INSTRUCTION FOR USE OF EPIFIX PLATING SYSTEM
For The Personal Attention Of The Operating Surgeon

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DESCRIPTION: Response EpiFix Plating System is developed for hemi-epiphysiodesis. The system controls growth of epiphysis to provide ideal bone alignment and contains plates, screws, accessories and instruments which have the aim of the fixation. The products of the system are non-sterile and implants in the set are single use. ***(**)Response EpiFix Plating System is applied invasively by the surgeon who has the technical information for the method of application in the operating room conditions.***

INTENDED USE: Response Epifix is used for correction of the lower limb deformities of pediatric patients who are between 18 moths and 17 years old and for continuous controlled growth which are provided by epiphysiodesis (growth plate).

PATIENT POPULATIONS: Response Distal Radius Plate System is convenient for pediatric usage. Various lengths of products are designed to provide the geometric conformity between plate and bone for the patients who have different anthropometry. Universal usage is aimed. General principles are applied to selection of the patient and implant. Selection of the correct implant is so important. Appropriate type and length should be defined with considering the anatomic and biomechanical factors like patient's age, level of mobility, patient's weight, bone and muscle conditions etc.

INDICATIONS: Angular deformity, valgus, varus and knee flexion contracture of pediatric patients. ***(**) Do not use apart from these indications. Important Warning: Device(s) Important Warning: Device(s) should be prescribed and implanted by doctor who is authorized only to make this type of surgery.***

CONTRAINDICATIONS: Patients whose growth plate is closed, overweight patients (patients which have the body mass indexes are between and over the 25-50), insufficient quantity or quality of bone and/or soft tissue, damaged tendons, patients who have high activity level, diabetic patients, patient who has osteoporosis, patients who have blood circulation problem, patient who has material sensitivity, psychologically and physiologically insufficient patients, elderly patients, active or latent infections. Stated contraindications are in common for this product group. ***(**) If material sensitivity is suspected, tests should be performed prior to implantation.***

IMPLANT WARNINGS: When the surgeon should be familiar with the methods of application of the implant and the surgical technique, implant is used effectively. **(**) Scratching should not be on the surface of the implant which will be used in the surgery. (**) The implant should not be cut.** Bending plates may weaken the device and could lead to failure of its load resistance because device is manufactured with pre-bending. The device is not designed to withstand the stress of weight bearing, load bearing, or excessive activity. **(**)If the implant experiences increased loads due to delayed union, nonunion, or incomplete healing, device failure or damage can occur. (**) Device should be inserted properly. (**) Patient must be cautioned in writing about usage, restrictions and potential 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 implementation technique, please read surgical technique TD.07 APPENDIX-14 Report Surgical Technique which is given by Response Ortho.
(**) Patient must be informed about to get in contact with the doctor in case of a negative effect occurs. The implants may cause distortion and/or block the view of anatomic structures on radiographic images. The components of these systems have not been tested for safety, heating, or migration in the MRI environment. Similar products have been tested and described in terms of how they may be used safely in clinical evaluation studies using MRI equipment.

SURGICAL INSTRUMENTS WARNINGS: 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. ***(**)If an 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.*** Please read surgical technique TD.07 APPENDIX-14 which is given by Response Ortho for information of accessories which are used in the surgical procedure. ***(**)The patient must be cautioned, preferably in writing as to the risks associated with these types of instruments.***

IMPLANT PRECAUTIONS: ***(**) 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 protect 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 result of the 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.

SURGICAL INSTRUMENT PRECAUTIONS: ***(**) 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.***

IMPLANT REMOVAL: Implant can be stay on patient's bone between 6 - 18 months and must be remove according to decision of doctor. Incision should be made according to the length of plate. Using soft tissue guide, soft tissue remove from the bone and the plate on the bone appears. A screw driver is used for dismantling of the tightened screws on the plate. Screw driver is rotated counterclockwise and screws are loosened and removed from the plate. Then, plate is removed from the bone and incision is sutured.

SURGICAL TECHNIQUES: Surgical techniques are available describing the usage of this system. Surgeon must be familiar with the procedure before use of 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. Please look TD.07 APPENDIX-14 Surgical Technique which is given by Response Ortho.

ADVERSE EFFECTS: Pain, discomfort, or abnormal sensations and nerve or soft tissue damage may occur due to the presence of an implant or due to surgical trauma. 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 inform about to get in contact with the doctor. (**)After the maintenance of the product, following the instructions may decrease the adverse effects.***

PREOPERATIVE PLANNING: Anatomical structures are different for each patient. For this reason, an experienced surgeon must select the type and size of the plate 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 surgeon, postoperative treatment procedure.

IMPLANT CLEANING: ***(**) 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. ***(**) 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 occurs 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 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 marked EpiFix Plating System is not a part of medicinal instrument as stated by 1st

Please contact the manufacturer if you have any negative situation. Manufacturer information is given in detail below.
MANUFACTURER: Response Ortho Teknolojik Üretim A.Ş.
CONTACT: ITOSB, 10. Cadde, No:1 Tepeoren-Tuzla- Istanbul / TURKEY
Phone:+90 (216) 314 11 04 Fax: +90 (216) 365 37 36 e-mail: info@responseortho.com web: www.responseortho.com

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 EN 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
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 ST79:2010 – comprehensive guide to steam sterilization and sterility assurance in health care facilities.

STORAGE INSTRUCTIONS: Store in a cool dry place and keep away from direct sunlight. Inspect container if any damage exist prior to use.

MAINTENANCE: Response EpiFix Plating System includes implants and is operated invasively. 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: Shelf-life of Non-sterile Products: Non-sterile products do not have a shelf life. Response EpiFix Plating System is manufactured as non-sterile, so that they do not have shelf life.

SHIPMENT OF THE PRODUCT: 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 INFORMATION: Product labels are prepared according Medical Devices Directive. Symbols on the labels are explained below table. (Please Look Explanations of Symbols)

SYMBOL LEGEND	
RESPONSE ORTHO	Company logo
eIFU indicator	Consult an electronic instructions for use
LOT	Batch code
	Manufacturer
	Date of manufacture
NON STERILE	Non-sterile product
CE 2195	Notified body number
REF	Catalogue number
	Do not re-use

NOTE: Bolt and italic lines starting with"(**)" are special warnings for the user.