DEVICE NAME

Spinal Implants

BRAND NAME

SAMAY, MEDIFIT

DESCRIPTION

The Spinal Implants are single use device supplied sterile. The devices are available in Titanium Grade 5 with different sizes. The Device package contains single use implant (Spinal Implants) of the SAMAY SURGICAL PRIVATE LIMITED.

INTENDED USE

Spinal Implants are intended to provide fixation, stabilization, and immobilization of spinal bones. Spinal Implants are intended for occipital, cervical, thoracic, lumbar and sacral segments of the spine.

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 in contraindication section.

POINT OF CONTACT

Spinal Implants comes in contact with tissue & bones of the human body.

USAGE FREQUENCY

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

INTENDED USER

Orthopaedic Surgeon

MEDICAL CONDITIONS

Spinal Fracture or Dislocation.

USE ENVIRONMENT

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

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.

INDICATIONS

- Intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation system.
- Spinal Implants provide the additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:
  - ✓ Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
  - ✓ Spondylolisthesis;
  - ✓ Trauma (i.e., fracture or dislocation);
  - ✓ Spinal stenosis;
  - ✓ progressive spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis);
  - ✓ Tumors;
  - ✓ Pseudo arthrosis and failed previous fusion.

CLINICAL BENEFITS

- Binds segments of the vertebrae together to stop unnecessary movement that causes pain.

- These implants can reduce pain by stabilizing the affected spinal segments, alleviating pressure on nerves, and promoting proper alignment.
- Treat deformity, strengthen the spine, and facilitate fusion
- Stabilize the unstable spine caused by trauma or by slipped vertebrae (spondylolisthesis) originating from degenerative intervertebral disc
- Spinal Implants promotes fusion, internal fixation, stabilization, and restoration of spinal 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 Orthopaedic Surgeon
- Device should not be reused or resterilized
- Safe for special cases like pregnant woman, children, Polymorbid patients and breastfeeding women, when the implant is used at the discretion of surgeon
- Implant removal process should be carried out considering patient's clinical conditions

PERFORMANCE CHARACTERISTICS

- Provides stabilization to promote fusion following reduction of fracture/dislocation or trauma
- Internal Fixation of fractures and reconstruction of spinal bones
- Improves the biomechanical stability of the spine
- Promotes higher fusion rates and restore the lost disc height

CONTRAINDICATIONS

Do not use the Spinal Implants in cases of:

- Inadequate bone quantity and/or bone quality, osteopenia/or Osteoporosis
- 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, 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, Osteopenia/or Osteoporosis.
- Injury to vessels, nerves and organs.
- Elevated fibrotic tissue reaction around the surgical area.
- Pain or loss of function in the implant area
- Weakness or fatigue
- Diarrhea
- Headache

LIMITATIONS

Spinal Implants 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 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.

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 be given by an anaesthesiologist specializing in the administration of anaesthetic agents during pregnancy. If possible Surgical procedure should be delayed, until after the first trimester.
  - 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 that is labelled to its contents properly. All Single use **sterile** implants are supplied.

STORAGE CONDITIONS

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

SHELF LIFE

5 Years

CORRECT SELECTION OF THE IMPLANTS IS EXTREMELY IMPORTANT

- 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.
- Our Spinal Implants 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 with Titanium Gr. 5)
- For selection of suitable implants, its accessories & related devices, kindly refer a product combination chart available on our website.

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/ IMPLANT FIXATION

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

- Also ensure the availability of same implant as standby.
- Surgeon should document the implant details (name, item, number, lot number) in surgery record.
- Combination Chart are useful to minimize specific 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 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 readily available.
- All requisite sterile implantation instruments must be available and in working order.
- Highly aseptic operating conditions are present.

STERILIZATION METHOD

- ***Spinal Implants*** 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.
- Extreme care and caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused. Bone cement should not be used because the safety and the effectiveness of bone cement has not been determined for spinal uses.
- Before closing the soft tissues, provisionally tighten all of set screws, especially screws or set screws that have a break off feature. Once this is completed go back and firmly tighten all of the screws and set screws.

- Recheck the tightness of all screws after finishing to made sure that none loosened during the tightening of the other set screws or screws. Failure to do so may cause loosening of the other components.
- Before locking the screw to the plate, 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 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
  - ✓ 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 Titanium Grade 5 material, which is 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 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 orthopaedic 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.

CLINICAL EVALUATION OF SPINAL IMPLANTS

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

DISPOSAL OF SPINAL IMPLANTS

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.

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 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

NOTICE TO THE USERS

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

FOR FURTHER INFORMATION

Please contact ***SAMAY SURGICAL PRIVATE LIMITED*** in case of any Query, Complain or Adverse Effect

Email: info@samaysurgical.com

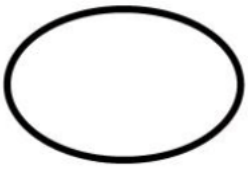
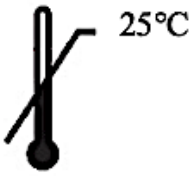
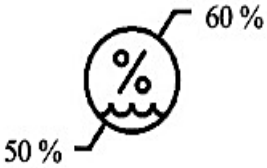
Tel: +91 7878152154

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

Symbol	Description	Symbol	Description
	**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		**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.		**Medical Device** Indicates the item is a medical device
	**Country of Manufacture** To identify the country of manufacture of products		**Catalogue Number** Note: This symbol be accompanied by the catalogue number relevant

Symbol	Description	Symbol	Description
			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. Email: info@samaysurgical.com Tel: +91 7878152154 Website: https://samaysurgical.com/
	**Keep Dry** Indicates a medical device that needs to be protected from moisture.	EC REP	**Authorized Representative in the European Community** **Name:** AMSTERMED B.V **Address:** Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands Contact No.: +31235656337

Symbol	Description	Symbol	Description
			Email Id: regulatory@amstermed.nl Website: https://www.amstermed.nl/
	**Do not re-sterilise** Indicating that the device should not be re-sterilized		**Sterilized using ethylene oxide** (Indicates a medical device that has been sterilized using ethylene oxide)
	**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)
	**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
	**Unique device Identifier** Indicates a carrier that contains Unique		**Importer** Indicates the entity importing the medical

Symbol	Description	Symbol	Description
	Device Identifier information		device into the 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	Approval Authority
00	25/01/2024	Initial Issue	GM & PRRC
01	15/08/2025	**Updated as per NB Comments** Added provision for adding link of summary of safety and clinical performance	GM & PRRC