



Instructions for Use - English

INSULATED NON-CONDUCTIVE INSTRUMENTS

Glossary of Symbols

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

STINGRAY SURGICAL PRODUCTS INSULATED NON-CONDUCTIVE INSTRUMENTS ARE NOT MADE WITH NATURAL RUBBER LATEX.



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SPECIAL INSTRUCTIONS & CAUTIONS

INDICATIONS FOR USE

Stingray Surgical Products, insulated non-conductive instruments designed to be re-useable surgical instruments with non-conductive properties.



CAUTIONS

- Device is provided non-sterile and must be cleaned and sterilized prior to use according to the directions outlined below.
- Inspect instrument insulation frequently before and after each use for cracks, nicks, cuts, dents, and depressions. Such defects may decrease the insulation effectiveness and lead to electric burn or shock when in contact with charged electrode.
- Avoid contact with sharp objects.
- Verify that no metal is visible underneath the insulation coating.

Product Life

The life cycle of the insulated non-conductive instruments 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. Insulated non-conductive instruments 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.



PRE-CLEANING

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

- 1.Keep instruments 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 instrument thoroughly to remove gross debris.

CLEANING/REPROCESSING INSTRUCTIONS

Special instructions for all instruments with irrigation/suction 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 instruments 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 instrument body. A round brush may be used to remove debris in channel or tube.

- 3.*Flush tube and/or channels with enzyme cleaner using a syringe or by other standard flushing methods.

- 4.*Flush tube and/or channels with deionized (DI) water.

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

- 6.*Using compressed air, pump fluid through the tube port to ensure the tubing 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 instrument 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 or abrasive detergents. Use of anything other than high quality brushes designed for instrument cleaning may result in damage to the instrument.

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 tube and/or channel to ensure the instrument 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 insulated non-conductive instruments. Check for nicks, misalignment, burrs or bent tips. Examine insulated non-conductive instruments for integrity; observe for cuts, gouges or any exposed metal.

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

•Wrap the instruments separately or place in a container to prevent the instruments 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 instruments in standard central supply wrap.

- 2.Steam sterilize using the following cycle parameters.

Note: Stingray Surgical Products does not recommend the insulated non-conductive instruments to be sterilized by Flash or Chemical Sterilization. *Any cleaning devices should not be left in the tube or channel, 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 instruments 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 insulated non-conductive instruments must be completely dry before storing and must be handled with care to prevent damage. Take precautions to prevent tip damage.

•As instruments 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. Instruments should be stored dry under a dust cover in an area with low traffic.

WARRANTY & REPAIR

WARRANTY

Stingray Surgical Products instruments 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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