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CE 2764

aap Joint GmbH
VarioLoc® Modular 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 VarioLoc® Modular Hip Prosthesis consists of a proximal body, a distal stem and a connecting screw as assessory.
The proximal body is made of titanium alloy, coated with commercially pure titanium(CP Ti) or grit blasted and is for cementless use only. The proximal body has two models: standard offset(STD) and lateral offset(LAT) configurations. They are offered with various sizes.
The distal stem is made of titanium alloy and grit blasted. The distal stem has two models: straight and angled. The distal stem has with various sizes.
Both proximal body and distal stem are for cementless use only and a connecting screw should be used to assemble them together.

INTENDED USE

The VarioLoc Modular Hip Prosthesis is intended for extended cementless prosthetic replacement of the proximal portion of the femur for hip arthroplasty.
The proximal body has various diameters and heights while the distal stem has various diameters and lengths. An assembly of proximal body and distal stem can achieve optimized fit with the patient anatomy by selecting the most appropriate size of proximal body and distal stem. The fixation is achieved through the taper design of the distal stem (with grooves) and the bone on-growth between the femur and the proximal body.

MATERIALS

Proximal body, distal stem and connecting screw: Titanium Alloy (Ti-6Al-4V)
Coating: Commercially pure titanium(CP Ti)

HOW PRODUCT IS SUPPLIED

Each component of the VarioLoc Modular Hip Prosthesis 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.

INDICATIONS FOR USE

The VarioLoc Modular Hip Prosthesis is intended for extended cementless prosthetic replacement of the proximal portion of the femur for 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. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head Involvement, unmanageable using other techniques.
E. Revision of previously failed total hip arthroplasty.

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 Machined taper surfaces of the femoral stem, head and acetabular cup must be clean and dry at the time of assembly to ensure proper seating of the implant.
E Never tamper with implants. Tampering may have a detrimental affect on the performance of the implant.
F 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.
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 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.
I Do not re-sterilize any products
J Please scrap any products removed from the patient in revision surgeries

The components in the VarioLoc® Modular Hip Prosthesis have not been evaluated for safety and compatibility in the MR environment. The components in the VarioLoc® Modular Hip Prosthesis 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 affects on the life expectancy of the implant. The metal femoral head can't be used with the ceramic insert.
G. Patients with pregnancy, cancer, children, breastfeeding women 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. Total 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, 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. 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 musculartension, early weight bearing, or inadequate reattachment.
J. Problems of the knee or ankle of the affected limb or contralaterallimb 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 an aap Joints representative or the company directly.

STERILIZATION AND HANDLING

All metal components have been sterilized through Gamma radiation.Do not use any component if the package has been breached. Use caution in handling coated/porous components to prevent contamination of the coating/porous structure or entrapment of debris in the coating/porous structure. Don't resterilize 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 acetabulum
Step 2: Placing the acetabular cup
Step 3: Placing the acetabular insert
Step 4: Shaping the proximal femoral bone
Step 5: Placing the distal stem and proximal body with the use of connecting screw
Step 6: Placing the femoral head
Step 7: 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
	Caution		Do not resterilize		Keep away from Sunlight		Use by date
	Sterilized using irradiation		Do not use if package is damaged		Consult Instructions for use		