UniX Standard (Hybrid-T-Ankle) Fixator Instruction for Use

Product Definition: UniX Standard (Hybrid-T-Ankle) Fixator is a fixation device designed for the stabilization of intra-articular and peri-articular fractures, used in the treatment of specified indications and consists of various materials. The products are non-sterile and the implants included in the set are single use.

Product Model Information: There are no different models of the product. Product components are available in various sizes for universal use.

Intended Use: The UniX Standard (Hybrid-T-Ankle) Fixator is adapted to multiple configurations. It is used in periarticular and diaphyseal applications, including complex fractures, malunions, fusions, and corrective osteotomies.

Patient Population: UniX Standard (Hybrid-T-Ankle) Fixator is suitable for use in pediatric and adult patients who do not interfere with surgery.

Indications: The UniX Standard (Hybrid-T-Ankle) Fixator is intended for use in the treatment of pediatric and adult patients, including, but not limited to, leg lengthening, osteotomies, arthrodesis, fracture fixation and other bone conditions suitable for treatment using external fixation. Additional indications are: correction of deformity, revision procedures where other treatments or devices fail, bone reconstruction procedures, foot fusions and replantations, charcot reconstruction and Lisfranc dislocations, ankle distraction (arthrodiastasis)

Important Warning:

(**) The device (s) may only be prescribed and implanted by a doctor authorized to perform this type of surgery.

(**) Do not use the product except for the indications written here.

Contraindications: Active or latent infection; patients with sepsis, osteoporosis, high-weight patients (body mass index 25-50 and above), insufficient skin tissue, bone or neurovascular condition, damaged tendon, patients with high activity levels, diabetes, high bleeding from vascular injury, blood circulation problems , material sensitivity, psychologically or physiologically inadequate patients. The contraindications mentioned are common to this product group.

(**) If there is a suspicion of sensitivity in the patient, tests must be performed before implantation.

(**) The product has not been studied on nursing mothers, pregnant women and cancer patients undergoing chemotherapy. The use of the product in these patients should be implemented at the surgeon's discretion.

Warnings for Implants: Surgeon; When the implant-related application methods and surgical technique are thoroughly familiar with the implant, the implant is used safely and effectively.

(**) There should be no scratches on the surface of the implant used during surgery.

(**) The device should not be cut.

Since the device is manufactured as pre-twisted, it will reduce its bending strength during surgery.

Device; It is not designed to withstand the stress caused by weight bearing, load bearing or excessive activity.

(**) If the implant is exposed to increase load associated with delayed union, non-union, or incomplete healing, breakage or damage to the device may occur.

(**) The device must be inserted correctly during implantation.

(**) The patient should preferably be warned in writing about the use, limitations and possible adverse effects of this implant.

(**) These cautions include the possibility of the device or treatment failing which is caused by loose fixation and/or loosening, stress, excessive activity and weight bearing and load bearing and if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing, and the possibility of nerve or soft tissue damage related to either surgical trauma or presence of the implant.

For the correct application method, review the surgical technical document and / or surgical animation provided by Response Ortho on www.responseortho.com

(**) If a negative case occurs, the patient must be inform about to get in contact with the doctor. The implants may cause distortion and/or block the view of anatomic structures on radiographic images.

MRI Compatibility: Parts of the system have not been tested for safety, heating or migration in the MRI environment. In the clinical evaluation study, tests were found on how to use similar products safely using MRI equipment.

Warning for Surgical Instruments: The surgeon must be familiar with the instrument, the method of application, and the recommended surgical technique for safe effective use of any Response Ortho instruments.

In case of any negative situation about the product, please contact the manufacturer. Manufacturer information details are given below.
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Contact Information: ITOSB- Istanbul Tuzla Organized Industrial Zone, 10th Street, No. 1 Tepeören-Tuzla- Istanbul / TURKEY **Tel:** +90 (216) 314 11 04 **Fax:** +90 (216) 365 37 36 **E-mail:** info@responseortho.com web: www.responseortho.com

(**) If the instrument is subjected to excessive loads, improper use or unintended use, breakage or damage, as well as tissue damage, can occur.

(**) Additionally, instruments for the surgery must be clean after sterilization. For the correct application technique, please read surgical technique and check the surgical animation if available on www.responseortho.com web site.

(**) The patient must be cautioned, preferably in writing as to the risks associated with these types of instruments.

Precautions For Implants:

(**) An implant should not be reused.

(**) Previous stresses may have created imperfections, which can lead to a device failure. For this reason, instruments shall be inspected for wear or damage prior to usage.

(**) Implants must be protected against scratching and nicking which are stress concentrations; they can lead to failure.

(**) Bending plates multiple times may cause weaken the device and could lead to premature implant fracture and failure.

(**) Damaged implant shall never be used. The benefits from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon.

Precautions for Surgical Instruments:

(**) Surgical instruments must be cleaned and sterilized according to instrument cleaning procedure.

(**) Previous stresses may have created imperfections, which can lead to a device failure.

(**) Rod cutting should be maintained after 300 cuts.

Removing the Implant: The duration of the product in the patient is between 2 months and 6 months. The fixator can be removed with a simple outpatient procedure. An appropriate dose of paracetamol is administered to the patient before the fixator frame is removed. The trimmer clamps and nuts are loosened and the fixator is detached from the bone screws. Turning the bone screws counterclockwise will easily loosen them and remove them from the bone. Wounds are closed by placing dry sterile gauze on them.

Surgical Technique: Surgical techniques are available describing the usage of this system. Surgeon must be familiar with the procedure before using these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use. For the correct application technique, please read surgical technique and check the surgical animation if available on www.responseortho.com web site.

Advers Effects: Pain, discomfort, or abnormal sensations and nerve or soft tissue damage due to the presence of an implant or due to surgical trauma may occur. Fracture of the implant may occur due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Metal sensitivity, histological, allergic or adverse foreign body reaction resulting from implantation of a foreign material may occur.

(**) If a negative case occurs, the patient must be informed about to get in contact with the doctor.

(**) After the maintenance of the product, following the instructions may decrease the adverse effects.

Preopertaive Planning: Anatomy differs for each patient. For this reason, an experienced surgeon must select the type and size that best meets the patient's requirements for close adaptation and firm seating with adequate support according to radiographic images of fracture. In this procedure, which is called preoperative planning, surgical operation must be planned for each patient. Just only to select proper implant for the patient is not adequate to carry out the surgery. Patient position on the operation table, selection of the implant, correct incision, applying exact technique to the joint, making out the pathologic anatomy, and having enough knowledge are necessity for making preoperative plan..

Situations Affecting Intended Performance:

Situations Depend on Patient: Age, weight, height and anatomical structure of the patient, pathologic situation of the patient, bone quality, soft tissue vitality, implementation procedure interacting with other implanted devices and activity of the patient.

Situations Depend on Surgeon: Surgical technique of the surgery, postoperative treatment procedure.

Cleaning Conditions of the Implant:

(**) Implants should not be reused. Non-used and non-sterile implants that have not been used, but have become soiled, should be processed according to manual, ultrasonic and mechanical processing.

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(**) Resterilization of the implants should not be performed if the implant comes into contact with contamination unless the single use device has been reprocessed by an authorized facility who has received appropriate regulatory clearance for such.

(**) Cleaning a single use device after it comes into contact with human blood or tissue signifies reprocessing.

(**) If the surface of implant has been damaged, it should not be used and it should be discarded as a medical waste.

(**) All users should be qualified personnel with documented evidence of training and competency.

(**) Users should wear appropriate personal protective equipment.

Implants that are required re-processing and reusable surgical instruments should be carried to cleaning area to prevent drying of the blood on the implant surface. Implants should be carried inside a closed box to prevent drying of the blood on the implant surface. Instruments should be prepared for cleaning and complex parts of them like cannulated or rough surfaces should be demounted before pre-cleaning process. Organic wastes like blood, soil and tissue residual on the products should be cleansed with pressurized water for removing of the wastes. In this step, a soft brush should be used for complex part to clean cannulated or rough surfaces of the products. Products should be clean using the one of the systems ultrasonic cleaning or washer disinfector processes after the pre-cleaning process is carried out.

Ultrasonic Processing: (Equipment: Ultrasonic cleaner Disinfectant: It should include wide microbiological spectrum free of phenol and aldehyde and should include a corrosion inhibitor.) The devices which will be used in this process should be large enough for placing the implants and instruments. Prepare a solution using warm tap water and detergent (or cleaner).Follow recommendations of the detergent manufacturer during the solution preparation, pay attention to the correct exposure time, temperature, water quality, and concentration. Immerse pre-cleaned products inside the solution and start up the cleaning device. Clean implants ultrasonically 20 minutes. Rinse products 5 minutes with pressurized water after the ultrasonic cleaning to remove residual of cleaning solution. Dry the products with a compressed air hammer for 5 minutes and pay attention to not keep the product damp.

Mechanical Processing: (Equipment: Washer or disinfector): Disinfectant should be proper to automated cleaning disinfection machine. Disinfectant which has the ability to clean organic wastes (protein, blood, soil or tissue residue etc.) should be an alkaline cleaner and include corrosion inhibitor. Follow recommendations of the manufacturer company for the amount of the disinfectant. Prepare the disinfectant cleaner according to recommendations of the manufacturer company and place the product with paying attention to not contact each product with others. Start the disinfectant cleaner loop. Dry the products with a compressed air hammer if it is necessary after the disinfectant cleaning process.

Instrument Cleaning Instructions: After the surgical procedure, decontamination occur on instruments immediately. Before the cleaning procedure, do not allow contaminated instruments to dry. Blood and debris on the items should be wiped. All users should be qualified personnel with documented evidence of training and competency. Training should be including of current guidelines and standards and hospital policies. Surgical equipment should be dried to prevent the corrosion even if they are manufactured from high grade stainless steel. Before the sterilization, cleanliness of surfaces, joints, and lumens, proper function, and wear and tear of all instruments must be inspected.

(**) Do not use metal brushes or scouring pads during manual cleaning process. Use cleaning agents with low foaming surfactants in order to see instruments in the cleaning solution. Cleaning agents must be easily rinsed from instruments to prevent residue. Mineral oil or silicone lubricants should not be used on Response Ortho instruments. Neutral pH enzymatic and cleaning agents are recommended for cleaning reusable instruments. It is very important that alkaline cleaning agents are thoroughly neutralized and rinsed from instruments. Anodized aluminum must not come in contact with certain cleaning or disinfectant solutions. Avoid strong alkaline cleaners and disinfectants or solutions containing iodine, chlorine or certain metal salts.

(**) RESPONSE ORTHO TEKNOLOJİK ÜRETİM A.Ş. declares RESPONSE ORTHO marked products are not a part of medicinal instrument as stated by 1st provisions of 2001/83 EC Regulation, does not include Human Blood Derivatives and Medical Product as stated by both 2007/47 EC regulation and part 7.4 in APPENDIX-I of 93/42 EEC regulation of European Parliament and Council, does not include animal tissue, phthalate and PFOS (perfluorooctane sulfonate) as stated by Regulation council number

2006/122 EC of European Parliament and Council of 2003/32 EC.

Sterilization: Non-sterile products may be provided to market but sterilization process should be applied to them. Unless labeled clearly as sterile products, all implants and instruments must be considered non-sterile and sterilized by the hospital prior to use. Below table shows preparation of sterilization for single use and reusable instruments. Validation and maintenance of autoclaves should be determined according to 285/EN 13060, EN 17665 ANSI AAMI ST79. Response Ortho recommends steam sterilization for products at the following parameters.

(**) Sterilization of the product in a proper way is the responsibility of the hospital stuff / product user.

Parameters Steam Sterilization

Temperature 134°C (273,2 F)

Program Period 4 minute

Preparation of Sterilization: Surgical implants and instruments should be sterilized prior to use. Before the sterilization process, their containers should be check if any damage exists. Containers should be sterilized with a chemical indicator placed between double green wraps which cover the container. Before the sterilization procedure, cleaning the reusable products is important. Reusable products should be placed inside a container for sterilization process after the cleaning. Containers should not be placed one on the top of the other. Consult your equipment manufacturer's written instructions for specific sterilizer and load configuration instructions.

Sterilization Methods: Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI / AAMI ST79: 2017– comprehensive guide to steam sterilization and sterility assurance in health care facilities.

Parameters	Steam Sterilization
Temperature	134° C
Program Period	4 minute

Storage Instructions: Store in a cool dry place and keep away from direct sunlight. Inspect container if any damage exist prior to use. Storage conditions are as follows:

Temperature: 20 °C – 25 °C (± 3°C tolerance)
Humidity: %30 - %60 RH

Maintance: Response Ortho UniX Standard (Hybrid-T-Ankle) Fixator is invasive medical devices. Recommendation of doctor should be consider after the surgery. Pay attention to warning section to prevent breakage of device and performance decrease. Implants should not be in contact with other devices to prevent any damage on their surface. Inspect container if any damage exist prior to use. Patients should be informed about things to take into account by the doctor.

Shelf Life: There is no shelf life in non-sterile products. Because Response Ortho UniX Standard (Hybrid-T-Ankle) Fixator is produced non-sterile, there is no shelf life.

Product Shipment: Non-sterile products placing inside a set tray with labels are shipped. Containers are produced from SS-304 stainless steel.

(**) Sets are sterilized before the surgery. Sterile container should be opened when it arrived to operating room.

(**) Clearance of sterile materials, existence of the damage on the container and content of the set should be controlled.

Label Informations: The product label has been prepared with reference to the Medical Device Directive. An explanatory table regarding the symbols on the label is given below ***(See Symbol Explanation).***

Symbol Definition	
RESPONSE ORTHO	**Company Logo.**
eIFU indicator	**Please read Electronic Instruction for Use.**
LOT	**Lot Number.**
	Producer Information.
	Production Date.
NON STERILE	**Product is non-sterile.**
CE 2195	**Notified Body Number.**
REF	**Product Reference Number.**

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The Product is single use.

Note: Articles beginning with (**) are special warnings that the user should pay attention to.

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