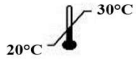
Instruction For Use

Smit Medimed Total Hip Replacement system

Manufactured By:

SMPL®
SMIT MEDIMED PVT. LTD.

MANUFACTURE OF ORTHOPAEDIC IMPLANTS
Plot No.10, Phase-1, B/h. Prashant Eng., G.I.D.C. Vatva,
Ahmedabad-382 445. (Gujarat) INDIA.
Phone : +91-79-25896751, 25896752
Fax : +91-79-25894150
E-mail : info@smitmedimed.com;
Visit us : www.smitmedimed.com

Symbol & Definitions	
REF	Catalog Number
	Refer e-IFU
	Manufacturer
	Date of Manufacturing
	Do Not Reuse
	Do Not Re-Sterile
STERILE R	Sterilized by Gamma Radiation
	If package opened or damaged DO NOT USE
	Storage temperature range
	Caution, consult accompanying documents
LOT	Batch Code

DESCRIPTION

The device is supplied as sterile.

MATERIAL

The implants are made of SS 316 L, ISO 5832-1, Co Cr Mo Alloy, titanium grade 5, UHMWPE, as mentioned on label

INTENDED USE

Total hip joint system used in hip replacement bone surgery for human body, to replace the diseased hip joints and to abridge the discomfort and pain. Poor healing after fracture of femoral head (neck); Necrosis of femoral head; Osteoarthritis; Acetabular dysplasia; Other surgery failures (e.g. failure of arthroplasty, double cups, joint instrumentation, partial hip or total hip replacement); Other situations that require joint replacement.

Correct selection of the implants is extremely important:

Responsibility of the proper selection of implant, adequate training, experience in the choice, placement of the implant & the decision to leave or remove implant postoperatively, rests with the surgeon.

The Surgeon should discuss the expectation of the surgery inherent the use of the product with the patient. Particular attention should be given to a discussion postoperatively & the necessity should be focused for periodic medical follow-up.

The Correct selection of the product is extremely important. The product should be used in the correct anatomical location, consistent with the accepted standard for the internal fixation. Failure to use the appropriate product for the application may result in a premature clinical failure. Failure to use the proper component to ensure adequate blood supply & provide rigid fixation may result in loosening, bending or cracking of the product and/ or bone fracture.

CONTRAINDICATIONS

Do not use the Orthopaedics implants in cases of:

- General or local acute/latent infection;
- Severe osteoporosis and poor bone quality;
- Excessive fat;
- Other diseases that affect post-operative function.

ADVERSE REACTIONS

Adverse reactions may include but are not limited to:

Early stage

Infection, Dislocation, Pain, Venous thrombus and pulmonary embolism, etc., Hematoma, Dysfunction, Severe rejection reaction

Late stage

Loosening, sinking and pain, Wear of prosthesis surface, bone resorption, osteoporosis, Fracture of the prosthesis, Other post-operative symptoms

SAFETY PRECAUTIONS

- The Product should only be used by the medical personnel who hold relevantqualification.
- Never use the product that has been damaged by Improper handling in the hospital or in any other way.
- Never reuse an implant. Although the implant appears to be undamaged, previous stresses may have created non-visible damage that could result inimplant failure.
- The product must be assumed to be non-sterile and must not be used if the pre-operative inspection shows that the packing is damaged. No repeated sterilization is allowed;
- No surgery before sufficient and complete pre-operative preparation; Heavy physical labour or excessive loading or stresses are not allowed after the surgery; Collision and squeezing should be avoided in transportation;

Sterilization: All implants are provided STERILE. Sterile devices are clearly labeled STERILE. Sterilization is achieved by exposure to a dose of minimum of25kGy of Gamma irradiation

HOW SUPPLIED/STORAGE:

The sterile implants must be stored in original unopened packaging away frommoisture.

IMPORTANT: inspect sterile packaging. If the package is opened or damageddo not use.

Note: devices should be considered sterile unless the inner tray package has beenopened or damaged.

Remove device from package using aseptic or technique only after the correct size has been determined and the operative site is prepared for implantation. Handle product with powder free glover.

INSPECTION:

Before use, inspect the box carefully. Do not use when

- Implants has scratches & damage
- Improper threads with damages
- Prior to surgery check suitability of fixation of this implant with its corresponding implant, and also ensure strength of whole assembly.

OPERATING INSTRUCTIONS

The Smit Medimed implants should be implanted only with the related corresponding instruments made by Smit Medimed. Also ensure the availability of same implant as standby. Surgeon should document the implant details (name,item, number, lot number) in surgery record.

PRE-OPERATIVE

- Prior to use, thoroughly read the provided operation manual and become familiar with the surgicaltechnique.
- Keep the instructions for use accessible to all staff.
- The operating surgeon must have a thorough understanding of both, the hands-on and conceptual aspects of the established operating techniques. Proper surgical performance of the implantation isthe responsibility of the operating surgeon. The operating surgeon draws up an operation plan specifying and documenting the following:
- Implant component(s) and their dimensions.
- Determination of intra-operative orientation points. The following conditions must be fulfilled prior to application:
- All requisite sterile implantation instruments must be available and in working order.
- Highly aseptic operating conditions are present.

WARNING:

The use of implants for surgery other than those for which they are intended may result in damage/breakage of implants or patient injury.

- The operating surgeon and operating room team must be thoroughly familiar with the operating technique, as well as the range of implants and instruments to be applied. Complete information onthese subjects must be readily available at the workplace.
- The operating surgeon must be especially trained in orthopaedic surgery, biomechanical principlesof the skeleton, and the relevant operating techniques.
- The operating procedure must be explained to the patient, and the patient's understanding of thefollowing information must be documented:
- The patient is aware of the risks associated with general surgery, orthopaedic surgery, and withgeneral anaesthesia.
- The patient has been informed about the advantages and disadvantages of the implant & implantation procedure and about possible alternative treatments.
- The implant can be failed due to excessive load, wear and tear or infection.
- The service life of the implant is determined by body weight and physical activity. The implantmust not be subjected to overload too early through extreme strain, work-related or athletic activities.
- Corrective surgery may be necessary if the implant fails.
- The patient must have his/her physician to carry out follow-up examinations of the implants atregular intervals.

INTRA-OPERATIVE

- Prior to use, verify the integrity of the implant.
- Modification of the Smit Medimed Orthopaedic Implant Set is not allowed.
- Choose the appropriate hip joint system based on patient situation; Expose hip joint; Implant hip joint system and adjust; Replace patellar if necessary.

POST-OPERATIVE

- Reiterate preoperative instructions to the patient.
- During the post-operative phase, in addition to mobility it is of vital Importance that the physician keeps the patient well informed about postsurgical behavioural requirements.
- Ensure that the patient is aware of physical activity restrictions and possibleadverse reactions.

REVISION SURGERY / IMPLANT REMOVAL

Metallic implants can be loosen, fracture, migrate, cause pain, or stress shield bone even after a fracture is healed, particularly in young active patients. The surgeon must make the final decision on implant removal if either of these occurs. If there are not any of these complications, we recommend the permanentimplantation of these implants because of the risk of re-fracture and the possible complications of an additional operation.

CLINICAL EVALUATION OF DEVICE

The Smit Medimed Pvt. Ltd. total hip replacement system is clinically safe, and effective in use as discussed and proved up to the mark in the clinical evaluation of the device.

DISPOSAL OF DEVICE

Please note that using a single use device (SUD) which comes into contact with human blood or tissue constitutes, it is a biohazard. Dispose it in a safe manner by hospital or disposed by authorize disposerhaving Pollution control board clearance.

FOR FURTHER INFORMATION

Please contact Smit Medimed Private Limited.
Email: info@smitmedimed.com
Tel :+91-79-25896751