



REUSABLE MONOPOLAR AND BIPOLAR CABLES

MAINTAINING, CLEANING & STERILIZATION

***THIS CORD IS REUSABLE AND IS SUPPLIED NON-STERILE. PROCESS THE CORD THROUGH CLEANING AND STERILIZATION PRIOR TO INITIAL USE, 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 TO 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 FOR WHICH IT IS INDICATED WILL USUALLY RESULT IN A DAMAGED OR BROKEN CORD.

EXTENDING CORD LIFE : THESE CORDS HAVE BEEN VALIDATED FOR TWENTY-FIVE USES. HOWEVER, 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 CORDS CABLE.
- STORING CORDS LOOSELY COILED (4-5' DIAM.). AVOIDING KINKING, OR 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. KEEPING A SUPPLY OF INDIVIDUALLY WRAPPED, STERILE CORDS.
- COMPLETELY DRY THE CORD BEFORE STORING.
- NOT ROLLING 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 A CRITERIA IS 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 INSTITUTIONS 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 UNDERGO 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 SOLUTION 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.
- ONCE THE CORD IS FREE OF CLEANING SOLUTION AND DEBRIS, THOROUGHLY DRY 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/ SYRINGE.

CLEANING AND DISINFECTION

PLACE THE CORD(S) IN A BATH WITH A TESTED CLEANSING AND DISINFECTANT AGENT SUCH AS RENU-KLENZ™ (STERIS) (1/4 OZ/GAL) PREPARED ACCORDING 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 IMMERSSED 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.

THE CORD(S) SHOULD THEN BE DRIED USING A CLEAN, SOFT CLOTH AND VISUALLY EXAMINED USING THE NAKED EYE UNDER NORMAL LIGHTING CONDITION TO DETERMINE THAT ALL ADHERENT VISIBLE SOIL, (E.G., BLOOD, PROTEIN SUBSTANCES AND OTHER DEBRIS) HAD BEEN REMOVED FROM ALL SURFACES AND CREVICES.

PHASE	RECIRCULATION TIME (MINUTES)	WATER TEMP	DETERGENT TYPE & CONCENTRATION
PRE-WASH 1	2:00	COLD TAP WATER	N/A
ENZYME WASH	2:00	HOT TAP WATER	KLENZYME™, 1OZ/GALLON
WASH 1	2:00	65°C (SET POINT)	RENU-KLENZ™, 1/8OZ/GALLON
RINSE 1	1:00	HOT TAP WATER	N/A
DRYING	7:00	90°C	N/A

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 LAYER) 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 LAYER) 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 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 (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 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 SETTING HAVING A BIPOLAR OUTPUT VOLTAGE EXCEEDING 1200Vp-P OR THIS MONOPOLAR CORD WITH GENERATOR SETTING 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 HANDPIECE WHEN THE GENERATOR'S ACTIVATING SWITCH IS PRESSED, CHECK THE CORD CONNECTION WITH THE DEVICE AND WITH THE GENERATOR. IF PROPER FUNCTION IS STILL NOT ACHIEVED AND THE ACCESSORY HANDPIECE 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 POSSIBLE CONTAMINATED WITH BLOOD, TISSUE, OR OTHER POTENTIALLY INFECTIOUS MATERIAL PRESENT A BIOLOGICAL RISK AND MUST BE DISCARDED IN A CLOSABLE, LEAK-PROOF, PUNCTURE-RESISTANT RECEPTACLE, THAT IS ADEQUATELY LABELED (E.G., COLOR CODING OR SYMBOLOGY) FOR EASY IDENTIFICATION AS BIOHAZARD WASTE.

WARRANTY:

- ALL ELMED INSTRUMENTS ARE WARRANTED AGAINST DEFECTS IN MATERIAL & WORKMANSHIP FOR 1 YEAR.
- ROUTINE RESHARPENING, REINSULATING, AND ADJUSTMENTS AS WELL AS REPAIR OF DAMAGED INSTRUMENTS IS AVAILABLE FOR A MODEST CHARGE.
- ANY SERVICING OF ELMED INSTRUMENTS PERFORMED BY ANY SOURCE OTHER THAN ELMED, INC. *VOIDS* THIS WARRANTY.
- ELMED, INC., AS A MANUFACTURER AND SELLER OF THE PRODUCT, ACCEPTS NO LIABILITY FOR INDIRECT DAMAGE OR SUBSEQUENT DAMAGES THAT RESULT BY IMPROPER USAGE, IMPROPER HANDLING OR THROUGH IMPROPER PREPARATION, STERILIZATION OR MAINTENANCE.
- INSTRUMENTS ARE ONLY TO BE USED AS DESIGNATED IN THEIR SPECIALIZED MEDICAL FIELDS BY THE RESPECTIVE TRAINED AND QUALIFIED PERSONNEL. THEY ARE NOT INTENDED TO BE USED ON THE CENTRAL CIRCULATORY OR CENTRAL NERVOUS SYSTEM.

WE DESIGN, MANUFACTURE, & SELL THE TOOLS THE SURGEONS USE

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