Instruction concerning for Bone Screws made by Smit Medimed Pvt. Ltd.

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- The Device package contains single use implant Bone Screws of the Smit Medimed Pvt. Ltd.

DESCRIPTION

- The Bone Screws are single use device supplied Non-sterile. The devices are available in SS 316L, SS 316LVM& Titanium Grade 5 with different sizes.

FUNCTIONAL CHARACTERISTICS

- Implants hold the broken bones in proper position, the bone grows from the old bone surface towards the implant surface in an appositional manner which helps to healing process of bone.

INTENDED USE

Bone Screws

- The bone screw is intended to use for internal fixation of bone fractures and reconstruction of bones, there are several types of screw like locking head screw, general cortical screw or femur head bone screw are used for fixing of Femur head compression plate, locking plates which is used for osteotomy patients Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and mal-unions.

INTENDED CONDITIONS OF USE

- Bone Facture or dislocation.

CONTRAINDICATIONS

Do not use the Bone Screws in cases of:

- Inadequate bone quantity and/or bone quality
- Hypersensitivity to metal or allergic reaction
- Early or Late Infection, both deep and / or superficial.
- Patients with limited blood supply
- Patient within whom co-operation or mental competence is lacking, thereby reducing patient compliance

ADVERSE REACTIONS

Adverse reactions may include but are not limited to:

- Clinical failure (i.e. pain or injury) due to bending, loosening, breakage of implant, loose fixation, dislocation and/or migration
- Pain, discomfort, and/or abnormal sensations due to the presence of the implant.
- Primary and/or secondary infections.
- Allergic reactions to implant material.
- Necrosis of bone or decrease of bone density.
- Injury to vessels, nerves and organs.
- Elevated fibrotic tissue reaction around the surgical area.

SIDE EFFECTS

- Pain or loss of function in the implant area
- Weakness or fatigue
- Diarrhea
- Headaches
- Deep Vein Thrombosis (DVT)
- Venous thromboembolism (VTE)

- Fat Embolism

SAFETY PRECAUTIONS

- The Product should only be used by the medical personnel who hold relevant qualification.
- 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 in implant failure.
- Safety Precaution for Special Cases

  Pregnant Women
  - ✓ Ensure that there should be less blood loss during the surgery.
  - ✓ Anaesthesia should not be used in such case.
  - ✓ Operational environment must be free from radiation.

  Infant / Children
  - ✓ Ensure that there should be less blood loss during the surgery.
  - ✓ Operational environment must be free from radiation.
  - ✓ Epiphysis should not be damaged

  Polymorbid& Breastfeeding Women
  - ✓ On Polymorbid patients and breastfeeding women, the implant shall be used at the discretion of surgeon.

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 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 on these subjects must be readily available at the workplace.
- The operating surgeon must be especially trained in orthopedic surgery, biomechanical principles of the skeleton, and the relevant operating techniques.
- The patient is aware of the risks associated with general surgery, orthopedic surgery, and with general anesthesia.
- 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 implant must 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 at regular intervals.
- If device used in joints, kindly inform to patient do not move excessively, it may cause pain or damage surrounding tissue where implant was placed.

PACKAGING/STORAGE:

The implants are individually packed in protective packaging that is labelled to its contents properly. All Single use **Non-sterile** implants are supplied.

- Implants should be stored in the original protective packaging.
- Store the implants in a dry and dust-free place (standard hospital environment).

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.
- Any modification in the implants size, shape and surface condition is not permissible or possible.

OPERATING INSTRUCTIONS/INSTRUCTIONS FOR USE

SELECTION OF IMPLANT

- The selection of the proper size, shape & design of the implant for each patient is extremely important to the success of the procedure.
- Responsibility of the proper selection of patients, adequate training, experience in the choice, placement of the implant & the decision to leave or remove implant postoperatively, rests with the surgeon.
- 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.
- Bone Screws are available in variety of configurations, these shall be used in combination with related corresponding implants & instruments made by Smit Medimed Pvt. Ltd. only.
- The product should be used in combination with the devices made up similar material only. (Titanium implants with Titanium & SS implants with SS)
- Also ensure the availability of same implant as standby.
- Surgeon should document the implant details (name, item, number, lot number) in surgery record.
- For selection of suitable implants, its accessories & related devices, kindly refer a product combination chart available on our website.
- ***Note: Product combination chart is available on our website.(http://www.smitmedimed.com/ifu/product-combination-chart)***

IMPLANT FIXATION

- The Smit Medimed Pvt. Ltd. implants should be implanted only with the related corresponding instruments made by Smit Medimed Pvt. Ltd.
- 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

- 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 is the 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 required implant components are sterilized and readily available.
- All requisite sterile implantation instruments must be available and in working order.
- Highly aseptic operating conditions are present.

Sterilization: All Single use NON-STERILE implants and instrument used in the surgery must be cleaned & Sterile prior to use.
Remove plastic packing of implant before cleaning.

Cleaning Procedure:

New products must be carefully cleaned before initial sterilization. Only trained personnel must perform cleaning
Equipment: various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, neutral enzymatic cleaner or neutral detergent with a pH 7.

- Rinse Implants under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to clean the Implants.
- Soak Implants in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality, and concentration.
- Rinse Implants with cold water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels, and other hard to reach areas.
- Manually clean Implants for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution using a soft-bristled brush. Clean Implants under water to prevent aerosolization of contaminants.
  Note: Freshly prepared solution is a newly-made, clean solution.
- Rinse Implants thoroughly with deionized (DI) or purified (PURW) water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens and channels.
- Visually inspect Implants.
- Perform a final rinse on Implants using DI or PURW water.
- Dry Implants using a clean, soft, lint-free cloth or clean compressed air.

Note: Cleaning Agent Information: We used the following cleaning agents during internal processes of these cleaning recommendations. These cleaning agents are not listed in preference to other available cleaning agents which may perform satisfactorily- neutral pH enzymatic detergents (e.g. Prolystica 2X Concentrate Enzymatic Cleaner, Enzol, Endozime, and NeodisherMedizym) and neutral pH detergents (e.g. Prolystica 2X Neutral Detergent).

We are suggesting following parameter for the sterilization;

Method	Temperature	Exposure time	Pressure
Steam (autoclave)	121 Deg C.	15 Minutes	103421 Pa / 0.1 MPa / 15 psi

Note: Recommended Steam Sterilizer (Autoclave) is Class B.As our devices are manufactured using Stainless Steel & Titanium material, there is no effect of sterilization on product functionality or performance.

INTRA-OPERATIVE

- Prior to use, verify the integrity of the implant.
- Modification of the Implant Set is not allowed.
- Small bending of the Bone Screws is possible. when contouring this Screws do not over bend and / or bend back in original shape
- Use the appropriate Drill Guide, Drill and Tap set to make the holes and threading for the bone screws to avoid damage of the Bone Screws & bone.
- We provide Torque Limiting Screw Drivers during surgery with our instrument sets to avoid over-tightening of screw. We strictly recommend our devices to be used by trained healthcare professional who is aware with the torque and force to be applied on the devices by taking care of overtightening of screws.
- Ensure sufficient rinsing in-situ for cooling and removing of potential wear material.
- Before locking the screw to the Bone Screws, the bone has to be correctly repositioned.

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 post-surgical behavioral requirements.
- The Patient must be warned that loosening and or breakage of the implant are complications which occur as result of early or excessive weight-bearing, mechanical vibration & muscular activity.
- The patient should be advised not to smoke tobacco, consume alcohol, nicotine etc. which decreases healing process.
- If a state of non-union persists or if the components loosen, bend or break, device should be revised and/or removal surgery shall be performed immediately before serious injury occurs.
- Ensure that the patient is aware of physical activity restrictions and possible adverse reactions.
- Doctor shall ensure that proper follow-up timelines are given to patients as in when required. During the follow-ups, doctor need to verify whether the product is meeting its specified intended purpose.
- Doctor shall also communicate to patient regarding the cases when the follow-up has to be done like having abnormal reactions e.g., swelling, severe pain etc.
- Information regarding weight bearing and other physical activities timelines shall be communicated to patient.
- 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.
- Proper fixation of implant can be verified by post-operative X- rays & functioning can be verified during follow-ups.

IMPLANT REMOVAL/REVISION SURGERY

- 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 permanent implantation of this implants because of the risk of re-fracture and the possible complications of an additional operation.
- The surgeon must make the final decision on implant removal if either of these occurs;
  - ✓ Choice of Patient
  - ✓ Doctor's Advice based on the clinical condition of the patient
  - ✓ Deep Wound Infection/Bone Atrophy
  - ✓ Growing Skeleton
  - ✓ Tenosynovitis
  - ✓ Intra-Articular Material
  - ✓ Post – traumatic Arthritis
  - ✓ Avascular Necrosis
  - ✓ Intractable Pain
  - ✓ Perforating Material
  - ✓ Infection
  - ✓ Paresthesia
- Time of removal of implant shall be suggested by the doctor depending upon the clinical condition of the patient either after the surgery or during the follow ups.
- Removal of Implant may cause the risk of re-fracture, neurovascular injury & infection.
- Bone in-growth and wear of the implant can make the removal difficult.

MRI SAFETY INFORMATION

- Smit Medimed Pvt. Ltd. implants are manufactured from SS 316L, SS 316LVM & Titanium Grade 5 material, all are non-magnetic material, hence it do not pose any safety risk.
- Patients should be directed to seek a medical opinion before entering potentially adverse environments that could affect the performance of the implants, such as electromagnetic

or magnetic fields, including a magnetic fields, including a magnetic resonance environment.

- Doctor shall analyse the Risk before directing the patient to enter electromagnetic or magnetic fields or including a magnetic resonance environment.
- The Smit Medimed Pvt. Ltd. implants has not been evaluated for safety and compatibility in the MR environment but on the basis of literature study below mentioned points can be taken care during MRI
  - ✓ The minimum recommended time after the implantation that allows patients to safely undergo MRI examination or allowing the patient or an individual to enter the MRI environment is 6 (six) weeks.
  - ✓ The maximum recommended time limit for MRI examination in patients implanted with the evaluated device is 30 min with a scanner operating at 1.5T (Tesla) or less.

MR IMAGE ARTEFACTS

- Magnetic resonance (MR) imaging and multidetector computed tomography (CT), artifacts arising from metallic orthopedic hardware are an obstacle to obtaining optimal images.
- Implants made of titanium alloy are nonferromagnetic and produce much less severe artifacts than the ferromagnetic implants made up of stainless steel.

CLINICAL EVALUATION OF BONE SCREWS.

- The Smit Medimed Pvt. Ltd. Bone Screws are clinically safe, and effective in use as discussed and proved up to the mark in the clinical evaluation of the device.

DO NOT REUSE AND RESTERILE IMPLANTS

- Used implants which appear undamaged may have internal and external defects. It is possible that individual stress analysis of every part may fail to reveal the accumulated stress on the metals as a result of use within the body. This may ultimately lead to implant failure.
- Once an implant comes in contact with body fluids, it is contaminated with possible allergens and pathogens. Resterilization by autoclave should reduce the microbes and pathogens, but it is never 100% pathogen free. Autoclaving will NOT eliminate allergens. Allergens can cause the loss of an implant by a host allergic response. Autoclaving can also contaminate the surface of the implant with whatever metals have been present in the autoclave previously. Some metals such as the heavier metals are toxic to tissues. These toxic metals can damage bone. Resterilzation by autoclaving is no guarantee that the implant is free of pathogens, allergens or other contaminants.

DISPOSAL OF BONE SCREWS.

- Please note that using a single use device (SUD) which comes into contact with human blood or tissue constitutes, these device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

FOR FURTHER INFORMATION

Please contact Smit Medimed Pvt. Ltd. in case of any Query, Complain or Adverse Effect

Contact No.: +91 79 2589 6751; **Email:** info@smitmedimed.com

	**Non-Sterile** Indicating that the device has not been sterilized.

	**Consult Instructions For Use** Note: This symbol advises the reader to consult the operating instructions for information needed for the proper use of the device.
	**Do not re-use** Single use or use only once
	**Date Of Manufacture** Note: This symbol is accompanied by the date that the device was manufactured. The date could be year, year and month, or year, month and day, as appropriate.
	**Catalogue Number** Note: This symbol be accompanied by the catalogue number relevant to the device bearing the symbol.
	**Batch Code** Note: This symbol should be accompanied by the batch code relevant to the device bearing the symbol.
	**Do Not Use If Package Is Damaged** Do not use, if the packaging is compromised.
	**Caution** This symbol is to denote that there some warning or precautions associated with device, which are not otherwise found on labels
Qty	In Single Pack Number Of Quantity Packed
Material	Raw Material used for manufacturing
SMPL Smit Medimed Pvt. Ltd.	Manufacturers Company Logo
EC REP	**Authorized Representative in the European Community** **CMC Medical Devices & Drugs S.L.,** C/ HoracioLengo Nº 18, CP 29006, Málaga, Spain Tel: +34951214054; Fax: +34952330100 EMAIL: mmateos@cmcmedicaldevices.com
	**Manufacturer** **SMIT MEDIMED PVT. LTD.** Plot No.10, Phase-1, B|h. Prashant Engineering, G.I.D.C., Vatva, Ahmedabad-382445, Gujarat, India. Contact No.: +91 79 2589 6751 Web: www.smitmedimed.com Email: info@smitmedimed.com

CE 2803	CE marking with Notified Body Number
	Keep Dry
	Keep away from Sunlight

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