TOTAL JOINT ORTHOPEDICS

TOTAL JOINT ORTHOPEDICS, INC.
Klassic® Knee 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® Knee System Surgical Technique Manual for information on implantation technique and preoperative planning. (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 Knee System is intended for prosthetic replacement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis and osteoarthritis
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis
- Patients with failed previous surgery where pain, deformity, or dysfunction persists
- Correctable varus-valgus deformity and moderate flexion contracture
- Revision of a previously failed knee arthroplasty
- Patients who require a total knee replacement

The Klassic Knee System is indicated for cemented use only, except for the Klassic Femur with Cobalt 3D®, the Klassic Tibial Baseplate with Ti-Coat®, and the Universal® Cone with Ti-Coat, which are indicated for cementless use.

The Klassic Knee System is also indicated for temporary use (maximum 180 days) as an adjunct to total knee replacement (TKR) in patients undergoing a two-stage procedure due to a septic process and where gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organism(s). These devices are intended for implantation with FDA cleared gentamicin loaded bone cement following implant removal and radical debridement, and in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach for an infection). For the first stage revision, these devices are not intended for use for more than 180 days, at which time they must be explanted and permanent devices implanted, or another appropriate treatment performed (e.g., resection arthroplasty, fusion, etc.). These devices are only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers, canes) throughout the implantation period.

PRODUCT DESCRIPTION & IMPLANT MATERIALS

The Klassic Knee System is a cemented total knee joint replacement system intended for use in primary knee surgery. The Klassic Knee System is a semi-constrained design and both the medial and lateral collateral ligaments must be intact. The Klassic Knee System utilizes a symmetrical design, eliminating the need for left/right orientations. The patella-femoro-tibial prosthesis includes a metal femoral component, a tibial component consisting of a polyethylene tibial bearing fixed to a metal tibial baseplate with a polyethylene dome extension, and a metal tibial insert set screw or All-Poly Tibia, and a polyethylene patellar component. Refer to Tables 1-3 for the listing of component materials for the Klassic Knee System. The implantable components are intended for single-use only in a single patient and are only to be used with other Klassic Knee System implants.

PRODUCT HANDLING

The Klassic Knee System is provided sterile and should always be stored unopened. Prior to use, inspect package for damage that may compromise sterility. If packaging has been opened or damaged, contact TJO Customer Service. Before opening the Klassic Knee 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 Knee System shall be stored in a clean, dry location at room temperature.

CONTRAINDICATIONS

The Klassic Knee System is contraindicated for use in patients with:

- Vascular deficiency at the bone site
- Inadequate bone stock to assure both a firm press fit and close apposition of the cut bone surfaces to the prosthesis
- Inadequate bone quality (e.g., severe osteoporosis)
- The inability to make bone cuts so as to assure both correct component position and intimate apposition of bone and prosthetic surfaces
- Sensitivity to implant materials
- Sepsis or osteomyelitis
- Insufficient bone structure or quality, which may affect the stability of the implant
- Rapid joint destruction or bone absorption
- Skeletal immaturity
- Severe instability secondary to advanced loss of osteochondral structure or the absence of collateral integrity
- Other conditions that will place excessive demands on the joint, including:
  - Muscle deficiencies
  - Multiple joint disabilities
  - Refusal to modify postoperative physical activities
  - Obesity

Conditions that tend to impose severe loading on the affected extremity include, but not limited to, the following:

- Heavy labor
- Active sports
- History of falls
- General neurological abnormalities or neurological conditions, including mental conditions (mental illness, senility, drug use, alcoholism) that tend to pre-empt the patient's ability or willingness to follow the surgeon's postoperative instructions.

CONTRAINDICATIONS FOR 1ST STAGE OF A 2 STAGE TREATMENT FOR PERIPROSTHETIC JOINT INFECTION

Patient's two-stage arthroplasty procedure is contraindicated based on decreased immune response or systemic clinical conditions.

- Infection of the TKR cannot be confirmed. Infecting bacterium/pathogens resistant to gentamicin
- Infecting bacterium/pathogens are not susceptible to gentamicin
- A remote infection (systemic/secondary) is suspected or verified
- Myastenia gravis
- The patient does not have a TKR and the infection is secondary to trauma, septic arthritis or other surgical procedures
- Patient is unable or rejecting the use of protected weight bearing devices throughout the implantation period (canes, walkers, crutches, etc.)
- Age, weight or activity level, may cause the surgeon to expect possible, early failure of the knee spacer
- Patient exhibits hypersensitivity (allergy) to PMMA bone cement, aminoglycosides or gentamicin

WARNINGS

- Component loosening or fracture, particularly of smaller sized implants, is most likely to occur in patients who are young, physically active, and/or heavy

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.
- The components should be protected from mechanical damage and should not contact any metallic or other hard surface
- Improper component selection, placement, positioning, or fixation may result in unusual stress conditions, reducing the service life of the prosthetic implants
- 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.

Prior to 1st stage implantation of a 2-stage treatment for periprosthetic joint infection (temporary use), antibiotic susceptibility testing should be performed following a fine needle aspiration from the joint site. When being used as a spacer, the Klassic Knee System must not remain implanted for more than 180 days. The operative area should be rigorously irrigated and rinsed after device extraction to remove all cement debris prior to implantation of the permanent prosthesis or other surgical procedures (fusion, resection arthroplasty, etc.). Survival of the revision implant may be jeopardized if cement and/or bone debris are not thoroughly removed. The device has specific indications for use. Thus its use under conditions other than the intended ones is unlikely to provide any benefit to the patient.

- NOTE: THE SNAP MECHANISM ON THE TIBIAL INSERT MAY BE ENGAGED ONLY ONE TIME.

continued

DO NOT ATTEMPT TO REINSERT AN ALREADY UTILIZED TIBIAL INSERT

- NOTE: THE TIBIAL INSERT SET SCREW MUST BE USED WITH THE TIBIAL INSERT. NOT APPLICABLE FOR THE ALL-POLY TIBIA COMPONENTS

ADVERSE EFFECTS

The following adverse effects have been reported for total knee replacement:

- Corrosion of metal implants
- Deep wound infections
- Disassembly of modular components
- Dislocation and subluxation
- Early or late loosening of components
- Malalignment of the prosthetic knee components
- Fatigue fracture
- Venous thromboembolic disease
- Inflammatory reactions or osteolysis
- Metal sensitivity
- Peripheral neuropathies or subclinical nerve damage
- Tissue or allergic reaction to corrosion, wear, or cement particles

STERILITY

Unless opened or damaged, the Klassic Knee 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 metal components of the Klassic Knee System are sterilized by gamma irradiation to achieve a Sterility Assurance Level (SAL) of 10^{-6}; polyethylene components (Tibial Inserts, Patellae and All-Poly Tibia components) are sterilized by Ethylene Oxide gas 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.

For 1st stage implantation of a 2-stage treatment for periprosthetic joint infection (temporary use), postoperative treatment is comparable with a primary knee implant, however, weight-bearing can be only partial (use of canes, crutches, etc.). It is recommended that partial weight-bearing be assessed on an individual basis in relation to the anatomic conditions of the femur and tibia, bone trophism and the clinical conditions of the patient during rehabilitation stages. Avoid weight bearing or forced mobilization which could cause the implant to damage the biological structure. If needed, a brace (possibly articulated) to assist flexion may be suggested in cases at risk of dislocation (in relation to the stability and/or the condition of the extensor apparatus).

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.
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Phone: 888.890.0102
Fax: 801.486.6117

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

TABLE 1: KLASSIC KNEE SYSTEM COMPONENT MATERIALS

Component	Materials	Sizes
Klassic Femur, Nonporous	CoCr	Sizes: 1-7
Klassic Femur with Cobalt 3D®	CoCr	Sizes: 1-7
Klassic Femur with Aurum®	Ti6Al4V Alloy, TiN	Sizes: 1-7
Klassic Femur, PS-Post®	CoCr	Sizes 1-7
Klassic Femoral Peg	CoCr	One Size
Klassic Tibial Baseplate, Nonporous	Ti6Al4V Alloy	Sizes: 1-6
Klassic Tibial Baseplate with Ti-Coat®	Ti6Al4V Alloy	Sizes: 1-6
Klassic Tibial Insert, CR/ Congruent with E-Link® Poly	UHMWPE, Vitamin E	Sizes: 1-6 Thickness: 10-14, 16, 18mm
Klassic Tibial Insert, CR/ Congruent	UHMWPE	Sizes: 1-6 Thickness: 10-18mm (in 2mm increments)
Klassic Tibial Insert, Ultra-PS® with E-Link Poly	UHMWPE, Vitamin E	Sizes: 1-6 Thickness: 10-14, 16, 18mm
Klassic Tibial Insert, Ultra-PS	UHMWPE	Sizes: 1-6 Thickness: 10-18mm (in 2mm increments)
Klassic All-Poly Tibia, CR/ Congruent	UHMWPE	Sizes: 1-6 Thickness: 10-16mm
Klassic All-Poly Tibia, Ultra-PS	UHMWPE	Sizes: 1-6 Thickness: 10-16mm
Klassic Tibial Insert, PS-Post, E-Link Poly	UHMWPE, Vitamin E	Sizes: 1-6 Thickness: 10-14, 16, 18, 21, 24mm
Klassic Tibial Insert, PS-Max®, Std Poly	UHMWPE	Sizes: 1-6 Thickness: 10-14, 16, 18, 20-22, 24mm
Klassic Domed Patella	UHMWPE	Sizes: 1-4
Klassic Sombrero Patella	UHMWPE	Sizes: 1-4 Thickness: 7, 10mm
Klassic Tibial Dome Extension	UHMWPE	One Size
Klassic Tibial Insert Set Screw	Ti6Al4V Alloy	One Size
Klassic Stem Adapter, Femoral	Ti6Al4V Alloy	One Size
Klassic Femoral Augment, Distal	Ti6Al4V Alloy	Sizes: 1-2, 3-4, 5-7 Thickness: 5, 10mm
Klassic Femoral Augment, Posterior	Ti6Al4V Alloy	Sizes: 1-2, 3-4, 5-7 Thickness: 5, 10mm
Klassic Tibial Augment	Ti6Al4V Alloy	Sizes: 1-2, 3-4, 5-6 Thickness: 5, 10mm
Klassic Femoral Augment Screw, Distal	Ti6A14V Alloy	Lengths: 5, 10mm
Klassic Augment Screw	Ti6Al4V Alloy	Lengths: 5, 10mm
Klassic Universal® Cone with Ti-Coat	Ti6Al4V Alloy	Sizes: 1-7

continued

TABLE 2: KLASSIC REVISION KNEE SYSTEM COMPONENT MATERIALS

Component	Materials	Sizes
Klassic Tibial Baseplate, Revision	Ti6Al4V Alloy	Sizes: 1-6
Klassic Tibial Stem Extension	Ti6Al4V Alloy	Lengths: 25-150mm
Klassic Stem Extension, Cemented	Ti6Al4V Alloy	Diameters: 12, 14mm Lengths: 50, 70, 120mm
Klassic Stem Adapter, Femoral	Ti6Al4V Alloy	One Size
Klassic Femoral Augment, Distal	Ti6Al4V Alloy	Sizes: 1-2, 3-4, 5-7 Thickness: 5, 10mm
Klassic Femoral Augment, Posterior	Ti6Al4V Alloy	Sizes: 1-2, 3-4, 5-7 Thickness: 5, 10mm
Klassic Tibial Augment	Ti6Al4V Alloy	Sizes: 1-2, 3-4, 5-6 Thickness: 5, 10mm
Klassic Femoral Augment Screw, Distal	Ti6A14V Alloy	Lengths: 5, 10mm
Klassic Augment Screw	Ti6Al4V Alloy	Lengths: 5, 10mm
Universal® Cone with Ti-Coat	Ti6Al4V Alloy	Sizes: 1-7

TABLE 3: KLASSIC INFECTION SPACER SYSTEM COMPONENT MATERIALS

Component	Materials	Sizes
Klassic Infection Spacer	UHMWPE	Sizes: 1-6 Thickness: 10, 18mm
Klassic Infection Spacer – Dome Extension	UHMWPE	One Size
Klassic Infection Spacer Augment	UHMWPE	Sizes: 1-2, 3-4, 5-6 Thickness: 2, 4, 6mm

MRI Safety Information

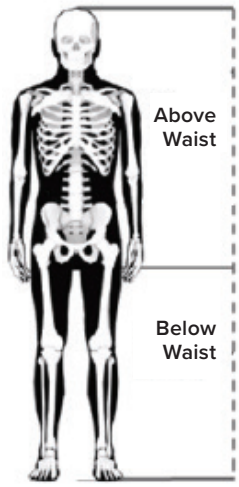
A person with the Total Joint Orthopedics Klassic Knee System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Family	Total Joint Orthopedics Klassic Knee System
Static Magnetic Field Strength (B0)	1.5T or 3.0T
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Volume RF body coil
Operating Mode	Normal Operating Mode as defined below
Maximum Whole-Body SAR	See **MRI Restricted Zone Summary**
Maximum Head SAR	2 W/kg (Normal Operating Mode)
Scan Duration	Scan duration up to 60 minutes as detailed in the MRI Restricted Zone Summary
Scan Regions	Landmark restrictions as detailed in the **Operating Mode section** and the **MRI Restricted Zone Summary**
Image Artifact	The presence of The Klassic Knee System may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.

MRI RESTRICTED ZONE SUMMARY

Total Joint Orthopedics Klassic® Knee System

Landmark Region	1.5 T	3.0 T
Above the Waist	Whole body SAR 2 W/kg, patient can be safely scanned continuously for 60 minutes	Whole body SAR 2 W/kg, patient can be safely scanned continuously for 60 minutes
Below the Waist	0.2 W/kg or B1 + rms at 1.9μT, patient can be safely scanned continuously for 60 minutes	



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