



SYRINGE-STYLE KLEPPINGER LAPAROSCOPIC BIPOLAR FORCEPS

ASSEMBLY, CLEANING & STERILIZATION INSTRUCTIONS
FOR MODEL NO. **52205-100** AND MODEL NO. **52105-100**

IMPORTANT:

THESE INSTRUMENTS ARE FOR MINIMAL INVASIVE SURGERY. THEY ARE SHIPPED NON-STERILE AND MUST BE STERILIZED BEFORE USE. ELMED, AS THE 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 FIELDS BY THE RESPECTIVE, TRAINED AND QUALIFIED PERSONNEL. THEY ARE NOT INTENDED TO BE USED ON THE CENTRAL CIRCULATORY OR CENTRAL NERVOUS SYSTEM.

INTENDED USE:

THE ELMED SYRINGE -STYLE KLEPPINGER LAPAROSCOPIC BIPOLAR FORCEP INSTRUMENT IS INTENDED FOR USE IN MINIMALLY INVASIVE AND SPECIALLY LAPAROSCOPIC SURGICAL PROCEDURES. THE DEVICE IS TO BE PASSED THROUGH A LAPAROSCOPIC CANNULA. THE BIPOLAR FORCEPS IS A BIPOLAR INSTRUMENT FOR USE WITH ELECTROSURGICAL GENERATORS DURING LAPAROSCOPIC PROCEDURE. IT HAS A REMOVABLE INNER TONG. COAGULATION IS ACHIEVED USING ELECTROSURGICAL ENERGY UNDER LAPAROSCOPIC SUPERVISION.

THIS DEVICE IS INTENDED TO BE USED WITH THE OUTPUTS OF COMPATIBLE ELECTROSURGICAL GENERATORS SUCH AS ELMED, ERBE, VALLEYLAB AND COMPARABLE GENERATORS.

CAUTION: BIPOLAR COAGULATION INSTRUMENTS SHOULD BE USED ONLY BY INDIVIDUALS WHO ARE TRAINED AND LICENSED TO USE SUCH DEVICES.

AS INDICATED BIPOLAR COAGULATION CURRENT MAY BE SELECTIVELY APPLIED TO THE TISSUE. THE MAXIMUM OUTPUT VOLTAGE OF THE GENERATOR MUST NOT EXCEED 500 V.

MAINTENANCE AND CARE:

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

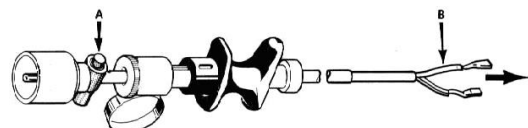
EXTREME CARE MUST BE EXERCISED WHILE USING, TRANSPORTING, CLEANING, STERILIZING AND STORING. DAMAGE TO THE FUNCTION AND SAFETY OF THE INSTRUMENT MAY OCCUR IF THE INSTRUMENT IS HANDLED ROUGHLY OR IMPROPERLY, OR USED FOR SOMETHING OTHER THAN ITS INTENDED PURPOSE.

WARNING & PRECAUTIONS:

- CHECK FOR PROPER GROUNDING OF INSTRUMENT AND PATIENT PRIOR TO USE. VISUAL INSPECTION ALONE MAY NOT BE SUFFICIENT TO ENSURE THAT THE INSULATION IS INTACT. USE AN ENDO TEST TO ASSURE THE INSTRUMENTS INSULATION.
- LAP PROCEDURES SHOULD BE PERFORMED ONLY BY PHYSICIANS HAVING ADEQUATE TRAINING & FAMILIARITY WITH LAP TECHNIQUES
- A THOROUGH UNDERSTANDING OF THE PRINCIPLES & TECHNIQUES OF ELECTROSURGERY IS NECESSARY TO AVOID SHOCK AND BURN HAZARD TO THE PATIENT, OPERATOR, AND OPERATING ROOM PERSONNEL
- DO NOT USE IN PATIENTS WHO HAVE ELECTRONIC IMPLANTS SUCH AS CARDIAC PACEMAKERS WITHOUT FIRST CONSULTING A QUALIFIED PROFESSIONAL.
- DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS OR OXIDIZING GASES SUCH AS NITROUS OXIDE (N₂O) & OXYGEN) OR IN CLOSE PROXIMITY TO VOLATILE SOLVENTS (SUCH AS ETHER ALCOHOL), AS EXPLOSION MAY OCCUR
- DO NOT PLACE INSTRUMENTS NEAR OR IN CONTACT WITH FLAMMABLE MATERIALS SUCH AS GAUZE OR SURGICAL DRAPES). INSTRUMENTS THAT ARE ACTIVATED OR HOT FROM USE MAY CAUSE A FIRE.
- WHEN NOT USING INSTRUMENTS, PLACE THEM IN A CLEAN, DRY, HIGHLY VISIBLE AREA NOT IN CONTACT WITH THE PATIENT. INADVERTENT CONTACT WITH THE PATIENT MAY RESULT IN BURNS.
- INSPECT INSTRUMENTS AND CABLES FOR DAMAGE PRIOR TO EACH USE, ESPECIALLY THE INSULATION OF LAPAROSCOPIC/ENDOSCOPIC INSTRUMENTS. THIS MAY BE DONE VISUALLY UNDER MAGNIFICATION OR WITH A HIGH VOLTAGE INSULATION TESTING DEVICE. INSULATION FAILURES MAY RESULT IN BURNS OR OTHER INJURIES TO THE PATIENT OR OPERATOR.
- THE SURFACE OF THE ACTIVE ELECTRODE MAY REMAIN HOT ENOUGH TO CAUSE BURNS AFTER THE RF CURRENT IS DEACTIVATED
- DUE TO CONCERNS ABOUT CARCINOGENIC AND INFECTIOUS OF ELECTROSURGICAL BYPRODUCTS, PROTECTIVE EYEWEAR, FILTRATION MASK AND EFFECTIVE SMOKE EVACUATION SHOULD BE USED DURING THE PROCEDURES
- CONNECT ADAPTERS AND ACCESSORIES TO THE ELECTROSURGICAL UNIT ONLY WHEN THE ENERGY IS OFF
- DO NOT ACTIVATE THE INSTRUMENT WHEN NOT IN CONTACT WITH TARGET TISSUE, AS THIS MAY CAUSE INJURIES DUE TO CAPACITIVE COUPLING WITH OTHER SURGICAL EQUIPMENT.

CAUTIONS: THE INTENSITY SHOULD BE SET AS LOW AS IS NECESSARY TO ACHIEVE THE DESIRED EFFECT. KEEP THE ELECTRODES CLEAN. BUILD-UP OF ESCHAR MAY REDUCE THE INSTRUMENT'S EFFECTIVENESS. DO NOT ACTIVATE THE INSTRUMENT WHILE CLEANING. INJURY TO OPERATING ROOM PERSONNEL MAY RESULT.

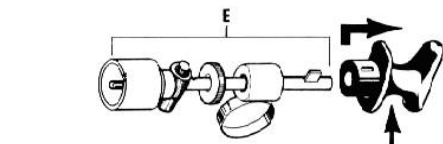
DISASSEMBLY



STEP 1
HOLD FORCEPS AT PROXIMAL END. DEPRESS BUTTON "A" AND REMOVE INNER TONG "B" BY PULLING GENTLY OUT OF FORCEPS TOWARD THE FRONT IN DIRECTION OF ARROW.



STEP 2
HOLD FORCEPS BY THE SHAFT (PART "C") AND UNSCREW KNURLED NUT (PART "D") IN COUNTER CLOCKWISE DIRECTION. WHEN NUT IS LOOSE, HOLD DISTAL END AND GENTLY PULL SHAFT AWAY FROM HANDLE IN DIRECTION OF ARROW.



STEP 3
HOLD REMAINING (PART "E") IN ONE HAND AND WITH THE OTHER HAND LIFT FINGER GUIDE (PART "F") FROM POST AND GENTLY PULL UNTIL FREE. THIS WILL COMPLETE DISASSEMBLY OF THE INSTRUMENT.

REASSEMBLY

TO REASSEMBLE, REVERSE ABOVE PROCEDURE.

****IMPORTANT WHEN REINSTALLING INNER TONG—**PRESS BUTTON "A", SLIDE "B" INTO "A" (IN DIRECTION OF ARROW)

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 AND PROLONG SERVICE LIFE.

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.

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.

****BEFORE EACH USAGE THE INSTRUMENTS MUST BE CHECKED IF THEY ARE CORRECTLY AND FUNCTIONALLY ASSEMBLED.**

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 DISSEMBLED. HOWEVER, ELMED 3-PIECE LAPAROSCOPIC 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

STERIS V-PRO LOW TEMPERATURE STERILIZATION

VALIDATED- ADHERE TO THE STERILIZATIONS 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 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 RESTRICTION 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.

CHEMICLAVING – SOAKING: NOT RECOMMENDED

THIS IS DESTRUCTIVE TO THE INSULATING AND SILICONE MATERIALS OF ESPECIALLY 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.

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

ELMED INC.
35 N. BRANDON DR.
GLENDALE HEIGHTS, IL
60139
USA

WE SUBSCRIBE TO COST
CONTAINMENT AND
PROTECTION OF THE
ENVIRONMENT



THEREFORE, WE
MANUFACTURE
REUSABLE PRODUCTS FOR
A CLEANER WORLD

PH (224) 353-6446
FAX (224) 653-8178
EMAIL
MEDICAL@ELMED.COM
WWW.ELMED.COM