INSTRUCTION FOR USE OF K-WİRES AND BONE SCREWS
For The Personal Attention Of The Operating Surgeon

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DESCRIPTION: Response K-wires are designed for use with external fixators, bone screws are used with plates, nails and external fixators. All k-wires and bone screws are single used. Response K-wires and bone screws are applied invasively in a sterile operating room condition by the surgeons who are familiar with the instrument, the method of application, and the recommended surgical technique..

INTENDED USE: Response K-wires are used with external fixators to provide bone detection on the patient who is applied external fixator. Bone screws are used with plates, nails and external fixators to ensure fractured bone fixation.

PATIENT POPULATIONS: Response K-wires and bone screws are convenient for patient at all ages except ones who are incapable of operations. Various radius of products are designed to provide the geometric conformity between K-wires / bone screws 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: Pseudoarthrosis, deformity, malunion, nonunion and tumor treatments, traumas, osteotomies and distraction applications. ***(**)Do not use apart from these indications. Important Warning: Device(s) should be prescribed and implanted by doctor who is authorized only to make this type of surgery.***

CONTRAINDICATIONS: Active or latent infections, patients who has vessel or nerve tissue damage which cause to prevent the surgery, previously implant applied patients or insufficient bone quantity of patients, material sensitivity, overweight patients (patients which have the body mass indexes are between and over the 25-50), insufficient soft tissue, psychologically and physiologically insufficient patients, any mentally or neuromuscular damaged patients, diabetic patients, patient who has osteoporosis, patients who have blood circulation problem, bone or neuromuslar conditions, damaged tendons, patients who have high activity level, elderly patients and existence of internal diseases. Stated contraindications are in common for this product group. ***(**)If material sensitivity is suspected, tests should be performed prior to implantation.***

RESPONSE K-WİRES AND BONE SCREW WARNINGS: For safe effective use of the implant, the surgeon must be thoroughly familiar with the implant, the methods of application and surgical technique for the device. ***(**)Scratching should not be on the surface of the implant which will be used in the surgery.*** The device is not designed to withstand the stress. ***(**)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 which is given by Response Ortho. ***(**)Patient must be inform 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.

IMPLANT PRECAUTIONS: ***(**)An implant should not be reused certainly. (**)Previous stresses may have created imperfections, which can lead to a device failure. (**) Implants must be protect against scratching and nicking which are stress concentrations; they can lead to 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. Implants are colored due to their different radius. Correct implant raidus must be used.

IMPLANT REMOVAL: Implant can be stay on patient's bone between 2-6 months and must be remove according to doctor decision. Incision should be made according to the region applied in the patient. Using soft tissue guide, soft tissue remove from the bone and the part of the wire placed in the edge of the bone is removed using with a holder. Opened 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 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.***

PREOPERATIVE PLANNING: Surgeon must plan surgery for each patient before the operation according to radiographic images of fracture in this process which is called preoperative planning. 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 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. Implants should be prepared for 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. 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.

(**)RESPONSE ORTHO TEKNOLOJİK ÜRETİM A.Ş. declares RESPONSE marked K-Wires and Bone Screws 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 must be considered non-sterile and sterilized by the hospital prior to use. Below table shows preparation of sterilization for single use .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 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 K- Wires and Bone Screws include 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 K- Wires and Bone Screws are 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 to Medical Devices Directive. Symbols on the labels are explained below table. (Please Look Explanations of Symbols)

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

SYMBOL LEGEND	
	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.