TOTAL JOINT ORTHOPEDICS

TOTAL JOINT ORTHOPEDICS, INC.
Klassic HD® Hip 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 HD® Hip System Surgical Technique Manual for information on implantation technique and preoperative planning and postoperative care. (For a copy of the Surgical Technique Manual, please visit tjoinc.com/stm.)

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

## INDICATIONS FOR USE
The Klassic HD Hip System is intended for prosthetic replacement without bone cement in treatment of the following:
- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis, osteoarthritis, ankylosis, protrusio acetabuli and painful hip dysplasia
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis
- Patients with failed previous surgery where pain, deformity, or dysfunction persists
- Revision of a previously failed hip arthroplasty
- Patients who require a total hip replacement

## PRODUCT DESCRIPTION & IMPLANT MATERIALS
The Klassic HD Hip System is simple, easy to use, and based on clinically proven design philosophies. The Klassic HD Hip System employs a prosthesis designed to help surgeons restore hip joint biomechanics intraoperatively by independently addressing the size of the femur and acetabulum, version, leg length, and offset.

The Klassic HD Hip System is comprised of modular components, with varying sizes available for each component for a cementless hip joint replacement application. Components of the Klassic HD Hip System include the femoral stem, femoral head, femoral head adapter sleeve, acetabular cup, acetabular insert and cancellous bone screws. Refer to Table 1 for the listing of component materials for the Klassic HD Hip System. The implantable components are intended for single-use only in a single patient and are only to be used with other Klassic HD Hip System implants.

## PRODUCT HANDLING
The Klassic HD Hip System is 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 HD Hip System, 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 HD Hip System should be stored in a clean, dry location at room temperature.

## CONTRAINDICATIONS
The Klassic HD Hip 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.

## MRI SAFETY INFORMATION
The Klassic HD Hip System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Klassic HD Hip System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

## 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 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 the Klassic HD Hip System 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 themated 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.
- Do not assemble a BIOLOX®*delta* Femoral Head, 12/14 Taper, or BIOLOX CONTOURA® Femoral Head onto a Femoral Stem taper that has had a femoral head previously removed. An Adapter for BIOLOX®OPTION Femoral Head, along with a BIOLOX®OPTION Femoral Head should be used on a previously assembled stem taper. Use the BIOLOX®OPTION Femoral Head only if taper exhibits minor scratches from previous femoral head assembly and removal. Do not use BIOLOX®OPTION Head on excessively damaged stem tapers.
- Exercise care with the heads of femoral hip prostheses. Remove protective coverings only prior to implantation.
- A BIOLOX®*delta* Femoral Head, 12/14 Taper, BIOLOX CONTOURA® Femoral Head, BIOLOX®OPTION Femoral Head, or Adapter for BIOLOX®OPTION Head must not be re-used if previously impacted and removed.

## ADVERSE EFFECTS
The following adverse effects have been reported for total 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 HD Hip System components are supplied sterile in a double sterile barrier system. 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.

All components of the Klassic HD Hip System are sterilized by gamma irradiation to achieve a Sterility Assurance Level (SAL) of $10^{-6}$ with the exception of the Klassic HD Hip System – Acetabular Inserts and Platform Acetabular Inserts which 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.

*continued*

## 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 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

Total Joint Orthopedics, Inc.
1567 East Stratford Ave.
Salt Lake City, UT 84106
Phone: 888.890.0102
Fax: 801.486.6117

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

TABLE 1: KLASSIC HD HIP SYSTEM COMPONENT MATERIALS

| Component | Materials | Sizes |
|---|---|---|
| Klassic HD Hip System – Femoral Stem with Ti-Coat® | Ti6Al4V Alloy and CP Ti porous coating | 1-9 |
| Klassic HD Hip System – Offset Femoral Stem with Ti-Coat® | Ti6Al4V Alloy and CP Ti porous coating | 2-9 |
| Klassic HD Hip System – Klassic Blade Femoral Stem | Ti6Al4V Alloy and CP Ti porous coating | 1-12 |
| Klassic HD Hip System – Klassic Blade Offset Femoral Stem | Ti6Al4V Alloy and CP Ti porous coating | 1-12 |
| Klassic HD Hip System – Femoral Head | CoCrMo Alloy | 32 & 36mm: -3.5, +0, +3.5, +7mm head length |
| BIOLOX®*delta* Ceramic Femoral Head | $Al_2O_3$, $ZrO_2$ – ceramic | 22mm: +2, +4mm head length<br>28mm: -3.5, 0, +3.5 head length<br>32 & 36mm: -3.5, +0, +3.5, +7mm head length |
| BIOLOX® OPTION Ceramic Revision Femoral Head | $Al_2O_3$, $ZrO_2$ – ceramic | 28, 32, 36mm |
| BIOLOX CONTOURA® Ceramic Femoral Head | $Al_2O_3$, $ZrO_2$ – ceramic | 28mm: -3.5, +0, +3.5mm head length<br>32 & 36mm: -3.5, +0, +3.5, +7mm head length |
| Klassic HD Hip System – Femoral Head Adapter Sleeve | Ti6Al4V Alloy | -3.5, +0, +3.5, +7, +10.5mm head length |

| Component | Materials | Sizes |
|---|---|---|
| Klassic HD Hip System – Acetabular Cup with Ti-Coat® | Ti6Al4V Alloy and CP Ti porous coating | 44-64mm (in 2mm increments) |
| Platform Acetabular Cup with Ti-Coat® | Ti6Al4V Alloy and CP Ti porous coating | 44-64mm (in 2mm increments) |
| Klassic HD Hip System – Acetabular Insert with E-Link® Poly | UHMWPE, Vitamin E | 48-64mm (32 & 36mm heads only) (in 2mm increments) |
| Klassic HD Hip System – Hooded Acetabular Insert with E-Link® Poly | UHMWPE, Vitamin E | 44-64mm (in 2mm increments) |
| Klassic HD Hip System – Low Profile Acetabular Insert with E-Link® Poly | UHMWPE, Vitamin E | 48-64mm (in 2mm increments) |
| Platform Neutral Acetabular Insert with E-Link® Poly | UHMWPE, Vitamin E | 44-64mm (28, 32 & 36mm heads only) (in 2mm increments) |
| Platform Hooded Acetabular Insert with E-Link® Poly | UHMWPE, Vitamin E | 44-64mm (28, 32 & 36mm heads only) (in 2mm increments) |
| Klassic HD Hip System – Acetabular Insert with XLPE | UHMWPE | 48-64mm (32 & 36mm heads only) (in 2mm increments) |
| Klassic HD Hip System – Cancellous Bone Screw | Ti6Al4V Alloy | 15-45mm (in 5mm increments) |