Instruction for Use

CE 1023

Instruction concerning Spinal surgical Implants (Spinal Implants) made by Miraclus Orthotech Pvt Ltd., locate at Plot No. 1112, Phase - 3, G.I.D.C., Vatva, Ahmedabad-382445, Gujarat, India

CONTENTS

The Device package contains single use implant (Spinal Implant) of the Miraclus Orthotech Pvt. Ltd

DESCRIPTION

The Spinal Implants are single use device supplied Non-sterile. The devices are available in different sizes.

INTENDED USE

Spinal Implants are used in the surgical procedures related to the spinal injuries and spinal diseases.

Correct selection of the implants is extremely important:

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 Spinal Implants are available in variety of configurations, these shall be used in combination with related corresponding implants & instruments made by Miraclus Orthotech Pvt. Ltd only.

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.

CONTRAINDICATIONS

Do not use the Spinal implants in cases of:

• Inadequate bone quantity and/or bone quality
• Hypersensitivity to metal or allergic reaction
• Early or Late Inspection, 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.
- Limb shortening due to compression of the fracture or bone resorption
- Necrosis of bone or decrease of bone density.
- Injury to vessels, nerves and organs.
- Elevated fibrotic tissue reaction around the surgical area.

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.

HOW SUPPLIED/STORAGE:

Instruction for Use

CE 1023

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.

OPERATING INSTRUCTIONS

The Miraclus Orthotech Pvt. Ltd. implants should be implanted only with the related corresponding instruments made by Miraclus Orthotech 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.

1. Rinse Spinal Implants under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to clean the Spinal Implants
2. Soak Spinal 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.
3. Rinse Spinal 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.
4. Manually clean Spinal Implants for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution using a soft-bristled brush. Clean Spinal Implants under water to prevent aerosolization of contaminants.

Note: Freshly prepared solution is a newly-made, clean solution.

5. Rinse Spinal 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.
6. Visually inspect Spinal Implants.

7. Perform a final rinse on Spinal Implants using DI or PURW water.
8. Dry Spinal 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).

We are suggesting following parameter for the sterilization;

Method	Temperature	Exposure time	Pressure
Steam (autoclave)	121 Deg C.	15 Minutes*	15 lbs

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

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 Spinal surgery, biomechanical principles of the skeleton, and the relevant operating techniques.
- The patient is aware of the risks associated with general surgery, Spinal 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.

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.
- Ensure that the patient is aware of physical activity restrictions and possible adverse reactions.

Instruction for Use

CE 1023

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.

MRI SAFETY INFORMATION

Miraclus Orthotech implants are manufactured from PEEK & Titanium (Gr-5) material, both are non-magnetic material, hence it do not pose any safety risk.

CLINICAL EVALUATION OF SPINAL **IMPLANTS**

The Miraclus Orthotech Pvt. Ltd. Spinal Implant is 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, it is a biohazard. Dispose it in a safe manner by hospital or disposed by authorize disposer having Pollution control board clearance.

FOR FURTHER INFORMATION

Please contact Miraclus Orthotech Pvt. Ltd. in case of any Query, Complain or Adverse Effect

Email: info@miraclus.com , Tel (+91) 079 25831332/33

	**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.

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.
	**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
Miraclus® Implanting LIFE	Manufacturers Company Logo
EC REP	**Authorized Representative in the European Community** **CMC Medical Devices & Drugs S.L** C/Horacio Lengo N° 18, CP 29006, Malaga, Spain Tel: +34 951 214 054 Email: info@cmcmedicaldevices.com
	**Manufacturer** **Miraclus Orthotech Pvt. Ltd** Plot No. 1112, Phase - 3, G.I.D.C., Vatva, Ahmedabad-382445, Gujarat, India
CE XXXX	CE marking with Notified Body Number (This symbol shall be used only after completion of conformity assessment & availability of valid CE certificate)

Instruction for Use

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Rev.-00