| | Instructions for use<br>for<br>Adler® Total Hip Replacement Prosthesis | Doc. No.: IU/10<br>Rev. No.: 10<br>Rev. Date: 14AUG2017 |
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**Important Information on Adler Femoral Hip Stems and Modular Heads**

*For use by an Accredited Orthopaedic Surgeon only*

## *1. DEVICE DESCRIPTION – General Information:*

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 child-bearing age.

## *2. Intended Purpose, Indications:*

Adler femoral hip stems (Endofit/Legend) and Adler Modular Heads are indicated for use in total hip/partial hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.

Manufactured by:
Adler Mediequip Pvt. Ltd.
Plot No. A-1, MIDC Sadavali, Tal. Sangameshwar, Dist. Ratnagiri, Maharashtra State, INDIA, PIN 415804.
Ph: +91 (0) 2354 260348, 260548 FAX: +91 (0) 2354 260418
European Authorized Representative:
EC REP Smith & Nephew Orthopaedics GmbH,
Alemannenstrasse 14, 78532 Tuttlingen, Germany

- 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, or total hip replacement.
- Certain cases of ankylosis.

Total or hemi-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) This includes severely crippled patients with multiple joint involvement for whom a gain in hip mobility may lead to an expectation of significant improvement in the quality of their lives.

## *3. System Description and Materials:*

Adler EndoFit femoral hip stems are manufactured from forged high nitrogen stainless steel (ISO 5832-9/ ASTM F1586). Endofit stems are meant for cemented use, available in multiple sizes to suit patient anatomy are internally certified for taper compatibility with all Adler Modular Heads. Surgeons may optionally use Adler Stem Centralisers to achieve a central position of the femoral stem in the intramedullary canal and further optionally use Adler Cement Restrictors to block off the intramedullary canal to achieve cement pressurization.

Adler Legend cementless hip stems are manufactured from forged Titanium-Vanadium alloy (ASTM F-136 ELI/ISO 5832-3), fully coated with Hydroxyapatite (ISO 13779) and are available in multiple sizes to suit patient anatomy. Legend stems are internally certified for taper compatibility with Adler CoCrMo Modular Heads and are meant for cementless use.

Legend Femoral Stems should not be combined with Stainless Steel Modular Heads.

Each system component is individually packaged in secure inner/outer packaging with an outer protective box and individually labeled.

Adler Modular Heads feature a 12/14 internal taper, certified for taper compatibility with all Adler femoral hip stems and are manufactured from high nitrogen stainless steel (ISO 5832-9/ ASTM F1586) or Cobalt-Chrome alloy (CoCrMo - ISO 5832-12/ASTM F1537)

Adler Stem Centralisers are manufactured from PMMA conforming to USP Class VI.

Adler Cement Restrictors are manufactured from UHMWPE certified to ISO 5834-2.

## *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 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

## *5. Possible Adverse Effects:*

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

- Early or 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, 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.
- Cardiovascular Accident such as stroke
- Femoral or acetabular perforation, or fracture
- Femoral fracture while seating the device
- Cardiovascular disorders including venous thrombosis, pulmonary embolism or myocardial infarction or death
- Progressive bone resorption and osteolysis
- Trochanteric non-union due to inadequate reattachment and/or early weight bearing
- Implant migration due to trauma or loss of fixation

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

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 as it including risk of infection / disease.

**Intra-operative:**

Adler 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 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 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.

## *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. 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-sterilization of 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 Sterilization 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.

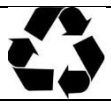
Any retrieved implant / External Fixator component should be treated in such a manner so as to render further use / re-use of the components, impossible. Used implants / External Fixator Component that appear undamaged may have internal and external defects caused through accumulated stresses while in 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 |
|  | European Authorised Representative |  | Do not re-sterilise |  | Do not use if package is opened or damaged |
|  | Sterilised by radiosterilisation process |  | Consult instructions for use |  | Non Sterile |
|  | Caution: check for specific warnings or precautions | REF: | Code Number / Part No. |  | Avoid moisture or water contact |
|  | Sterilised by ETO Gas Sterilisation process |  | Recycle |  | To be sold only against prescription |

### *13. 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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**Plot No. A-1, MIDC Sadavali, Tal. Sangameshwar, Dist. Ratnagiri, Maharashtra State, INDIA, PIN 415804.**

**Ph: +91 (0) 2354 260348, 260548 FAX: +91 (0) 2354 260418**

European Authorized Representative:

EC REP **Smith & Nephew Orthopaedics GmbH,**

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