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Instructions For Use (IFU)

Non-Sterile, Reusable;
Electrosurgical Bipolar Forceps

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anthony products, inc.

	Name	Signature	Date
Approved by:	Abdul Rehman Chief Executive		01 July 2016

Group	Division	User	Document Control Stamp
RB	Electrosurgical	QA	

RB MEDIKAL INSTRUMENTS
INSTRUCTIONS FOR USE AND CARE
REUSABLE BIPOLAR FORCEPS

This product is reusable and is supplied **NON-STERILE**. Process the forceps through cleaning and sterilization prior to initial use, following guidance as outlined in this IFU. For questions or additional information on our complete line of forceps, please contact RB MEDIKAL INSTRUMENTS at +92 52 3552898 or on the web at www.rbmedikal.com.

INDICATIONS: These reusable forceps are electrosurgical devices designed to be used in soft tissue surgical procedures.
WARNING: Any use of this forceps for tasks other than for which it is indicated will usually result in a damaged or broken forceps.
CAUTION*: Federal (USA) law restricts this device to sale by or on the order of a physician.*
EXTENDING FORCEPS LIFE RB MEDIKAL has validated these forceps for twenty-five uses. However, the number of uses obtained from the forceps depends upon the degree of care taken in processing and handling, and the surgical procedures and techniques in which the forceps is used. To achieve maximum life, RB MEDIKAL recommends the following:

- Not allowing gross organic contaminates to dry on the forceps (e.g., blood, mucus, and tissue), by initiating forceps decontamination immediately after completion of the surgical procedure.
- Do not allow forceps tips to touch each other while ESU is active or activated.
- Completely drying forceps before storage.
- Protecting forceps from inadvertent damage while in storage, by wrapping them and avoiding extremes in temperature and humidity.

NOTE: Spotting or discoloration may result from inadequate cleaning prior to sterilization or may be due to mineral deposits in water used to autoclave.
INSPECTION OF FORCEPS RB MEDIKAL recommends establishing a procedural review, by which the forceps are inspected frequently (before and after each use) for damage such as:

- Tip misalignment.
- Tip damage e.g., burrs, bending, or discoloration.
- For insulated instruments: cracks, nicks, lacerations, or abrasions in insulation.
- Cracks or nicks in the base of the instrument, where the tines are seated.

RB MEDIKAL recommends establishing a procedural review (before and after each use) by which the forceps showing such damage or wear are either sent for refurbishing, discarded and/or replaced.
CAUTION*: Using forceps which are damaged or worn can be hazardous to both the patient and operating room personnel.*
REPROCESSING AND STERILIZATION (i.e., cleaning & sterilization) Institutional device sterilization and reprocessing should occur in facilities that are adequately designed, equipped, monitored, and staffed by trained personnel. Sterilize and clean per your institution's validated procedures and cycle parameters. The following parameters for cleaning and the most commonly utilized methods of sterilization are recommended as guidelines for validation.
NOTE: Reprocessing this device dictates that it undergo a thorough cleaning prior to sterilization.
WARNING: Clean and sterilize after each use.
MANUAL CLEANING

- Rinse forceps thoroughly with sterile purified water to remove any accululated debries.
- Hand wash the surface of the forceps using a soft bristled cleaning brush, and enzyme cleaner e.g., Tergazyme™ solution (Alconox, Inc.) or equivalent, to remove visible residual debris. For irrigating forceps, also flush irrigating lumen with approximately 10 ml of enzyme detergent.
- ***CAUTION****: Avoid use of abrasive cleaners or solvents.*
- After hand washing, the surface is to be thoroughly flushed with sterile, purified water until no visible detergent residual remains.
- For irrigating forceps, also flush irrigating lumen thoroughly with sterile purified water until no visible detergent residual remains.
- Once the forceps are free of cleaning solution and debris, thoroughly dry using a sterile wipe.

AUTOMATED PRE-CLEANING INSTRUCTIONS Rinse the instruments under warm running tap water until visibly clean. Use a soft bristle brush (plastic brush) as needed for hard to remove soil. Hard to reach areas such as, internal spaces should be flushed with a water pistol/syringe. Irrigating forceps are provided with a stylet to clean the lumen during rinsing.
CLEANING AND DISINFECTION Place the forceps in a bath with a tested cleansing and disinfectant agent such as Renu-Klenz™ (Steris) (1/4 oz/gal) prepared according manufacturer's recommendations using lukewarm tap water. The forceps must be completely covered with the solution. **NOTE**: The application times, temperatures, and concentration stated by the manufacturer of the cleansing / disinfectant agent must always be observed. The lumen of irrigating forceps must then be flushed with the prepared detergent. The forceps (particularly irrigating forceps) are then immersed in the detergent solution and allowed to sonicate for ten minutes. Repeat the cleansing process if visible contamination is still present on the instrument. Fresh solutions must be prepared daily. In case of severe soiling, the solution must be changed sooner. A high contamination load in the ultrasonic bath impairs the cleansing action and promotes the risk of corrosion. The cleansing solution must be renewed regularly according to the conditions of use. The criterion is visibly apparent soiling. In any case, a frequent change of bath is necessary, at least once a day. National guidelines must be observed.
AUTOMATED MACHINE-CLEANING INSTRUCTIONS The forceps are then to be transferred via a suitable container (e.g., wire mesh basket) into the automated washer. The following cycle is recommended with these parameters programmed; set to high.

Phase	Recirculation Time (minutes)	Water Temperature	Detergent Type and Concentration
Pre-Wash 1	02:00	Cold Tap Water	N/A
Enzyme Wash	02:00	Hot Tap Water	KlenzymeTM, 1 oz/gallon
Wash 1	02:00	65oC (set point)	Renu-KlenzTM, 1 oz/gallon
Rinse 1	01:00	Hot Tap Water	N/A
Drying	07:00	90oC	N/A

The device(s) should then be dried using a clean, soft cloth and visually examined using the naked eye under normal lighting condition to determine that all adherent visible soil (e.g., blood, protein substances and other debris) had been removed from all surfaces, lumens, crevices and serrations. Klenzyme™ and Renu-Klenz™ are trademarks of Steris.

STERILIZATION

NOTE: Remove stylet if supplied

- STEAM / GRAVITY DISPLACEMENT: **DOUBLE WRAP** forceps in muslin i.e., CSR blue hospital wrap, and place (single layer) in a production type steam sterilization vessel. Process at 132°C (270°F) for 30 minute cycle.
- STEAM / PRE-VACUUM: **DOUBLE WRAP** forceps in muslin i.e., CSR blue hospital wrap, and place (single layer in a production type, steam sterilization vessel. Process at 132°C (270°F) using pre-vacuum conditions for a 4 minutes cycle
- CHEMICAL STERILIZATION: Totally immerse the forceps in CIDEX® activated dialdehyde solution, (Johnson & Johnson Medical, Inc.), or equivalent. Expose the forceps to the CIDEX® for 10 hours at 25°C (77°F). Following chemical exposure, rinse and flush the forceps with copious amounts of sterile water for a minimum of one minute three separate times.

- STERRAD®100S: **DOUBLE WRAP** forceps with Spunguard® Heavy Duty Sterilization Wrap (Kimberly-Clark), or equivalent. Process a total exposure time of 50 minutes diffusion and 15 minutes plasma.

SETUP AND USE Attach the sterile forceps to the sterile cord ensuring that the forceps pins are fully seated in the cord's receptacles. This condition ensures that the connection is splash proof.

CAUTION: *The cord to the surgical electrodes should be positioned in such a way that contact with the PATIENT or other leads is avoided. Temporarily unused ACTIVE ELECTRODES should be stored isolated from the patient.* For irrigating forceps, RB MEDIKAL recommends gravity fed irrigation with appropriate solution. A stylet is provided for clearance of the irrigating lumen, as needed.

CAUTION: *Because of the variability of output voltages and modes from generator to generator,* ***DO NOT USE*** *this forceps with generator setting having a bipolar output voltage exceeding 1200Vp-p. . Refer to the appropriate electrosurgical generator manual for indications and instructions on voltage output characteristics to ensure that all safety precautions are followed. If no RF output is delivered to the accessory handpiece when the generator's activating switch is pressed, check the cord connection with the device and with the generator. If proper function is still not achieved and the accessory handpiece and generator function are confirmed as sound, replace the cord and refer the questionable cord to qualified personnel for further evaluation.*

WARNING: Connect Bipolar accessories to the Bipolar receptacle only, and Monopolar accessories to the Monopolar receptacle. Improper connection of accessories may result in inadvertent accessory activation or other potentially hazardous conditions. Power setting guidelines may vary due to differences in surgical techniques, patients, electrodes and surgical set-up. Start at the lowest power setting and increase as necessary to achieve the desired clinical effect.

PROPER DISPOSAL of forceps and sharps possibly contaminated with blood, tissue, or other potentially infectious material present a biological risk and must be discarded in a closable, leak-proof, puncture-resistant receptacle, that is adequately labeled (e.g., color coding or symbology) for easy identification as biohazard waste.

RETURNS Contact your RB MEDIKAL distributor or RB MEDIKAL directly in the event a forceps has to be returned for evaluation. Call RB MEDIKAL Customer Service at +92 52 3552898 for a Return Goods Authorization (RGA). When returning forceps follow these instructions:

- **CLEAN AND STERILIZE**, prior to shipping. RB MEDIKAL shall not accept forceps it deems contaminated, and a health hazard to its employees.
- Ship forceps in a sturdy shipping box, with sufficient soft packaging materials to protect them.
- Secure box with heavy tape. Clearly identify the box as return with the Lot Number / Purchase Order Number on the outside to expedite the process
- Ship to:
  Anthony Products, Inc.
  7740 Records Street
  Indianapolis, IN 46226
  800-428-1610
  www.anthonyproducts.com

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REF Catalogue Number
LOT Lot Number
Fragile, Handle with Care
See Instruction For Use
Product is supplied Non-Sterile
Keep dry
Keep away from sunlight
CE 0120 Product Complies with requirements of directive 93/42/EEC for medical devices and harmonized standards BS EN AAMI ANSI IEC 60601-1 & BS EN AAMI ANSI IEC 60601-2-2

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