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| | Instructions for use<br>for<br>RESTOR® Modular Resection Prosthesis Lower Limb | Doc. No.: IU/17<br>Rev. No.: 01<br>Rev. Date: 10FEB2022 |

## Important Information on RESTOR® Modular Resection Prosthesis Lower Limb
## For use by an Accredited Orthopaedic Surgeon only

### 1. PURPOSE
The RESTOR® Modular Resection Prosthesis Lower Limb 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
The system consists of various components, which can be assembled into different configurations with each configuration tailor made to an individual clinical presentation. The components for RESTOR® Modular Resection Prosthesis Lower Limb system mainly comprise of Trochanteric Component, Resection Piece for RESTOR® Prosthesis, RESTOR® Resection Coupler, RESTOR® Pivot Pins, Split Poly Bushes, RESTOR® Retaining Ring, RESTOR® Femur FR, Femur TR, RESTOR® Tibia FR, Tibia TR and RESTOR® Intramedullary Stems (Curved and Straight).

Restor can be additionally combined with Moduloc Bipolar Cup and Modular head to form proximal femoral assembly.

RESTOR® is a modular system with components that can be selected either pre - operatively or intra-operatively. RESTOR® implants made of cast CoCr alloy conforming to ISO 5832-4/ASTM F75, CoCrMo alloy confirming to ISO 5832-12/ASTM F1537, Titanium alloy as per ISO 5832-3/ASTM F136, stainless steel conforming to ISO 5832-1 and High nitrogen stainless steel conforming to ISO 5832-9/ASTM F1586. 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. INTENDED USE AND INDICATIONS
The RESTOR® Modular Resection Prostheses System is intended 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. The system consists of various components which can be assembled into different configurations with each configuration tailor made to an individual clinical presentation.
Indications for limb salvage surgery with reconstruction using the RESTOR® Modular Resection Prosthesis Lower Limb system would include Primary malignant bone tumors, Metastatic bone tumors, and benign

bone tumors (where intra-lesional methods may be unsuitable). 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.

## 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 multi plearthropathies, 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

- 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.
- Aseptic Loosening
- Flexion contractures, knee stiffness, reduction in mobility.
- Abnormal gait related to limb length discrepancy and/or muscle weakness.
- Postoperative wound infection and wound haematoma.
- Periprosthetic fractures of the tibia, femur or patella.
- Patella related complications such as retro-patellar pain and decreased range of movement.
- Acetabular erosion, hip instability in cases involving proximal femur resections.
- Pulmonary embolisms leading to ARDS which can be life-threatening.
- Foreign body reactions.

- Excessive wear of the polyethylene components, specifically the polyethylene bushes, due to intraoperative damage to the components, loose cement and/or bone fragments and/or high patient activity levels or weight. Such cases may require a re-bushing procedure.
- Temporary or permanent nerve damage resulting in pain, numbness or a degree of paralysis of the affected limb.
- Progressive bone resorption.
- Inadequate range of motion due to improper selection or positioning of components, impingement.
- Disease recurrence and/or progression in bone and/or soft tissue.

## 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:

### A. 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 implant is strictly prohibited.

### B. 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.
- Any taper surfaces of modular components must be thoroughly cleaned and dried.
- Any taper 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.

### C. 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.
- Patient labels provided inside the implant boxes should be carefully preserved and added to the patient records wherever applicable.

### D. 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.

### E. 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

The components of system are supplied sterile to a Sterility Assurance Level (SAL) of $10^{-6}$. The method of sterilization is gamma irradiation for all Restor components and Modular Heads and EtO gas sterilization for Moduloc Bipolar Cup.

### 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 and correspondingly labeled, as gamma irradiation sterilized (gamma sterilization, 25 kGy min).
- 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 that the implant is within the sterility period indicated on the label.
- Ensure that the surfaces of the implants are not damaged under any circumstance. Under no circumstance should the implants be used that have been damaged, surgically implanted or removed.

## 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 surgical 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.

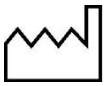
In addition to physiotherapy and muscle training, it is the responsibility of the operating surgeon to educate the patient about the limitations of metallic implants and precautions to be followed to avoid unnecessary stresses to the implant.

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, 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 predisposes such components to premature failure.

Implant components from one manufacturer should not be used with those of another.

## 10. SYMBOLS USED IN IFUs, LABELS AND PACKAGING MATERIALS

| Symbol | Definition | Symbol | Definition | Symbol | Definition |
|---|---|---|---|---|---|
|  | Single use (Do not re-use) |  | Manufactured by |  | Use by Date (Date of Expiry) YYYY-MM-DD |
|  | Date of Manufacture YYYY-MM-DD |  | Do not re-sterilize |  | Do not use if package is opened or damaged |
|  | Caution: check for specific warnings or precautions |  | Consult instructions for use |  | Symbol for method of sterilization using irradiation. |
|  | Sterilized by ETO Gas sterilization process |  | Code Number / Part No. |  | Avoid moisture or water contact |
|  | Recycle |  | Keep away from heat /sunlight and radioactive sources | | |
|  | Batch Number |  | To be sold only against prescription | | |

*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-customer.care@adler-healthcare.com**.