	INSTRUCTION FOR USE		DOC NO. : OMMCPL/INS/IFU/01	
	FIXATION SYSTEM		PAGE : 1 OF 7	
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- The Device package contains various Fixation System according to the requirement of surgery.

DESCRIPTION

- a) The Fixation Systems are reusable devices supplied in Non-sterile condition. The devices are available in with different sizes.
- b) The Material for Fixation Systems made by Ortho Max Mfg. Co. Pvt. Ltd. are STAINLESS STEEL 316 L, STAINLESS STEEL 304, STAINLESS STEEL 410 ALUMINUM HE 30, DELRIN, FIBER, SILICON, CARBON FIBER.

FUNCTIONAL CHARACTERISTICS

- Fixation System is used to Minimize the Movement of body parts so that the healing process can take place.
- Fixation System are a very important tools for the surgery.

INTENDED USE

- **Fixation System**

A tool or device for performing specific actions or carrying out desired effects during a surgery or operation, Realignment of the bone fracture to the normal alignment.

INTENDED CONDITIONS OF USE

- Bone Fracture or dislocation & in surgeries.

CONTRAINDICATIONS

Do not use the Fixation Systems 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
- 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:

- Pain, discomfort, and/or abnormal sensations due to the presence of the Fixator.
- Primary and/or secondary infections.
- Allergic reactions to Fixator material.

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.
- Safety Precaution for Special Cases
- The product is used as per proper surgical technique.

WARNING

The use of Fixators for surgery other than those for which they are intended may result in damage/ breakage of Fixators or patient injury.

- The operating Orthopedic Surgeon and operating room team must be thoroughly familiar with the operating technique, as well as the range of Fixators and Fixators to be applied. Complete information on these subjects must be readily available at the workplace.
- The operating Orthopedic 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 Fixators can be failed due to excessive load.

PACKAGING/STORAGE:

The Fixators are individually packed in protective packaging that is labelled to its contents properly. All are reusable **Non-sterile** Fixators are supplied.

- Fixators should be stored in the original protective packaging or metal box
- Store the Fixators in a dry and dust-free place (standard hospital environment).

INSPECTION:

Before use, inspect the box carefully. Do not use when

- Fixators has scratches & damage
- Improper threads with damages

OPERATING INSTRUCTIONS/INSTRUCTION FOR USE:
SELECTION OF FIXATORS

- The selection of the proper size, shape & design of the Fixator for each surgery is extremely important to the success of the procedure.
- Our Fixators are available in variety of configurations, these shall be used in combination with related corresponding Implants & Fixators made by OMMCPL only.

PRE-OPERATIVE

- Keep the instructions for use accessible to all staff.
- The operating Orthopedic Surgeon must have a thorough understanding of both, the hands-on and conceptual aspects of the established operating techniques. Proper surgical performance of the Fixator is the responsibility of the operating Orthopedic Surgeon. The operating Orthopedic Surgeon draws up an operation plan specifying and documenting the following:
 - ✓ Fixator component(s) and their dimensions.
 - ✓ Determination of intra-operative orientation

points. The following conditions must be fulfilled prior to application:

- All required Fixator components are sterilized and readily available.
- All requisite sterile Fixators must be available and inworking order.
- Highly aseptic operating conditions are present.

Sterilization:

All Single use NON-STERILE Fixators and implants used in the surgery must be cleaned & Sterile prior to use.

Method	Temperature	Exposure time	Pressure
Steam (autoclave)	121 Deg C.	15 Minutes	103421 Pa / 0.1 MPa / 15 psi

Remove plastic packing of Fixator 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 Fixators under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to clean the Fixators.
- Soak Fixators 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 Fixators 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 Fixators for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution using a soft-bristled brush. Clean Fixators under water to prevent aerosolization of contaminants.
Note: Freshly prepared solution is a newly-made, clean solution.
- Rinse Fixators 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 Fixators.
- Perform a final rinse on Fixators using DI or PURW water.
- Dry Fixators 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

INTRA-OPERATIVE

- Prior to use, verify the integrity of the Fixator.
- Modification of the Fixator Set is not allowed.
- 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 Plates.
- We provide Torque Limiting Screw Drivers during surgery with our Fixator sets to avoid over-tightening of screw. We strictly recommend our devices to be used by trained healthcare professional who is aware with the torque and force to be applied on the devices by taking care of overtightening of screws.
- Ensure sufficient rinsing in-situ for cooling and removing of potential wear material.

Details of Symbols & Meaning of Each Symbol

	<p align="center">Date Of Manufacture</p> <p>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.</p>
	<p align="center">Catalogue Number</p> <p>Note: This symbol be accompanied by the catalogue number relevant to the device bearing the symbol.</p>
	<p align="center">Batch Code</p> <p>Note: This symbol should be accompanied by the batch code relevant to the device bearing the symbol.</p>
	<p align="center">Caution</p> <p>This symbol is to denote that there some warning or precautions associated with device, which are not otherwise found on labels</p>
<p align="center">Qty</p>	<p align="center">In Single Pack Number Of Quantity Packed</p>
<p align="center">Material</p>	<p align="center">Raw Material used for manufacturing</p>
	<p align="center">Manufacturer Company Logo</p>
	<p align="center">Manufacturer Company Name, Address & Contact</p> <p align="center">ORTHO MAX MFG. CO. PVT. LTD.</p> <p align="center">C-1-B/886/4, GIDC Industrial Estate, Makarpura, Vadodara – 390010 Gujarat. India.</p> <p align="center">Cust. Care No: +91-8980015555, E-mail : admin@orthomaxindia.net Website: www.orthomaxindia.net</p>
	<p align="center">Refer Instruction for Use (IFU)</p>



Do not use if package is damaged.