For use by an Accredited Orthopaedic Surgeon only

1. *DEVICE DESCRIPTION:*

The advancement of partial and total hip replacement has provided surgeons with the means of restoring mobility, reducing pain and correcting deformity in many patients. While the implants used are largely successful in achieving these goals, it must be recognized that implants are manufactured using metals, plastic and ceramic materials. Thus, no hip replacement system should be expected to withstand activity levels and loads as normal healthy human bone. Hip replacement implants would not therefore be as strong, durable or reliable as a natural human hip joint.

Operating surgeons should be aware of the following aspects related to the use of partial/total joint replacement prostheses:

1.1 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.

1.2 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.

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 childbearing age.

2. *System Description and Materials*

ModuLoc Bipolar Cups consist of a polyethylene liner encased in an outer metallic shell. Liner inner diameters are either 22.20mm or 28.00mm depending on the outer shell diameter. Outer and inner diameters are clearly marked on individual product labels.

Materials used in the construction of ModuLoc Bipolar Cups include ultra-high-molecular weight polyethylene (UHMWPE) conforming to ISO 5834-2, stainless steel conforming to ISO 5832-1, stainless steel conforming to IS:6911, chrome-cobalt alloy conforming to ISO 5832-6 for wrought alloy and ISO 5832-4 for Casting Alloy

3. *Intended Purpose, Indications*

The ModuLoc Bipolar Cup is designed for uncemented use in conjunction with a standard cemented or Uncemented 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.

4. ***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 an artificial joint
- Obesity and overweight patients
- Expected overloading of the joint implant
- Drug abuse or alcoholism
- Lack of patient co-operation.

5. ***Possible Adverse Effects***

A listing of the possible adverse events, includes, but is not limited to the following:

- Early of late loosening, disassembly, 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, postoperative changes in the length of the leg and joint pain
- Primary and secondary infection
- Venous thromboses, pulmonary embolisms and cardiac arrest
- Nerve damage, haematomas and wound-healing impairment
- Periarticular calcification with joint pain and restricted movement.
- Dislocation / Dissociation of bipolar cup

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.

6. ***Warnings and Precautions:***

Pre-operative

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

Intra-operative:

The ModuLoc Bipolar Cup is available with various outside diameters to suit the acetabulum being treated. The various nominal outside diameters are explicitly marked on the packaging and the implants themselves. Each ModuLoc Bipolar Cup also has a specified inside diameter that corresponds to the diameter of the Adler Modular Head to be used. The nominal inside diameter is also explicitly marked on the packaging. Always

make certain that the inside diameters of the ModuLoc Cups and the diameter of the Adler Modular Heads are compatible.

ModuLoc Bipolar Cups have a specified technique to enable assembly of the Cup with the corresponding Adler Modular Head. The technique is clearly described in the ModuLoc product literature. Ensure that the technique is correctly followed and that the assembly of the ModuLoc Cup and the Adler Modular Head is fully and completely achieved.

Caution: Incomplete or inadequate assembly of the ModuLoc Bipolar Cup with the Adler Modular Head could lead to undesirable surgical outcomes including dissociation of the implant components, severe early wear of the polyethylene liner or dislocation.

Selection of the outside diameter of the ModuLoc Bipolar Cups is accomplished using trial implants provided as part of the EndoFit/ModuLoc Instrument Set.

Selection of the Adler Modular Head neck length as well as the EndoFit femoral stem is performed with the aid of trial implants provided in the EndoFit/ModuLoc Instrument Set.

Prior to wound closure, all 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 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 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.

7. 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.

8. 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. The set of instruments used for the surgery must be carefully checked for completeness and individual instruments must be inspected for functionality and absence of damage prior to surgery. The set of instruments used for the surgery must be carefully checked for completeness and individual instruments must be inspected for functionality and absence of damage prior to surgery.

Implants supplied in unsterile condition are indicated by NON-STERILE or NON STERILE on the label which must be properly sterilized by suitable method prior to surgery.

Metallic components may be re-sterilised using steam or ethylene oxide sterilization process. Re-sterilization of PE components is not permitted.

9. ***STERILISATION / RE-STERILIZATION:***

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 in correspondingly labeled, radiosterilized (gamma sterilization, 25 kGy min.)/ ETO sterilized (Ethylene Oxide) protective packages.
- 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 Green in case of ETO sterilization) 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 circumstances. Under no circumstances may implants that have been damaged, surgically implanted or removed again be reused.

RE-STERILIZATION:

- Re-sterilizationof devices supplied in sterile form carries various risks. Various components of joint replacement prosthesis include UHMWPE parts that are known to carry a high risk of oxidative degradation if not packed and sterilized according to closely controlled and monitored conditions. Small imperfections caused on the surfaces of metallic joint replacement components are known to increase the risk of fatigue failure. Such imperfections could be caused by improper handling by untrained staff. In consideration of the above re-sterilization of joint replacement prosthesis components by user facilities is not recommended.

For non-metal components: If packaging appears to be damaged, non-metal components should not be re- sterilized and used.

For metal components only: Adler recommends that if the packaging appears to be damaged, metal components should not be re-sterilized and used. If the packaging appears to be damaged and metal components are to be used however, then the device must be cleaned and re-sterilized prior to implantation, according to the following Instructions:

Cleaning (metal components only):

If packaging of a metal component appears to be damaged and the metal component is to be used, the metal component should be cleaned prior to re-sterilization as follows:

- Use deionized, or distilled, warm (room temperature) water for soaking, cleaning and rinsing. Disassemble as appropriate. Soak soiled products for a minimum of 10 minute. For non-ceramic coated components: immerse and hand wash with a neutral pH or mild detergent. Scrub with a soft bristle brush paying close attention to threads and hard to reach areas. If product is cannulated, insert a soft nylon brush into cannula. Rinse all components immediately and thoroughly after washing. Immediately dry product. Inspect all products prior to sterilization and storage.

Recommended Steam Sterilisation Cycle Parameters:

- Dynamic Air Removal (Prevacuum) Steam Cycle: 132°C (270°F) for 4 minutes or 135°C (275°F) for 3 minutes
- Gravity Displacement Steam Cycle: 132°C (270°F) for 30 Minutes and a minimum vacuum drying time of 30 minutes
- Flash Steam Cycle (Reusable Instruments only): Exposure temperature: 132°C (270°F) for 10 minutes in gravity displacement cycle or 4 minutes in a Dynamic Air Removal (Prevacuum) Cycle.
- United Kingdom Steam Cycle: 134°C for 3 minutes and a minimum vacuum drying time of 30 minutes. (Note: Sterilisation evacuation and pulsing should be carried out in accordance with HTM 2010).

Containment devices should be wrapped with an approved central supply wrap (CSR) or placed in an approved reusable rigid container for sterilization. All sterilization wraps may not be approved for all cycle types. Check with manufacturer for approvals.

NOTE: This is not a recommendation as to the sterilization parameters to be followed. The adequacy of any sterilization procedure must be suitably tested. It is critical that appropriate process parameters be validated for each facility's Sterilization equipment and Product/load configuration by persons who have training and expertise in sterilization processes to substantiate the process and its reliability and reproducibility. Flash sterilization may be conducted, if applicable, according to the specific health care facility's policy.

10. ***STORAGE CONDITIONS:***

Store in dry place. Protect devices from exposure to direct sunlight, radioactive sources and rains. Do not stack devices.

11. ***IMPORTANT INFORMATION:***

The operative surgeon is responsible for carrying out the internal fixation 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.

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.

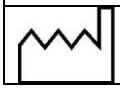
Detailed instructions must be given to the patient concerning the use and limitations of the implanted device. If partial weight bearing is required or recommended prior to bony union, the patient must be warned that loosening, bending and / or breakage of the device are complications which may occur 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.

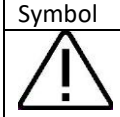
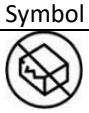
Any retrieved implant / External Fixator component should be treated in such a manner so as to render further use / re-use of the components, impossible. Used implants / External Fixator Component that appear undamaged may have internal and external defects caused through accumulated stresses while in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

Implant components from one manufacturer should not be used with those of another. In case such combinations are necessary, they would be possible only if the surgeon can ascertain that all implants being used are manufactured to correct dimensional specifications and tolerances and from chrome-nickel-molybdenum alloyed austenitic stainless-steel complying with or compatible to the relevant standards referred to above.

Manufacturing Traceability Records for the device are available for 15years after the manufacturing date mentioned on the label.

12. ***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

Symbol	Definition	Symbol	Definition	Symbol	Definition
	Caution: check for specific warnings or precautions		Do not re-sterilise		Do not use if package is opened or damaged
	Sterilised by ETO Gas Sterilisation process		Consult instructions for use		Avoid moisture or water contact
	Recycle	REF:	Code Number / Part No.	℞ only	To be sold only against prescription

13. <u>Further information:</u>

For further information concerning use of these devices, please check with Adler Customer Service at the address given herein or e-mail to **adler-customer.care@adler-healthcare.com**.

Manufactured by:

Adler Healthcare Pvt. Ltd.

Plot No. A-1, MIDC Sadavali, Tal. Sangameshwar, Dist. Ratnagiri, Maharashtra State, INDIA, PIN 415804.Ph: +91 (0)8055136000, 8055146000