Reusable Bipolar and Monopolar Cords Instructions for Use

This cord is reusable and is supplied **NON-STERILE.** Process the cord through cleaning and sterilization prior to initial use, and follow guidance as outlined in this IFU.

CAUTION: *Federal (USA) law restricts this device to sale by or on the order of a physician.*

INDICATION : Reusable cords are designed to connect an electrosurgical device to an electrosurgical generator. Please refer to the labeling to determine the particular connectors and specific use of the cord.

WARNING : Any use of this cord for tasks other than that for which it is indicated will usually result in a damaged or broken cord.

EXTENDING CORD LIFE

The number of uses obtained from the cord depends upon the degree of care taken in processing and handling. To achieve maximum life, the following is recommended:

- Use the molded plug at the end of the cord to disconnect. DO NOT PULL ON THE CORD'S CABLE. SEE DIAGRAM BELOW.

- Store cords loosely coiled (4-5" diam.). Avoid kinking, sharply bending the cords, or placing heavy objects on them to prevent damaging the insulation or inner wire.
- Use a different cord for each procedure during the day. Keep a supply of individually wrapped sterile cords.
- Completely dry the cord before storing.
- Do not roll heavy tables, carts, etc., over the cord.

INSPECTION OF CORD

It is recommended to establish a procedural review, by which the cord's electrical continuity is regularly tested with an ohmmeter as well as frequent inspection of the cord's insulation (before and after each use) for cracks, nicks, lacerations, or abrasions, and by which criteria are set for the discarding and replacement of those cords which may be worn and hazardous to the patient and operating room personnel.

WARNING: Using a cord which is damaged, worn, or until its inevitable failure, it is possible that it will overheat and either ignite itself or ignite nearby materials and is inherently dangerous to both the patient and operating room personnel.

REPROCESSING AND STERILIZATION (i.e., cleaning & sterilization) Institutional device reprocessing and sterilization should occur in facilities that are adequately designed, equipped, monitored, and staffed by trained personnel. Clean and sterilize per your institution's validated procedures and cycle parameters. The following parameters for cleaning, and for five of the commonly utilized methods of sterilization, are recommended as guidelines for validation.

NOTE: Reprocessing this device dictates that it undergoes a thorough cleaning prior to sterilization.

WARNING: Clean and sterilize after each use.

MANUAL CLEANING

- Rinse the cord thoroughly with sterile, purified water to remove any accumulated debris.
- Hand wash the surface of the cord using a soft-bristled cleaning brush and enzyme cleaner to remove visible residual debris.
- ***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 residue remains.
- Once the cord is free of cleaning solution and debris, thoroughly dry it 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 or syringe.

CLEANING AND DISINFECTION

Place the cord(s) in a bath with a tested cleansing and disinfectant agent prepared according to the manufacturer's recommendations using lukewarm tap water. The cord(s) 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 cord(s) 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 cord(s) 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	See manufacturer's directions
Wash 1	02:00	65.0°C (Set Point)	See manufacturer's directions
Rinse 1	01:00	Hot Tap Water	N/A
Drying	07:00	90°C	N/A

The cords(s) should then be dried using a clean, soft cloth and visually examined using the naked eye under normal lighting conditions to determine that all adherent visible soil (e.g., blood, protein substances, and other debris) had been removed from all surfaces and crevices.

WARNING: Reusable cords connect electrosurgical generators to devices. Damaged cords or cords whose connectors have not been thoroughly rinsed and dried may cause electrical burns to the patient or operating room personnel.

STERILIZATION

- ***STEAM/ GRAVITY DISPLACEMENT: DOUBLE WRAP*** cord in muslin (i.e., CSR blue hospital wrap) and place single layered in a production type steam sterilization vessel. Process at 132° C (270° F) for a 30 minute cycle.
- ***STEAM/ PRE-VACUUM: DOUBLE WRAP*** cord in muslin (i.e., CSR blue hospital wrap) and place single layered in a production type steam sterilization vessel. Process at 132°C (270°F) using pre-vacuum conditions for a 4 minute cycle.
- ***ETHYLENE OXIDE {EO}: DOUBLE WRAP*** cord in muslin (i.e., CSR blue hospital wrap) and place single layered in a production type EO sterilizer. Process at a nominal 600 mg/LEO concentration using Oxyfume 2000 (10:90) gas for a full 2-hour cycle. Immediately following the exposure cycle, aerate for 18 hours at 50° C (122°F).
- ***FLASH - STEAM/GRAVITY DISPLACEMENT, UNWRAPPED:*** Process at 134°C (273°F) for a 10-18 minute cycle.
- ***FLASH - PRE-VACUUM, UNWRAPPED:*** Process at 132°C-134°C (270°F-273°F) for a 3-18 minute cycle.

SETUP AND USE

Attach the sterile cord to the sterile device ensuring that the cord connector is fully seated against the device connector.

WARNING: Connect cords, adapters, and accessories to the electrosurgical generator only while the generator is off (standby). Failure to do so may result in injury or electrical shock to the patient or healthcare provider.

WARNING: Connect Bipolar accessories to the Bipolar receptacle and Monopolar accessories into the Monopolar receptacle only. Improper connection of accessories may result in inadvertent accessory activation or other potentially hazardous conditions.

CAUTION: Because of the variability of output voltages and modes from generator to generator, **DO NOT USE** this Bipolar cord with generator settings having a Bipolar output voltage exceeding 1200Vp-p, or this Monopolar cord with generator settings having a Monopolar output voltage exceeding 7000Vp-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 hand piece when the generator's activating switch is pressed, check the cord's connection with the device and with the generator. If proper function is still not achieved and the accessory hand piece and generator function are confirmed as sound, replace the cord and refer the questionable cord to qualified personnel for further evaluation.

At the lowest power setting, test the cord by pressing the generator's activating switch.

CAUTION: *The devices cord should be positioned in such a way that contact with the PATIENT or other leads is avoided. Temporarily unused ACTIVE DEVICES should be stored isolated from the patient.*

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

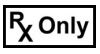
Symbols Used on Labeling:


Manufacturer

Item/Catalog Number

Lot/Batch Number

Quantity



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Consult Instructions for Use

Non-Sterile


Caution, Precaution, or Warning

Handling & Storage only between 1°C - 35°C


Handling & Storage only in a dry location

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A TRADITION OF FINE SURGICAL INSTRUMENTS

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Safety Guidelines and Recommendations to Reduce Surgical Fires and Related Patient Injury:
FDA Safety Communication excerpt

FDA Date Issued:
May 29, 2018

Audience:

- **All health care professionals** involved in surgical procedures, including surgeons, surgical technicians, anesthesiologists, anesthesiologist assistants, certified registered nurse anesthetists (CRNA), physician assistants, nurses, etc.
- **Health care facility staff** responsible for patient safety and risk management.

Purpose:

The FDA is reminding health care professionals and health care facility staff of factors that increase the risk of surgical fires on or near a patient. The FDA is also recommending practices to reduce these fires from occurring, including the safe use of medical devices and products commonly used during surgical procedures.

Summary of Problem and Scope:

Although surgical fires are preventable, the FDA continues to receive reports about these events. Surgical fires can result in patient burns and other serious injuries, disfigurement, and death. Deaths are less common and are typically associated with fires occurring in a patient's airway.

Surgical fires can occur at any time when all three elements of the fire triangle are present:

1. **Oxidizer** (e.g., oxygen, nitrous oxide)
2. **Ignition source** (e.g., electrosurgical units (ESUs), electrocautery devices, lasers, and fiber-optic illumination systems)
3. **Fuel source** (e.g., surgical drapes, alcohol-based skin preparation agents, the patient's tissue, hair, or skin)

Most surgical fires occur in oxygen-enriched environments, when the concentration of oxygen exceeds 30 percent. When supplemental oxygen is delivered to a patient in an operating room, an oxygen-enriched environment can be created. An open oxygen delivery system, such as nasal cannula or mask, presents a greater risk of fire than a closed delivery system, such as a laryngeal mask or endotracheal tube. In an oxygen-enriched environment, materials that may not normally burn in room air can ignite and burn.

Recommendations to Reduce Surgical Fires:

Health care professionals and staff who perform surgical procedures should be trained in practices to reduce surgical fires. Training should include factors that increase the risk of surgical fires, how to manage fires that do occur, periodic fire drills, how to use carbon dioxide (CO2) fire extinguishers near or on patients, and evacuation procedures.

Specific recommendations to reduce surgical fires include:

- **A fire risk assessment at the beginning of each surgical procedure.**
  - Be aware the highest risk procedures involve an ignition source, delivery of supplemental oxygen, and use of an ignition source near the oxygen (e.g., head, neck, or upper chest surgery).
- **Encourage communication among surgical team members.**
  - Ensure communication exists between the anesthesia professional delivering medical gases, the surgeon controlling the ignition source, and the operating room staff applying skin preparation agents and drapes.
- **Safe use and administration of oxidizers.**
  - Evaluate if supplemental oxygen is needed for your patient.
    - Any increase in oxygen concentration in the surgical field increases the chance of fire.
    - At concentrations of approximately 30 percent, a spark or heat can ignite a fuel source.
  - If supplemental oxygen is necessary, particularly for surgery in the head, neck, or upper chest area:
    - Titrate to the minimum concentration of oxygen needed to maintain adequate oxygen saturation for your patient.
  - When appropriate and possible, use a closed oxygen delivery system.
    - If using an open delivery system, take additional precautions to exclude oxygen and flammable/combustible gases from the operative field, such as draping techniques that avoid accumulation of oxygen in the surgical field.
- **Safe use of any devices that may serve as an ignition source.**
  - Consider alternatives to using an ignition source for surgery of the head, neck, and upper chest if high concentrations of supplemental oxygen (greater than 30 percent) are being delivered.
    - If an ignition source must be used, be aware that it is safer to do so after allowing time for the oxygen concentration in the room to decrease. It may take several minutes for a reduction of oxygen concentration in the area even after stopping the gas or lowering its concentration.

- Inspect all instruments for evidence of insulation failure (device, wires, and connections) prior to use. Do not use if any defects are found.
- In addition to serving as an ignition source, monopolar energy use can directly result in unintended patient burns from capacitive coupling and intra-operative insulation failure. If a monopolar electrosurgical unit (ESU) is used:
  - Do not activate when near or in contact with other instruments. Use a return electrode monitoring system.
- Tips of cautery instruments should be kept clean and free of char and tissue.
- When not in use, place ignition sources, such as ESUs, electrocautery devices, fiber-optic illumination light sources and lasers in a designated area away from the patient (e.g., in a holster or a safety cover) and **not** directly on the patient or surgical drapes.
- Recognize that other items that generate heat, including drills and burrs, argon beam coagulators, and fiber-optic illuminators, can also serve as potential ignition sources.

- **Safe use of surgical suite items that may serve as a fuel source.**
  - Allow adequate drying time and prevent alcohol-based antiseptics from pooling during skin preparation and assess for pooling or other moisture to ensure dry conditions prior to draping.
  - Use the appropriate size applicator for the surgical site. For example, do not use large (e.g., 26mL) applicators for head and neck cases.
  - Be aware of other surgical suite items that may serve as a fuel source, including:
    - Products that may trap oxygen, such as surgical drapes, towels, sponges, and gauze – even those which claim to be "flame-resistant."
    - Products made of plastics including some endotracheal tubes, laryngeal masks, and suction catheters.
    - Patient-related sources such as hair and gastrointestinal gases.
- **Plan and practice how to manage a surgical fire.**
  - Stop the main source of ignition. Turn off the flow of flammable gas and unplug any electrical devices that may be involved.
  - Extinguish the fire – use fire blankets, water or saline, and a CO2 extinguisher if the fire persists.
  - Remove all drapes and burning materials and assess for evidence of smoldering materials.
  - For airway fires, disconnect the patient from the breathing circuit, and remove the tracheal tube.
    - Move the patient to a safe environment. Reestablish the airway to resume respiratory care.
  - Review the fire scene and remove all possible sources of flammable materials.

FDA Activities:

The FDA is working with The Joint Commission (TJC) and other organizations to inform health care professionals and health care facility staff about risks of surgical fires and provide recommendations to reduce them. The FDA also reviews product labeling for drugs and devices that are components of the fire triangle to ensure the appropriate warnings about the risk of fire are included.

Reporting Problems to the FDA:

Prompt reporting of adverse events will help the FDA identify and better understand the risks and adverse events associated with surgical fires. If you experience a surgical fire, we encourage you to file a voluntary report through Medwatch, the FDA Safety Information and Adverse Event Reporting program (/Safety/MedWatch/HowToReport/default.htm). Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationsandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm) should follow the reporting procedures established by their facilities.