IFU for Interlocking Nails

Instruction concerning Orthopaedic Implants (Interlocking Nails) made by Bombay Ortho Industries.

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The Device package contains single use implant (Interlocking Nails) of the Bombay Ortho Industries

DESCRIPTION

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

The Product catalogue are available on the company website https://bombayortho.com/

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. The nail connects the bone fragments in the manner of an internal splint. The nail is also stabilised with a crossways bolt or locking screws so that it cannot displace itself. The nail is correctly positioned with the help of x-ray imaging.

INTENDED USE

Interlocking Nails are used for Intramedullary Fixation & Locking of humerus, tibia and femur fracture.

INTENDED CONDITIONS OF USE

- Bone Fracture or dislocation.

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.
- Our Interlocking Nails are available in variety of configurations, these shall be used in combination with related corresponding implants & instruments made by Bombay Ortho Industries 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) as the different materials exhibit different properties. Mixing of metals may cause inflammatory response, metal sensitivity reactions, and/or long term detrimental systemic effects. In addition, it can reduce the mechanical strength of the implant.
- 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.
- For selection of suitable implants, its accessories & related devices, kindly refer a product combination chart available on our website.
- The Product Combination Chart and Surgical Technique for the products are available on the company website
  Product Combination Chart
  https://bombayortho.com/combinationchart/interlocking-nail-product-combination-chart/
  Surgical Techniques-
  https://bombayortho.com/combination-chart/surgical-technique/

CONTRAINDICATIONS

Do not use the Interlocking Nails in cases of:

- Inadequate bone quantity and/or bone quality
- 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

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.

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- Limb shortening due to compression of fracture or bone resorption
- Elevated fibrotic tissue reaction around the surgical area.
- Malrotation of bone due to misalignment.

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.
  - ✓ General 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

  Polymorbid & Breastfeeding Women
  - ✓ On Polymorbid patients and breastfeeding women, the implant shall be used at the discretion of Orthopedic Surgeon.

HOW SUPPLIED/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).

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 Bombay Ortho Industries implants should be implanted only with the related corresponding instruments made by Bombay Ortho Industries.
- 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

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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. Prior to steam sterilization, wrap the product in a plain paper.

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 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 Interlocking Nails set is possible. when contouring this Interlocking 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, Interlocking Nails& bone.
- Ensure sufficient rinsing in-situ for cooling and removing of potential wear material.
- Before locking the screw to the Interlocking 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 implant removal is most recommended in the surgeries where implant is placed near to or on the moving parts of the body, some examples include, but not limited to ankle, olecranon and femoral IM nails.
- The decision of implant removal solely depends on the surgeon, based on age of patient, severity of the injury, clinical condition of the patient & consideration of the post-surgery complication of implant removal. ;
  Following are the indication of implant removal decision:
  - ✓ Choice of Patient
  - ✓ Doctor's Advice based on the clinical condition of the patient

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- ✓ Deep Wound Infection/Bone Atrophy
- ✓ Growing Skeleton
- ✓ Tenosynovitis
- ✓ Intra-Articular Material
- ✓ Post – traumatic Arthritis
- ✓ Avascular Necrosis
- ✓ Intractable Pain
- ✓ Perforating Material
- ✓ Infection
- ✓ Paresthesia

- Removal of Implant may cause the risk of re-fracture, neurovascular injury, impaired wound healing, post-operative bleeding & infection.
- Bone in-growth and wear of the implant can make the removal difficult, leading to incomplete removal of the implant.
- While the physician makes the final decision on when to remove the implant, it is advisable – if possible and appropriate for the individual patient – to remove fixation products after the healing process is complete. This holds true particularly for young and active patients.

MRI SAFETY INFORMATION

- Bombay Ortho Industries 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 Bombay Ortho Industries 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 INTERLOCKING NAILS

- The Bombay Ortho Industries Interlocking Nails is clinically safe, and effective in use as discussed and proved up to the mark in the clinical evaluation of the device.

DO NOT REUSE AND RESTERILE IMPLANTS

- 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 will not guarantee the product to be 100% free from microbes.

DISPOSAL OF INTERLOCKING 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.

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FOR FURTHER INFORMATION

Please contact Bombay Ortho Industries in case of any Query, Complain or Adverse Effect

Email: bombayortho@gmail.com, Telephone: + 91-9978928286

	**Non Sterile** Indicates a medical device that has not been subjected to a sterilization process.
	**Consult Instructions For Use** Indicates the need for the user to consult the instructions for use.
	**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.
	**Keep away from Sunlight** Indicates a medical device that needs protection from light sources.
	**Manufacturer** Indicates the medical device manufacturer, as defined in EU Directives 93/42/EEC. **Bombay Ortho Industries.** G/551, Metoda, Lodhika G.I.D.C., Kalawad Road, Gate No. 3,Rajkot - 360021,India. Tele/fax No.: +91-9978928286

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	**Date Of Manufacture** Indicates the date when the medical device was manufactured.
	**Authorized Representative in the European Community** Indicates the Authorized representative in the European Community. **CMC Medical Devices & Drugs S.L** C/HoracioLengo N° 18, CP 29006, Malaga, Spain Tel: +34 951 214 054 Email: info@cmcmedicaldevices.com
	**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**