	Instructions for use For ADLER[®] Cementless Bipolar Hemiarthroplasty Prosthesis	Doc. No.: IU/10b
		Rev. No.: 05
		Rev. Date: 06DEC2017

Important Information on ADLER[®] Cementless Bipolar Hemiarthroplasty Prosthesis

For use by an Accredited Orthopaedic Surgeon only

1. Device Description:

Adler bipolar hemi-arthroplasty implants are used during a surgical procedure to replace the head of a damaged femur with an implant designed to stabilize the femur and restore hip function. During the procedure, only the ball of the femur is replaced. The system comprises of the Legend Cementless stems, the Moduloc Bipolar Cup, and Adler modular heads. The Legend stems, each available in various sizes are intra-operatively locked with the Adler Modular Heads, also available in multiple sizes by way of a self-locking 12/14 taper.

The Legend Hip Stem is a fully hydroxyapatite coated titanium alloy implant designed for cementless fixation. Adler modular heads are made of CoCrMo Alloy conforming to ASTM F1537, available in multiple neck length options are designed to be coupled with the Legend stem to enable multiple offset variations to suit variations in patient offset. Moduloc Bipolar Cups consist of a polyethylene liner (UHMWPE; ISO 5834-2) encased in a factory-assembled outer metallic stainless steel shell (ISO 5832-1). Liner inner diameters are either 22.20mm or 28.00mm depending on the outer shell diameter designed to ensure minimum UHMWPE liner thickness of 5.5mm in all cases.

2. Intended Purpose, Indications

Adler[®] Cementless Bipolar Hemiarthroplasty Prosthesis is indicated for use in Partial hip arthroplasty in skeletally mature patients with the following conditions:

- Treatment of proximal femoral non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
- Avascular necrosis of the femoral head.
- Acute traumatic fracture of the femoral head or neck.
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty.
- Certain cases of ankylosis.

Partial hip arthroplasty may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for hemi-hip replacement outweighs the risks associated with the age of the patient and if limited demands regarding activity and hip joint loading can be assured. (See WARNINGS AND PRECAUTIONS section)

Moduloc Bipolar Cup

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The Moduloc Bipolar Cup is designed for un-cemented use in conjunction with a standard cemented or un-cemented femoral replacement implant for the following:

- Treatment of proximal femoral non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
- Non-inflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post-traumatic arthritis.
- Rheumatoid arthritis.
- Arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis.
- Revision procedures where other treatment or devices have failed.

Notes:

Correct prosthesis selection is extremely important: Selection of the proper size, shape and design of the prosthesis significantly influences the potential for success of the procedure. Careful implant seating and adequate bony support are required. Small statured patients with relatively smaller anatomical dimensions may require the use of smaller sized implants. These smaller sized implants may not be appropriate for other patients. Regardless of the endosteal area of the bone, surgeons are encouraged to use their best medical judgment to choose the proper implant size for a given patient.

The following factors related to patient selection can be critical to eventual success of the procedure.

- Patient Weight:** Prostheses can be severely loaded due to overweight obese patients. Such overloads can lead to failure of the prosthesis. This can be a major consideration in cases where patients are small statured with small anatomical dimensions that require the use of a small sized implant.
- Patient occupation or activity:** Activities by operated patients that involve substantial walking, running, lifting or other activities that can cause muscle strain can result in forces that can cause failure of the fixation, the device or both. Patient's must be cautioned against unrealistic expectations of function and must bear in mind the fact that joint replacement prostheses do not possess the capability of restoring function to the level expected from normal healthy human bone.
- Alcoholism, senility, mental illness:** Patient's suffering from these conditions, among others, may be led to ignore certain necessary limitations and precautions related to having been implanted with a joint replacement implant, leading thereby to failure or other complications.
- Foreign body sensitivity:** Where sensitivity to materials is suspected, patients should be subjected to appropriate tests prior to material selection or implantation.

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Special Note: Patients with renal insufficiency may be sensitive to potential metal ion release. Further, since not much is known about the transport of metal ion release across the placenta, these devices should be used with caution in women of child-bearing age.

3. Contraindications:

Contraindications include, but are not limited to the following:

- Acute or chronic infections in the vicinity of the joint or of a systemic nature.
- Accompanying illnesses affecting the function of the joint implant.
- Systemic illnesses and metabolic disturbances.
- Severe osteoporosis or osteomalacia.
- Severe damage to bony structures that stands in the way of stable implantation of the implant components.
- Bone tumours in the area of implant anchoring.
- Bony deformities, axial mal-positioning or bony conditions that rule out implantation of the implant components.
- Obesity and severely overweight patients.
- Expected overloading of the joint implant due to any reason.
- Drug abuse or alcoholism.
- Lack of patient co-operation.
- Sensitivity to Implant Materials

4. Possible Adverse Effects:

- Early or late loosening, disassembly, implant migration, bending and/or breakage of any or all of the implant components.
- Foreign body (allergic) reaction to implants, corrosion products and debris including metallosis, tumour formation, staining and/or auto-immune disease.
- Joint dislocations, limited flexibility, Instability, post-operative changes in the length of the leg and joint pain.
- Primary and secondary infection.
- Nerve damage, haematomas and wound-healing impairment.
- Periarticular calcification with joint pain and restricted movement.
- General medical complications including but not limited to Deep Vein thrombosis, Cerebrovascular accident, renal failure, heart failure, Sores, Pneumonia, Heterotopic ossification or myositis ossificans etc.
- Peri-prosthetic Fracture/Fissure

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- Intra-operative fracture leading to non-unions due to inadequate reattachment and/or early weight bearing
- Subsidence, Implant migration due to trauma or loss of fixation,
- Progressive bone resorption and osteolysis

Note: Diabetes, at present, has not been established as a contraindication. However, because of the increased risk for complications such as infection, slow wound healing, etc., the physician should carefully consider the advisability of hip replacement in the severely diabetic patient.

5. Warnings and Precautions:

Pre-operative:

Joint replacement implants manufactured by Adler Mediequip Pvt. Ltd. should only be used by orthopaedic surgeons experienced with joint replacement surgery.

Before surgery, the surgeon must plan the operation with a view to correct selection and sizing of the implant components and their positioning in the bone. The surgeon needs to ensure that:

- All necessary implant components are available
- Highly aseptic surgical conditions are present
- The implantation instrumentation is complete and in good working order
- The implant bed is prepared using the appropriate Adler instruments for the specific replacement procedure being performed
- All informational material concerning the range of implants, instrumentation and surgical technique has been reviewed and is available and the surgeon and the surgical team are familiar with this information
- The rules of medical skill, the state of the art, and the contents of scholarly publications by medical authors are known and observed
- In uncertain preoperative situations, especially with implants already in place, prior relevant information has been obtained from the concerned manufacturer
- Re-use of any implant is prohibited.

Caution - The following conditions, singularly or concurrently, tend to impose severe loading on the affected extremity thereby placing the patient at higher risk of failure of the prosthesis.

- Obesity or excessive patient weight.
- High levels of patient activity.

Intra-operative:

Adler cemented femoral hip stems are available in various sizes and offsets to suit the patient's femoral anatomy. Details of the implant size and offset are explicitly marked on the packaging and/or on the

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implants themselves. In addition, the related product literature carries detailed information related to the selection of a particular size and the resultant combinations of offset and leg length resulting from the selection of various Adler Modular Heads. Always ensure that femoral stems and modular heads are from the same company to ensure the use of only compatible taper combinations.

Caution: Selection of the Adler Modular Head neck length as well as the selected Adler cemented femoral hip stem is performed with the aid of trial implants provided in the corresponding Adler Instrumentation Set. The correct use of these components is clearly described in the relevant product literature corresponding with the femoral hip stem being implanted.

Prior to wound closure, any exposed bone cement and bone residue should be removed. Bone cement particles and pieces of bone that find their way into the gliding surfaces of the implant are known to cause abnormal (third body) wear that could lead to early failure and the need for revision surgery.

Note: Modular implant components made by different manufacturers may not be compatible with one another. Combining modular implant components of different manufacturers, in the absence of specific prior manufacturer confirmation, is not permitted.

Post-operative

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important:

- Detailed instructions must be given to the patient concerning the use and limitations of the implanted device. The patient must be warned that loosening, bending and/or breakage of the device are complications that may occur due to early or excessive weight bearing or muscular activity. The patient should be warned to avoid falls or sudden jolts of any nature.
- The patient must be made to understand that artificial joint replacement implants are always inferior to the function of the natural joint, and only a relative improvement of the preoperative condition can be achieved.
- The patient must be explained that an artificial joint can loosen due to overloading, wear and tear, or infection. Implant loosening can necessitate a revision operation that, under some circumstances, offers no opportunity to restore joint function again.
- Following joint replacement, the patient will have to submit to regular medical follow-ups.
- The patient must appreciate that the implant cannot be subjected to undue stress through extreme loading, work, and sporting activities.

The warnings and precautions mentioned above cover all the relevant warnings and precautions and clinically relevant information, as consistent with the clinical data.

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6. Special Note to Users:

Implant components that have been implanted and removed must never be re-used even if they appear undamaged due to the high risk of fatigue failure due to internally accumulated material stresses.

7. Packaging and Labeling:

Implant components supplied in pre-sterile condition are packed in double packaging kept inside suitable size of outer box. Sterilisation is carried out using the gamma irradiation process indicated by **STERILE R** on the label or ETO Sterilisation Process indicated by **STERILE EO** on the label with a suitable dose of sterilization cycle depending on the materials contained by the implant. Packaging must be carefully checked for perforation or other damage prior to surgery.

8. Sterilization:

Endofit stem and Adler modular heads are sterilized by gamma irradiation. Moduloc Bipolar Cups are sterilized by ETO. Stem Centralisers and Cement Restrictors are sterilized by gamma irradiation. The components of system are supplied sterile to a Sterility Assurance Level (SAL) of 10^{-6} . The method of sterilization is noted on the package label.

Sterility and Handling:

- Correct handling of the implants prior to and during surgery is decisive for the success of surgical procedure. Implant components supplied in pre-sterile condition are individually packed and correspondingly labeled, as gamma irradiation sterilized (gamma sterilization, 25 kGy min).
- Prior to opening a sterile packed implant, verify that the package is undamaged and shows no signs of tampering, the "sterile" sticker that seals the outer box is intact, the sterility indicator button is of the right colour indicating a properly sterilized implant (red in case of Gamma Irradiation) and that the implant is within the sterility period indicated on the label.
- Ensure that the surfaces of the implants are not damaged under any circumstance. Under no circumstance should the implants be used that have been damaged, surgically implanted or removed.

9. Storage Conditions:

Store in dry place. Protect devices from exposure to direct sunlight, radioactive sources and rains.

10. Important Information:

The operative surgeon is responsible for carrying out the surgical procedure correctly and must have mastered the acknowledged updated and latest operating techniques related to the type of surgery being performed, in theory and practice. Complications due to incorrect diagnosis and operating technique and limitations of the method of treatment or lack of aseptic conditions are not the responsibility of the manufacturer.

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In addition to physiotherapy and muscle training, it is the responsibility of the operating surgeon to educate the patient about the limitations of metallic implants and precautions to be followed to avoid unnecessary stresses to the implant.

Detailed instructions must be given to the patient concerning the use and limitations of the implanted device. If partial weight bearing is required or recommended, the patient must be warned that loosening, bending and / or breakage of the device are complications which may occur due to early or excessive weight bearing or muscular activity. The patient should be warned to avoid falls or sudden jolts of any nature. If the patient is demented, debilitated or otherwise unable to use crutches or other supporting devices, the risk of loosening, bending and / or breakage may be increased. The patient must be made aware of this fact.

Any retrieved implant / External Fixator component should be treated in such a manner so as to render further use / re-use of the components, impossible. Used implants / External Fixator Component that appear undamaged may have internal and external defects caused through accumulated stresses while in use. Reuse of implant components predisposes such components to premature failure.

Implant components from one manufacturer should not be used with those of another.

11. Symbols Used In IFUs, Labels and Packaging Materials:

Symbol	Definition	Symbol	Definition	Symbol	Definition
	Single use (Do not re-use)		Batch Number		Keep away from heat /sunlight and radioactive sources
	Date of Manufacture YYYY-MM		Manufactured by		Use by Date (Date of Expiry) YYYY-MM
	European Authorized Representative		Do not re-sterilize		Do not use if package is opened or damaged
	Sterilized by irradiation process		Consult instructions for use		Avoid moisture or water contact
	Caution: check for specific warnings or precautions		Code Number / Part No.		

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	Sterilised by ETO Gas Sterilisation process		Recycle		To be sold only against prescription
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12. Further information:

For further information concerning use of these devices, please check with Adler Customer Service at the address given herein or e-mail to adler-in.info@smith-nephew.com.

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