Instructions for Use

Acetabular Shells

Manufacturer
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DESCRIPTION

The Escalade® and Legend® Acetabular Shells are wrought titanium alloy (Ti-6Al-4V) hemispherical one-piece shells designed for cementless use. The Escalade shell has a commercially pure titanium (CPTi) plasma spray coating. The Legend shell has a highly porous ingrowth surface manufactured from a commercially pure titanium (CPTi) sintered porous coating. Initial implant fixation is achieved through press-fit design. The shells are available in no-hole, three-hole and multi-hole options to provide additional screw fixation.

The Acetabular Liner is manufactured from ultra-high molecular weight polyethylene (UHMWPE) which has been crosslinked by radiation (extensively cross-linked polyethylene, EXLPE) and is compression molded (compression molded polyethylene, CMPE). The Acetabular Liners are available in neutral, hooded, lateralized, and face-changing options, with inside diameter options of 26, 28, 32, 36 and 40mm. The Acetabular Liner may be used in both the Escalade and Legend Acetabular Shells. All components are individually sterile packed.

The Cancellous Bone Screw is intended for use in conjunction with the Escalade and Legend Acetabular Shells for adjunct fixation. The 6.5mm diameter screw is available in lengths from 15mm to 65mm in 5mm increments, and is manufactured from wrought titanium alloy (Ti-6Al-4V).

The Apical Hole Plug is provided for optional sealing of the acetabular shell apical hole and is manufactured from wrought titanium alloy (Ti-6Al-4V).

INDICATIONS

The Escalade and Legend Acetabular Shells are indicated for use in total hip arthroplasty procedures where the means of shell fixation is cementless, biological fixation. The Escalade and Legend Acetabular Shells are compatible with hip stems manufactured by Ortho Development and with Ortho Development CoCr Femoral Heads, and CeramTec BIOLOX®delta Femoral Heads. Total hip arthroplasty is indicated for the following conditions:

1. Notably impaired hip joints due to osteoarthritis, rheumatoid arthritis and/or post traumatic arthritis.
2. Previously failed hip surgery.
3. Fractures of the femoral neck or head.
4. Avascular necrosis of the femoral head.
5. Congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

CONTRAINDICATIONS

1. Any joint with active or suspected local or systemic infection.
2. Any pathological condition of the joint that would preclude rigid fixation, appropriate range of motion

or adequate support or fixation of the component.
3. Loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb rendering the procedure unjustifiable.
4. Certain systemic or metabolic bone conditions.
5. Skeletal immaturity.
6. Poor bone quality that cannot provide adequate support or fixation of the implant.
7. Any disease, ligamentous or severe muscle laxity or inadequate soft tissue coverage which may compromise the normal healing process or function of the implant.
8. Obese or overweight patients who may place undue loads on the prosthesis which can result in failure of the device.
9. Pathological conditions, neuromuscular disorders or mental conditions whereby the risks associated with these conditions outweigh the benefits to be derived.

PRECAUTIONS
Before using any implant the surgeon should be familiar with the fundamentals of total hip arthroplasty as well as the limitations of the device. Instruction should be given to the patient on the limitations of the prosthesis and how to modify their lifestyle accordingly. Proper selection of the implant is extremely important as the potential for success in total joint replacement is increased by the selection of the proper size implant. Total joint replacement requires careful seating and adequate bone support. Extreme care should be taken by the surgeon and the O.R. staff to protect the component surface from being marred as a result of contact with metal or abrasive objects. The Escalade and Legend Acetabular Shells should not be used with other systems, unless specifically labeled for such use. Different specifications and dimensional incompatibilities among the various systems may cause premature failure. These devices are intended for use with other components, trials, and instruments manufactured by Ortho Development Corporation.

The Escalade and Legend Acetabular Shells have not been evaluated for safety and compatibility in the magnetic resonance (MR) environment, and have not been tested for heating or migration in the MR environment.

WARNINGS
The Escalade and Legend Acetabular Shells, Acetabular Liners, Apical Hole Plugs, and Cancellous Bone Screws are sold sterile. Do not implant these or any device that has been used or that has evidence of damage or tampering. Take extreme care to protect these devices from coming in contact with any hard or abrasive surfaces especially in polished bearing or machined taper areas. Never tamper with the implant. Do not bend or contour the implant, as this may reduce the fatigue strength and may cause immediate or eventual failure of the implant.

The following factors may tend to impose risk of implant failure:
1. Obesity.
2. Heavy Labor.
3. Active sports participation.
4. History of falls.
5. Drug or alcohol addiction and/or abuse.
6. Foreign body sensitivity.
7. Severe deformities, congenital dislocation.
8. Local tumors of the bone.
9. Systemic and metabolic bone disorders.
10. History of infectious disease.

ADVERSE EFFECTS
All prosthetic replacements have the potential for adverse effects including but not limited to:

Intraoperative
1. Acetabular/Femoral perforation.
2. Fracture during bone preparation or impaction.
3. Damage to blood vessels or nerves.
4. Death (secondary to cardiac arrest).
5. Subluxation or dislocation of the implant due to improper selection and/or positioning of components and/or muscle and fibrous tissue laxity.
6. Undesirable shortening or lengthening of the affected extremity.
7. Inadequate abutment in the direction of the resultant joint force.

Early Postoperative
1. Cardiovascular disorders including venous thrombosis, pulmonary embolism, pneumonia, atelectasis, cerebrovascular accident, myocardial infarction and death.
2. Hematoma and delayed wound healing.
3. Systemic or wound infection.
4. Sensitivity or allergic reactions to the materials used to manufacture the component.

Late Postoperative
1. Trochanteric avulsion from excessive muscular tension or early weight bearing and inadvertent intraoperative weakening.
2. Aggravated problems in the knee and ankle joints of the affected or contralateral extremities caused by leg length discrepancy.
3. Femoral or acetabular fracture by trauma or excessive loading, bone defects from previous surgery or reaming, and bone resorption.
4. Failure due to implant fracture.
5. Tissue reactions, allergic reactions, and loosening caused by metallic corrosion or the accumulation of wear debris from the acetabular socket or loose particles.

MAGNETIC RESONANCE (MR)
The Escalade and Legend Acetabular Shells, Acetabular Liners, Apical Hole Plugs, and Cancellous Bone Screws have not been evaluated for safety and compatibility in the MR environment. The Escalade and Legend Acetabular Shells, Acetabular Liners, Apical Hole Plugs, and Cancellous Bone Screws have not been tested for heating, migration, or image artifact in the MR environment. The safety of these devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PACKAGING AND STERILITY
All metallic implants have been sterilized by a minimum dose of 25 kGy gamma irradiation at a sterility assurance level of 10^{-6}. Acetabular Liners are sterilized by Ethylene Oxide (ETO) exposure. Sterile product packaging should be inspected for flaws before and after opening. In the presence of a flaw or if implant sterility has been compromised prior to implantation the product must be assumed non-sterile and should not be implanted. Resterilization of the implant is not recommended.

INSTRUMENT STERILITY
All instruments should be thoroughly cleaned prior to sterilization. *Please refer to the Ortho Development Reusable Instrument Care Manual for cleaning and sterilization details.

Table 1: Recommended Sterilization Parameters

Cycle Type	Minimum Sterilization Exposure Temperature	Minimum Sterilization Exposure Time	Minimum Dry Time*
Prevacuum	132° C (270° F)	4 minutes	30 minutes

Table 2: Exceptions by Kit Number

Escalade Offset Acetabular Instrument sets 270-9007 containing Offset Shell Inserter Handle T16612 have the following Sterilization Parameters unless the Offset Inserter Handle is sterilized separately.

Cycle Type	Minimum Sterilization Exposure Temperature	Minimum Sterilization Exposure Time	Minimum Dry Time*
Prevacuum	132° C (270° F)	6 minutes	40 minutes

Escalade Offset Acetabular Instrument sets containing Offset Shell Inserter Handle 270-5103 and T16612R may be sterilized using the normal 4 min Sterilization Parameters listed in Table 1.

PRODUCT HANDLING

Implants should always be stored unopened in their respective protective packages. Prior to use, inspect packaging for damage which may compromise sterility. When removing the implant from its packaging, the relevant aseptic techniques must be observed. Protect the prosthesis from contact with objects which may damage the surface finish. Inspect each implant prior to use for visual damage. Do not implant this or any device that has been used, even if it appears undamaged.

PRODUCT COMPLAINTS

Any complaint or dissatisfaction with product quality, performance, labeling, and/or safety should be reported to Ortho Development® Corporation. If any of the implants or instruments “malfunction” (i.e., do not meet any of their performance specifications or does not perform as intended), and/or are suspected to have caused or contributed to the death or serious injury of the patient, Ortho Development® Corporation should be notified immediately by phone, fax or written correspondence. When filing a complaint, please provide the product description, product number, lot number, complainant’s name and address, and the nature of the complaint.

CAUTION

Federal Law (USA) restricts this device to sale, distribution and use by or on the order of a physician.

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