IFU for Bone Plates : IFU-HI-03-18, rev.02, Dated 20/07/2020

Instruction concerning Orthopaedic Implants (Bone Plates) made by Hardik International Private Limited, locate at Plot No. G -2041 / 42 A, Kishan Gate, Lodhika, G.I.D.C, Kalawad Road, Metoda - 360021, Rajkot, Gujarat, India

CONTENTS

The Device package contains single implant (Bone Plates) of the Hardik International Private Limited,
Hardik International Private Limited implants are manufactured from SS 316L or SS 316LVM or Titanium Ti-6Al-4V (TitGr.5) material, kindly refer label for exact material identification.

DESCRIPTION

The devices are supplied Non-sterile; The devices are available in 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

The Bone Plates is intended for internal fixation of fractures and reconstruction of bones including the Scapula, Olecranon, Humerus, Radius, Ulna, Pelvis, Distal, Tibia, Fibula, Hand and Foot in adults and for long bones in adolescents 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. This system can be used for ventral, dorsal or orthogonal application.

INTENDED CONDITIONS OF USE

- Bone Facture or dislocation.

CONTRAINDICATIONS

Do not use the Orthopedics implants in cases of:

- Inadequate bone quantity and/or bone quality
- Hypersensitivity to metal or allergic reaction
- Acute localized infections
- Patients with limited blood supply
- Patients with unstable physical and / or mental health conditions
- Patient with Osteopenia and Osteoporosis

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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, loos 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

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.
  - Anesthesia 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.

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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 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 operating procedure must be explained to the patient, and the patient's understanding of the following information must be documented:
- 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.

HOW SUPPLIED/STORAGE:

- The implants are individually packed in protective packaging that is labelled to its contents properly. All 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.

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OPERATING INSTRUCTIONS

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.
- Our Bone Plates are available in variety of configurations, these shall be used in combination with related corresponding implants & instruments made by Hardik International 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 316LVM implants with SS 316LVM & SS 316L implants with SS 316L)
- For selection of suitable implants, its accessories & related devices, kindly refer a product combination chart available on our website ***(https://www.hardikinternational.com/details.php?id=298)*.**

IMPLANT FIXATION

The Hardik International Private Limited implants should be implanted only with the related corresponding instruments made by Hardik International 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 sterilized and readily available.
- All requisite sterile implantation instruments must be available and in working order.
- Highly aseptic operating conditions are present.

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Sterilization: All NON STERILE implants and instrument used in the surgery must be cleaned & Sterile prior to use.

Remove plastic packing of implant before cleaning.

After cleaning of implant, we recommended implants should be wrapped in medical grade paper and placed in Autoclave for Sterilization of medical device as per recommended parameter.

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 SS 316LVM, SS 316L & Titanium Gr.5 material, there is no effect of sterilization on product functionality or performance.

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.

1. Rinse device under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to clean the device.
2. Soak device 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.
3. Rinse device 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.
4. Manually clean device for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution using a soft-bristled brush. Clean device under water to prevent aerosolization of contaminants. Note: Freshly prepared solution is a newly-made, clean solution.
5. Rinse device 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.
6. Visually inspect device.
7. Perform a final rinse on device using DI or PURW water.
8. Dry device 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).

It is highly recommended that only above mentioned chemicals to be used in cleaning process.

INTRA-OPERATIVE

- Prior to use, verify the integrity of the implant.
- Modification of the Orthopedic Implant Set is not allowed.
- Bending of the Bone Plates set is possible. When contouring these plates, do not over bend and / or bend back in original shape.
- Ensure sufficient rinsing in-situ for cooling and removing of potential wear material.
- 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.
- Ensure that the patient is aware of physical activity restrictions and possible adverse reactions.
- 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.

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 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

- Hardik International Private Limited 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 Hardik International 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 Gr.5 are non-ferromagnetic and produce much less severe artifacts than the ferromagnetic implants made up of stainless steel.

CLINICAL EVALUATION OF DEVICE

The Hardik International Private Limited Bone Plates 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 disposer having Pollution control board clearance.

DO NOT REUSE OR RE-STERILIZATION OF DEVICE:

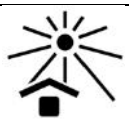
Used implants which appear undamaged may have internal and external defects. It is possible that individual stress analysis of every part may fail to reveal the accumulated stress on the metals as a result of use within the body. This may ultimately lead to implant failure.

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.

FOR FURTHER INFORMATION

Please contact Hardik International Private Limited

Email: info@hardikinternational.com, Tel: + 91 97370 47470 / 71 /72

	**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
	**Caution** This symbol is to denote that there some warning or precautions associated with device, which are not otherwise found on labels
	Do Not Use If Package Is Damaged Do not use, if the packaging is compromised.
	Keep Dry (Only in shipping label)
	Keep away from Sunlight (Only in shipping Label)
	**Manufacturer Address** This symbol shall be adjacent to the name and address of the manufacturer. **Hardik International Private Limited** Plot No. G -2041 / 42 A, Kishan Gate, Lodhika, G.I.D.C, Kalawad Road, Metoda - 360021, Rajkot (INDIA). Email: info@hardikinternational.com Tel: + 91 97370 47470 / 71 /72

	**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.
	**Authorized Representative in the European Community** This symbol shall be adjacent to the name and address of the authorized representative in the European Community. The address is not required on an immediate container unless the immediate container is the outer container. **Med Devices Lifesciences B.V.** Kraijenhoffstraat 137 A, 1018 RG Amsterdam, Netherlands. Email: info@meddevices.net Phone: +31-202254558 **Website:** www.meddevices.net
	**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.
	Specifying Material Of the Product
Qty	In Single Pack Number Of Quantity Packed
Drug Lic No.	INDIAN FDA License Number

HARDIK® INTERNATIONAL PVT. LTD.	Manufacturers Company Logo
CE 1023	CE marking with Notified Body Number