



aap Joints GmbH
Dual Mobility 4X Hip Prosthesis
Dual Mobility Hip (DMH) 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

Dual Mobility 4X Hip Prosthesis has a Cobalt Chrome Liner and a polyethylene bearing. The liner has a polished inner surface which articulates with the bearing with corresponding outer diameters. The liner can be used with titanium acetabular cups (VarioCup TPS, VarioCup Pressfit and OSSEOMATRIX Cup). The bearings are made of Highly cross-linked Ultra-High Molecular Weight Polyethylene (HXL UHMWPE) and Highly cross-linked Ultra-High Molecular Weight Polyethylene (HXL UHMWPE) with α -tocopherol. The modular head articulates with the bearing, which in turn articulates with a CoCrMo liner directly and the bearing can also be used with DMH Cup directly. All components are for cementless use only. The Dual Mobility 4X Hip Prosthesis has only one model and sizes are determined according to the diameters.

Dual Mobility Hip (DMH) System has a Cobalt Chrome cup coated with commercially pure titanium and a polyethylene bearing. The cup is for cementless use only and has peripheral ribs to achieve initial fixation. The bearings are made of Highly cross-linked Ultra-High Molecular Weight Polyethylene (HXL UHMWPE) with α -tocopherol. The bearing is designed to fit over 28mm modular metal or ceramic heads. The modular head articulates with the bearing, which in turn articulates with a DMH acetabular cup directly. All components are for cementless use only. The Dual Mobility Hip (DMH) System is available in one design with a wide range of cup diameters

Intended Use

The Dual Mobility 4X Hip Prosthesis bearing and liner is intended for use by trained orthopedic surgeons with the VarioCup or Osseomatrix Cup acetabular shell for prosthetic replacement of the acetabular joint section in total hip arthroplasty to alleviate pain and to restore function.

Dual Mobility 4X Hip Prosthesis consists of the CoCrMo liner and a polyethylene bearing. The CoCrMo liner is placed into an acetabular cup which is implanted into the prepared acetabulum before. The inner surface of the liner is highly polished and is going to articulate with the polyethylene bearing. The inner surface of the polyethylene bearing articulates with a metal or ceramic femoral head, which is attached to a femoral stem. The outer surface of the polyethylene bearing articulates with the CoCrMo Liner. There are two articulating surface: one between the liner and the bearing, another between the bearing and the femoral head. The design allows a large ROM and can reduce dislocation risks.

Dual Mobility Hip System consists of the CoCrMo acetabular cup and a polyethylene bearing. The acetabular cup is placed into the prepared acetabulum and the porous coated outer surface can enhance bone in-growth. The inner surface of the cup is highly polished and is going to articulate with the polyethylene bearing. The inner surface of the polyethylene bearing articulates with a metal or ceramic femoral head, which is attached to a femoral stem. The outer surface of the polyethylene bearing articulates with the CoCr acetabular cup. There are two articulating surface: one between the cup and the bearing, another between the bearing and the femoral head. The design allows a large ROM and reduces dislocation risks.

MATERIAL

DMH Cup: Cobalt Chrome Alloy (CoCrMo)

Coating: Commercially pure titanium (CPTi) (Only DMH cup is coated)

Liner: Cobalt Chrome Alloy (CoCrMo)

Bearing: Highly cross-linked Ultra-High Molecular Weight Polyethylene (HXL UHMWPE) and Highly cross-linked Ultra-High Molecular Weight Polyethylene 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 the current price list, surgical technique or catalog for the catalog numbers and sizes available. aap Joints implant can be used with the instruments specifically designed for aap Joints implant and manufactured by Youshi Medical.

INDICATIONS FOR USE

The Dual Mobility 4X Hip Prosthesis and Dual Mobility Hip (DMH) System are designed for total hip arthroplasty.

The indications for use are:

- A. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- B. Rheumatoid arthritis;
- C. Correction of functional deformity;
- D. Revision procedures where other treatments or devices have failed;
- E. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
- F. Dislocation risks

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.

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. Machined taper surface and the inner surface of the acetabular cup must be clean and dry at the time of assembly to ensure proper seating of the implant
- G. Tight fixation of all cementless components at the time of surgery is critical to the success of the procedure. Each component must properly press fit into the host bone which necessitates precise operative technique and the use of specified instruments. Bone stock of adequate quality must be present and appraised at the time of surgery.
- H. In order to minimize the risks of dislocation and loosening of the shell-acetabular bone interface that may occur when using a metallic shell intended for biological fixation, surgeons should consider providing immediate resistance to tensile forces between the metallic shell and the acetabular bone through the use of bone screws.
- I. The bearing may ONLY be used in conjunction with aap Joints's metal or ceramic femoral heads.
- J. Do not use the components with the products manufactured by other companies.
- K. Do not re-sterilize any products
- L. Please scrap any products removed from the patient in revision surgeries
- M. Do not impact the CoCrMo Liner with a metal head

The components in the total hip system have not been evaluated for safety and compatibility in the MR environment. The components in the total 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, cancer or the contraindications above for total or hemi hip replacement.
- H. Only instruments for which the compatibility with the implants of aap Joints GmbH has been tested and proven shall be used. A complete list of compatible instruments manufactured by our cooperation partner Youshi Medical can be found in the surgical technique.

ADVERSE EFFECTS

- A. All prosthetic replacements have the potential for adverse effects, including infection, loosening, fracture, breakage, bending of the components, component disassembly, subluxation, dislocation, osteolysis or positional changes of the components.
- B. Sensitivity and 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 in congruencies 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. Reoperation may be necessary to correct adverse effects.
- L. On rare occasions, complications may require arthrodesis, Girdlestone procedure or amputation of the limb.
- M. Other complications generally associated with surgery, drugs, blood use, or ancillary devices used.

INFORMATION

Surgical techniques and additional information may be obtained from a 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 coated components to prevent contamination of the coating or entrapment of debris in the coating. 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 re-sterilize 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: Preparing the Acetabulum side

Step 2: Placing the cup [Dual Mobility Hip (DMH) system] or the cup and liner [Dual mobility 4X Hip Prosthesis]

Step 3: Assemble the bearing and the femoral head

Step 4: Place the bearing/head assembly

Step 5: 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 re-sterilize		Keep away from sunlight		Use by date
	Do not use if package is damaged		Sterilized using ethylene oxide		Sterilized using irradiation