Patient Information Leaflet - Australia
Ortho Development Hip Joint Replacement Prostheses

Manufacturer Information:
Ortho Development® Corporation
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PRODUCT DESCRIPTION

The **Ortho Development Hip Joint Replacement Prostheses** are joint replacement devices designed to treat adults who need to have their hip joint replaced.

The reasons for needing a total hip replacement include:
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. Non-union of proximal femoral neck fractures.
6. Treatment of fractures that are unmanageable using other forms of therapy.
7. Congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

The components for the Ortho Development Hip Joint Replacement Prostheses are listed in this leaflet. Following the procedure, refer to your Patient ID Card for the devices which were selected for your surgery.

The Ortho Development Hip Replacement Devices include the following components:

- Hip Stem
  - Ovation (material: titanium alloy, commercially-pure titanium)
  - Ovation Tribute (material: titanium alloy, commercially-pure titanium)

- Femoral Head
  - Cobalt-Chrome Femoral Head (material: Cobalt chromium alloy)
  - Biolox Delta Ceramic Femoral Head (material: Alumina/Zirconia Ceramic alloy)

- Actabular Shell
  - Escalade Acetabular Shell (material: titanium alloy, commercially-pure titanium)

- Acetabular Liner
  - Escalade Acetabular Liner (material: polyethylene, UHMWPE)

- Bone Screw (material: titanium alloy, Ti-6Al-4V ELI)
- Apical Plug (material: titanium alloy, Ti-6Al-4V ELI)

ADVERSE EFFECTS

Potential complications may occur with this procedure. These may be similar to those occurring with any hip joint replacement and include:
Intraoperative
1. Acetabular/Femoral perforation.
2. Femoral 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 selection and/or positioning of components and/or muscle and fibrous tissue laxity.
6. Undesirable shortening or lengthening of the affected extremity.
7. Traumatic arthrosis of the knee from intraoperative positioning of the extremity.
8. 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.
If you are experiencing any atypical pain, instability, or signs of any complication listed above or described by your physician, it is advised that you contact your physician. It is recommended you report any concerns regarding these symptoms, or any others, to your physician as long as the devices are implanted.

PRECAUTIONS AND MAINTENANCE

The manufacturer recommends that patients follow and comply with all physician recommendations, precautions, and post-surgical medical appointments. This may include routine radiographic follow-up. Patients are encouraged to participate with follow up routines in order to monitor prosthesis performance and durability as well as patient health and/or adverse effects.
Physicians should instruct patients on the limits of the prosthesis and the impact of excessive loading through patient weight or activity. Patients should also be taught to govern and/or restrict their activities accordingly. Strict adherence to physician's instructions is essential to maximize the success of the procedure and the service life of the devices. The durability of the devices can be affected by patient activity and body weight among other factors (e.g., localized trauma, patient anatomy, etc.). The majority of patients who undergo total hip replacements will not require a revision hip surgery within ten to fifteen years under normal wear. However, it is possible that your hip replacement could last longer, or less, than ten years. Your activity and body weight may affect how long your hip replacement lasts. Patients should discuss appropriate activity, body weight maintenance, and precautions in order to preserve the long-term performance and durability of the devices.

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.

MAGNETIC RESONANCE (MR)

The Ortho Development Hip System implants have not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. Further, they have not been tested for heating or migration in the MR environment. Thus, the safety of these implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 do not perform as intended) and/or are suspected to have caused or contributed to the death, serious injury of the patient, or serious deterioration in state of health, Ortho Development Corporation should be notified immediately by phone, fax or written correspondence. In these events, the Australia Therapeutic Goods Administration should also be notified (https://www.tga.gov.au/).
When filing a complaint, please provide the product description, product number, lot number, complaint's name and address, and the nature of the complaint.

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