

Manufacturer
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DESCRIPTION

The Entrada Hip Stem is intended for use in cementless applications. It is manufactured from titanium alloy (Ti-6Al-4V ELI), and is a single-piece, tapered, femoral hip stem. The proximal neck surface is highly polished and transitions to hydroxyapatite (HA) coating. The Entrada stem is offered with or without a collar, in a variety of sizes, in both standard and extended neck offsets. Both stem variations have a 12/14 trunnion taper. The Entrada Hip Stems are provided in individually sterilized packaging for single use.

INDICATIONS

This device is intended for use in total and hemi-hip arthroplasty. The device is intended for uncemented, press-fit use only in cases of:

1. Notably impaired hip joint due to osteoarthritis, rheumatoid arthritis, and/or posttraumatic arthritis.
2. Previously failed hip surgery.
3. Proximal femoral neck fractures or dislocation.
4. Idiopathic avascular necrosis of femoral head.
5. Non-union of proximal femoral neck fractures.
6. Treatment of fractures that are unmanageable using other forms of therapy.
7. Benign or malignant bone tumors, 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. Poor bone quality that cannot provide adequate support or fixation of the implant.
6. Any disease, ligamentous or severe muscle laxity or inadequate soft tissue coverage which may compromise the normal healing process or function of the implant.
7. Obese or overweight patients who may place undue loads on the prosthesis which can result in failure of the device.
8. Pathological conditions, neuromuscular disorders or mental conditions whereby the risks associated with these conditions outweigh the benefits to be derived.
9. Skeletal immaturity.

PRECAUTIONS

Before using any implant, the surgeon should be familiar with the fundamentals of 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, and should be restricted to limited functional stress. 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 any abrasive objects.

The Entrada Hip Stem should not be used with other hip systems and vice versa, unless specifically designated and labeled for such use. These devices are intended for use with other components, trials, and instruments manufactured by Ortho Development® Corporation. Different specifications and dimensional incompatibilities among the various systems may cause premature failure.

WARNINGS

The Entrada Hip Stem is sold sterile. Do not implant these or any devices that have been used or that have evidence of damage or tampering. Take extreme care to protect the device from coming in contact with any hard or abrasive surfaces especially in polished bearing or machined taper areas. The machined taper surface of the femoral trunnion/neck must be dry and free from any tissue or fluid at the time of assembly with the femoral head to ensure proper seating of the implant. The femoral head must be properly impacted to prevent neck length discrepancy, disassociation, or dislocation. 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. 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 cement particles.

MAGNETIC RESONANCE (MR)

The Entrada Hip Stem has not been evaluated for safety and compatibility in the MR environment. The Entrada Hip Stem has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Entrada stem in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PACKAGING AND STERILITY

All implants have been sterilized by a minimum of 25 kGy gamma irradiation at a sterility assurance level of 10^{-6} . 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, the product must be considered 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. Cases should be placed in two layers of FDA cleared 1-ply polypropylene wrap, such as Kinguard KC600, using sequential wrapping techniques prior to sterilization. Cleaning instructions for reusable instruments are provided in the Ortho Development Corporation Reusable Instrument Care Manual. The following Steam Sterilization Cycles must be followed in order to ensure sterility:

Prevacuum Cycle: 4 minutes at 132° C (270° F), dry time 30 minutes

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 do 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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