DEVICE NAME:

Bone Plates

BRAND NAME:

SORATH ORTHO & SORATH

DEVICE DESCRIPTION:

The Bone Plates are single use devices supplied in non-sterile. The devices are available in SS 316L, SS 316LVM (As per material specification mentioned in ISO 5832-1) and Titanium Grade 4 and Titanium Grade 23 (As per material specification mentioned in ISO 5832-3) with different sizes. The Device package contains a single-use implant manufactured by ***SIGMA SURGICAL PVT. LTD.***

INTENDED USE:

The bone plates are intended for temporary fixation of fractures, correction/construction/stabilization of bones in various anatomical regions including the Scapula, Olecranon, Humerus, Radius, Ulna, Pelvis, Distal, Tibia, Fibula, Hand and Foot and for long bones in whom the growth plates are fused. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and mal-unions. Bone Plates can be used for ventral, dorsal or orthogonal application. Bone Plates are intended to be implanted along with implants like Bone Screws/Wires/ Pins.

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.

POINT OF CONTACT:

Bone plates comes in contact with tissue & bone of the human body.

USAGE FREQUENCY:

This device is intended for Single use only. All Bone Plates are supplied in non-sterile condition, are to be sterilized before use 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:

- Indicated to heal/repair the fractures, fusions, and osteotomies of bone at various sites (Humerus, clavicle, humerus, radius, ulna, phalanx, metacarpal, metatarsal, malleolus, tibia, fibula, hand and foot in adults and for long bones in adolescents) of the human body.
- To provide fixation for fractures, fusions or osteotomies.
- Restore the anatomical and functional alignment of the broken pieces of fracture bones.
- Intra-articular fractures & Extra articular fractures
- Nonunion and malunions
- Supracondylar fractures
- Fractures requiring additional stability

CLINICAL BENEFITS:

- Increasing the stability of the fracture fragments

- Transferring loads across the fracture site and maintaining the anatomical alignment to induce bony union
- Early mobilization and aiding in fracture healing
- Minimize the fracture gap and increase the biomechanical stiffness
- Restoration of structural integrity and stability in fractured bones, leading to improved function and long-term support, enhancing patients' overall quality of life.

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
- On 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:

- Bone Plates come in different sizes and shapes depending on the size of the bone, anatomical shape and type of fracture
- Bone Plates produces compression to provide stable fixation and promotes direct healing at the fracture site
- Bone Plates hold the broken pieces of bone together and helps in anatomical fracture reduction

CONTRA-INDICATIONS:

Do Not use the Plates in cases of:

- Inadequate bone quantity and/or bone quality, 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/ Side effects may include but are not limited to:

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

LIMITATIONS

Bone Plates 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 anesthesia.
- 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/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).
- Keep away from sunlight

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 Plates are available in variety of configurations, these shall be used in combination with related corresponding implants & instruments made by ***SIGMA SURGICAL PVT. LTD.***
- The product should be used in combination with the devices made up similar material only. (Titanium Gr.4 implants with Titanium Gr.4, Titanium Gr.23 implants with Titanium Gr.23 & SS 316L implants with SS 316L, SS 316LVM implants with SS 316LVM)
- 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.

Note: Combination chart and Surgical Technique are available on our website.
(Link to access the Combination chart and Surgical Techniques are provided in section "Useful Links" below in the IFU).

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:

The ***SIGMA SURGICAL PVT. LTD.*** implants should be implanted only with the related corresponding instruments made by ***SIGMA SURGICAL PVT. LTD.***

- 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.

Note: Combination chart and Surgical Technique are available on our website.
(Link to access the Combination chart and Surgical Techniques are provided in section "Useful Links" below in the IFU).

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 sterilized and readily available.
- All requisite sterile implantation instruments must be available and in working order.

Highly aseptic operating conditions are present

CLEANING AND 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 Neodisher Medizym) and neutral pH detergents (e.g., Prolystica 2X Neutral Detergent).

STERILIZING PROCEDURE:

We are suggesting following parameters for sterilization-

Type	Temperature	Exposure time	Pressure
Steam (autoclave)	121 Degree C.	15 minutes	103421 Pa / 0.1 MPa / 15 psi

Note: Recommended Steam Sterilizer (Autoclave) is Class B.

As our devices are manufactured using SS 316L, SS316LVM & Titanium Gr.4, & Titanium Gr.23 material, there is no effect of sterilization on product functionality or performance.

Steps to be followed after sterilization

- ***Implants need to be transferred via stainless steel trolley only.***
- ***After washing & sanitizing their hand, the autoclaved person should open first layer of cloth ensuring that the second layer is intact.***
- ***The second layer of cloth should be opened in the operation theatre before surgery.***

INTRA-OPERATIVE:

- Prior to use, verify the integrity of the implant.
- Modification of the Implant Set is not allowed.
- Small bending of the Plates is possible. when contouring this Plates, 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 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:

- SIGMA SURGICAL PVT. LTD. implants are manufactured from SS 316L, SS 316LVM, Titanium Grade 4, & Titanium Grade 23 material, all are non-magnetic 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 ***SIGMA SURGICAL 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.
- 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 PLATES:

The ***SIGMA SURGICAL PVT. LTD. Bone Plates*** 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 PLATES:

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 Plates, 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.

USEFUL LINKS:

Product Combination Chart:

https://www.sorathortho.co.in/combination-chart/

Surgical Techniques:

https://www.sorathortho.co.in/twin-lock-bone-compression-plate-system-for-clavicle/

https://www.sorathortho.co.in/twin-lock-bone-compression-plate-system-for-distal-radius/

https://www.sorathortho.co.in/elbow-plating-system/

https://www.sorathortho.co.in/bcp-proximal-humerus-proton-plate/

https://www.sorathortho.co.in/bcp-distal-fibula-plate/

https://www.sorathortho.co.in/femur-plating/

https://www.sorathortho.co.in/twin-lock-bcp-anarel-plate-3-5-mm-left-right/

https://www.sorathortho.co.in/tibia-plating-system/

FOR FURTHER INFORMATION

Please contact SIGMA SURGICAL PVT. LTD. in case of any Query, Complaint or Adverse Effect.

Email: info@sorathortho.com

Tel :+91-079-22976132

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
 eIFU Indicator	**Consult electronic instructions for use** Indicates the need for the user to consult the electronic instructions for use		**Date of Manufacture along with country 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. Additionally, the "IN' in the symbol denotes the country of manufacture.
	**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
	**Unique device Identifier** Indicates a carrier that contains Unique Device Identifier information		Manufacturers Brand Logo
	**Keep Away from Sunlight** The symbol denotes the medical device that needs protection from light sources.		**Manufacturer** Survey No.:1636/1, Opposite Bharat Petroleum Petrol Pump, Village-Kuha, Indore Highway, Taluka: Daskroi, District: Ahmedabad – 382433, Gujarat, India Email: info@sorathortho.com Tel: +91-079-22976132
	**Keep Dry** Indicates a medical device that needs to be protected from moisture.		**Authorized Representative in the European Union** Amstermed B.V **Address:** Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands **Contact No.:** +31235656337 **Email ID:** regulatory@amstermed.nl

Symbol	Description	Symbol	Description
	**Do not resterilize** Indicating that the device should not be re-sterilized		Non-sterile
	**MR Conditional:** An item with demonstrated safety in the MR environment within defined conditions		**Catalogue Number** Note: This symbol be accompanied by the catalogue number relevant to the device bearing the symbol.

REVISION HISTORY

Sr. No.	Description of Change	Revision No.	Revision Date	Approval Authority
1.	Initial Issue	00	15.09.2023	MR
2.	Updated as per Notified Body comment- - Added the Symbol for MR Conditional. - Added the link of Combination Chart and Surgical Technique Links	01	31.01.2024	MR
3.	Updated as per Notified Body comment- - Added the section for Link to SSCP for provide the link of SSCP to user.	02	16.03.2026	MR
4.	Updated the manufacturer logo and add the symbol of eIFU indicator Update the brand name “Sigma Ortho” to “SORATH Ortho”	03	20.07.2026	MR