ADLER	Instructions for use for RESTOR® Modular Resection Prosthesis Rotating Hinge	Doc. No.: IU/19 Rev. No.: 00 Rev. Date: 21NOV2019

Important Information on RESTOR® Modular Resection Prosthesis Rotating Hinge (RESTOR® Rotating Hinge)
For use by an Accredited Orthopaedic Surgeon only

Device Description:
The RESTOR® Modular Resection Prosthesis Rotating Hinge system is designed to restore distal and total femur skeletal stability and enable functional joint mobility in patients undergoing limb salvage surgery for bone tumors or in patients undergoing severe trauma or 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. The components for Restor Rotating Hinge system mainly comprise of Restor RH Femur FR, Restor RH Tibia FR Keel Base plate, Restor RH Tibia FR Rotating Component, Restor RH Tibial Insert FR, Resection Piece for Restor Prosthesis, Restor RH Pivot Pin FR, Restor RH Femoral Bush FR, Restor RH Tibial Sleeve FR, Restor RH Bumper FR, Restor RH Tibial Stem and Restor Intramedullary Stems (Curved and Straight).

Restor can be additionally combined with Trochanteric component, Restor Resection Coupler, Moduloc Bipolar Cup and Modular head to form total femoral assembly.

RESTOR® Rotating Hinge implants are made of cast COCR (ASTM F75 / ISO 5832-4), titanium alloy (Ti6Al4V ELI) ASTM F136-08 / (Ti6AL4V) ISO 5832-3 or stainless steel conforming to ISO 5832-1 or ISO 5832-9, UHMWPE (ISO 5834-2), CoCrMo alloy 1 / alloy 2 confirms to ISO 5832-12 or ASTM F1537-11, 7.5 MRAD Cross linked UHMWPE. PE components are made from UHMWPE (ISO 5834-2). Implant components of Restor rotating hinge system provided in sterile condition. Metallic component sterilized by gamma sterilization whereas PE component by EtO sterilization.

Summary:
Operating surgeons should be aware of the following aspects related to the use of metallic implants.

1. Proper size, length, side and type selection, as well as proper handling and use of implants are essential for safe and effective treatment. See NOTES, INDICATIONS, CONTRAINDICATIONS, and PREOPERATIVE PLANNING below.
2. Proper operative technique and follow-up care is essential to enable desired outcomes. See WARNINGS, POSTOPERATIVE CARE and POSSIBLE ADVERSE EFFECTS below.
3. Metallic surgical implants are NEVER TO BE REUSED (single use).

Notes:
RESTOR® Rotating Hinge system is intended to be used for distal/ total femur skeletal stability. Metallic surgical implants are intended to be used to 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. Weight bearing on bones that have failed to heal or healed partially or improperly can cause stress and fatigue in metallic surgical implants with consequent breakage or failure of

the implants. Surgeons should consider this and inform patients of pertinent information relevant to the patients' health and safety.

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.

Indications:

The RESTOR® Rotating Hinge 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® Rotating Hinge Modular Resection Prosthesis 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 severe trauma or 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.

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.

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

1. Surgical Technique: Correct surgical technique is essential to a successful outcome. Proper reduction of fractures and proper placement of implants are necessary to effectively treat patients using metallic surgical implants.
2. Implant Selection: The surgeon must exercise appropriate caution and judgement in the selection and use of these devices. Selection of the proper size, shape, design of the complete set of Implants and Instruments is a crucial parameter for success of the operative procedure which should be ensured by the operating surgeon. All Implants, Instruments and its sub-assemblies should be checked for intact packaging on receipt. All implants and instruments must be carefully checked for completeness and should be carefully inspected for compatible dimensions.
3. The following factors should be considered:
    - 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 Restor Rotating Hinge System must be avoided and 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.
    - 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 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.

Magnetic Resonance Imaging (MRI) Safety:

RESTOR◇ Modular Resection Prosthesis Rotating Hinge System has not been evaluated for safety and compatibility in the MR environment. This System has not been tested for heating or migration in the MR environment.

No Reuse:

Metallic surgical implants are NEVER TO BE REUSED. Stresses and fractures, even though not noticeable by visual inspection, may have been created during implantation. Single use devices should not be reused due to risks of breakage, failure or patient infection.

Possible Adverse Effects:

- Early stem loosening.
- Excessive wear of polyethylene components related to mal-aligned implant components leading to altered biomechanics, intraoperative component damage, loose cement and/or bone fragments and/or high patient activity levels or weight causing overloading that may require a re-bushing or insert change procedure.
- Soft tissue failure.
- Inadequate range of motion due to improper selection or positioning of components, impingement.
- Aseptic Loosening.
- Disease recurrence and/or progression in bone and/or soft tissue.
- 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.
- Per prosthetic fractures of the tibia, femur or patella.
- Taper Disengagement requiring an additional procedure or revision surgery.
- Infection.
- Abnormal gait related to limb length discrepancy and/or muscle weakness.
- Progressive bone resorption.
- Patella related complications such as retro-patellar pain and decreased range of movement.
- Hip Instability.
- Postoperative wound infection and wound haematoma.
- Flexion contractures, knee stiffness, reduction in mobility.
- Pulmonary embolisms leading to ARDS which can be life-threatening.
- Temporary or permanent nerve damage resulting in pain, numbness or a degree of paralysis of the affected limb.
- Foreign body reactions.

Packaging and Labeling:

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. Implant components supplied pre-sterile condition are packed in two stage of packaging (Primary Packaging – Blister Packaging and Secondary packaging – Corrugated box packaging). Main label

on outer packaging (Secondary Packaging) are indicated as STERILE R or STERILE EO, depending on the method of sterilization.
Pre-sterile devices not to be sterilized before use.

Sterilization:
The components of system are supplied sterile to a Sterility Assurance Level (SAL) of 10^{-6}. The method of sterilization is gamma irradiation or EtO sterilization which is also noted on the package label.

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.

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

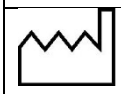
Important Information:
The operative surgeon is responsible for carrying out the surgical procedure correctly and must have mastered the acknowledged updated and latest operating techniques related to the type of surgery being performed, in theory and practice. Complications due to incorrect diagnosis 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.

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

Symbols Used in IFUs, Labels and Packaging Materials:

Symbol	Definition	Symbol	Definition	Symbol	Definition
	Single use (Do not re-use)		Batch Number		Sterilization by ethylene oxide
	Date of Manufacture YYYY-MM-DD		Manufactured by		Use by Date (Date of Expiry) YYYY-MM-DD
	To be sold only against prescription		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.
	Keep away from heat /sunlight and radioactive sources	REF:	Code Number / Part No.		Avoid moisture or water contact
	Recycle				

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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