AMBLER SURGICAL REUSABLE CABLES

INSTRUCTIONS FOR USE & CARE - REUSABLE CABLES

This product is reusable and is supplied nonsterile. Process the cable through cleaning and sterilization prior to initial use.

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

MAXIMIZING CABLE LIFE
The number of uses obtained from the cable depends upon the sterilization method, care taken in processing and handling, and the surgical procedures and techniques in which the cable is used. To achieve maximum life Ambler Surgical recommends the following:

- Sterilization with ethylene oxide (EO).
- Not pulling on the cable cord itself, but using the strain relief handle of the cable to disconnect cables from the generator and instrument.
- Storing cables loosely coiled (4-5" diam.). Avoiding kinking, or sharply bending the cables, or placing heavy objects on them to prevent damaging the insulation or inner wire.
- Using a different cable for each procedure during the day. Keeping a supply of individually wrapped, sterile cables.

INSPECTION OF CABLE
Ambler Surgical recommends establishing a procedural review, by which the cable insulation is inspected frequently (before and after each use) for cracks, nicks, lacerations, or abrasions, and by which a criteria is set for the discarding and replacement of those cables which may be worn and hazardous to the patient and operating room personnel.

CAUTION: USING A CABLE UNTIL ITS INEVITABLE FAILURE, IS INHERENTLY DANGEROUS 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 institutions validated procedures and cycle parameters. The following parameters for cleaning, and for four of 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 the cable thoroughly with sterile, purified water to remove any accumulated debris.
- Hand wash the surface of the cable using a soft bristled cleaning brush, and enzyme cleaner e.g., Terg-a-zyme solution (Alconox, Inc.) or equivalent, 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 residual remains.
- The cable free of cleaning solution and debris, thoroughly dry using a sterile wipe.

CAUTION: REUSABLE CABLES CONNECT ELECTROSURGICAL GENERATORS TO INSTRUMENTS. DAMAGED CABLES, OR CABLES WHOSE CONNECTORS HAVE NOT BEEN THOROUGHLY RINSED AND DRIED, MAY CAUSE ELECTRICAL BURNS TO THE PATIENT OR DOCTOR.

STERILIZATION

- STEAM /GRAVITY DISPLACEMENT: Double wrap cable in muslin i.e., CSR blue hospital wrap, and place (single layer) in a production type, steam sterilization vessel. Process at 132° C for a 30 minute cycle.
- STEAM /PRE-VACUUM: Double wrap cable in muslin i.e., CSR blue hospital wrap, and place (single layer) in a production type, steam sterilization vessel. Process at 132° C using pre-vacuum conditions for a 4 minute cycle.
- ETHYLENE OXIDE (EO): Double wrap cable in muslin i.e., CSR blue hospital wrap, and place (single layer) in a production type, EO sterilizer. Process at a nominal 600 mg/L EO 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.

SETUP and USE
Attach the sterile cable to the sterile instrument ensuring that the cable connector is fully seated against the instrument connector.

WARNING: Connect 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 operating room personnel.

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

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

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