

IMPORTANT:

THESE INSTRUMENTS ARE FOR MINIMAL INVASIVE SURGERY. THEY ARE NON-STERILE, REUSABLE. ELMED, AS MANUFACTURER AND SELLER OF THE PRODUCT, ACCEPTS NO LIABILITY FOR INDIRECT DAMAGE OR 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.

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 THE 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.

CAUTION: DISINFECTED INSTRUMENTS ARE **NOT STERILE**. NEVER EXPOSE STAINLESS STEEL INSTRUMENTS TO BLEACH OR OTHER CORROSIVE CHEMICALS TO DISINFECT. EXPOSURE TO BLEACH MAY RESULT IN INSTRUMENT PITTING AND WILL VOID ALL MANUFACTURER GUARANTEES.

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:

- PREPARE A CLEANING BATH ACCORDING TO THE MANUFACTURER'S INSTRUCTIONS.
- DIRECTLY AFTER USE, REMOVE ANY COARSE SOILING FROM THE INSTRUMENTS WITH A DISPOSABLE SPONGE MOISTENED WITH WATER
- 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
- PREPARE ENZYMATIC CLEANER ACCORDING TO THE PRESCRIBED DIRECTION ON THE CONTAINER
- BEFORE CLEANING, REMOVE THE FLASHING PORT CAP
- THE DEVICE SHOULD BE RINSED IN DEIONIZED WATER AND BRUSHED TO REMOVE ALL VISIBLE SOIL.
- 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.
- USING A SECOND 20CC SYRINGE, FLUSH THE LAPAROSCOPIC DEVICE 3 TIMES WITH 15 ML OF DEIONIZED WATER, AS IS STEP 6.
- IMMERSE INSTRUMENTS IN A CLEANING SOLUTION FOR AT LEAST 5 MINUTES
- CLEAN INSTRUMENTS WITH A SOFT BRUSH UNTIL ALL VISIBLE CONTAMINANTS ARE REMOVED
- RINSE OUT INSTRUMENTS FOR 20 SECONDS OR, IN PULSED MODE, WITH 5 PRESSURE SURGES (3 - 4 BAR) USING A WATER CLEANING GUN.
- CLEAN THE JAW SECTION OF THE INSTRUMENT AND HINGE AREA USING A BRUSH
- 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: MACHINE OPERATED THERMAL DISINFECTION HAS TO BE CARRIED OUT IN CONSIDERATION OF THE NATIONAL REQUIREMENTS WITH REGARD TO THE A0 VALUE (SEE ISO15883).

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

WARNING: ELMED RECOMMENDS THAT THE INSTRUMENTS BE STERILIZED WHILE DISSEMBLED. HOWEVER, ELMED INSTRUMENTS MAY BE STERILIZED ASSEMBLED IN A STEAM PRE-VACUUM STERILIZER ONLY.

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/WRAPPED	270° F (132° C)	4 MINUTES	30 MINUTES
GRAVITY/WRAPPED	250° F (121° C)	30 MINUTES	45 MINUTES
GRAVITY/WRAPPED	270° F (132° C)	30 MINUTES	45 MINUTES

**IT IS IMPORTANT THAT THE LONGEST DRYING CYCLE POSSIBLE IS EMPLOYED, TO PREVENT BUILD UP OF MOISTURE INSIDE THE INSTRUMENT. IF THE CYCLE OF YOUR AUTOCLAVE ALLOWS A 45 MIN DRY TIME, WE RECOMMEND IT. CORROSION, PITTING OR INTERMITTENT OPERATION ARE USUAL SIGNS OF A MOISTURE INDUCED CORROSION PROBLEM.*

ETO STERILIZATION

WITH A PRESSURE READING NOT TO EXCEED 12 PSI, AND A TEMPERATURE NOT TO EXCEED 68.3°C (155°F), THE ELECTROSURGICAL ACCESSORIES CAN BE STERILIZED BY ETHYLENE OXIDE IN ANY STANDARD CYCLE.

CONCERNING HUMIDIFICATION, VACUUM, CYCLE TIME, GAS CONCENTRATION AND TEMPERATURE, WE RECOMMEND FOLLOWING THE MANUFACTURER'S INSTRUCTIONS FOR THE ETO STERILIZATION UNIT.

STERIS V-PRO LOW TEMPERATURE STERILIZATION

VALIDATED- ADHERE TO THE STERILIZATIONS INSTRUCTIONS PROVIDED BY THE MANUFACTURER. (STERIS CORPORATION)

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

CHEMICLAVING - SOAKING: NOT RECOMMENDED

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

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).

***3 IMPORTANT:** ADHERE TO PROPER DRYING CYCLE TO MAKE SURE THAT INSTRUMENTS ARE COMPLETELY DRY ON THE INSIDE.

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

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WE SUBSCRIBE TO COST
CONTAINMENT AND
PROTECTION OF THE
ENVIRONMENT



MADE IN THE
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THEREFORE, WE
MANUFACTURE
REUSABLE PRODUCTS FOR
A CLEANER WORLD

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