

SCISSOR-STYLE KLEPPINGER LAPAROSCOPIC BIPOLAR FORCEPS

ASSEMBLY, CLEANING & STERILIZATION INSTRUCTIONS
FOR MODEL NO. **52205-200** AND MODEL NO. **52105-200**

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:

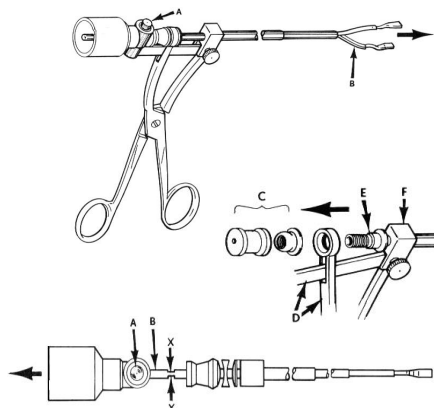
THE ELMED SCISSOR-STYLE KLEPPINGER LAPAROSCOPIC BIPOLAR FORCEPS INSTRUMENT IS INTENDED FOR USE IN MINIMALLY INVASIVE AND SPECIALTY LAPAROSCOPIC SURGICAL PROCEDURES. THE DEVICE IS TO BE PASSED THROUGH A LAPAROSCOPIC CANNULA. COAGULATION IS ACHIEVED USING ELECTROSURGICAL ENERGY UNDER LAPAROSCOPIC SUPERVISION.

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.

USE AND SAFETY INSTRUCTIONS:

- ALL INSTRUMENTS HAVE TO BE COMPLETELY CLEANED, DISINFECTED AND STERILIZED BEFORE INITIAL USE AND ANY SUBSEQUENT USE.
- IT IS VERY IMPORTANT TO CHECK EACH SURGICAL INSTRUMENT FOR VISIBLE DAMAGE AND WEAR SUCH AS CRACKS, BREAKS OR INSULATION DEFECTS BEFORE EACH USE. AREAS SUCH AS BLADES, TIPS, NOTCHES, LOCKING AND BLOCKING DEVICES AS WELL AS ALL MOBILE PARTS, INSULATED AND CERAMIC ELEMENTS MUST BE CHECKED CAREFULLY. *NEVER USE DAMAGED INSTRUMENTS.*
- NEVER USE THE INSTRUMENTS IN THE PRESENCE OF FLAMMABLE OR EXPLOSIVE SUBSTANCES.
- THE INSTRUMENT MUST NEVER BE LAID DOWN ON THE PATIENT.



DISASSEMBLY:

STEP 1

PRESS BUTTON "A" TO RELEASE "B" INNER TONG AND WITHDRAW IN DIRECTION OF ARROW

STEP 2

REMOVE "C" THREADED NIPPLE BY TURNING COUNTER-CLOCKWISE (SEALING CAP CAN BE REMOVED WITH THREADED NIPPLE). SQUEEZE HANDLE TO MOVE FLANGE "E" AGAINST "F" AND LIFT HANDLE "D" OVER THREADED END "E". COMPLETE HANDLE "D" WILL HANG OUT OF WAY TO REMOVE "E" (INNER SHAFT) IN DIRECTION OF ARROW.

REASSEMBLY:

TO REASSEMBLE, REVERSE ABOVE PROCEDURE.

IMPORTANT WHEN REINSTALLING INNER TONG

PRESS BUTTON "A", SLIDE "B" INTO "A" (IN DIRECTION OF ARROW). BE CERTAIN THAT INDENTATION "X-X" IS IN POSITION AS SHOWN.

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.

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.

MANUAL CLEANING

THE INSTRUMENT IS NOW IN FOUR PIECES: HANDLE, SCISSOR HANDLE, INNER TONG ASSEMBLY (TIP) AND OUTSIDE SHAFT. PREPARE A CLEANING BATH ACCORDING TO THE MANUFACTURER'S INSTRUCTIONS.

- RINSE ALL PARTS WITH DEIONIZED COLD TAP WATER TO REMOVE ANY DEBRIS.
- HAND WASH ALL PARTS USING NEUTRAL OR ENZYMATIC CLEANER*¹ AND A SOFT BRUSH FOR CLEANING EXTERNAL PARTS AND ALL LUMENS AND CHANNELS. THOROUGHLY CLEAN THE INSIDE OF THE INSULATED OR INSULATED STAINLESS STEEL SHAFT USING A SOFT ROUND BRUSH*² AND FLUSHING SOLUTION THROUGH IT. *Do Not Use STEEL WOOL, WIRE BRUSHES AND/OR ABRASIVE DETERGENTS.* CLEAN*³ ENTIRE SURFACE OF INSERT WITH SOFT BRUSH PAYING SPECIAL ATTENTION TO THE TIP AREA TO BE SURE ALL BLOOD AND DEBRIS IS REMOVED FROM THE JAW LINKAGE, THE INSIDE AND OUTSIDE OF THE JAW HOUSING, THE ENTIRE SHAFT AND RINSE WITH FLUSHING SOLUTION.
- 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, LIST NO. **52003-31** & **52003-42**.

*³ RECOMMENDED ELMED WATER JET CLEANING KIT, LIST NO. **52003-80** & **52003-81**.

MACHINE REPROCESSING:

PLACE THE INSTRUMENTS IN A BASKET ON THE INSERT MODULE OR ON THE INSERTS OF THE MIS MODULE AND START THE CLEANING PROCESS.

1. PRE-RINSE FOR 1 MINUTE WITH COLD WATER
2. DISCHARGING
3. PRE-RINSE FOR 3 MINUTES WITH COLD WATER
4. DISCHARGING
5. WASH FOR 5 MINUTES AT 55° C WITH A 0.5% ALKALINE OR AT 45°C WITH AN ENZYMATIC CLEANING AGENT
6. DISCHARGING
7. NEUTRALIZE FOR 2 MINUTES WITH WARM TAP WATER (> 40° C) AND A NEUTRALIZING AGENT
8. DISCHARGING
9. RINSE FOR 2 MINUTES WITH WARM TAP WATER (> 40° C)
10. DISCHARGE

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.

IMPORTANT: MACHINE REPROCESSING
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 PROPERLY. THE INNER TONG SHOULD BE TESTED FOR PROPER CONDUCTIVITY PRIOR TO STERILIZATION. RECOMMENDED ELMED BIPOLAR TESTER ITEM NO. **5297**.
***BEFORE EACH USAGE THE INSTRUMENTS MUST BE CHECKED IF THEY ARE CORRECTLY AND FUNCTIONALLY ASSEMBLED.*

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
IF A WRAPPING METHOD IS USED, MAKE CERTAIN THAT THE INSTRUMENTS ARE INDIVIDUALLY WRAPPED OR SEALED IN A STERILE PACK. METAL OBJECTS SHOULD NEVER COME IN CONTACT WITH THE INSULATING MATERIAL OF THE FLEXIBLE INSTRUMENTS, OR WITH RF-CONNECTION CABLES. SUCH POINTS OF CONTACT MAY CAUSE MELTING OF THE INSULATION.
WE RECOMMEND THE FOLLOWING VALUES/PARAMETERS, BUT WE ALSO SUGGEST FOLLOWING THE MANUFACTURER'S 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
THE INSTRUMENT MAY BE STERILIZED BY ETHYLENE OXIDE, FOLLOWING THE INSTRUCTIONS RECOMMENDED BY THE MANUFACTURE OF THE STERILIZATION EQUIPMENT. TYPICAL CONDITIONS ARE 500 MG/L ETHYLENE OXIDE, 30-70% RELATIVE HUMIDITY AND 120-135°F TEMPERATURE. TEMPERATURE SHOULD NOT EXCEED 68.3°C (155°F). EXPOSURE TIME WILL DEPEND ON THE TYPE OF EQUIPMENT USED.

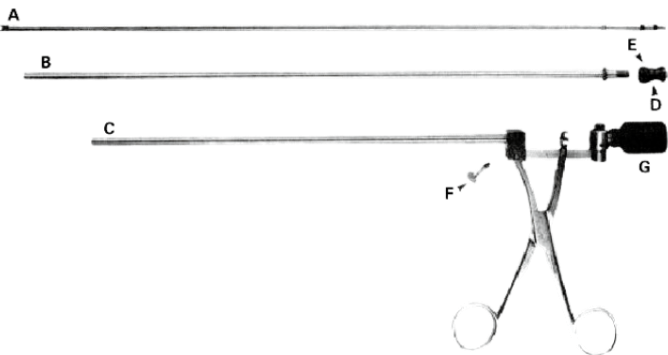
STERRAD STERILIZATION PROCESS INCLUDING STERRAD NX
THE STERILIZATION PROCESS IS A MULTIPLE STERILIZATION PROCESS THAT UTILIZES A COMBINATION OF EXPOSURE TO HYDROGEN PEROXIDE VAPOR AND PLASMA TO AFFECT STERILIZATION. THE STERRAD NX STERILIZER CAN STERILIZE INSTRUMENTS WHICH HAVE DIFFUSION RESTRICTED SPACES, 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 STERILIZATION: MINIMUM EXPOSURE TIME 4 MINUTES AT 132°C. AVERAGE DRYING TIME 8 TO 15 MINUTES.
IMPORTANT! 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 THE MOST DESTRUCTIVE METHOD TO THE INSULATING AND SILICONE MATERIALS OF ELECTROSURGICAL ACCESSORIES AND CAN CAUSE RAPID DETERIORATION AND FAILURE.

**** IMPORTANT:** ADHERE TO PROPER DRYING CYCLE TO MAKE SURE THAT INSTRUMENTS ARE COMPLETELY DRY ON THE INSIDE (SAME APPLIES FOR BIPOLAR CABLES). MOISTURE WILL PREVENT PROPER BIPOLAR ELECTROSURGICAL CONDUCTIVITY.
*****FOR PROPER STERILIZATION AND STORAGE OF YOUR FORCEPS AND CABLES WE RECOMMEND OUR ELMED CONTAINERS: ITEM NO. 52037-00 OR 52037-01 (DEPENDING ON THE LENGTH OF YOUR INSTRUMENT).**

SPARE PARTS	32CM	45CM
A. INNER TONG – FLAT KLEPPINGER TIP *	52205-101	52105-101
B. INNER SHAFT	52205-200-10	52105-200-10
C. OUTER SHAFT	52205-200-11	52105-200-11
D. SEALING CAP	52005-13W	52005-13W
E. SEALING CAP HOUSING	52205-200-14	52105-200-14
F. SET SCREW	52205-200-15	52105-200-15
G. HANDLE WITH CABLE HOUSING	52205- 200-16	52105-200-16



****OPTIONAL INNER TONG ASSEMBLIES—REFER TO DATA SHEET**

BIPOLAR RF-CONNECTION CABLES

52005-23	FOR KLEPPINGER (WOLF) FORCEPS AND ELMED AND WOLF ELECTROSURGICAL GENERATORS
52005-24	FOR KLEPPINGER (WOLF) FORCEPS AND ELECTROSURGICAL GENERATORS WITH DUAL BANANA PLUG

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

ELMED INC.
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USA

WE SUBSCRIBE TO COST
CONTAINMENT AND
PROTECTION OF THE
ENVIRONMENT



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