IFU for Intramedullary Nails

Instruction concerning Orthopaedic Implants (Intramedullary Nails) made by Nebula Surgical Pvt. Ltd.,
Locate at Factory: G/1921/3, Gate no. 02, G.I.D.C. At – Metoda - 360 021, Dist. Rajkot (Gujarat) INDIA.
Office: "Nebula" 5th Floor, Narmada Park-3, Vidyakunj Society Main Road, Opp. Kings Height Appt., Amin Marg, Rajkot 360 005 (Gujarat) India.

CONTENTS

The Device package contains single use implant (Intramedullary Nails) of the Nebula Surgical Pvt. Ltd.

DESCRIPTION

The Intramedullary Nails are single use device supplied Non-sterile. The devices are available in SS 316L & Titanium Grade 23 with different sizes.

INTENDED USE

Intramedullary Nails are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femurs, femoral shaft, tibia and humerus.

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 Intramedullary Nails are available in variety of configurations, these shall be used in combination with related corresponding implants & instruments made by Nebula Surgical Pvt. Ltd. only.
- The product should be used in combination with the devices made up similar material only. .(Titanium Gr.23 implants with Titanium Gr.23 & 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.

CONTRAINDICATIONS

Do not use the Intramedullary Nails 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.
- 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.
- Safety Precaution for Special Cases

  Pregnant Women
  - ✓ Ensure that there should be less blood loss during the surgery.
  - ✓ Anaesthesia 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

HOW SUPPLIED/STORAGE:

IFU for Intramedullary Nails

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 Nebula Surgical Pvt. Ltd. implants should be implanted only with the related corresponding instruments made by Nebula Surgical 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.

- 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).

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.

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.

IFU for Intramedullary Nails

- 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.

INTRA-OPERATIVE

- Prior to use, verify the integrity of the implant.
- Modification of the Implant Set is not allowed.
- Small bending of the Intramedullary Nails set is possible. when contouring this Intramedullary Nails, 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 screws, Intramedullary Nails & bone.
- Ensure sufficient rinsing in-situ for cooling and removing of potential wear material.
- Before locking the screw to the Intramedullary Nails, 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.

IMPLANT REMOVAL

- 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

- Nebula Surgical Pvt. Ltd. implants are manufactured from SS 316L & Titanium Grade 23 material, both 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.
- The Nebula 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.

CLINICAL EVALUATION OF INTRAMEDULLARY NAILS

- The Nebula Surgical Pvt. Ltd. Intramedullary Nails is clinically safe, and effective in use as discussed and proved up to the mark in the clinical evaluation of the device.

IFU for Intramedullary Nails

DISPOSAL OF INTRAMEDULLARY NAILS

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

FOR FURTHER INFORMATION

Please contact Nebula Surgical Pvt. Ltd. in case of any Query, Complain or Adverse Effect
Email: info@nebulasurgical.com, Telephone: + 91-281223898

	**Non Sterile** Indicates a medical device that has not been subjected to a sterilization process.		**Keep away from Sunlight** Indicates a medical device that needs protection from light sources.
	**Consult Instructions For Use** Indicates the need for the user to consult the instructions for use.		**Date Of Manufacture** Indicates the date when the medical device was manufactured.
	**Manufacturer** Indicates the medical device manufacturer, as defined in EU Directives 93/42/EEC. **NEBULA SURGICAL PVT. LTD.** **Factory:** G/1921/3, Gate no. 02, G.I.D.C. At – Metoda - 360 021, Dist. Rajkot (Gujarat) INDIA. **Office:** "Nebula" 5th Floor, Narmada Park-3, Vidyakunj Society Main Road, Opp. Kings Height Appt., Amin Marg, Rajkot 360 005 (Gujarat) India.		**Authorized Representative in the European Community** Indicates the 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
	**Do not re-use** Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.		**Caution** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	**Do not use if package is damaged** Indicates a medical device that should not be used if the package has been damaged or opened.		**Keep Dry** Indicates a medical device that needs to be protected from moisture.
	**Catalogue Number** Indicates the manufacturer's catalogue number so that the medical device can be identified.		**Batch Code** Indicates the manufacturer's batch code so that the batch or lot can be identified.
	**CE marking with Notified Body Number**		