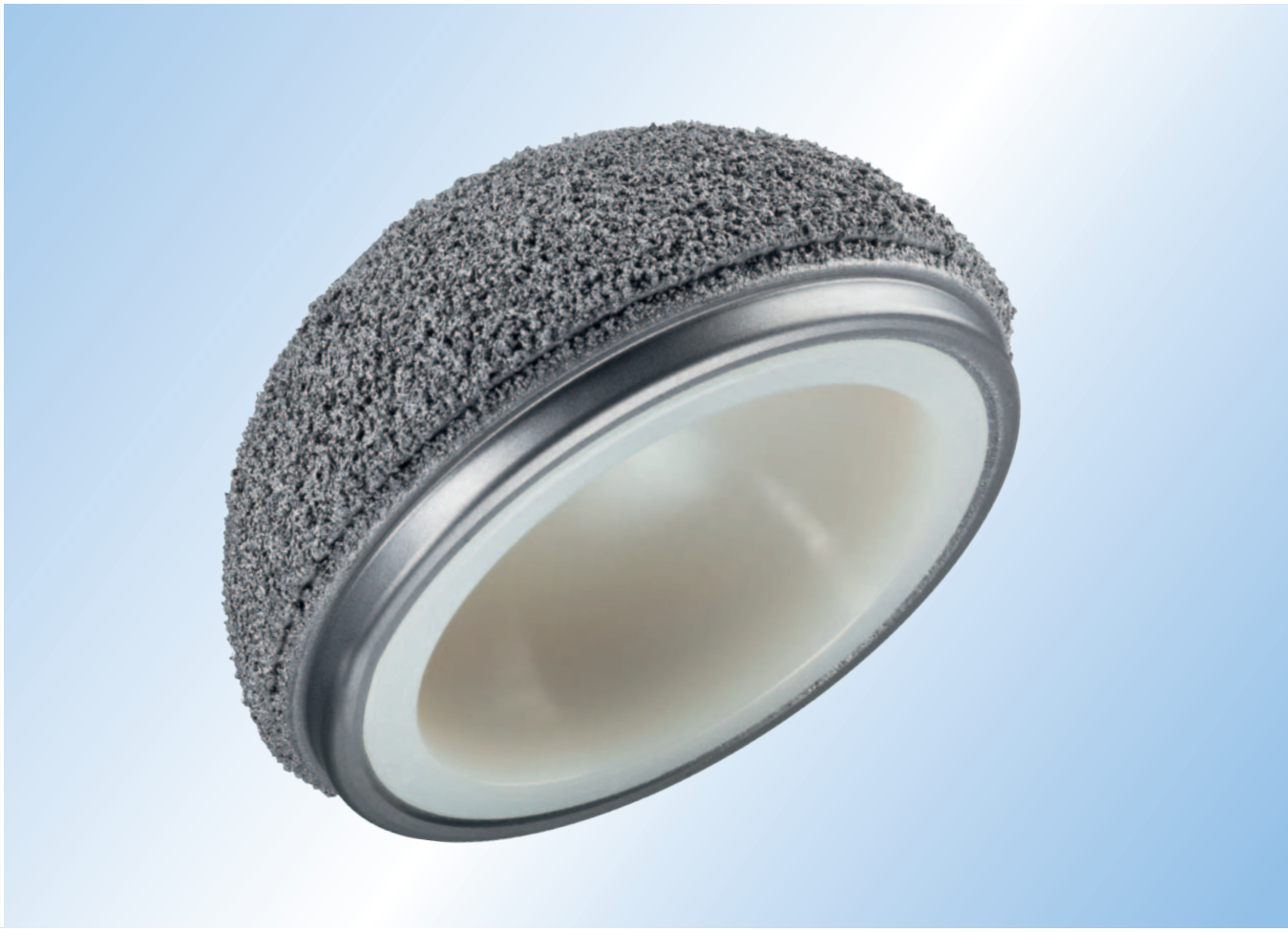
Plasmafit™ PRO Acetabular System with Vitelene™ Liner

Feel the Fit



Aesculap Orthopaedics

AESCULAP®
Implant Systems

Plasmafit™ Pro Acetabular System with Vitelene™ Liner

The Plasmafit™ Pro Acetabular System with Vitelene™ liner represents a new approach for stability and performance when used in conjunction with a prosthetic femoral head and hip stem as treatment for total hip arthroplasty.

The System: The two-piece system consists of a cementless titanium acetabular shell and a highly crosslinked ultra-high molecular weight polyethylene (UHMWPE) vitamin E blended liner.

The Stability: The hemispherical and slightly flattened design of the titanium cup along with a rough titanium plasma spray on the outer surface, provides a high level of primary stability.

The Integrity: The vitamin E blended polyethylene liner provides a bearing surface with oxidative stability that maintains mechanical properties and resists wear.

FEEL THE FIT

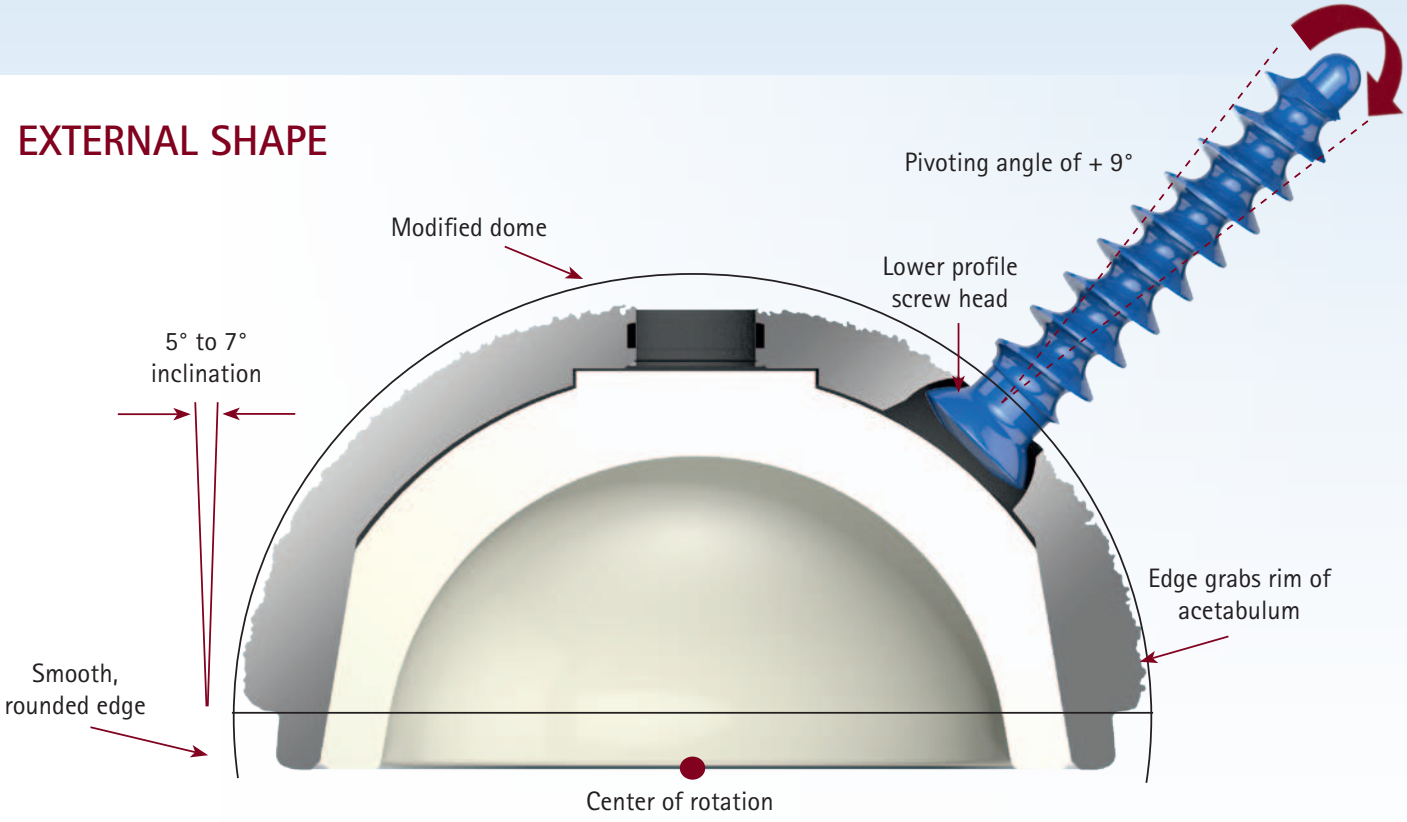
of the Plasmafit Pro Acetabular System

Smooth, rounded edge for a low-profile design that does not interfere with the seating of the liner within the shell. This design also helps prevent impingement and protects soft tissues which can be irritated during movement.

Feel the Fit

The Plasmafit™ Pro acetabular cup design features a modified dome shape for exceptional anchoring, providing immediate grip-feel during implantation. The equatorial pressfit design grabs the rim of the acetabulum, directing stress forces at the pelvic rim not the medial wall.

EXTERNAL SHAPE



Equatorial pressfit directs forces to the rim for RELIABLE stability.

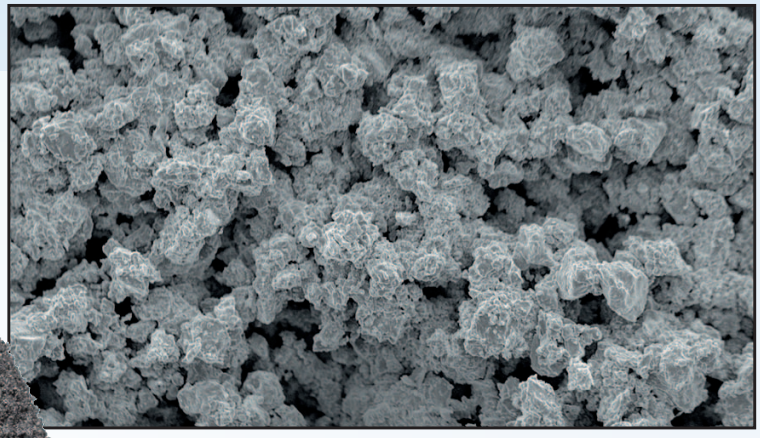
- Reduced potential for mal-alignment since overstuffing the socket is avoided.
- Improved stability due to secure pressfit at rim to minimize chance of movement when seated in the socket.

FEEL THE grip

Plasmafit™ PRO Acetabular System with Vitelene™ Liner

The Plasmafit Pro acetabular shell promotes strong primary stability as well as long-term implant fixation.

ENHANCED SURFACE



Coated with a titanium porous plasma spray designed to allow biologic fixation between bone and prosthesis for LONG-TERM SURVIVORSHIP.

- Rough, titanium porous plasma spray coating provides primary implant stability via the high coefficient of friction against bone.
- The load-bearing structure prevents migration of the implant and supports rotational stability.
- Secondary implant stability is reinforced by the structure of the coating: direct bone apposition on an increased implant surface for long-term fixation.

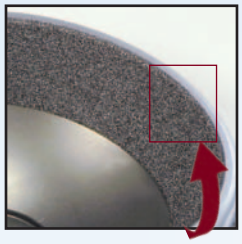
Aesculap has been manufacturing
fixation combined with the grit

FEEL THE
stability

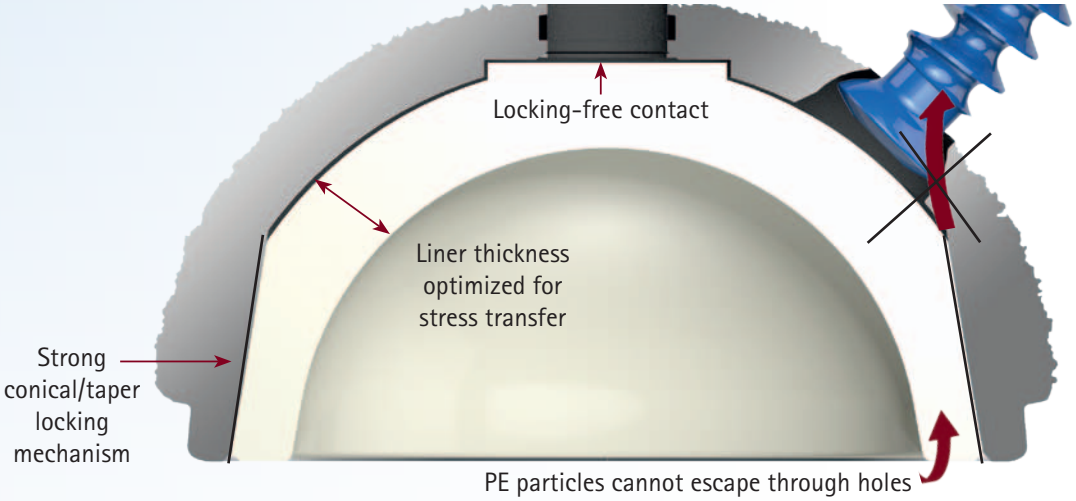
Feel the Fit

The Plasmafit™ Pro acetabular cup system design provides a strong interlock between the shell and liner that restricts micro-movement and reduces the risk of osteolysis.

INTERNAL DESIGN



grit-blasted surface minimizes movement of liner



SECURE fixation of the liner facilitates a high stability against tilting and rotational forces in vivo.

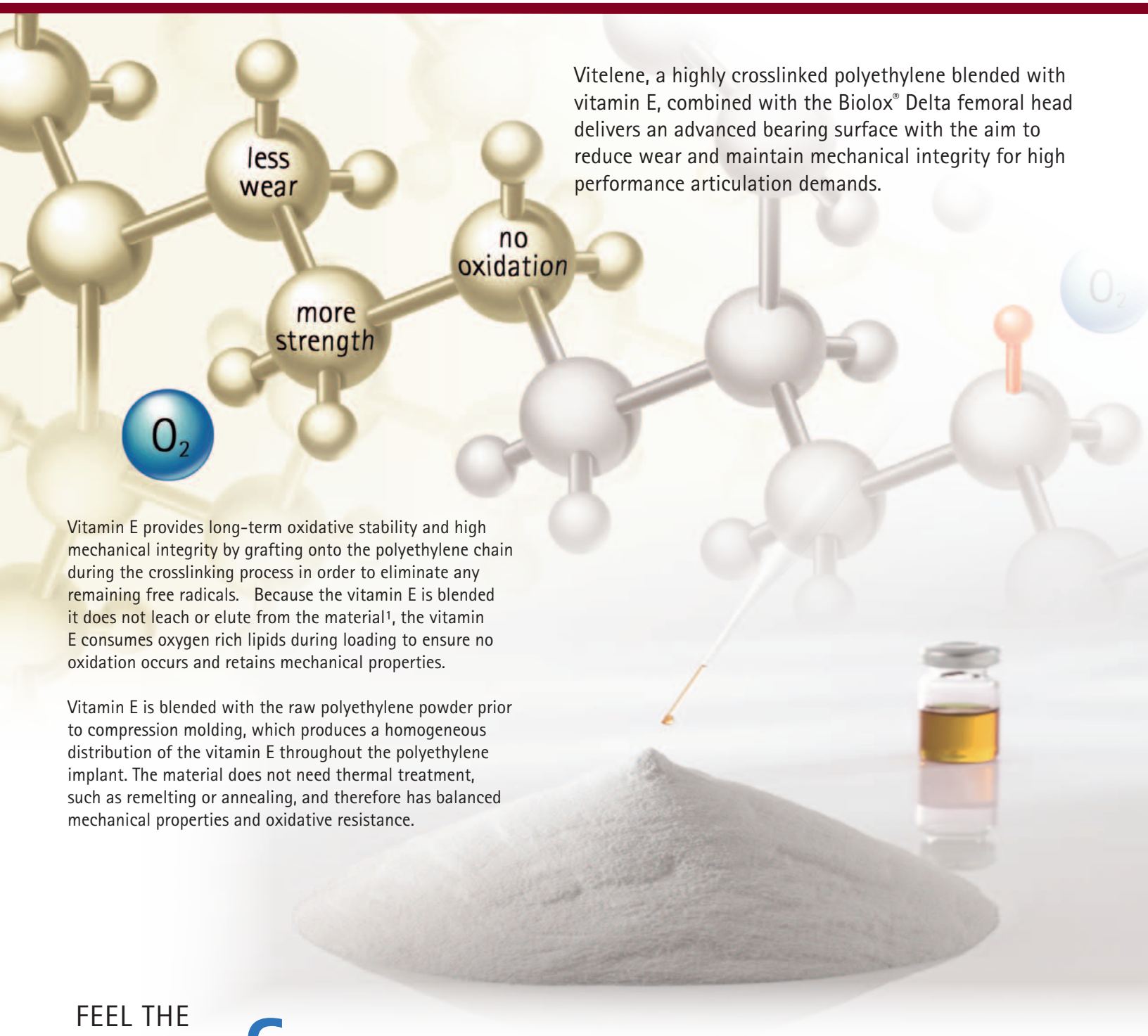
- Taper locking mechanism stabilizes the liner, requiring a precise fit of the liner within the cup.
- Lock-free contact with the base of the shell reduces mal-alignment of the liner, facilitating a fully congruent seating of the liner.
- Roughened, grit-blast inner surface resists motion between the liner and the shell to eliminate debris generation.

The combination of the grit blast inner surface and taper locking mechanism form a strong fixation of the liner within the shell. This fixation not only restricts relative micro-movement during transmission of forces, but also forms a seal against the migration of polyethylene particles from the articulating joint, thereby reducing the risk of osteolysis adjacent to the screw holes. This fixation is highly stable against tilting and rotational forces in vivo.

implants using the safe taper
blast inner surface since 1997.

FEEL THE
strength

Plasmafit™ PRO Acetabular System with Vitelene™ Liner



Vitelene, a highly crosslinked polyethylene blended with vitamin E, combined with the Biolox® Delta femoral head delivers an advanced bearing surface with the aim to reduce wear and maintain mechanical integrity for high performance articulation demands.

Vitamin E provides long-term oxidative stability and high mechanical integrity by grafting onto the polyethylene chain during the crosslinking process in order to eliminate any remaining free radicals. Because the vitamin E is blended it does not leach or elute from the material[1], the vitamin E consumes oxygen rich lipids during loading to ensure no oxidation occurs and retains mechanical properties.

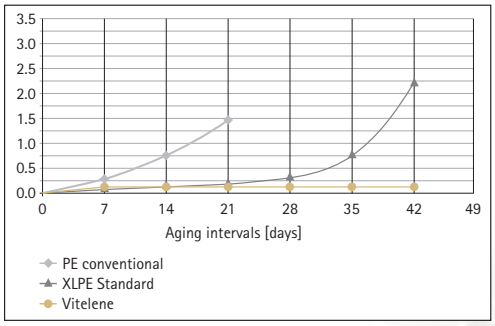
Vitamin E is blended with the raw polyethylene powder prior to compression molding, which produces a homogeneous distribution of the vitamin E throughout the polyethylene implant. The material does not need thermal treatment, such as remelting or annealing, and therefore has balanced mechanical properties and oxidative resistance.

FEEL THE
performance

[1] Data on file.

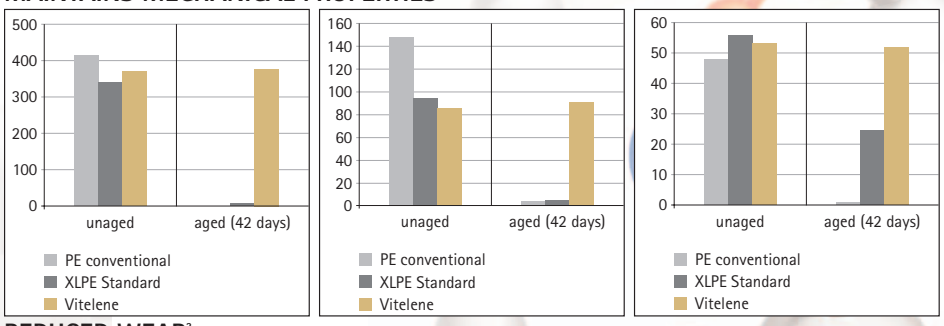
Feel the Fit

ANTIOXIDANT DEFENSE[1]



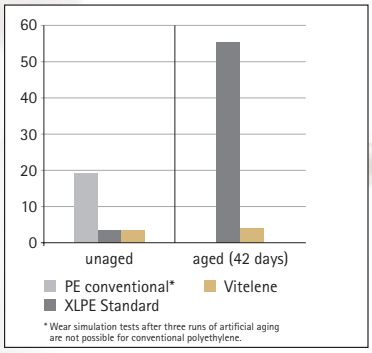
Vitelene™ is formulated with antioxidant protection that prevents oxidation and degradation of polyethylene, displaying no measurable oxidation during accelerated aging testing per ASTM F2003.

MAINTAINS MECHANICAL PROPERTIES[1]



Vitelene retains mechanical strength after accelerated aging per ASTM F2003.[1]

REDUCED WEAR[2]



Vitelene showed an 89% reduction in wear compared to conventional polyethylene after accelerated aging testing per ASTM F2003.[2]

Disclaimers:

[1] Bench testing is not necessarily indicative of clinical performance. Data on file.

[2] The results of in vitro hip wear simulator tests have not been shown to quantitatively predict clinical wear performance. Data on file.

INDICATIONS FOR USE

The Plasmafit™ Pro Acetabular Cup System and Vitelene Insert are intended to replace a hip joint.

The device is intended for:

1. Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur
2. Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral ephiphysis
3. Patients suffering from disability due to previous fusion
4. Patients with acute femoral neck fractures

The Plasmafit Pro acetabular cup and Vitelene insert are intended for cementless applications.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Presence of fever, infection or inflammation (systemic or localized)
2. Morbid obesity
3. Pregnancy
4. Mental illness or drug abuse
6. Severe osteopenia (or any medical or surgical condition) which would preclude potential benefits of implants
7. Suspected or documented metal allergy or intolerance
8. Mixing of implant components from other manufacturers
9. Any case not listed in the indications
10. Patients unwilling or unable to follow postoperative are instructions
11. Skeletal immaturity

Please refer to the instructions for use for important product information, including warnings, precautions, and possible adverse effects.

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