PLASMAFIT PRO ACETABULAR CUP SYSTEM AND VITELENE INSERT

**CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.**

**INDICATIONS FOR USE**

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

- 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
- Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

Plasmafit Pro Acetabular Cup System and Vitelene Insert are intended for cementless applications.

**WARNING:** Only Ti plasma sprayed components should be implanted without cement. All other devices are designed for use with bone cement.

**DEVICE DESCRIPTION**

Aesculap Plasmafit Pro Acetabular Cup System is a modular hip prostheses system intended to be used in conjunction with a prosthetic femoral head and hip stem in total hip arthroplasty. The system consists of a cementless titanium acetabular cup and a highly crosslinked (β-75 kGy) ultra-high molecular weight polyethylene (UHMW-PE) vitamin E insert. Vitelene is available in three similar designs that are either symmetrical, asymmetrical or posterior wall, each designed with a taper-fit to the interior surface of Plasmafit Pro cups. The hemispherical titanium cup with a slightly flattened dome is coated with a titanium plasma spray on the outer surface which aims to provide a high level of primary stability with its rough finish. Plasmafit Pro cups are available in three (3) similar designs only varying in the number of holes (0, 3, 5/7) around the apex. The number of holes are adapted for optional titanium alloy anchoring screws that may be used to ensure primary stability. Anchoring screws are offered in sizes 16mm-68mm.

The vitamin E insert has been shown to be more resistant to oxidation than conventional UHMWPE. Characterization of the oxidation indices of aged (ASTM F2003) and un-aged Vitelene measured according to ISO 5834-4 did not decrease. Further, Vitelene remains resistant to oxidation after 5 million cycles of wear as demonstrated in testing performed in accordance to ISO 14242-1 and ISO 1424-2.

Plasmafit Pro Acetabular Cup System and Vitelene insert are compatible with cleared Aesculap Hip Implant Systems Plasmafit Pro Acetabular Cup System and Vitelene Insert, Metha, Prevision, and Unisyn and the following cleared Aesculap ceramic femoral heads: Biolox® Option, Biolox® Forte, Biolox® Delta, and Aesculap CoCrMo femoral heads to offer several interoperative implant options taking into consideration different patient bone conditions.

Ceramic heads are to be used only with uncemented, titanium alloy stems. The ceramic heads should NOT be used with the CoCrMo cemented stems. CoCrMo heads can be used with either cemented or uncemented stems.

Femoral heads are available with an 8/10 and 12/14 internal bore in various sizes and dimensions.
Plasmafit Pro cups are available in sizes ranging from 40mm – 70mm, thus Aesculap BioLOX® Delta and ISODUR® (CoCrMo) 40mm ball heads are also offered.

Further details on implantation of compatible Aesculap femoral heads and femoral components can be found in their respective Manuals.

**MATERIAL**

Plasmafit Pro Acetabular cups are manufactured from a Titanium alloy (ISO 5832-3). The outer surface of the cups is coated with Titanium plasma spray (ISO 5832-3).

Vitelene insert is an ultra-high molecular weight polyethylene (UHMW-PE) blended with 1000 ppm (0.1% w/w) alpha-tocopherol (Vitamin E). The finished homogenous product conforms to ISO 5834-2.

Further details on materials of compatible Aesculap femoral heads and femoral components can be found in their respective Manuals.

The specialized instruments are made primarily of surgical grade stainless steel (ISO 7153-1).

**HOW SUPPLIED**

Plasmafit Pro Acetabular Cup System and Vitelene Insert implants are provided **sterile**. The instruments are provided **non-sterile** and must be cleaned and sterilized prior to use according to the procedures outlined in this document.

**CONTRAINDICATIONS**

Contraindications include, but are not limited to:

- presence of fever, infection or inflammation (systemic or localized);
- morbid obesity;
- pregnancy;
- mental illness or drug abuse;
- severe osteopenia (or any medical or surgical condition) which would preclude potential benefits of implants;
- suspected or documented metal allergy or intolerance;
- mixing of implant components from other manufacturers;
- any case not listed in the indications;
- patients unwilling or unable to follow postoperative instructions;
- skeletal immaturity

**WARNINGS and POTENTIAL RISKS**

The Plasmafit Pro Acetabular Cup System and Vitelene Insert implants are designed for **single patient use only and must never be reused**. As with all other orthopedic implants, the Plasmafit Pro Acetabular Cup System and Vitelene Insert components should never be re-implanted under any circumstances.

The mixing of different manufacturer implant components is not recommended due to metallurgical, mechanical and functional reasons. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Do not use implants or instruments from other systems or manufacturers.

Aesculap ceramic heads should only be used with the Ti plasma sprayed femoral stem.
The Plasmfit Pro Acetabular Cup System and Vitelene Insert implants can become loose or break if subjected to increased loading. Factors such as the patient’s weight, activity level and adherence to weight-bearing or load-bearing instructions can affect the implant’s longevity. Damage to the weight-bearing bone cement and/or bone structures caused by infection can give rise to loosening of the components and/or fracture of the bone.

The Plasmfit Pro Acetabular Cup System and Vitelene Insert implants have not been evaluated for safety and compatibility in the MR environment. The Plasmfit Pro Acetabular Cup System and Vitelene Insert implants have not been tested for heating or migration in the MR environment.

These warnings do not include all adverse effects which could occur with surgery, but are important considerations specific to metallic devices. The risks associated with orthopedic surgery, general surgery and the use of general anesthesia should be explained to the patient prior to surgery. See the PRECAUTIONS and POSSIBLE ADVERSE EFFECTS sections for additional warnings.

**PRECAUTIONS**

In order to minimize the risks of dislocation and loosening of the shell-acetabular bone or shell-bone cement interface that may occur when using a metallic shell intended for biological fixation or cemented use only, surgeons should consider providing immediate resistance to tensile forces between the metallic shell and the acetabular bone or bone cement interface through the use of orthopedic bone fixation devices such as bone screws, spikes, screw threads, fins, or other bone fixation devices.

To correctly position the metallic locking ring, surgeons should consult the manufacturer’s instructions for appropriate device assembly. Physicians should consider component malposition, component placement, and the effect on range of motion when using modular heads (with sleeves or skirts) and extended liners.

The Plasmfit Pro Acetabular Cup System and Vitelene Insert’s intended to be used by surgeons specializing in orthopedic surgery who have a thorough knowledge of hip arthroplasty, joint morphology and the biomechanical principles of the hip.

Pre-operative assessment of the suitability of the patient’s anatomy for accepting implants is made on the basis of x-rays, CT scans and other radiological studies.

Only patients that meet the criteria described in the Indications for Use section should be selected.

**Correct selection of the implant is extremely important.** The morbidity as well as patient weight height, occupation and/or degree of physical activity should be considered.

**Proper implant handling before and during the operation is crucial.** Handle the implant components properly. Ensure packaging integrity for implant sterility. Do not use any implant where the packaging has been breached. Do not resterilize an implant. Do not allow the implants surfaces to be damaged.

**Adequately instruct the patient.** The physician should inform the patient about hip implant advantages and disadvantages, post-operative limitations, weight/load bearing stresses which could affect bone healing, implant limitations, and the fact that premature physical activity and full weight/load bearing stresses have been implicated in premature loosening, damage and/or fracture of hip prostheses.
POSSIBLE ADVERSE EFFECTS
Pre-operatively, the patient should be made aware of the possible adverse effects of orthopedic surgery. Additional surgery may be necessary to correct some of these anticipated events including, but not limited to:

• Early or late loosening, disassembly and/or breakage of any or all implants;
• Metal sensitivity to a foreign body (implant material allergic reaction), including metallosis, staining, tumor formation, auto-immune disease and/or scarring;
• Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown, penetration, pain, irritation and/or wound complications;
• Tissue damage resulting from improper placement of implants or instruments;
• Infection;
• Joint dislocation;
• Nerve or vascular damage due to surgical trauma, including loss of neurological function, neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, appearance of radiculopathy, and paralysis (complete or incomplete);
• Bone loss due to resorption or stress shielding, decrease in bone density or bone fracture at operative site;
• Pain, discomfort or wound healing complications at the surgical site;
• Hemorrhage, hematoma, seroma, damage to blood vessels, embolism, stroke, excessive bleeding, wound necrosis and/or dehiscence;
• Misalignment of anatomical structures, including loss of proper hip alignment, loss of varus and/or valgus correction and/or loss of height;
• Gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium;
• Loss of hip mobility or operation and/or inability to perform daily living activities;
• Peri-articular adhesion and fibrosis;
• Death

DIRECTIONS FOR USE
To implant the Plasmafit Pro Acetabular Cup System and Vitelene Insert implants, use only the specialized Plasmafit Pro Acetabular Cup System and Vitelene Insert instrumentation. Do not use implants or instruments from any other system or manufacturer.

The Plasmafit Pro Acetabular Cup System and Vitelene Insert implants are provided sterile. Plasmafit Pro Acetabular Cup System and Vitelene Insert instruments are provided non-sterile and must be cleaned and sterilized prior to use according to the procedures outlined in this document. All Plasmafit Pro Acetabular Cup System and Vitelene Insert device system components should be carefully inspected to ensure proper working condition. Critical areas, including joint surfaces, should be checked for wear, damage or irregularities. Damaged or broken Plasmafit Pro Acetabular Cup System and Vitelene Insert devices must not be used or processed and should be returned to Aesculap Implant Systems for evaluation.

Before using the Plasmafit Pro Acetabular Cup System and Vitelene Insert for the first time, the surgeon should be thoroughly familiar with the Plasmafit Pro Acetabular Cup System and Vitelene Insert Surgical Technique Manual as well as the functionality and assembly of the various components. Pre-operative planning by the surgeon should determine the type of implant required and an adequate supply of the implant sizes should be available prior to surgery, including larger and smaller sizes than those expected to be used.
For complete instructions regarding the proper use and application of all Plasmfit Pro Acetabular Cup System and Vitelene Insert implants and instruments, please refer to the Plasmfit Pro Acetabular Cup System and Vitelene Insert Surgical Technique Manual (available at no charge upon request).

CARE AND HANDLING

Plasmfit Pro Acetabular Cup System and Vitelene Insert hip implants are provided sterile and should be stored in the original packaging until used. Plasmfit Pro Acetabular Cup System and Vitelene Insert hip instruments are provided non-sterile and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be sterilized according to the standard hospital procedure. Refer to the STERILIZATION section for recommended parameters.

Instruments

Before being used for the first time and each use thereafter, the procedures outlined below should be followed to ensure safe handling of biologically contaminated instruments: (For Consensus instrument sets consult the Consensus CS2 Instrument Care Guide):

1. Pre-Cleaning

Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. The decontamination process should begin immediately after completion of the surgical procedure.

Remove gross contaminants with a steady stream of lukewarm / cool water (below 110°). Be sure to rinse each instrument thoroughly. Do not use saline or chlorinated solutions as these can damage the instrument surface.

Fully open jaws of hinged instruments for cleaning. Instruments with more than one part or piece must be disassembled in order to expose all surfaces to the cleaning process. Retain all parts for re-assembly.

2. Cleaning

Hand wash using a low-sudsing, neutral pH (7-9), protein dissolving detergent. Follow the detergent manufacturer’s directions regarding the proper concentration, temperature and contact time. Totally immerse the instruments during the cleaning process in order to prevent aerosolization. Use appropriate-sized, soft nylon brushes - Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.

To avoid coagulation of mucus, blood or other body fluids, do not soak instruments in hot water, alcohol, disinfectants or antiseptics. Do not exceed two hours soaking in ANY solution.

3. Ultrasonic Cleaning

For ultrasonic cleaning, follow the manufacturer’s specifications for suggested water level, concentration, and temperature.

When using mechanical washers, make sure the instruments are secured in place, and do not touch or overlap.

Rinse the instruments thoroughly with tap water, deionized water or distilled water. Make sure all lumens, stopcocks and ratchets are thoroughly rinsed.

4. Decontamination / Disinfection

Warning: The decontamination process does not sterilize instruments. Refer to and process the instruments as outlined in the STERILIZATION section.

Select a proper product for high-level disinfection (examples include the glutaraldehyde-family of disinfectant products). Follow the cleaning agent’s recommended directions regarding the proper concentration, temperature, contact time and solution re-use.
Do not use high acid (pH <4.0) or high alkaline (pH >10) products for disinfection, such as bleach, bichloride of mercury.

Completely immerse instruments in disinfecting solution - force solution into all areas and cavities.

Using a large syringe or pulsating water jet, thoroughly flush all channels and lumens with the disinfecting solution to remove debris.

**5. Rinsing**

Thoroughly rinse all internal lumens, stopcocks and ratchets with distilled water to remove all traces of the disinfecting solution. **USE STERILE WATER ON THE FINAL RINSE.**

**6. Drying**

Instruments must be thoroughly dried to remove all residual moisture before they are stored. Use a soft, absorbent towel/cloth to dry external surfaces. Compressed air or a 70% alcohol rinse can also be used to aid the drying process.

**7. Testing / Preparation for Sterilization**

*Warning: The use of damaged instruments may increase the risk of tissue trauma, infection and length of operative procedures.*

Instruments should be visually inspected and prepared for sterilization following the disinfection process. Instruments should be visually clean. Contaminated devices should not be reprocessed. Check for misalignment, burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored or damaged instruments.

Use a non-silicone, water-soluble lubricant prior to sterilization. Special attention should be given to boxlocks and moveable parts (joints). Only lubricate dry instruments and do not use mineral oil, petroleum, or silicone-based products.

Reassemble instruments, as necessary, before placing into baskets or trays. Close ratcheted instruments in the first ratchet position to avoid temperature-induced stress cracks in the joints.

**STERILIZATION**

*Warning: Aesculap Implant Systems does not recommend the Plasmafit Pro Acetabular Cup System and Vitelene Insert instruments be sterilized by Flash, EtO or Chemical sterilization.*

Sterilization may be accomplished by steam autoclave in a standard prevacuum cycle. To achieve a sterility assurance level of $10^6$, Aesculap Implant Systems recommends the following parameters:

<table>
<thead>
<tr>
<th>Aesculap Implant Systems</th>
<th>Orga Tray / Sterilcontainer (perforated bottom)</th>
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</thead>
<tbody>
<tr>
<td><strong>Minimum Cycle Parameters</strong></td>
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<tr>
<td><strong>PRE-VACUUM</strong></td>
<td><strong>TEMPERATURE</strong></td>
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<tr>
<td>132°C / 135°C</td>
<td>270°F / 275°F</td>
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*Aesculap Implant Systems has validated the above sterilization cycles and has the data on file. The validation was accomplished in an Aesculap Implant Systems Sterilcontainer cleared by FDA for the sterilization and storage of these instruments. Other sterilization cycles may also be suitable, however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.*
STORAGE
The Plasmafit Pro Acetabular Cup System and Vitelene Insert instruments must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

WARRANTY
Every product bearing the Aesculap Implant Systems name is guaranteed to be free of defects in workmanship and materials when used properly for its intended purpose. Any Aesculap Implant Systems product delivered from Aesculap Implant Systems, Inc. proving to be defective will be replaced or repaired, at Aesculap Implant System’s discretion, at no charge to the customer.

These warranties shall not apply to conditions or defects resulting from, but not limited to: negligence, improper use, improper care and handling, improper opening techniques, unauthorized repair work, caustic or abrasive cleaners, or items modified or customized by the customer at the customer’s request.

MAINTENANCE and REPAIR
Warning: Repair of Plasmafit Pro instruments by parties other than Aesculap Implant Systems will void the above warranty.

If your Plasmafit Pro Acetabular Cup System and Vitelene Insert instruments require repair or maintenance, return the instruments in the Aesculap Implant Systems Instrument Repair (A.I.R.) box or other sturdy box with adequate packaging material to protect the instruments. Send the packaged instruments to:

Aesculap Implant Systems, LLC
615 Lambert Pointe Dr.
Hazelwood, MO 63042

Attn: Aesculap Implant Systems Technical Services
(or call the Repair Hotline at 800-214-3392)

Note: Instruments returned to Aesculap Implant Systems must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

CUSTOMER SERVICE
For further information regarding the Plasmafit Pro Acetabular Cup System and Vitelene Insert Hip System or a copy of a Surgical Technique Manual, please contact:

Aesculap Implant Systems, LLC.
3773 Corporate Parkway,
Center Valley, PA 18034
1-800-234-9179

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