VEGA KNEE SYSTEM

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

INDICATIONS FOR USE

The VEGA Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

Posterior Stabilized (PS) components are also for absent or non-functioning posterior cruciate ligament and severe anteroposterior instability of the knee joint.

The VEGA Knee System is designed for use with bone cement.

DEVICE DESCRIPTION

Aesculap Knee Systems consist of femoral components, tibial components and accessories. The specific implant material is listed on the implant packaging. Components are available in a variety of sizes and designs. The VEGA Knee System is compatible with Aesculap Columbus cruciate retaining/posterior stabilizing tibial plateaus (CR/PS and CRA/PSA) and augments. VEGA tibial extension stems may be used with compatible Aesculap Columbus tibial trays. Further details on the implantation of Columbus CRA/PSA and VEGA All Poly Tibia may be found in the VEGA Columbus CRA/PSA surgical manual, and the All Poly Tibia Plateau surgical manual respectively.

MATERIALS

- ISO 5832-12: cobalt-chromium wrought alloy CoCr29Mo acc. to ISO 5832-12
- PVD multilayer coating
- Ultra-high molecular low-pressure polyethylene acc. to ISO5834-2
- ISO 5832-4: cobalt-chromium casting alloy CoCr29Mo acc. to ISO 5832-4
- PEEK-OPTIMA®
- ISODUR® is a registered trademark of Aesculap AG, 78522 Tutlingen / Germany.
- ISODUR® F: cobalt-chromium wrought alloy CoCr29Mo acc. to ISO 5832-12
- Polymethyl methacrylate (PMMA)
- Titanium alloy acc. to ISO 5832-3
- Tantalum acc. to ISO 13782
- Stainless steel acc. to ISO 5832-1

HOW SUPPLIED

Knee 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.

- The implant components are gamma-sterilized.
- Store implant components in their original packaging. Remove them from their original protective packaging only just prior to application.
- Prior to use, check the product expiry date and verify the integrity of the sterile packaging. Do not use implant components that are past their expiry date or whose packaging is damaged.

WARNING

- Do not resterilize implants supplied in sterile condition under any circumstances!
- If the present instructions for use do not offer explicit information in this respect, the product user bears all responsibility for any resterilization.
- Do not resterilize implants made from PEEKOPTIMA® or polyethylene, or implants with parts made from polyethylene.

CONTRAINDICATIONS

- Joint conditions that can be treated by reconstructive surgery (e.g. osteotomy)
- Acute or chronic infections near the joint, or systemic infections
- Secondary diseases that could influence joint implant functionality
- Systemic diseases and metabolic disorders
- Severe osteoporosis or osteomalacia
- Severely damaged bone structures that could prevent stable implantation of implant components
- Bone tumors in the region of implant fixation
- Bone malformations, axial malalignments or other bone conditions that rule out implantation of a prosthetic joint
- Predictable overload of the joint implant (e.g. due to adiposity)
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism
- Fever, infection or inflammation (systemic or local)

- Pregnancy
- Mental illness
- Severe osteopenia (or any other medical or surgical finding) that would preclude any benefit from the implants
- Combination with implant components from other manufacturers
- Inadequate patient compliance
- Foreign body sensitivity to the implant materials
- All cases not listed under indications

WARNINGS and POTENTIAL RISKS

Implants are designed for single patient use only and must never be reused. As with all other orthopedic implants, the 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, and do not mix cobalt-chromium and titanium implant components together in a total knee system.

The 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.

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

Aesculap Knee Systems are intended to be used by surgeons specializing in orthopedic surgery who have a thorough knowledge of knee arthroplasty, joint morphology and the biomechanical principles of the knee.

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 knee 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 knee prostheses.

The VEGA implants have not been evaluated for safety and compatibility in the MR environment. The VEGA implants have not been tested for heating or migration in the MR environment.

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:

- Loosening, wear and breakage of implant components
- Misalignment of anatomic structures, including loss of correct knee alignment, loss of varus and/or valgus correction and/or reduction in body height
- Loss of bone substance due to resorption or stress shielding, decrease in bone density, or bone fracture at the operating site
- Joint luxation
- Primary and secondary infections
- Venous thrombosis, lung embolism, and cardiac arrest
- Tissue reaction to implant materials
- Tissue damage due to incorrect arrangement of implants or surgical instruments
- Damage to nerves or blood vessels, including loss of neurological functions, neuropathy and paralysis (complete or partial)
- Skin or muscle sensitivity in patients with insufficient tissue cover of the operating site, potentially leading to skin rupture or puncture, pain, irritation and/or wound complications
DIRECTIONS FOR USE

The operating surgeon draws up an operating plan that specifies and appropriately documents the following steps:

- Selection of the implant components and their dimensions
- Positioning of the implant components in the bone
- Location of intraoperative landmarks
- All requisite implant components are ready to hand
- Operating conditions are highly aseptic
- The implantation instruments, including the special Aesculap implant system, are complete and in working condition.
- The operating surgeon and operating room team are thoroughly conversant with the operating technique and with the available range of implants and instruments; information materials on these subjects must be complete and ready to hand.
- The surgeon and the surgical team must be familiar with the rules governing medical practice, current scientific knowledge and relevant scientific publications by medical authors.
- The manufacturer has been consulted if the preoperative situation was unclear and if implants were found in the area operated on.
- The intervention has been explained to the patient, whose consent concerning the following information has been documented:
  - The functionality of the prosthetic joint is essentially inferior to that of the natural one.
  - The prosthetic joint can bring about only limited improvement in the patient's condition vis-à-vis their condition prior to the operation.
  - The prosthetic joint can come loose due to excessive load, wear and tear, or infection.
  - The service life of the prosthetic joint is determined by body weight and the amount of strain that is placed on the joint.
  - The prosthetic joint must not be subjected to overload through extreme strain, or through work-related or athletic activities.
  - Corrective surgery may become necessary if the implant loosens.
  - In the event that corrective surgery is performed, it may not be possible under certain circumstances to restore joint mobility and flexibility.
  - The revision of a knee endoprosthesis is a complex joint replacement procedure. Generally, the revision joint replacement will be inferior in its performance to the primary joint replacement.
  - The patient must undergo medical follow-up examinations of the prosthetic joint at regular intervals.
  - The preparation of the implant bed requires the following steps:
    - Opening and display of the joint, followed by tibial resection using the tibial saw instruments, observing the mechanical leg axis and the joint line.
    - Align the femoral bone dissection with reference to the femoral mechanical leg axis, the joint line and the width of the joint gap in flexion and extension.
    - Axial orientation is performed in accordance with the posterior condylar line or the transepicondylar axis; the mechanical leg axis, flexion/extension gap and ligament balance are also taken into account.
    - Prior to inserting the implants, carry out a test reduction and check the leg axis, the joint mobility and the joint stability. At this stage it is important to ensure that any osteophytes are removed carefully and good soft tissue balance is achieved.

WARNING

- Incorrect alignment of the bone dissections and inadequate management of the soft tissue situation adversely affect the durability and anchoring of the implants.
- Handle the implant components properly.
- Do not under any circumstances allow the implant surfaces to be damaged.
- Prior to implantation with bone cement, ensure that the bone facets are carefully cleaned and rinsed.
- Prepare and apply bone cement as described in the user instructions provided by the cement supplier.
- In order to forestall abnormal wear and tear on the prosthesis: Remove any loose bone cement or bone chips before closing the wound.

For complete instructions regarding the proper use and application of all implants and instruments, please refer to the Surgical Technique Manual (available at no charge upon request).

CARE AND HANDLING

Knee implants are provided sterile and should be stored in the original packaging until used. Knee 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:

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.

   Open fully 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 bodily 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, bi-chloride of mercury.

   Completely immerse instruments in disinfesting solution - force solution into all areas and cavities. Using a large syringe or pulsating water jet, thoroughly flush all channels and lumens with the disinfesting solution to remove debris.

5. Rinsing

   Thoroughly rinse all internal lumens, stopcocks and ratchets with distilled water to remove all traces of the disinfesting 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/choth 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. Check for misalignment, burns, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored or damaged instruments.
Lubrication is essential every time instruments are processed. Use a non-silicone, water-soluble lubricant prior to sterilization such as Aesculap’s Instrument Oil, JG598. 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 does not recommend that Knee 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 recommends the following parameters:

<table>
<thead>
<tr>
<th>Aesculap Orga Tray / SterilContainer (perforated bottom)</th>
<th>Minimum Cycle Parameters*</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEMPERATURE</td>
<td>TIME</td>
</tr>
<tr>
<td>132°C / 270°F</td>
<td>4 minutes</td>
</tr>
</tbody>
</table>

*Aesculap has validated the above sterilization cycles according to ANSI/AAMI ST79:2006 and has the data on file. 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 knee 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 LLC name is guaranteed to be free of defects in workmanship and materials when used properly for its intended purpose. Any Aesculap Implant Systems LLC product delivered from Aesculap Implant Systems, LLC proving to be defective will be replaced or repaired, at Aesculap Implant Systems LLC’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 Aesculap instruments by parties other than Aesculap Implant Systems LLC will void the above warranty.

If your Knee instruments require repair or maintenance, return the instruments in the Aesculap Instrument Repair (A.I.R.) box or other sturdy box with adequate packaging material to protect the instruments. Send the packaged instruments to:

Aesculap, Inc.
615 Lambert Pointe Dr.
Hazelwood, MO 63042
Attn: Aesculap Technical Services
(or call the Repair Hotline at 866-214-3392)

Note: Instruments returned to Aesculap 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 Aesculap Knee Systems or a copy of the specific Knee Surgical Technique Manual, please contact Aesculap Implant Systems LLC, or your local Aesculap Orthopaedic Distributor.

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