Sterile K-Wires and Bone Screws Instruction for Use

Product Definition: K-Wires and Bone Screws are designed to be used with external fixators, and bone screws are designed for use with plates, nails and external fixators. The products are gamma sterile and the implants included in the kit are single use.

Product Model Information: Models of this product are as follows:

- K-Wires
- Bone Screws
  - Half Pins
  - Transfix Screw
  - Cortical Locking Bone Screws
  - Cortical Non-Locking Bone Screws
  - Cancellous Locking Bone Screws
  - Cancellous Non-Locking Bone Screws
  - Cannulated Screws
  - Headless / Compression Screws
  - Snapp Off Screws
  - Staple
  - Support Screw
- Nail Screws
  - Nail Head Screws
  - Nail Proximal Locking Screw
  - Lag Screws
- Washers

Product models for universal use are available in various sizes.

Intended Use: K-Wires and Bone Screws are used to provide bone fixation in patients using an external fixator. Bone screws are used with plates, nails and external fixators to ensure broken bone fixation.

Patient Population: K-Wires and Bone Screws are suitable for use in all patients who will not interfere with surgery. Various sizes of our products have been designed to provide a geometrical harmony between k-wires / bone screws and bone in patients with different anthropometry. Universal use is intended. General principles are applied in patient and implant selection. Choosing the right implant is very important. The patient's age, movement level, weight, bone and muscle conditions, whether he has had an operation before, etc. Appropriate type and size should be determined by considering anatomical and biomechanical factors.

Indications: K-Wires and Bone Screws are indicated for the following treatments:

Pseudoarthrosis, deformity, malunion, nonunion and tumor treatments, traumas, osteotomies and lengthening applications.

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.

In case of any negative situation about the product, please contact the manufacturer. Manufacturer information details are given below.

Manufacturer: Response Ortho Teknolojik Üretim A.Ş.
Contact Information: Tepeören ITOSB Eski Ankara Asfaltı Maret Arkası 10.Cad. No:1 Tuzla **Tel:** +90 (216) 314 11 04 **Fax:** +90 (216) 365 37 36 **E-mail:** info@responseortho.com web: www.responseortho.com

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.

(**) 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 implant's stay in the patient is 2-6 months and should be removed according to the doctor's decision. In the patient, an incision is made on the applied area. With the help of the soft tissue guide, the tissue is taken aside and the wire, the part of which is at the edge of the bone, is reached to remove the implant applied from within the bone. With the help of the holder, the piece of wire outside the bone is pulled out. The opened incision is closed by stitching.

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.

Adverse 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.

Preoperative 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:

In case of any negative situation about the product, please contact the manufacturer. Manufacturer information details are given below.

Manufacturer: Response Ortho Teknolojik Üretim A.Ş.

Contact Information: Tepeören ITOSB Eski Ankara Asfaltı Maret Arkası 10.Cad. No:1 Tuzla **Tel:** +90 (216) 314 11 04 **Fax:** +90 (216) 365 37 36 **E-mail:** info@responseortho.com web: www.responseortho.com

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.

(**) 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.

In case of any negative situation about the product, please contact the manufacturer. Manufacturer information details are given below.

Manufacturer: Response Ortho Teknolojik Üretim A.Ş.

Contact Information: Tepeören ITOSB Eski Ankara Asfaltı Maret Arkası 10.Cad. No:1 Tuzla **Tel:** +90 (216) 314 11 04 **Fax:** +90 (216) 365 37 36 **E-mail:** info@responseortho.com web: www.responseortho.com

Sterile K-Wires and Bone Screws Instruction for Use

(**) 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: The sterile product was exposed to a minimum 25.0-kGy gamma irradiation. Response Ortho Teknolojik Üretim A.Ş does not recommend re-sterilizing the sterile packaged product. If the sterile packaging is damaged, this should be reported to Response Ortho Teknolojik Üretim A.Ş., the product should not be used and returned.

For the sterilization preparation of reusable devices to be used with the product, see the "Sterilization Preparation" section of the non-sterile product IFUs. Autoclaves must be maintained and verified according to EN 285 / EN 13060, EN 17665 ANSI AAMI ST79.

Sterilization Methods: Current AORN “Recommended Applications for Sterilization in Perioperative Application Locations” and ANSI / AAMI ST79: 2017-Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities.

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

Temperature: 20 °C – 25 °C (± 3°C tolerance)

Humidity: %30 - %60 RH

Maintenance: Response Ortho K-Wires and Bone Screws are surgical invasive devices. Accordingly, the doctor's warnings regarding the maintenance of the device after surgery should be taken into consideration. The warnings given in the warnings section should be taken into consideration in order not to break the device or decrease its performance. Care should be taken to protect implant devices, especially to prevent scratches that may occur as a result of contact with other instruments used. Before opening sterile packages, it should be checked for damage. Issues to be considered about the patient must be reported to the patient by the doctor.

Shelf Life: For the shelf life of sterile products, attention should be paid to the date printed on the box.

Product Shipment: The products are placed in the kit and shipped sterile with the product label.

Sterile packages are produced from PET-G raw material.

(**) Since the packages are shipped sterile, preoperative sterilization is not required.

(**) Sterile packages should be opened when they enter the operating room.

(**) Each package should be checked for cleanliness, damage to the package and content.

Label Information: 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.**
REF	**Product Reference Number.**
	Producer Information.
	Production Date.
STERILE R	**Product is gamma sterile.**
CE 2764	**Notified Body Number.**
	The Product is single use.
	Product expiration date.
	Keep the product in a dry environment.
	It cannot be resterilized.
	Do not use if the packaging is open and / or damaged.
25°C 20°C	**Storage temperature condition.**

In case of any negative situation about the product, please contact the manufacturer. Manufacturer information details are given below.

Manufacturer: Response Ortho Teknolojik Üretim A.Ş.

Contact Information: Tepeören ITOSB Eski Ankara Asfaltı Maret Arkası 10.Cad. No:1 Tuzla **Tel:** +90 (216) 314 11 04 **Fax:** +90 (216) 365 37 36 **E-mail:** info@responseortho.com web: www.responseortho.com

Keep away from sunlight.

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

In case of any negative situation about the product, please contact the manufacturer. Manufacturer information details are given below.

Manufacturer: Response Ortho Teknolojik Üretim A.Ş.

Contact Information: Tepeören ITOSB Eski Ankara Asfaltı Maret Arkası 10.Cad. No:1 Tuzla **Tel:** +90 (216) 314 11 04 **Fax:** +90 (216) 365 37 36 **E-mail:** info@responseortho.com web: www.responseortho.com