	Instructions for use for HEMI-ENDOPROSTHESIS	Doc. No.: IU/6
		Rev. No.: 01
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For use by an Accredited Orthopaedic Surgeon only

1. ***PURPOSE:***

HEMI ENDOPROSTHESIS are intended to be used by qualified and trained orthopaedic surgeons to carry out a partial or 'hemi' replacement of the femoral head of the hip joint in cases involving degenerative or traumatic changes to the femoral head, where there is x-ray evidence of a satisfactory acetabulum and sufficient bone in the femoral neck to seat the prosthesis with or without bone cement.

These devices are meant to bear load while in use and are subjected to various mechanical forces. The extent to which the device would withstand these forces is limited by the operating surgeon achieving appropriate restoration of hip biomechanics and peri-articular soft tissues.

2. ***MATERIALS:***

The Material used for these devices, complies with the international standards in ISO 5832 series or relevant Material Standards in IS 6603, IS 6911 or IS 6528 - Grade X02Cr17Ni12Mo2 (316L) or ASTM F745. Sometimes UHMWPE Materials are also used which confirms to ISO 5834 Series of standards and PEEK Materials confirms to ASTM F2026-2.

3. ***PREPARATION:***

Before the operation, an operative plan must be drawn up by the operating surgeon, ensuring that –

- All implant components necessary are available in the required quantities
- Aseptic operating conditions are present.
- The required set of instruments is complete, operable and compatible.
- All pertinent documents related to the set of instruments and the implants being used are present and the surgeon and the operating team are, familiar with them.
- The operating surgeon is experienced in performing internal fixation procedures to stabilize fractures using implants and in particular with the specific operative procedure being performed, involving the use of the implant.

4. ***INDICATIONS:***

Hemi Endoprostheses have been designed to carry out primary prosthetic replacement of the femoral head and neck where there is sufficient x-ray evidence of a satisfactory acetabulum and sufficient bone in the femoral neck to seat the prosthesis with or without bone cement. They are used in acute fractures of the femoral neck with dislocation or any neck fracture that cannot be accurately reduced and securely immobilized, idiopathic avascular necrosis, comminuted fractures of the femoral head or neck, osteoarthritis (degenerative) or rheumatoid arthritis with a fracture of the neck of the involved hip, osteoarthritis in which only the femoral head is affected and the acetabulum is not involved, old fractures of the femoral neck with non union or as an alternative to a total hip arthroplasty in active individuals more than 60 years of age with unilateral advanced disease when the femoral head is greatly distorted or collapsed.

5. ***CONTRAINDICATIONS:***

Contraindications for the use of this device include but are not limited to the following:

- Infection
- Loss of musculature or neuromuscular diseases involving the affected limb
- Severe osteoporosis
- Any condition causing distortion or irregularity of the acetabulum
- Immunological intolerance
- Patients displaying metal sensitivity or allergic reactions to any of the elements in implant grade materials, e.g. Nickel or Chromium
- Mental illness
- Convulsive disorders
- Alcohol and/or drug addiction
- Obesity
- Poor patient compliance
- Expected overloading of the implants

6. IMPLANT SELECTION AND HANDLING:

- All implant components should be checked for intact packaging on receipt. In case a loaner or consignment set of instruments and implant components is used, all instruments and implants must be carefully checked for completeness and all components should be carefully inspected for absence of damage prior to use.
- Selection of the proper size, shape and design of the implanted device is a crucial parameter for success of the operative procedure and must be ensured by the operative surgeon.
- All pre-operative handling on implants must be done with care to ensure that the handling does not cause scratches, notches or dents on the surface of the implants that may predispose the device to failure.

7. WARNINGS:

- The correct selection of device components is extremely important. The appropriate size should be selected for the patient. Failure to use the largest possible components or improper positioning may result in loosening, bending, cracking, or fracture of the device or bone or both.
- Because of unbalanced muscle forces, sub trochanteric fractures and osteotomies place extreme loads on implants, substantially reducing the chance of fracture healing with bending or breaking implant components. Additional precautions and internal or external supports should be utilized to enhance the stability of the fracture and to minimize internal stress loading of the implant and broken bone until solid bony union is evident by radiograph. Supplementary procedures such as bone graft or medial displacement osteotomy may also be considered.
- Subtrochanteric and comminuted trochanteric fractures and osteotomies place increased stresses on bone plates. Plate length should be increased to provide maximal fixation. Length of plate must allow engagement of the maximum number of cortical screws in the intact femoral shaft distal to the fracture line. The length of time for non- or limited weight bearing should be correspondingly increased until solid bony union occurs.

8. PRECAUTIONS:

- Use extreme care in handling and storing implant components. Cutting, bending or scratching the surface of metal components can cause internal stresses which significantly reduce the strength and fatigue resistance.
- Postoperative instructions to patients and appropriate nursing care are critical. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact.
- The surgeon should be familiar with the devices, instruments and surgical technique prior to surgery.

9. POSSIBLE ADVERSE EFFECTS:

- Loosening, bending, cracking or fracture of implant components.
- Loss of anatomic position with malunion may occur.
- Infections, both deep and superficial, have been reported.
- Vascular disorders including thrombophlebitis, pulmonary emboli, wound hematomas, and avascular necrosis of the femoral head may result from the surgery and concomitant use of internal fixation devices.
- Leg length discrepancies and subsequent patient limp may occur.
- Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported.
- Tissue reactions which include macrophage and foreign body reactions adjacent to implants can occur.

10. 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.

11. 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, radio sterilized (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 color 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: Sterilization 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.

12. STORAGE CONDITIONS:

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

13. 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.

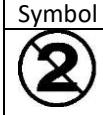
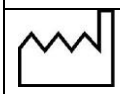
Detailed instructions must be given to the patient concerning the use and limitations of the implanted device. If partial weight bearing is required or recommended prior to bony union, the patient must be warned that loosening, bending and / or breakage of the device are complications which may occur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

14. 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
	Sterilised by radiosterilisation process		Do not re-sterilise		Do not use if package is opened or damaged
	Caution: check for specific warnings or precautions		Consult instructions for use		Avoid moisture or water contact
	Sterilised by ETO Gas Sterilisation process		Code Number / Part No.		To be sold only against prescription
	Recycle				

15. <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**.