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CE 2764

aap Joints GmbH
Bipolar Hip Prosthesis
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 Bipolar Hip Prosthesis consists of a bipolar head and a bipolar insert. The bipolar insert is comprised of a liner and a locking ring made from highly cross-linked UHMWPE or UHMWPE. During the hemiarthroplasty operation, the Bipolar Hip Prosthesis is usually combined with a plug-in femoral head and a hip stem. There are various sizes of bipolar outer shell diameters, ranging from 39mm to 59mm with 1mm increment to cater to different acetabulum sizes in different patients. Moreover, the bipolar insert is designed dependent on the outer shell diameters and the inner femoral hole diameters.

PRODUCT MODEL

Bipolar head and bipolar insert have only one model and are designed for hemi-hip arthroplasty. Different sizes are classified by diameters.

INTENDED USE

Bipolar head and bipolar insert are intended for prosthetic replacement of the femoral head in hemi-hip arthroplasty where there is evidence of a satisfactory natural acetabulum and sufficient femoral bone to seat and support the femoral stem with a femoral head implant, that must be used in conjunction with the device. The bipolar head and bipolar insert are supplied sterile and going to place the surface of a damaged hip by invasive surgery.

MATERIAL

Bipolar Insert Component: Highly Cross-linked Ultra-High Molecular Weight Polyethylene (HXL UHMWPE) or Ultra-High Molecular Weight Polyethylene (UHMWPE)
Bipolar Head Component: Cobalt Chrome Alloy (CoCrMo)

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 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.

INDICATIONS FOR USE

The indications for use are:

A. Fracture dislocation of the hip;
B. Nonunion of femoral neck fractures;
C. Avascular necrosis of the femoral head;
D. Pathological fractures of the femoral neck;
E. Certain high subcapital and femoral neck fractures in the elderly.

CONTRAINDICATIONS

A Any joint with active or suspected latent infection.
B Neuromuscular disorders or mental conditions whereby the risks associated with these conditions are outweighed by the benefits to be derived.
C Any condition of the bone stock in which sufficient support and fixation of the implant is in question.
D Obese or overweight patients who may place undue loads on the prosthesis which can result in failure of the device.
E Any pathological conditions of the joint that would interfere in achieving appropriate range of motion, adequate head stability, and a well seated and supported prosthetic combination.
F Ligamentous or severe muscle laxity or inadequate soft tissue coverage to allow for the normal healing process and for proper hip mechanics to be reestablished.
G For hemi-hip arthroplasty, any pathological condition of the acetabulum, such as distorted acetabuli with irregularities, Protrusio acetabuli (arthrokatadysis), or migrating acetabuli, that would preclude the use of the natural acetabulum as an appropriate articular surface for the hemi-hip prosthesis.

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 effect 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 and machined taper surfaces.
F The surgeon is responsible for verifying that the components selected are compatible with each other, considering the product compatiblity information provided by aap Joints. For ceramic-ceramic articulation, only a ceramic head and insert from the same manufacturer should be used.
G Do not re-sterilize any products.
H Please scrap any products removed from the patient in revision surgeries.

The components in the hemi-hip system have not been evaluated for safety and compatibility in the MR environment. The components in the hemi-hip 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. Proper selection of fixation type and placement of the femoral stem and acetabular component are critical factors in the prevention of unusual stress conditions and their potentially harmful effects on the life expectancy of the implant.
G. Patients with pregnancy, breast feeding woman, children or cancer or the contraindications above for total or hemi hip replacement.
H. 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. Joint replacement surgery is associated with serious complications including, but not limited to: bone fracture, nerve injury, direct arterial injury, false aneurysm, spontaneous vascular occlusion, deep vein thrombosis, ectopic ossification, non-union, subluxation, dislocation, myocardial infarction, disassociation, superficial and deep infection, aseptic loosening, component failure, cement breakdown, and acetabular erosion, 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. Periarticular calcification or ossification, with or without impediment of joint mobility.
F. Inadequate range of motion due to improper selection or positioning of components.
G. Undesirable shortening of limb.
H. Fretting and crevice corrosion can occur at interfaces between components.
I. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
J. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
K. 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. Do not re-sterilize the 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:

Step 1: Shaping the proximal femoral bone

Step 2: Placing the femoral stem
Step 3: Snapping the bipolar insert over the femoral head
Step 4: Snapping the bipolar head onto the bipolar insert
Step 5: Place the bipolar head/insert/femoral head assembly to the femoral stem
Step 6: 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 irradiation		Sterilized using ethylene oxide