

DESCRIPTION: Response Ortho Surgical Instruments are designed to use for implant systems and surgical techniques.

SURGICAL INSTRUMENT INFORMATION FOR USE: Surgical Instruments together with implant sets are consigned to user.

- Surgical Instruments which is provided with implant sets are consigned as nonsterile. All implants and instruments are regarded as non sterile if they are not labeled as sterile clearly.
- Surgical instruments can be reused if user fulfills the cleaning instructions that are recommended by Response Ortho.
- Surgical instruments have a limited lifespan. Prior to and after each use, reusable instruments must be inspected where applicable for sharpness, wear, damage, proper cleaning, corrosion and integrity of the connecting mechanisms. Particular care should be paid to drivers, drill bits and instruments used for cutting or implant insertion.

SURGICAL INSTRUMENT 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 instrument. Before using the surgical instruments, asking for more information from other experienced surgeons is the responsibility of the surgeons will operate. (**)Instrument breakage or damage, as well as tissue damage, can occur when an instrument is subjected to excessive loads, excessive speeds, dense bone, improper use or unintended use. (**)Additionally, instrument must be clean for surgical usage after the sterilization. Please read Surgical Technique document which is submitted by Response Ortho for using correct instrument during the surgery. (**)The patient must be cautioned, preferably in writing as to the risks associated with these types of instruments.*

SURGICAL INSTRUMENT PRECAUTIONS: Instrument cleaning instructions which are recommended by Response Ortho must be applied to surgical instruments before reutilizing them and product should be sterilized. Protect instruments against scratching and nicking, such stress concentrations can lead to failure.

INSTRUMENT CLEANING INSTRUCTIONS: Surgical instruments which are provided by Response Ortho must be clean according to below instruction before reutilizing. After the surgical procedure, surgical instruments must be carried to the cleaning area inside a closed box to prevent drying the blood on their surfaces. Devices should be prepared and their complex part should be demounted. After than, pre-cleaning should be applied. Organic wastes like blood, dirt and tissue residual on the surface of products should be clean under the pressurized water manually. 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 that are ultrasonic cleaning or disinfection processes after the pre-cleaning process are 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 surgical 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 surgical instruments 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 disinfectant) 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.

Warnings & Precautions: *Decontamination of instruments or accessories should occur immediately after completion of the surgery. Do not allow contaminated instruments to dry prior to reprocessing. Excess blood or debris should be wiped off to prevent it from drying onto the surface. All users should be qualified personnel with documented evidence of training and competency. Training should be inclusive of current applicable guidelines and standards and hospital policies. Surgical instruments must be dried thoroughly to prevent rust formation, even if manufactured from high grade stainless steel. All instruments must be inspected for cleanliness of surfaces, joints, and lumens, proper function, and wear and tear prior to sterilization.*

*(**) 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.*

STERILIZATION: Non-sterile products may be provided to market but sterilization process should be applied to them. Unless labeled clearly as sterile products, all instruments must be considered non-sterile and sterilized by the hospital prior to use. Below table shows preparation of sterilization for surgical 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 staff / product user.

Parameters	Steam Sterilization
Temperature	134°C
Program Period	4 minute

Preparation of Sterilization: Surgical 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.









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 Ortho Surgical Instruments have a limited lifespan. For this reason, prior to and after each use, reusable instruments must be inspected where applicable for sharpness, wear, damage, proper cleaning, corrosion and integrity of the connecting mechanisms. Particular care should be paid to drivers, drill bits and instruments used for cutting or implant insertion. Please take in your consideration the warnings which are written in instruction for use.

SHELF-LIFE: Shelf-life of Non-sterile Products: Non-sterile products do not have a shelf life. Response Surgical Instruments 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. (**)Sets are exposed to sterilization process before the operation. 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 for each consignment.

LABEL INFORMATION: Product labels are prepared according to Medical Devices Directive. Symbols on the labels are explained below table. (Please Look Explanations of Symbols)

SYMBOL LEGEND	
	Company logo
	Consult an electronic instructions for use
	Batch code
	Manufacturer
	Date of manufacture
	Non-sterile product
	Product complies with requirements of Medical Devices Directive for European Union Class 1 medical devices
	Catalogue number