

ELMED MODULAR SCREW-APART, 2-PIECE ENDOSCOPIC INSTRUMENTS

ASSEMBLY, CLEANING & STERILIZATION INSTRUCTIONS

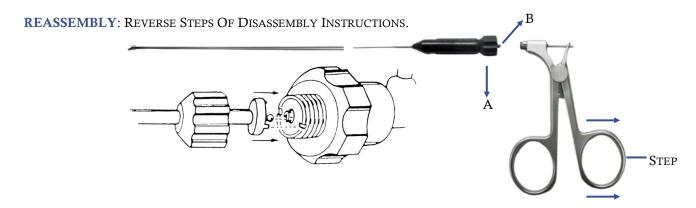
CLEANING AND CARE: EVERY INSTRUMENT MUST BE CLEANED AND STERILIZED BEFORE BEING USED FOR THE FIRST TIME AND AFTER EVERY SUBSEQUENT USE. APPROPRIATE CLEANING, INSPECTION AND MAINTENANCE HELP TO ENSURE THE SERVICEABILITY OF SURGICAL INSTRUMENTS.

CLEAN, INSPECT AND TEST ALL INSTRUMENTS THOROUGHLY, AND STERILIZE BEFORE USE. EFFECTIVE CLEANING AND MAINTENANCE WILL PROLONG SERVICE LIFE.

CLEANING AND RINSING SHOULD BE DONE PROMPTLY AFTER EVERY USE WITH THE INSTRUMENT DISASSEMBLED. 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.

DISASSEMBLY:

- 1. Turn Main Screw Cap (A) Counterclockwise Until It Disengages From The Handle
- 2. SET THE HANDLE IN THE OPEN POSITION & RELEASE THE **BALL (B) OF INNER ROD** OUT OF ITS FIXATION IN THE HANDLE PORT.



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: THE INSTRUMENT IS IN TWO PIECES: HANDLE AND OUTSIDE SHAFT. RINSE WITH DEIONIZED WATER TO REMOVE ANY DEBRIS. HAND-WASH ALL PARTS USING NEUTRAL PH DETERGENT OR ENZYMATIC CLEANER*1 AND A SOFT BRUSH, BEING SURE TO FLUSH ALL LUMENS AND CHANNELS WITH SOLUTION. THOROUGHLY CLEAN THE INSIDE OF THE OUTSIDE SHAFT USING A SOFT BRUSH*2 AND FLUSHING SOLUTION THROUGH IT. AVOID THE USE OF STEEL WOOL, WIRE BRUSHES, AND/OR ABRASIVE DETERGENTS.

CLEAN*3 ENTIRE SURFACE OF INSTRUMENT PAYING SPECIAL ATTENTION TO THE TIP AREA TO BE SURE ALL BLOOD AND DEBRIS IS REMOVED. THOROUGHLY RINSE INSTRUMENT WITH DEIONIZED WATER AFTER CLEANING TO REMOVE ANY RESIDUAL DEBRIS OR CLEANING SOLUTION.

- *1 RECOMMENDED MERITZ PLUS DISINFECTANT/DECONTAMINANT: ITEM NO. 52003-90.
- *2 RECOMMENDED ELMED CLEANING BRUSHES, ITEM NO. 52003-31 & 52003-42.
- *3 RECOMMENDED ELMED WATER JET CLEANING KIT, ITEM NO. 52003-80 & 52003-81.

IMPORTANT: BEFORE EACH USAGE THE INSTRUMENTS MUST BE CHECKED IF THEY ARE CORRECTLY & FUNCTIONALLY ASSEMBLED. MONOPOLAR INSTRUMENTS ARE ONLY TO BE ACTIVATED AT THE RESPECTIVE AREA WHERE THEY ARE TO BE USED. LARGER VERTICAL MOVEMENTS WITHIN THE TROCAR SLEEVE SHOULD NOT BE MADE IN AN ACTIVATED CONDITION. BEFORE EACH USAGE, INSULATED INSTRUMENTS SHOULD BE CHECKED ONCE AGAIN FOR EVENTUAL DAMAGE TO THE INSULATION AND IF SUCH IS FOUND, THEY SHOULD BE REPLACED. THE HF-CABLES USED MUST FIT PERFECTLY ONTO THE CONNECTOR. THE CONNECTOR CABLE MUST BE REMOVED WHEN CLEANING AND DISINFECTING THE INSTRUMENT.

STERILIZATION: THE INSTRUMENTS CAN BE STERILIZED FULLY ASSEMBLED (RECOMMENDED) OR IT CAN BE STERILIZED DISASSEMBLED AND THEN REASSEMBLED IN A STERILE FIELD IN THE OPERATING ROOM.

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

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: <u>NOT RECOMMENDED</u>: 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.
- 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.
- 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.

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

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