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CE 2764

aap Joints GmbH
PreciTotal Revision 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

PreciTotal Revision Knee System consists of a CoCrMo alloy femoral component, a CoCrMo alloy tibial component, a polyethylene tibial insert, an augment, an adaptor, an augment screw and a connecting screw. The tibial insert made of conventional polyethylene only has a PS version. The tibial insert has to be assembled with the tibial component and articulate with the femoral component. The polyethylene patellar component and tibial insert from PreciTotal Knee System and PreciTotal Cementless Knee System can be used with the femoral component and tibial component in PreciTotal Revision Knee System. The augment connects with with a femoral component/tibial component through an augment screw to replace lost bone and act as a space-filler adjacent to the prosthesis. The extension stem connects with a tibial or femoral component by using an adaptor and a connecting screw. PreciTotal Revision Knee System is for cemented use only.

Intended use

PreciTotal Revision Knee System is intended to use for either a primary or revision knee arthroplasty procedure. The components are supplied sterile and going to place the surface of a damaged knee by invasive surgery

MATERIAL

Femoral component, Tibial Component: Cobalt Chrome Alloy (CoCrMo)
Tibial insert: Ultra-High Molecular Weight Polyethylene (UHMWPE)
Augment, Adaptor, Screws and Extension Stem: Titanium Alloy (Ti-6Al-4V)

HOW PRODUCT IS SUPPLIED

Each component of PreciTotal Revision Knee System 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 the current price list, surgical technique or catalog 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 Component	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

INDICATIONS FOR USE

The PreciTotal RevisionKnee System is 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 fxation 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

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.
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, 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 been sterilized through an Ethylene Oxide sterilization process. 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.

BRIEF OPERATION STEPS:

Step 1: Remove knee component of previous knee arthoplasty surgery if it is a knee revision surgery
Step 2: Shaping the distal femoral bone
Step 3: Preparing the proximal tibial bone
Step 4: Preparing the patellar
Step 5: Placing the femoral component with augment or extension stem if necessary
Step 6: Placing the tibial components with augment or extension stem if necessary
Step 7: Placing the patellar component
Step 8: Closing the incision

Details please refer to Surgical Technique, which can be acquired from representative of aap Joints 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		Consult Instructions for use		Caution
	Do not resterilize		Keep away from sunlight		Use by date
	Do not use if package is damaged		Sterilized using ethylene oxide		Sterilized using irradiation