TOTAL JOINT ORTHOPEDICS

TOTAL JOINT ORTHOPEDICS, INC.
Klassic® BiPolar System
Instructions for Use (IFU)

Manufacturer:
Total Joint Orthopedics, Inc.
1567 East Stratford Ave.
Salt Lake City, UT 84106

Carefully read all instructions prior to use. Observe all contraindications and precautions noted in these directions. Refer to the Total Joint Orthopedics Klassic® BiPolar System Surgical Technique Manual for information on implantation technique and preoperative planning and postoperative care.

CAUTION: U.S. law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

The Klassic BiPolar System is intended for use in combination with a Total Joint Orthopedics Femoral Stem for primary or revision hemiarthroplasty of the hip, without the use of bone cement, for treatment of the following conditions:

- Femoral neck and trochanteric fractures of the proximal femur
- Osteonecrosis of the femoral head
- Revision procedures where other devices or treatments for these indications have failed.

PRODUCT DESCRIPTION & IMPLANT MATERIALS

The modular Klassic BiPolar System BiPolar Head, Klassic BiPolar System 22mm Femoral Head and Klassic BiPolar System 28mm Femoral Head ("Klassic BiPolar System Implants") are used in combination with The Klassic HD Femoral Stems, or Klassic HD Offset Femoral Stems, for primary or revision hemiarthroplasty. The Klassic BiPolar System BiPolar Head is assembled on the appropriate Klassic BiPolar System Femoral Head and Klassic HD Femoral Stem or Klassic HD Offset Stem during surgery to replace the head and the neck of the femur, without bone cement. The implantable components are intended for single-use in a single patient only.

PRODUCT HANDLING

The Klassic BiPolar System Implants are provided sterile and should always be stored unopened. Prior to use, inspect package for damage which may compromise sterility. If packaging has been opened or damaged, contact a manufacturer representative.

When unpacking the Klassic BiPolar System Implants, verify the labeling for the correct catalog number and size of each component and the expiration date to verify part has not expired. When removing the component from its packaging, the relevant aseptic protocols must be observed. Protect prosthesis from contact with objects that may damage the surface finish. Inspect each component prior to use for visible damage.

STORAGE

The Klassic BiPolar System Implants should be stored in a clean, dry location at room temperature.

CONTRAINDICATIONS

The Klassic BiPolar System is contraindicated for use in:

- Patients with conditions that may lead to inadequate skeletal fixation, (e.g. insufficient quality or quantity of bone resulting from conditions such as cancer or congenital dislocation, metabolic bone disease of the upper femur or pelvis, femoral osteotomy revision, girdlestone revision, osteoporosis, osteomyelitis) neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable, (e.g. the absence of musculoligamentous support structures or joint neuropathy).
- Patients with active or unresolved local or systemic infection.
- Patients who experience symptoms or diseases where surgery would be otherwise contraindicated.
- Patients with sensitivity to the implant materials.
- Skeletally immature patients.

WARNINGS

- Stem loosening or fracture, particularly of smaller sized stems, is most likely to occur in patients who are young, physically active and/or heavy.
- The Klassic BiPolar System has not been evaluated for safety and compatibility in the MR environment. The Klassic BiPolar System has not been tested for heating or migration in the MR environment. The safety of the Klassic BiPolar System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PRECAUTIONS

- Implants are for single use in a single patient only.
- Do not resterilize.
- Avoid notching, scratching, or striking the prosthesis. Do not use any component if damage is found or caused during setup or insertion.
- Improper implant or component selection, placement, positioning, or fixation may result in unusual stress conditions, reducing the service life of the prosthetic implants.
- Do not impact stem into the femoral canal after the components are assembled. Further impaction could damage the head component or taper attachment.
- Protect any porous-coated surfaces from mechanical damage, and do not allow contact between the surface and any metallic or other hard surface. Do not allow the porous coating to interface with cloth or other lint-shedding or dirty materials prior to implantation. Do not rely on conventional cleaning techniques to remove lint, dirt, or body tissue from porous coating.
- Do not assemble mating components without ensuring that the surfaces are free from blood or debris. Failure to ensure that mating surfaces are clean and dry could result in inadequate seating of the components, subsequent disassembly of the mated components, or fracture of the implant.
- Repeated assembly/disassembly of modular components could compromise the critical locking action of the Morse-style tapers. Use the trial components during trial reductions. Change the components only when clinically necessary.
- Exercise care with the heads of femoral hip prostheses. Remove protective coverings only prior to implantation.

ADVERSE EFFECTS

The following adverse effects have been reported for hip joint replacement:

- Corrosion of metal implants
- Deep wound infections
- Disassembly of modular components
- Dislocation and subluxation
- Early or late loosening of components
- Ectopic ossification
- Fatigue fracture
- Heterotopic bone formation
- Inflammatory reactions or osteolysis
- Metal sensitivity
- Perforation of the acetabulum or femur
- Peripheral neuropathies
- Possible detachment of coatings
- Subclinical nerve damage
- Trochanteric problems
- Vascular complications
- Wear

STERILITY

Unless opened or damaged, the Klassic BiPolar System Implant components are supplied sterile in double pouches. Inspect each package prior to use and do not use the component if any seal or cavity is damaged, breached, or if the expiration date has been exceeded.

The Klassic BiPolar System 22mm and 28mm Femoral Heads are sterilized by gamma irradiation to achieve a Sterility Assurance Level (SAL) of 10^{-6}. The Klassic BiPolar System BiPolar Heads are sterilized by Ethylene Oxide to achieve an SAL of 10^{-6}. Once opened, the component must be used or discarded. Do not use the device if the expiration date has passed. DO NOT RESTERILIZE.

PATIENT COUNSELING INFORMATION

Complications and/or failure of prosthetic implants are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or with patients who fail to complete required rehabilitation programs. Physical activity can result in loosening, wear, and/or fracture of the implant. The prospective implant patient must be counseled on the capabilities of the implant and the impact it will have on his or her lifestyle.

RETURN GOODS POLICY

For information on product returns and return authorization, contact Total Joint Orthopedics by calling 888.890.0102. All products returned to Total Joint Orthopedics must be accompanied by a Return Goods Authorization Number.

MEDICAL DEVICE REPORTING

Any potential adverse incident involving Total Joint Orthopedics products should be reported immediately by calling 888.890.0102.

WARRANTY AND LIMITATION OF LIABILITY

Total Joint Orthopedics, Inc. warrants that the product when delivered is free from defect in materials and workmanship and conforms to the manufacturer's product specifications. This warranty applies for the period of time up to and including the expiration date of the product. At its option, Total Joint Orthopedics will replace or provide a refund for this product if it is found to be defective. The product must be returned

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to Total Joint Orthopedics in the original packaging with the catalog and lot numbers, or according to the return goods policy. Total Joint Orthopedics shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of, or inability to use, its product.

THE FOREGOING WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES, WHETHER EXPRESSED OR IMPLIED, ARISING BY OPERATION OF LAW OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Total Joint Orthopedics neither assumes, nor authorizes any person to assume for it, any other additional liability or responsibility with respect to this product other than as set forth in writing herein.

CUSTOMER SERVICE INFORMATION

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For Symbol Glossary, please visit: tjoinc.com/ifu.

TABLE 1: KLASSIC BIPOLAR SYSTEM IMPLANT COMPONENT MATERIALS

Component	Materials
Klassic BiPolar System BiPolar Head	CoCrMo Alloy, UHMWPE, Ti6Al4V Alloy
Klassic BiPolar System 22mm and 28mm Femoral Head	CoCrMo Alloy