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CE 2764

aap Joints GmbH
PreciTotal Cementless Knee System
PreciTotal Knee System
Instructions for Use (IFU)

IMPORTANT INFORMATION FOR SURGEON: PLEASE READ PRIOR TO IMPLANTING THIS DEVICE IN A CLINICAL SETTING. THE SURGEON SHOULD BE FAMILIAR WITH THE SURGICAL TECHNIQUE.

DESCRIPTION

The PreciTotal Cementless Knee System consists of tibial insert, patellar, tibial tray and femoral component.

The tibial insert and patellar are made of UHMWPE and have various sizes.

The femoral component is made of CoCrMo alloy and the backside is coated with commercially pure titanium(CP Ti) and it has two versions: CR(cruciate retained) and PS(posterior stabilized) versions. The femoral component articulates with the patellar and the tibial insert. The CR femoral component has two pegs to achieve initial fixation. The PS femoral component has an inter-condyle box to accommodate the tibial insert spine. There is a bar at the end of the box and it works as a cam-spine mechanism with the tibial insert spine.

The OSSEOMATRIX Tibial Tray is manufactured through additive manufacturing process using titanium alloy powder. It has a porous region on the lower surface and on the keel, and has a solid on the upper surface. There are four pegs on the lower surface of the tibial tray. A tibial insert has to be assembled with the tibial component and articulate with the femoral component. OSSEOMATRIX Tibial Tray is used in total knee arthroplasty.

The femoral component and OSSEOMATRIX Tibial Tray are only for cementless use.

PreciTotal Knee System has two versions: CR(cruciate retained) and PS(posterior stabilized) versions. Each version has a CoCrMo alloy femoral component, a CoCrMo alloy tibial tray, and a polyethylene tibial insert. The polyethylene patellar component can be used with both CR and PS version femoral component. The tibial insert has to be assembled with the tibial component and articulate with the femoral component. The patellar has three pegs. The interior fixation surfaces of the femoral component and nonporous tibial component are bead blasted at the implant-cement-bone interface. PreciTotal Knee System is for cemented use only.

INTENDED USE

The PreciTotal Cementless Knee System and PreciTotal Knee System are designed for total knee arthroplasty. They are designed for primary bicondylar replacement of the knee joint or to replace a dysfunctional knee prosthesis.

Total knee arthroplasty is a surgical procedure to resurface a damaged knee. The components are supplied sterile and going to place the surface of a damaged knee by invasive surgery.

MATERIAL

Femoral component: Cobalt Chrome Alloy (CoCrMo)

Coating: commercially pure titanium (CPTi)

Tibial Tray: Titanium Alloy (Ti-6Al-4V) or Cobalt Chrome Alloy (CoCrMo)

Tibial insert, Patellar: Ultra-High Molecular Weight Polyethylene (UHMWPE) or Highly cross linked UHMWPE with α-tocopherol (VE HXL UHMWPE)

HOW PRODUCT IS SUPPLIED

Each component is supplied STERILE, is contained in individual boxes or packages designed to maintain sterility, and is available in a wide range of sizes. Please refer to surgical technique for the catalog numbers and sizes available. The recommended trial components are used for size determination, preparation, evaluation, trial reduction, and range of motion evaluation. The use of trials preserves the integrity of implants and sterile packaging.

SIZE COMPATIBILITY

Tibial Tray	1	2	3	4	5	6	7	8	9
Tibial Insert	1	2	3	4	5	6	7	8	9
Femoral Component	1,2	1,2,3,4	1,2,3,4,5	2,3,4,5,6	3,4,5,6,7	4,5,6,7,8	5,6,7,8,9	6,7,8,9	7,8,9

Note: The OSSEOMATRIX Tibial Tray doesn't have Size 9.

The femoral components and tibial components in PreciTotal Cementless Knee System can be used with the VE HXL UHMWPE tibial inserts and VE HXL UHMWPE patellar in PreciTotal Knee System.

The femoral components and tibial components in PreciTotal Knee System can be used with the UHMWPE tibial inserts and UHMWPE patellar in PreciTotal Cementless Knee System.

INDICATIONS FOR USE

The PreciTotal Cementless Knee System and PreciTotal Knee System are designed for total knee arthroplasty.

The indications for use are:

A. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis;
B. Varus, valgus, or post traumatic deformity;
C. Revision of previous unsuccessful knee replacement
D. CONTRAINDICATIONS
E. Any active or suspected latent infection in or about the knee joint.
F. Mental or neuromuscular disorders which would create unacceptable risk of prosthesis instability or complications in post-operative care.
G. Bone stock compromised by disease, infection, or prior implantation that cannot provide adequate support and fixation of the device.
H. Ligamentous or severe muscle laxity or inadequate soft tissue coverage to allow for the normal healing process and for proper mechanics to be re-established.
I. Conditions which tend to place increased loads on implants, such as age, weight, and activity level which are incompatible with a satisfactory clinical long-term result.

WARNINGS

A. All components are sold sterile. If packages appear damaged or tampered with, they should be returned to the supplier.
B. Do not implant any device that has been used, even if it appears undamaged.
C. Do not bend or contour an implant, as this may reduce its fatigue strength and may cause immediate or eventual failure under load.
D. Never tamper with implants. Tampering may have a detrimental affect on the performance of the implant.
E. The surgeon and O.R. staff must be extremely careful to protect all components from being marred, nicked, or notched as a result of contact with metal or any abrasive objects. This is particularly important for polished bearing areas.
F. Removal of implant may require the use of special instruments to disrupt the bone interface. These techniques may require practice in the laboratory before being attempted clinically.
G. Malalignment or soft tissue imbalance can place inordinate forces on the components, which may cause excessive wear to the patellar or tibial bearing articulating surfaces. Revision surgery may be required to reduce the risk of component failure.
H. Care is to be taken to ensure complete support of all parts of the device embedded in bone cement to reduce the risk of stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris, and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.
I. Do not use the components with the products manufactured by other companies.
J. Do not re-sterilize any products
K. Please scrap any products removed from the patient in revision surgeries
L. The components in the total knee system have not been evaluated for safety and compatibility in the MR environment. The components in the total knee system have not been tested for heating or migration in the MR environment. The risks of exposure to MR include heating and/or displacement of a metallic implant. Image artifacts including dead zones and distortion may occur, especially in the immediate area around the implant, requiring optimization of imaging parameters. Please refer to current local MR safety guidelines for additional investigation, patient monitoring and patient follow-up advice. Recommend that a professional familiar with the specific MRI apparatus to be used, assess the patient prior to any MRI examination or therapy.

PRECAUTIONS

A. Before any implant is used, the surgeon should be completely familiar with all aspects of the surgical procedure and the limitations of the device.
B. It cannot be expected that joint replacements will withstand the same activity levels as normal healthy bone.
C. Excessive physical activity may result in premature failure of the implant system due to loosening, component fracture, and/or wear. Activities which place unreasonable amounts of stress on the joint should be avoided. Patients should be instructed on the limitations of the prosthesis and how to modify their activities accordingly.
D. Obese patients may place severe loading on the affected extremity which can be expected to accelerate joint failure. If appropriate, patients should be advised to follow a weight reduction or maintenance program.
E. Prosthetic replacement is generally indicated only for patients who have reached skeletal maturity. Total joint replacement in younger patients should be considered only when explicit indications outweigh the associated risks of the surgery and modified demands regarding the activity and joint loading are assured.
F. Instruct patients on the limitations of the prosthesis and how to modify their activities accordingly.
G. Proper selection of type and placement of the knee components are critical factors in the prevention of unusual stress conditions and their potentially harmful effects on the implant service life.
H. Patients with pregnancy, breast feeding woman, children, cancer or the contraindications above for total knee replacement are not suitable.
I. Except for instruments generally used for joint surgery, only instruments included in the aap Joints instrument list can be used with the implants from aap Joints.

ADVERSE EFFECTS

A. All prosthetic replacements have the potential for adverse effects, including infection, loosening, fracture, breakage, bending of the components, component disassembly, instability, allergies, pain, dislocation or positional changes of the components.
B. Sensitivity or allergic reactions to component materials could occur, and should be ruled out preoperatively.
C. Total joint replacement surgery is associated with serious complications including, but not limited to: nerve injury, direct arterial injury, false aneurysm, spontaneous vascular occlusion, deep vein thrombosis, ectopic ossification, non-union, dislocation, disassociation, superficial and deep infection, aseptic loosening, component failure, cement breakdown, and third party wear associated with polymethylmethacrylate or UHMWPE.

D. Pain due to loosening of the implant, and/or localized pressure associated with incongruencies of the fit, or tissue inflammation of unknown etiology.
E. Postoperative femoral or tibial fracture can occur due to trauma, the presence of defects, or poor bone stock.
F. Periarticular calcification or ossification, with or without impediment of joint mobility.
G. Inadequate range of motion due to improper selection or positioning of components.
H. Undesirable shortening of limb.
I. Fretting and crevice corrosion can occur at interfaces between components.
J. Wear and/or deformation of articulating surfaces.
K. Valgus-varus deformity.
L. Patellar tendon rupture and ligamentous laxity.
M. Other complications generally associated with surgery, drugs, blood use, or ancillary devices used.

INFORMATION

Surgical techniques and additional information may be obtained from an aap Joints representative or the company directly.

STERILIZATION AND HANDLING

All metal components have been sterilized through Gamma radiation and all polyethylene components have EO sterilization. Do not use any component if the package has been breached. Use caution in handling polished components.

WARNING: Single Use Only: This product is intended for single use only. Do not attempt to re-use, even if the device appears to be undamaged. Risks include device damage leading to poor performance or failure, patient cross-contamination, inadequate sterilization and general liability. Don't resterilize the components.

INTENDED USER

The product should be implanted only by orthopedic surgeons who are thoroughly knowledgeable in the implant's material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations.

BRIEF OPERATION STEPS:

Step1:prepare the distal femur;
Step2:prepare the proximal tibial;
Step3:perform the trial reduction;
Step4:place the femoral component;
Step5:place the tibial components;
Step6:optional patellar resurfacing and patellar component placement;
Step7:wound closure.

Details please refer to Surgical Technique, which can be acquired from representative of aap Joints GmbH or service@aap-joints.com

PRODUCT STORAGE CONDITION: Products shall be stored in a dry and clean place with room temperature condition and avoid sun-shining.

CAUTION: Disposal of single-use implant device. This device should be regarded as bio-contaminated and handled accordingly. Plastic or metal implants should be terminally sterilized and disposed of following existing hospital policies and procedures. The products have not been evaluated for safety in the Magnetic Resonance (MR) environment. **CAUTION:** FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

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Symbols

	Manufacturer		Catalog number		Batch code		Do not re-use
	Caution		Do not resterilize		Consult Instructions for use		Use by date
	Sterilized using ethylene oxide		Sterilized using irradiation		Keep away from sunlight		Do not use if package is damaged