DEVICE NAME:

Bone Screws

BRAND NAME:

SAMAY, MEDIFIT

DEVICE DESCRIPTION:

Bone Screws are single use devices supplied sterile. The devices are available in SS 316L, Titanium Grade 5 with different sizes. The Device package contains a single-use implant manufactured by ***SAMAY SURGICAL PRIVATE LIMITED.***

INTENDED USE:

Bone Screws are intended for temporary fixation of fractures, correction/construction/ stabilization of bones in various anatomical regions including the Humerus, Tibia, Fibula, Hand, Foot and for long bones. Bone Screws fasten plates to bone, maintain bone fragments in their relative position, or hold together fragments of bone. They vary according to the manner in which they are inserted into bone, their function, size, the type of bone they are intended for, and the manner in which they couple with the screw driver (i.e., slot, cruciate, square, hexagon).

DURATION OF USE:

Long-term use (normally intended for continuous use for more than 30 days)

TARGETED POPULATION:

The device can be used in Children, Adults, Old - aged patients, Pregnant Women, Breast Feeding Women and Polymorbid patients. The exclusions are limited to the contradicted population as mentioned as mentioned in contra-indication section.

POINT OF CONTACT:

Bone Screws come in contact with tissue and bone of the human body.

USAGE FREQUENCY:

This device is intended for Single use only. Bone screws are supplied in sterile condition and are not intended for reuse.

INTENDED USER:

Orthopaedic surgeon

MEDICAL CONDITIONS:

Bone fracture or dislocation

USE ENVIRONMENT:

The device is intended to be used in Operating theatre only.

FUNCTIONAL CHARACTERISTICS:

Implant holds the broken bones in proper position, the bone grows from the old bone surface towards the implant surface in an appositional manner which helps in the healing process of bone.

INDICATION:

- Internal fixation of fractures, fusions and reconstruction of bones like clavicle, humerus, radius, ulna, ilium, femur, patella, fibula, tibia, talus, malleolus, and calcaneous, Hand and Foot in adults and for long bones in adolescents.
- Immobilize fractured bone segments to aid in the healing process.
- Osteotomies
- Indicated for fractures at various anatomical regions including cortical bone, cancellous bone.
- Proximal femur fractures including Intertrochanteric fractures, subtrochanteric fractures, intracapsular fractures.
- Distal femur fractures including intercondylar fractures, supracondylar fractures.
- Fracture of limbs and pelvis

CLINICAL BENEFITS:

- Bone screws compress the fragments together into normal anatomical alignment, essentially eliminate gap and strain between the fragments.
- Bone Screws used for attachment of implants to bone, bone to bone fixation or for soft tissue fixation or anchorage.
- Bone Screws protect the fractured bone from bending, getting rotated, and trivial loading forces.
- Screw fixation prevents movement of the implant which helps in early mobilization and aiding in fracture healing
- It helps in rigid fixation of the plates with the bone leading to fixation of fractures, correction/construction/ stabilization of bones

CLINICAL SAFETY:

- The product should be biocompatible
- The patient should have adequate bone quality
- The selection of the implant is very essential and it should be decided depending on the type of fracture & patient characteristics
- Device should be used by experienced Orthopedic Surgeon
- Device should not be reused or resterilized
- Safe for special cases like pregnant woman, children, polymorbid patients and breastfeeding women, the implant shall be used at the discretion of surgeon
- Implant removal process should be carried out considering patient's clinical conditions

PERFORMANCE CHARACTERSTICS:

- Based on the type of fractures, Bone Screws are designed in different sizes and can be used alone to hold a fracture, as well as with plates, wires & pins.
- Bone Screws positioned directly on the bone in "lag" fashion which creates interfragmentary compression for better and faster bone healing.
- Screws prevents movement of the implant which helps to hold broken pieces of bone together and helps in anatomical fracture reduction.

CONTRA-INDICATIONS:

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

POTENTIAL ADVERSE REACTIONS/ SIDE EFFECTS:

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 or loss of function in the implant area
- Weakness or fatigue
- Diarrhea
- Headaches
- 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.

LIMITATIONS

Bone Screws should not be used when contraindicated conditions are present in the patient.

WARNINGS:

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 orthopaedic surgery, biomechanical principles of the skeleton, and the relevant operating techniques.
- The patient is aware of the risks associated with general surgery, orthopaedic surgery, and with general anaesthesia.
- The patient has been informed about the advantages and disadvantages of the implant & implantation procedure and about possible alternative treatments.
- The implant can fail 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 a device is used in joints, kindly inform the patient to not move excessively, it may cause pain or damage surrounding tissue where the implant was placed.

SAFETY PRECAUTIONS:

- The Product should only be used by the medical personnel who hold relevant qualifications.
- 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.
- Anesthesia should not be used in such cases.

- 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

PACKAGING:

- The implants are individually packed in Tyvek Pouch with protective packaging that is labelled to its contents properly. Single use Sterile implants are supplied.

STORAGE CONDITIONS:

- Implants should be stored in the original packaging.
- Implants shall be stored at temperature 25°C ± 2°C & Humidity : 55% ± 5%RH
- Keep away from sunlight.

SHELF LIFE:

- 5 years

CORRECT SELECTION OF IMPLANTS:

- The selection of the proper size, shape and design of the implant for each patient is extremely important for 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.
- Our Bone screws are available in variety of configurations, these shall be used in combination with related corresponding implants & instruments made by ***SAMAY SURGICAL PRIVATE LIMITED*** only.

- The product should be used in combination with the devices made up similar material only. (Titanium Gr.5 implants with Titanium Gr.5 & SS 316L implants with SS 316L)
- 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.

INSPECTION:

Before use, inspect the box carefully.

- Check the product expiration date and verify the integrity of the sterile packaging.
- Do not use when, Implants has scratches & damage
- Do not use when, 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:

The ***SAMAY SURGICAL PRIVATE LIMITED*** implants should be implanted only with the related corresponding instruments made by ***SAMAY SURGICAL PRIVATE LIMITED***

- Also ensure the availability of the same implant as standby.
- Surgeon should document the implant details (name, item, number, lot number) in surgery record.
- Combination chart are useful to minimize risks associated with implantation.

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 operating plan specifying and documenting the following:

- Implants component(s) and their dimension.
- Determination of intra-operative orientation points

The following conditions should be fulfilled prior to application:

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

STERILIZATION METHOD:

- ***BONE SCREWS*** are supplied in sterile condition and are sterilized using ETO Sterilization

INTRA-OPERATIVE:

- Prior to use, verify the integrity of the implant.
- Modification of the Implant Set is not allowed.
- Use the appropriate Drill Guide, Drill and Tap set to make the holes and threading for the bone screws to avoid damage of the Plates and bone.
- Ensure sufficient rinsing in-situ for cooling and removing of potential wear material.
- Before locking the screw to the Plates, 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 behavioural requirements.
- 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.
- Post-operative X- rays can verify proper fixation of implant & functioning can be verified during follow-ups.

REVISION SURGERY/IMPLANT REMOVAL:

Metallic implants can be loosened, fractured, 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 these 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
- Paraesthesia

- 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:

- ***SAMAY SURGICAL PRIVATE LIMITED*** implants are manufactured from SS 316L & Titanium Grade 5 material, all are non-magnetic material, hence no reciprocal interference is posed, but SS implants can produce artifacts in the MRI, hence seek medical opinion before entering MRI environment.
- 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 field, 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 ***SAMAY SURGICAL PRIVATE LIMITED*** 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.
- The use of high magnetic field strengths at MR imaging produces more obtrusive artifacts than does the use of lower field strengths

INSTRUMENTS

- All instruments must be cleaned using hospital methods before sterilization and introduction into surgical field. All instrument moving parts should be well-labelled
- Be careful to use surgical lubricants
- Required instruments should be available in the operating room before initiating the surgical procedure.

CLINICAL EVALUATION OF BONE SCREWS:

The ***SAMAY SURGICAL PRIVATE LIMITED*** Bone Screws are clinically safe, and effective in use as discussed and proved up to the mark in the clinical evaluation of the device.

DISPOSAL OF BONE SCREWS:

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

NOTICE TO THE USERS:

Any serious incident that has occurred in the relation to the Bone Screws, should be reported to the Manufacturer and the competent authority of the Member state.

LINK TO SSCP:

A summary of safety and clinical performance can be found at the following link:

http://ec.europa.eu/tools/eudamed

Note: We will provide the SSCP link once the it is validated by notified body. The EUDAMED link will be available after the SSCP portal of European database on medical devices, EUDAMED, is launched.

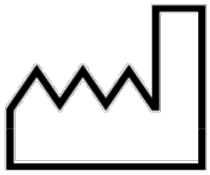
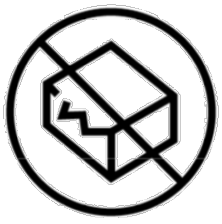
FOR FURTHER INFORMATION

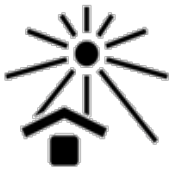
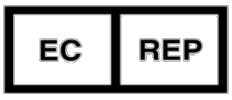
Please contact SAMAY SURGICAL PRIVATE LIMITED in case of any Query, Complaint or Adverse Effect.

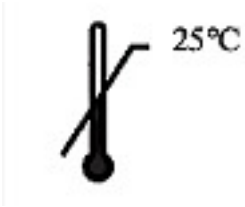
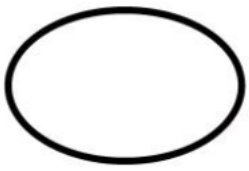
Tel:- 7878152154

Email:- info@samaysurgical.com

Website: https://samaysurgical.com/

Symbol	Description	Symbol	Description
CE 0297	CE marking with Notified Body Number		**Do not re-use** Single use or use only once
	**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.		**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.
	**Caution** This symbol is to denote that there some warning or precautions associated with device, which are not otherwise found on labels	LOT	**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.	MD	**Medical Device** Indicates the item is a medical device

Symbol	Description	Symbol	Description
	**Country of Manufacture** To identify the country of manufacture of products		**Catalogue Number** Note: This symbol be accompanied by the catalogue number relevant to the device bearing the symbol.
Medifit	**Manufacturers Brand Logo**	SAMAY	**Manufacturers Brand Logo**
	**Keep Away from Sunlight** The symbol denotes the medical device that needs protection from light sources.		**Manufacturer** Plot No. 12 and 13, Survey No. 896 and 897, Avadh Industrial Park - A, Village - Khambha, Rajkot-360311, Gujarat, India. Tel/ Fax No.: +91 7 878 15 21 54 Email: info@samaysurgical.com
	**Keep Dry** Indicates a medical device that needs to be protected from moisture.		**Authorized Representative in the European Community** Amstermed B.V **Address:** Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands **Contact No.:**

Symbol	Description	Symbol	Description
			+31235656337 **Email ID:** regulatory@amstermed.nl
	**Do not resterilise** Indicating that the device should not be re-sterilized		**Sterilized using ethylene oxide** Indicates a medical device that has been sterilized using ethylene oxide
	**Temperature Limit** Indicates the temperature limits to which the medical device can be safely exposed. **Temperature**: 25°C ± 2°C		**Humidity Limitation** Indicates the range of humidity to which the medical device can be safely exposed. **Humidity:** 55% ± 5%RH
	**Single Sterile Barrier System** Indicates a single sterile barrier system		**Use-by date** (Indicates the date after which the medical device is not to be used)
	**Unique device Identifier** Indicates a carrier that contains Unique		**Importer** Indicates the entity importing the medical device into the

Symbol	Description	Symbol	Description
	Device Identifier information		locale
	**Distributor** Indicates the entity distributing the medical device into the locale		**MR Conditional:** An item with demonstrated safety in the MR environment within defined conditions

Revision History

Rev. No.	Revision Date	Description
00	25/01/2024	Initial Issue
01	15/12/2024	**Updated as per NB Comments** Added provision for adding link of summary of safety and clinical performance