For use by an Accredited Orthopaedic Surgeon only

1. Implant Description:

Adler Total Knee System consists of three components intended to replace the femoral, Tibial, and patellar articular surfaces of the knee joint. For component usage compatibility see Surgical Technique Manual for Adler Total Knee Prosthesis.

2. MATERIALS:

- The femoral components are manufactured from metallic materials conforming to ISO 5832 Series of Materials especially Co-Cr-Mo alloy conforming to ASTM standard F-75. The geometry of the femoral condylar component matches the tibial bearing component in the major load bearing positions of extension and stance phase flexion. The femoral components are available in right and left configurations.

- The tibial trays are manufactured from metallic materials conforming to ISO 5832 series of materials and normally Co-Cr-Mo alloy conforming to ASTM standard F-75. The metal trays have a hollow, conical Intramedullary stem. The bearing component is fixed to the metal tray with special fixing process.

- The bearings and the Patellar Components are manufactured from UHMWPE materials conforming to ISO 5834 Series of standards.

3. INDICATIONS FOR USE:

Adler Total Knee System is indicated for cemented use in cases of osteoarthritis and rheumatoid arthritis. The tibial insert and femoral component are particularly indicated where a higher than normal degree of post-operative flexion is required.

4. HANDLING:

It is important that the size of the implant be properly selected initially, as once an implant has been inserted, cleaning and sterilization techniques cannot ensure removal of all debris from the surfaces. Implants once inserted should not be reinserted. Proper handling of any implant is mandatory. Any prosthesis should be handled at all times by personnel wearing surgical gloves. Prior to surgical use, a visual inspection of each implant for possible imperfections should be performed routinely. Damage or alterations to the implant may produce stresses and cause defects that could become the focal point for implant failure. Do not allow contact of the prosthesis with hard objects. Implant components should never be re-implanted. Even if the implant components appear undamaged; they may be fatigued from previous stresses and may have developed microscopic imperfections that could lead to implant failure.

5. HOW SUPPLIED:

All components of the Adler Total Knee System are supplied pre-packed and sterile. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised. Remove implants from packaging, using aseptic technique, only after the correct size has been determined.

For metal components only: If the sterile Implant is determined to be aseptically compromised but still acceptable for Intended use based on physician determination, the implant must be rinsed and sterilized prior to Implantation according to the following instructions. **POLYETHYLENE COMPONENTS SHOULD NEVER BE RE-STERILIZED. DO NOT USE POLYETHYLENE COMPONENTS IF THE STERILE PACKAGE APPEARS TO BE DAMAGED.**

6. CONTRAINDICATIONS:

The use of the Adler Total Knee System is contraindicated in:

- The presence of osteomyelitis, pyrogenic infection or other overt infection of the knee joint. Every effort should be made to rule out the possibility of preoperative sepsis in a patient who has one or more of the following abnormalities:
    - fever or local inflammation;
    - rapid destruction a bone resorption apparent on x-rays;
    - elevation of the erythrocyte sedimentation rate or white blood cell count unexplained by other disease a a marked shift in the white blood cell differential count.
- patients with any active Infection at sites such as the genitourinary tract, pulmonary system, skin or any other site. Should a patient have any infection prior to implantation, the foci of the infection must be treated prior to, during and after implantation.
- patients with loss of musculature or neuromuscular compromise leading to loss of function in the involved limb or in whom the requirements for its use would affect recommended rehabilitation procedures.
- patients with severe osteoporosis or other metabolic bone diseases of the knee.
- patients with any of the following conditions:
    - lesions of the supporting bone structures (e.g. aneurysmal or simple bone cysts, giant cell tumor or any malignant tumor).
    - systemic and metabolic disorders leading to progressive deterioration of solid bone support,
    - the presence of severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity, fixed deformities greater than 60° of flexion, 45° of genu varus or valgus,
    - known drug or alcohol addiction,
    - skeletally immature individuals and the presence of allergic reaction to implant metals or polyethylene are also contraindications for the above implants

7. WARNINGS:

Familiarity with and attention to the surgical technique utilized with this device are imperative for best results. The correct selection as well as the correct seating/placement of the prosthetic implant is extremely important. During surgery, particular attention to tracking of the patella is also required for a successful result. Thus, failure to use the optimum size implant, failure to adequately seat the component adjacent to adequate bone and failure to ensure that the component is stable may result in dislocation, subsidence, fracture or loosening of the components. The proper size selection, the choice of and careful use of the components and the use of trial prostheses are imperative. The Adler stem extensions can only be used with Adler revision tray components. Adler Total Knee components, instruments and trial prostheses should not be used together with those of another manufacturer. Because dimensional compatibility cannot be assured, adverse outcomes can result from the use of components from different manufacturers.

A postoperative management program is vital. It is recommended that the program be modified according to the condition of the patient and the extent of soft tissue and ligament reconstruction.

The safety and effectiveness of the use of the Adler Total Knee in patients depends on various factors which include, but are not limited to, surgical technique, patient build, pre-operative flexion and age.

8. PRECAUTIONS:

The surgeon should discuss all physical and psychological limitations inherent to the use of this device with the patient preoperatively. Particular discussion should be directed to the issues of premature weight bearing, activity levels and the necessity for periodic medical follow-up. Particular attention should be paid to the handling of the components.

9. 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.

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, 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 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.

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.

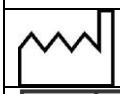
Any retrieved implant / External Fixator component should be treated in such a manner so as to render further use / re-use of the components, impossible. Used implants / External Fixator Component that appear

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
	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

15. 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

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