LIFE INSTRUMENTS

INSTRUCTIONS FOR USE AND CARE - REUSABLE BIPOLAR FORCEPS

This product is reusable and is supplied nonsterile. Process the forceps through cleaning and sterilization prior to initial use, following guidance as outlined below.

INTENDED USE: These reusable forceps are electrosurgical devices designed to be used in soft tissue surgical procedures.

MAXIMIZING FORCEPS LIFE
Reusable forceps have been designed to provide a minimum of 20 uses with normal care. However, the number of uses obtained from the forceps depends upon the sterilization method, 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, LIFE INSTRUMENTS recommends the following:

- Not allowing gross organic contaminates to dry on the forceps (i.e. blood, mucus, and tissue), by initiating forceps decontamination immediately after completion of the surgical procedure.
- 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
LIFE INSTRUMENTS 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 i.e., 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.

LIFE INSTRUMENTS recommends, that such a review establish criteria by which forceps showing such damage or wear are either sent for refurbishing, or discarded and replaced.

CAUTION: USING FORCEPS WHICH ARE DAMAGED OR WORN CAN BE HAZARDOUS TO BOTH THE PATIENT AND OPERATING ROOM PERSONNEL.

STERILIZATION AND REPROCESSING (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.

CLEANING

- Rinse forceps thoroughly with sterile, purified water to remove any accumulated debris.
- Hand wash the surface of the forceps using a soft bristled cleaning brush and enzyme cleaner e.g. Terg-A-Zyme 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.
- Once the forceps are free of cleaning solution and debris, thoroughly dry using a sterile wipe.

STERILIZATION: 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 a 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 minute 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.
- FLASH – STEAM/GRAVITY DISPLACEMENT, UNWRAPPED: Process at 134°C (273°F) for a 10 – 18-minute cycle.
- FLASH – PRE-VACUUM: Process at 132°C - 134°C (270°F - 273°F) for 3 – 18-minute cycle.
- STERRAD: Double wrap forceps with Spunguard Heavy Duty Sterilization Wrap, or equivalent. Process at total exposure time of 50 minute 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 receptacles. This condition ensures that the connection is splash proof. The cords 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.

CAUTION: BECAUSE OF THE VARIABILITY OF OUTPUT VOLTAGES AND MODES FROM GENERATOR TO GENERATOR, DO NOT USE THE FORCEPS WITH GENERATOR SETTINGS HAVING BIPOLAR OUTPUT VOLTAGES THAT EXCEED 1200 Vp-p. REFER TO THE APPROPRIATE ELECTROSURGICAL GENERATOR MANUAL FOR INDICATIONS AND INSTRUCTIONS ON BIPOLAR OUTPUT CHARACTERISTICS TO ENSURE THAT ALL SAFETY PRECAUTIONS ARE FOLLOWED.

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.

At the lowest power setting, test the forceps by pressing the generator's activating switch. If the generator fails to activate, check the forceps connection with the cord, and the cord with the generator. If activation is still not achieved, check the switching mechanism (footswitch or handswitch).

Manufactured for: LIFE INSTRUMENTS
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Warning, Cautions, and Precautions	Date of manufacture
Batch Code	Non-Sterile Product
CAUTION: Federal (USA) law restricts the device to sale by or on the order of a physician.	Not made with natural rubber latex
Catalog No.	Made in USA
Consult Instructions for use	

LIFE INSTRUMENTS™
REUSABLE FORCEPS