



ATTENTION:

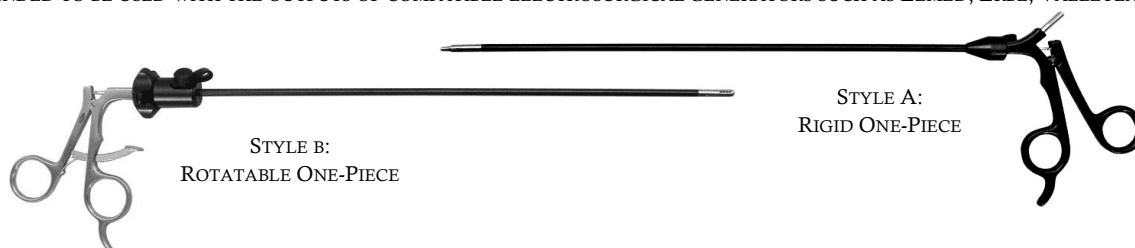
THIS INSERT IS TO SERVE AS A GUIDANCE DOCUMENT ONLY. IT IS NECESSARY TO MAINTAIN ALL NATIONAL REGULATIONS, STANDARDS AND HEALTHCARE FACILITY PROTOCOLS REGARDING THE REPROCESSING OF SURGICAL INSTRUMENTS AND/OR DEVICES. ELMED, INC. MAKES NO CLAIMS AS TO SPECIFIC CLEANING, DISINFECTING OR STERILIZING EQUIPMENT SETTINGS OR PARAMETERS.

IMPORTANT:

THESE INSTRUMENTS ARE SHIPPED NON-STERILE AND MUST BE STERILIZED BEFORE USE. IF AN INSTRUMENT WAS USED ON/IN A PATIENT WITH OR SUSPECTED TO BE INFECTED WITH CREUTZFELDT - JAKOB DISEASE (CJD), THE INSTRUMENT CANNOT BE REUSED AND MUST BE DESTROYED DUE TO THE INABILITY TO REPROCESS OR STERILIZE TO ELIMINATE THE RISK OF PATIENT/CAREGIVER CONTAMINATION. IT IS IMPORTANT TO CLEAN AND REPROCESS ALL INSTRUMENTS/DEVICES IMMEDIATELY AFTER USE TO PREVENT THE BUILD UP OF BIOHAZARD MATERIAL ALL INSTRUMENT/DEVICES MUST BE THOROUGHLY DRY BEFORE PUTTING AWAY.

INTENDED USE:

THE ELMED LAPAROSCOPIC INSTRUMENTS ARE INTENDED FOR USE IN A VARIETY OF LAPAROSCOPIC/ENDOSCOPIC, THERAPEUTIC AND MINIMALLY INVASIVE PROCEDURES FOR GRASPING, DISSECTING, MOBILIZING, RETRACTING, CUTTING, SUTURING, OCCLUDING, CLAMPING SELECTED BIOLOGICAL TISSUE. THE DEVICE IS TO BE PASSED THROUGH A LAPAROSCOPIC CANNULA. COAGULATION IS ACHIEVED USING ELECTROSURGICAL ENERGY UNDER LAPAROSCOPIC SUPERVISION IF THE SELECTED HANDLE HAS AN RF- CONNECTION. IT MUST BE CONNECTED TO THE MONOPOLAR OUTPUT OF AN ELECTROSURGICAL GENERATOR IF THE SELECTED HANDLE HAS AN RF- CONNECTION. THIS DEVICE IS INTENDED TO BE USED WITH THE OUTPUTS OF COMPATIBLE ELECTROSURGICAL GENERATORS SUCH AS ELMED, ERBE, VALLEYLAB AND COMPARABLE GENERATORS.



WARNING & PRECAUTIONS:

- CHECK FOR PROPER GROUNDING OF INSTRUMENT AND PATIENT PRIOR TO USE
- LAPAROSCOPIC PROCEDURES SHOULD BE PERFORMED ONLY BY PHYSICIANS HAVING ADEQUATE TRAINING AND FAMILIARITY WITH LAPAROSCOPIC TECHNIQUES.
- A THOROUGH UNDERSTANDING OF THE PRINCIPLES AND TECHNIQUES OF ELECTROSURGERY IS NECESSARY TO AVOID SHOCK AND BURN HAZARD TO THE PATIENT, OPERATOR, AND OPERATING ROOM PERSONNEL
- THE INSTRUMENT TIP WHEN ENERGIZED BY AN ELECTROSURGICAL GENERATOR HAS THE POTENTIAL TO BURN, CUT AND COAGULATE TISSUE. CARE SHOULD BE TAKEN WHEN USING THIS DEVICE AS CONTACT WITH SURROUNDING TISSUE IN THE FIELD CAN PRODUCE EXCESSIVE TISSUE BURN. VERIFY COMPATIBILITY OF INSTRUMENTATION AND ENSURE THAT ELECTRICAL ISOLATION OR GROUNDING IS NOT COMPROMISED AND THAT THE PATIENT IS PROPERLY GROUNDED AT ALL TIMES.
- DO NOT ENERGIZE THE INSTRUMENT UNLESS IT IS VISIBLE THROUGH THE LAPAROSCOPE.
- PRIOR TO EACH USE, INSPECT THE
- LAPAROSCOPIC INSTRUMENT FOR DEFECTS

MAINTENANCE AND CARE:

EVERY INSTRUMENT MUST BE CLEANED AND STERILIZED BEFORE BEING USED FOR THE FIRST TIME AND AFTER EVERY SUBSEQUENT USE. APPROPRIATE CLEANING, INSPECTION AND MAINTENANCE HELP TO ENSURE THE SERVICEABILITY OF SURGICAL INSTRUMENTS AND PROLONG SERVICE LIFE. CLEAN, INSPECT AND TEST ALL INSTRUMENTS THOROUGHLY, AND STERILIZE BEFORE USE.

CLEANING AND RINSING SHOULD BE DONE PROMPTLY AFTER EVERY USE. OTHERWISE TISSUE PARTICLES OR DRIED SECRETIONS MAY ADHERE TO IT, WHICH MAY MAKE SUBSEQUENT CLEANING AND STERILIZATION DIFFICULT, IF NOT IMPOSSIBLE. INSTRUMENTS MUST BE ENTIRELY FREE OF ANY FOREIGN BODIES.

HANDLING, STORAGE AND STERILIZATION:

EXTREME CARE MUST BE EXERCISED WHILE USING, TRANSPORTING, CLEANING, STERILIZING, AND STORING. DAMAGE TO THE FUNCTION AND SAFETY OF THE INSTRUMENT MAY OCCUR IF THE INSTRUMENT IS HANDLED ROUGHLY OR IMPROPERLY, OR USED FOR SOMETHING OTHER THAN ITS INTENDED PURPOSE.

CLEANING:

IMPORTANT: OBSERVE FOR ALL CLEANING METHODS.

BE SURE TO ALWAYS CHECK THE FORCEPS TIPS. THE TIPS SHOULD BE FREE FROM ANY TISSUE OR ANY OTHER MATERIAL THAT MAY HAVE ADHERED TO IT DURING COAGULATION. UNLESS THESE TIPS ARE COMPLETELY CLEAN, THE FORCEPS WILL NOT COAGULATE PROPERTY. THE INNER TONG SHOULD BE TESTED FOR PROPER CONDUCTIVITY PRIOR TO STERILIZATION.

IMMEDIATELY AFTER EACH SURGICAL PROCEDURE, CLEAN ALL INSTRUMENTS THOROUGHLY AS FOLLOWS:

1. PREPARE A CLEANING BATH ACCORDING TO THE MANUFACTURER'S INSTRUCTIONS.
2. DIRECTLY AFTER USE, REMOVE ANY COARSE SOILING FROM THE INSTRUMENTS WITH A DISPOSABLE SPONGE MOISTENED WITH WATER
3. SAFE STORAGE AND TRANSPORT OF THE INSTRUMENTS TO THE REPROCESSING ROOM IN A CLOSED CONTAINER TO PREVENT DAMAGE TO THE INSTRUMENTS AND CONTAMINATION OF THE ENVIRONMENT
4. PREPARE ENZYMATIC CLEANER ACCORDING TO THE PRESCRIBED DIRECTION ON THE CONTAINER
5. BEFORE CLEANING, REMOVE THE FLASHING PORT CAP
6. THE DEVICE SHOULD BE RINSED IN DEIONIZED WATER AND BRUSHED TO REMOVE ALL VISIBLE SOIL.
7. USING A 20CC SYRINGE, DRAW 15 ML OF ENZYMATIC CLEANER. ATTACH SYRINGE TO LURE FITTING AND FLUSH OUT THE LAPAROSCOPIC DEVICE. REPEAT FOR A TOTAL OF 3 TIMES.
8. USING A SECOND 20CC SYRINGE, FLUSH THE LAPAROSCOPIC DEVICE 3 TIMES WITH 15 ML OF DEIONIZED WATER, AS IS STEP 6.
9. IMMERSE INSTRUMENTS IN A CLEANING SOLUTION FOR AT LEAST 5 MINUTES
10. CLEAN INSTRUMENTS WITH A SOFT BRUSH UNTIL ALL VISIBLE CONTAMINANTS ARE REMOVED
11. RINSE OUT INSTRUMENTS FOR 20 SECONDS OR, IN PULSED MODE, WITH 5 PRESSURE SURGES (3 - 4 BAR) USING A WATER CLEANING GUN.
12. CLEAN THE JAW SECTION OF THE INSTRUMENT AND HINGE AREA USING A BRUSH
13. ALL PARTS SHOULD BE INSPECTED FOR BURRS, NICKS, MISALIGNMENT OR BENT COMPONENTS. INSULATION MATERIAL SHOULD BE FREE OF NICKS, GOUGES, SCRATCHES, AND ANY EXPOSED METAL OR BREAKS IN THE INSULATION.

DISINFECTION:

PREPARE A DISINFECTANT BATH ACCORDING TO THE INSTRUCTIONS OF THE DISINFECTANT MANUFACTURER. PLACE THE INSTRUMENTS IN THE DISINFECTANT BATH AND OBSERVE THE SPECIFIED RESIDENCE TIME. RINSE THE PRODUCTS THOROUGHLY WITH FULLY DEMINERALIZED WATER TO REMOVE THE DISINFECTANT WITHOUT RESIDUE.

DRYING:

DRY THE OUTSIDE OF THE INSTRUMENTS BY CARRYING OUT A DRYING CYCLE OF THE CLEANING / DISINFECTION MACHINE. IF NECESSARY, MANUAL DRYING MAY ADDITIONALLY BE CARRIED OUT USING A LINT FREE CLOTH. DRY CAVITIES BY BLOWING WITH STERILE COMPRESSED AIR.

FUNCTION CHECK, MAINTENANCE: CHECK VISUALLY FOR CLEANLINESS. IF NECESSARY, REPEAT THE REPROCESSING PROCEDURE UNTIL THE INSTRUMENT APPEARS VISUALLY CLEAN.

MACHINE CLEANING: FOLLOW MANUFACTURER RECOMMENDATIONS

AUTOMATIC WASHERS: FOLLOW MANUFACTURER RECOMMENDATIONS

STERILIZATION

STERILIZATION OF INSTRUMENTS MAY BE ACCOMPLISHED BY STEAM OR A CHEMICAL STERILANT. TIME AND TEMPERATURE PARAMETERS REQUIRED MAY VARY ACCORDING TO TYPE OF STERILIZER, CYCLE DESIGN AND PACKAGING MATERIAL. EACH INSTITUTION IS RESPONSIBLE FOR DETERMINING THE EFFICACY OF THE STERILIZATION SCHEDULE USED TO STERILIZE THIS LAPAROSCOPIC INSTRUMENT. PLEASE CONSULT WITH THE MAKER OF YOUR STERILIZER OR YOUR FACILITY'S POLICY FOR SPECIFIC GUIDELINES AND INSTRUCTIONS. THE FOLLOWING IS PROVIDED FOR INFORMATIONAL PURPOSES

STEAM AUTOCLAVING: WHEN USING THE WRAP METHOD, MAKE CERTAIN THAT ALL COMPLETE INSTRUMENTS AND ALL PARTS ARE INDIVIDUALLY WRAPPED OR SEALED IN A STERILE PACK. METAL OBJECTS SHOULD NEVER COME IN CONTACT WITH THE INSULATING MATERIAL OF FORCEPS AND HANDLES, OR WITH RF-CONNECTION CABLES. SUCH POINTS OF CONTACT WILL CAUSE SEVERE MELTING.

WE RECOMMEND THE FOLLOWING VALUES/PARAMETERS, BUT ALSO SUGGEST FOLLOWING THE MANUFACTURER'S STERILIZATION UNIT INSTRUCTIONS FOR STEAM STERILIZATION:

CYCLE	STERILIZING TEMP.	STERILIZING TIME	DRYING TIME* ³
PRE VACUUM/WAPPED	270° F (132° C)	4 MINUTES	30 MINUTES
GRAVITY/WAPPED	250° F (121° C)	30 MINUTES	45 MINUTES
GRAVITY/WAPPED	270° F (132° C)	30 MINUTES	45 MINUTES

STERIS V-PRO LOW TEMPERATURE STERILIZATION: VALIDATED- ADHERE TO THE STERILIZATION'S INSTRUCTIONS PROVIDED BY THE MANUFACTURER. (STERIS CORPORATION)

ETO STERILIZATION: INSTRUMENTS CAN BE STERILIZED BY ETHYLENE OXIDE IN ANY STANDARD CYCLE. PRESSURE READING SHOULD NOT EXCEED 12 PSI. TEMPERATURE SHOULD NOT EXCEED 68.3°C (155°F).

IT IS RECOMMENDED TO FOLLOW THE MANUFACTURER'S INSTRUCTIONS FOR THE ETO STERILIZATION UNIT CONCERNING HUMIDITY, VACUUM, CYCLE TIME, GAS CONCENTRATION AND TEMPERATURE

STERRAD STERILIZATION PROCESS INCLUDING STERRAD NX

THE STERILIZATION PROCESS IS A MULTIPLE STERILIZATION PROCESS THAT UTILIZES A COMBINATION OF EXPOSURE TO HYDROGEN PEROXIDE VAPOR AND PLASMA TO AFFECT STERILIZATION. THE STERRAD NX STERILIZER CAN STERILIZE INSTRUMENTS WHICH HAVE DIFFUSION RESTRICTED SPACES, SUCH AS HINGED PORTIONS OF FORCEPS AND SCISSORS.

ADHERE TO THE STERILIZATION INSTRUCTIONS PROVIDED BY THE MANUFACTURER. (ADVANCED STERILIZATION PRODUCTS A JOHNSON & JOHNSON COMPANY)

FLASH AUTOCLAVING (FAST HEATING/COOLING CYCLE): FLASH AUTOCLAVING WILL REDUCE THE USEFUL LIFE OF THE INSTRUMENT, PARTICULARLY WHEN IT IS CONSTRUCTED OF VARIOUS MATERIALS, ENCOMPASSING DIFFERENT EXPANSION RATES.

CAUTION: CONTINUED USE OF THIS PROCESS WILL CAUSE PREMATURE FAILURE OF INSTRUMENTS, ESPECIALLY THE INSULATION.

CHEMICLAVING – SOAKING: *NOT RECOMMENDED*

THIS IS DESTRUCTIVE TO THE INSULATING AND SILICONE MATERIALS OF ELECTROSURGICAL ACCESSORIES AND CAN CAUSE RAPID DETERIORATION AND FAILURE.

***3 IMPORTANT:** ADHERE TO PROPER DRYING CYCLE TO MAKE SURE THAT INSTRUMENTS ARE COMPLETELY DRY ON THE INSIDE (SAME APPLIES FOR CABLES). MOISTURE WILL PREVENT PROPER ELECTROSURGICAL CONDUCTIVITY.

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

ELMED INC.
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WE SUBSCRIBE TO COST
CONTAINMENT AND
PROTECTION OF THE
ENVIRONMENT



MADE IN THE USA

THEREFORE, WE
MANUFACTURE
REUSABLE PRODUCTS
FOR A CLEANER
WORLD

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