	Instructions for use for ResTOR® Prosthesis	Doc. No.: IU/8 Rev. No.: 08 Rev. Date: 14AUG2017

For use by an Accredited Orthopaedic Surgeon only

IMPORTANT MEDICAL INFORMATION

1. PURPOSE:

The ResTOR® system is designed to restore structural skeletal stability and enable functional joint mobility in patients undergoing limb salvage surgery for bone tumors or in patients undergoing revision of conventional joint replacement prosthesis with extensive bone loss.

Patient selection criteria for use of the ResTOR® system must be carefully observed and must respect the following criteria:

- Patients whose anatomic features allow for implant dimensions adequate to withstand expected loading and degree of activity.
- Patients who are willing and able to respect their physician's directions, particularly with regard to the necessary stress reduction on the implant, either partially or totally in the immediate post-operative period, if indicated.

The largest possible diameter of intramedullary stem should be selected from the ResTOR® system, particularly for obese patients. Patients must be cautioned about the consequences of participation in sports or any other activity that could cause excessive loading or strain on the implanted components.

2. SYSTEM DESCRIPTION AND MATERIALS:

ResTOR® is a modular system with components that can be selected either pre-operatively or intra-operatively. ResTOR® implants consist of cast cobalt-chromium-molybdenum alloy (ISO 5832-4), wrought titanium-Aluminium-vanadium alloy Ti_6Al_4V ELI (ISO 5832-3) or stainless steel AISI316L. PE components are made from UHMWPE (ISO 5834-2). Adler Mediequip warrants that these devices are fabricated from the material specifications defined herein. No other warranties, either expressed or implied, are made. ResTOR® system components are strictly single-use devices.

3. INDICATIONS:

The use of modular prosthesis is frequently the consequence of resection of a bone tumor. Other indications could include revision of conventional joint replacement prosthesis with extensive bone loss.

Careful preoperative planning and precise surgical technique form the basis required to achieve optimal results with the ResTOR® system. Operating surgeons must consider different factors in order to minimize the risk of postoperative complications, such as the anatomical stress situation, available soft tissue support and alignment of the components planned. It is usually advisable to implant the ResTOR® system only in patients with fully grown skeletal structures.

The ResTOR® system can enable quick restoration of function and considerably improve the quality of life of the patient. However, at no stage must the primary goal of achieving oncological clearance be compromised in the attempt to restore function.

4. CONTRAINDICATIONS:

Primary contraindications include bacterial infections; defects in soft tissues caused by irradiation and expected bone growth. Other contraindications would include:

- Anatomical conditions which do not allow for an adequate implant size.
- Anatomical conditions that would not maintain sufficient bony support for the implant.

- Insufficient blood supply caused by prior surgeries or vessels affected by alcohol abuse or due to other factors.
- Mental or other neurological conditions that could affect the patient's capability to follow restrictions in activity. Such conditions would include but would not be restricted to drug abuse, mental illness, senility and general neurological limitations.
- Any conditions that could cause extreme stress on the implanted components such as multiple arthropathies, myopathies etc.
- Sensitivity to Implant materials
- Marked osteoporosis or poor bone stock.
- History of general or local infections.
- Severe deformities leading to impaired fixation or improper positioning of the implant.
- Allergic reactions to implant materials (e.g., bone cement, metal, polyethylene).

Contraindications may, in many cases, be of a relative nature rather than an absolute contraindication. Hence, contraindications must be carefully considered with respect to the complete status of the patient as well as the comparative prognosis of alternative therapies.

5. POSSIBLE ADVERSE EFFECTS:

- Loosening, distortion or fracture of one or more components of the device. Usually, these effects are likely to be caused by one or more of the factors listed as contraindications.
- Migration, subluxation or rotation of the implant, flexion contractures, reduction in mobility, increase or decrease in leg length and bone wear.
- Acute postoperative wound infection and severe sepsis.
- Postoperative fractures of the tibia, femur, patella or humerus.
- Cardiovascular disorders, wound haematomas, venous thromboses, pulmonary embolisms.
- Tissue reactions such as phagocytal reactions, foreign body reactions or myositis ossificans.
- Excessive wear of the polyethylene components due to intraoperative damage to the components, loose cement and/or bone fragments and/or high patient activity levels or weight
- Temporary or permanent nerve damage resulting in pain, numbness or a degree of paralysis of the affected limb
- Acute limb ischaemia
- Progressive bone resorption and osteolysis
- Inadequate range of motion due to improper selection or positioning of components, impingement and/or periarticular calcification.

6. WARNINGS AND PRECAUTIONS:

The possibility of implant loosening, bending, fissure and/or breakage and other complications can greatly increase if the following instructions and warnings are not considered and followed:

PREOPERATIVE:

- In every surgery, all implant sizes, must be available. Before insertion, implant components must be carefully checked to ensure absence of damage during preoperative handling and to confirm correct size selection.
- Implant components must be handled with great care at all times. Cutting, bending, denting or scratching of the implant surfaces can considerably reduce stability and resistance to fatigue and wear. Even defects that are not easily visible could lead to stress conditions within the implant that could lead to premature failure on dynamic loading.

- If preoperative planning and analysis indicates that the available modular components may not suit the patient, the use of a customized implant is necessary.
- Allergies and other reactions to implanted materials should be considered and tested for if indicated to enable preoperative exclusion.
- Instruments used to introduce the implant must be compatible with the implant components and hence must necessarily belong to the ResTOR- system.
- The operating surgeon must be sufficiently familiar with principles and operative techniques related to the surgery being performed as well as the recommended surgical technique and instrumentation for this system and its proper use. A description of the surgical technique with this system is available with the manufacturer.
- Re-use of any implant is prohibited as it including risk of infection / disease.

INTRAOPERATIVE:

- Adequate and durable component support achieved through proper cementation technique and/or bone graft and correct component size selection are critical for optimal results.
- Repositioning of implant components during the phase of cement hardening must be avoided.
- It is extremely important to achieve correct axial and rotational alignment of the implant. Not doing so could lead to subluxation, dislocation, unusual early component wear and/or breakage of implant components. Particular attention should be paid to curved intramedullary stems which may rotate while being inserted leading to incorrect alignment.
- Revision surgeries following a preceding primary surgery could be extremely demanding. Common mistakes during revision surgeries include incorrect surgical access, insufficient identification and mobilization of bony structures, insufficient removal of ectophytic bone material or imprecise positioning of the components. Extreme blood loss and postoperative instability are possible consequences. Overall, longer operating times, risk of pulmonary embolism and wound haematoma, increased blood loss are factors that must be taken into consideration in cases of revision surgery.
- The tapered interlocking surfaces of modular components must be thoroughly cleaned and dried before assembly with the corresponding mating component. Any unremoved particle present on the surface could cause extreme friction and wear and may be responsible for premature failure.
- Modular components once assembled must not be disassembled and re-used due to microscopic surface changes during the assembly process.

POSTOPERATIVE:

- Postoperative instructions and warnings by the physician and patient care in the postoperative period are of great importance. External support to the operated limb in the immediate postoperative period to enhance the healing process is recommended in some cases.
- Postoperative therapy should support the process of healing and prevent the leg from being submitted to excessive stresses.
- Caution must be exercised in carrying out active and passive movements.
- Patients should be repeatedly reminded of the need to reduce their activity levels as recommended by the physician.

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.

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.

7. 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.

8. STORAGE CONDITIONS:

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

9. 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.

Manufactured by:
Adler Mediequip Pvt. Ltd.
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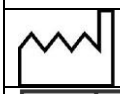
European Authorized Representative:
EC REP Smith & Nephew Orthopaedics GmbH,
Alemannenstrasse 14, 78532 Tuttlingen, Germany

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

10. 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-DD		Manufactured by		Use by Date (Date of Expiry) YYYY-MM-DD
	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		Code Number / Part No.		Avoid moisture or water contact
	Sterilised by ETO Gas Sterilisation process		Recycle		To be sold only against prescription

11. 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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