STINGRAY SURGICAL PRODUCTS

Instructions for Use - English

ELECTROSURGICAL BIPOLAR COAGULATING FORCEPS

Glossary of Symbols

LOT	LOT number
	Manufacturer
	Date of manufacture
	Caution, general warning symbol Caution, see IFU for precautions
	Refer to instructions for use (IFU)
NON STERILE	Non-sterile
	Keep away from rain
REF	Reference number
QTY	Quantity in package
	Do not use if package is damaged
Rx only	Caution: Federal law in the USA restricts this device to sale by or on the order of a physician or hospital.

STINGRAY SURGICAL PRODUCTS BIPOLAR COAGULATING FORCEPS ARE NOT MADE WITH NATURAL RUBBER LATEX.

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SPECIAL INSTRUCTIONS & CAUTIONS

INDICATIONS FOR USE

Stingray Surgical Products, bipolar coagulating forceps are designed to grasp, manipulate and coagulate selected tissue for use in general surgical procedures. They are connected through a suitable bipolar cable output of an electrosurgical generator. Bipolar forceps must only be used with bipolar coagulation current. Coagulation is achieved using electro- surgical energy generated by the electrosurgical generator unit and activated by a foot switch. The Stingray bipolar forceps have not been shown to be effective for tubal sterilization procedures and should not be used for these procedures.

COMPATIBILITY

All Stingray Surgical Products bipolar cords are compatible with all generators with 4mm outlets.

Stingray Surgical Products Bipolar are compatible with U.S. 2-pin round plugs.

⚠ CAUTIONS

•Device is provided non-sterile and must be cleaned and sterilized prior to use according to the directions outlined below.

•Because there is variability of output voltages in generators, do not use the bipolar forceps with bipolar generator settings exceeding 1200 Vpp.

•Non-insulated bipolar forceps should be used with extra caution, and is not recommended for surgical sites where the patient may come into contact with the tines or handles of the bipolar forceps.

•Always use the lowest power setting available to achieve the desired surgical effect.

•The use of bipolar forceps for tasks other than those for which they are indicated will usually result in damaged or broken instruments. Surgeons and surgical staff involved in the use of this product should be fully trained in the use of electro-surgical devices prior to use. Please read these instructions prior to use.

Product Life

The life cycle of the bipolar forceps depends on the use and care of the product. Please see the "TESTING/ PREPARATION" which describes specific indicators which allow the determination of endpoint of the product life. Bipolar forceps have been validated to provide a minimum of 20 normal uses.

Disposal

Adhere to national regulation when disposing of or recycling the product, it's components and it's packaging.

⚠ ELECTROSURGERY PRECAUTIONS

Refer to your electrosurgical system operator's manual for proper use and set-up. Ensure that all manufacturers' precautions have been observed. The inspection, handling and use of electro-surgical devices are the responsibility of the user.

•Do not perform electrosurgery in the presence of flammable anesthetics or other flammable gases, near flammable fluids or objects, or in the presence of oxidizing agents, as fire could result.

•When using instruments in electrosurgery, keep the voltage/power as low as possible to achieve the desired effect. The user should only activate the device when it is in contact with the target tissue or is in a position to deliver energy to target tissue by fulguration.

•Place active electrodes in a non-conductive dedicated instrument holder or in a clean, dry, non-conductive area away from the patient when not in use: Inadvertent contact with the patient may result in burns. Contact with drapes may cause a fire.

USE INSTRUCTIONS

PREPARATION AND USE

•Attach a bipolar cord to the connector end of the forceps until the cord receptacle sleeve connects securely against the connector cup on the forceps. *When using irrigation forceps connect tubing to back end of forceps, use Luer adapter if necessary.

•Connect end of cord to bipolar coagulation unit. *When using irrigation forceps connect tubing to generator and prime it according to generators manual.

•Connect accessories to electro-surgical generators only while the system is "off". Failure to observe this precaution or handling of these connections while the system is activated may result in injury or electrical shock to the patient or operating room personnel.

PRE-CLEANING

The procedures outlined below should be followed to ensure safe handling of biologically contaminated instruments.

1.Keep forceps moist and do not allow blood and/or body fluids to dry on the instruments. The decontamination process should begin immediately after completion of the surgical procedure.

2.Using a steady stream of lukewarm/cool water, rinse each forceps thoroughly to remove gross debris.

CLEANING/REPROCESSING INSTRUCTIONS

*Special instructions for all instruments with lumen and irrigation tubing are labeled with an asterisk(*).

CLEANING

Deviations from the suggested cleaning method may result in damage to the instruments. Should you choose to try alternate cleaning procedures, Stingray Surgical Products is not responsible for any adverse consequences that may occur.

1.Hand wash using a low-sudsing, neutral pH (pH 7-9), protein dissolving detergent. Follow manufacturers' directions regarding concentration, temperature, and contact time.

2.Totally immerse instruments during cleaning to prevent aerosolization. Gently scrub the tips of the forceps with a soft non-metallic brush. This practice should loosen any bulk solids residuals at the tips, particularly between serrated tips. Next, lightly brush the remainder of the forceps body, including connector pins.

3.*Flush lumen (irrigation tube) channels with enzyme cleaner using a syringe or by other standard flushing methods.

4.*Flush lumen (irrigation tube) channels with deionized (DI) water, use stylet to remove clogs if necessary.

5.*Visually inspect, examine that the lumen tube is free and clear of detergent, debris and soil by using a syringe with (DI) water.

6.*Using compressed air, pump fluid through the lumen port to ensure the lumen is thoroughly dry.

7.Repeat cleaning if gross debris or dirt is observed. If not removable, do not use unclean instruments.

Note: Do not soak forceps in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed two hours soaking in ANY solution. Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents. Use of anything other than high quality brushes designed for instrument cleaning may result in damage to the instrument. Tarnishing of non-stick tips is normal; however, this may be removed with polishing cloth catalog# S04-990. Rub tips gently with polishing cloth until tarnish is removed.

RINSING / DRYING

1.Thoroughly rinse forceps with deionized (DI) water to remove all traces of disinfecting solution.

2.Instruments must be thoroughly dried to remove residual moisture before they are stored.

3.Use a soft, absorbent towel/cloth to dry external surfaces.

4.*Using medical compressed air, pump fluid through the lumen (irrigation tube) port to ensure the lumen (irrigation tube) is thoroughly dry.

Note: Water droplets on the instrument provide favorable conditions for microbial growth and can cause rusting or spotting on device surfaces.

STERILIZATION INSTRUCTIONS

TESTING / PREPARATION

•Instruments should be inspected and prepared for sterilization following the disinfection process.

•Visually inspect bipolar forceps. Check for nicks, misalignment, burrs or bent tips. Examine insulated bipolar forceps for integrity; observe for cuts, gouges or any exposed metal.

•Mechanically test the working parts to verify that the instrument functions correctly.

•Wrap the pair of forceps separately or place in a container to prevent the forceps from contacting other instruments.

WARNING: Do not use damaged instruments. Use of damaged instruments may increase the risk of tissue trauma, infection and length of operative procedures.

STERILIZATION

1.Double wrap forceps in standard central supply wrap.

2.Steam sterilize using the following cycle parameters.

Note: Stingray Surgical Products does not recommend the bipolar forceps to be sterilized by Flash or Chemical Sterilization. *The stylet for irrigation forceps should not be placed in the forceps but can be autoclaved separately.

The recommended sterilization parameters are as follows:

Minimum Exposure Time:

Sterilization Method	Temp.	Wrapped
PRE-VACUUM	132°C / 270°F	4 minutes

Dry cycle 25 minutes. Do not handle forceps until they are thoroughly cooled.

WARNING

If this device is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CDJ), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross contamination.

HANDLING & STORAGE

HANDLING

•Stingray Surgical Products bipolar forceps must be completely dry before storing and must be handled with care to prevent damage. Take precautions to prevent tip breakage.

•As forceps are removed from the sterilization cart, they should be visually inspected. Any items with torn or compressed packaging or with packaging that appears to be wet should not be used, nor should any items dropped on the floor.

STORAGE

•Instruments should be stored in areas, which provide protection from extremes of temperature and humidity. Forceps should be stored dry under a dust cover in an area with low traffic.

WARRANTY & REPAIR

WARRANTY

Stingray Surgical Products bipolar coagulating Forceps are guaranteed to be free of functional defects in workmanship and materials when used normally for their intended surgical purpose and life.

•Care must be taken in the use and reprocessing of this product.

•Any branded Stingray Surgical Products instrument, delivered from Stingray Surgical Products, proving to be defective will be replaced or repaired, at our discretion, at no charge.

•Repair of the product may be necessary after repeated use, or if damage occurs in handling or reprocessing.

•Use of alternative cleaning procedures or sterilization methods will void the warranty.

REPAIR

If the instrument requires repair, return the instrument in the Instrument sturdy box with adequate foam, bubble wrap or other packaging material to protect the instrument.

Repair of the instruments by other parties other than Stingray Surgical Products will void the warranty.

Send instruments to:

Stingray Surgical Products, 156 NW 16th Street, Boca Raton, Florida 33432

Instruments returned to Stingray Surgical Products for repair must have a statement, which testifies that each instrument has been thoroughly cleaned and sterilized. Failure to supply evidence of cleaning and disinfections will result in a cleaning charge and delayed processing of your Instrument repair.

CONTACT US

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