



BIPOLAR COAGULATION LAPAROSCOPIC FORCEPS

MODELS: 52205-96S/96F/96M—52105-68S/68F/68M

ASSEMBLY, CLEANING & STERILIZATION INSTRUCTIONS

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 INSTRUMENT IS INTENDED FOR USE IN MINIMALLY INVASIVE AND SPECIALLY LAPAROSCOPIC SURGICAL PROCEDURES. THE DEVICE IS TO BE PASSED THROUGH A 5.5MM 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.

THE BIPOLAR INSTRUMENT IS DESIGNED TO MANIPULATE, GRASP AND COAGULATE SELECTED TISSUE. IT MUST BE CONNECTED TO THE BIPOLAR OUTPUT OF AN ELECTROSURGICAL GENERATOR. AS INDICATED BIPOLAR COAGULATION CURRENT MAY BE SELECTIVELY APPLIED TO THE TISSUE. THE MAXIMUM OUTPUT VOLTAGE OF THE GENERATOR MUST NOT EXCEED 500 V.

CAUTION: IN PARTICULAR WHEN USING THE SCISSORS, PARENCHYMAL TISSUE MAY DEFLAGRATE.

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. IN PARTICULAR, AREAS SUCH AS BLADES, TIPS, NOTCHES, LOCKING AND BLOCKING DEVICES AS WELL AS ALL MOBILE PARTS, INSULATED AND CERAMIC ELEMENTS HAVE TO 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.

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.

DISASSEMBLY AND REASSEMBLY



DISASSEMBLY

STEP 1

ON HANDLE "A1" PRESS BUTTON "A2" TO RELEASE "B" INNER TONG. REMOVE TONG OUT THE DISTAL END.

STEP 2

UNSCREW COUNTERCLOCKWISE "C1" FROM HANDLE "A1"

UNSCREW COUNTERCLOCKWISE "C2" FROM HANDLE "A1"



REASSEMBLY

REVERSE ABOVE PROCEDURE

CLEANING

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.

MANUAL CLEANING:

PREPARE A CLEANING BATH ACCORDING TO THE MANUFACTURER'S INSTRUCTIONS.

1. RINSE PRODUCTS WITH COLD TAP WATER (<40°C) UNTIL ALL VISIBLE ACCUMULATIONS OF DIRT HAVE BEEN REMOVED. REMOVE STUCK DIRT BY USING A SOFT BRUSH.
2. PLACE PRODUCTS IN THE PREPARED CLEANING BATH SO THAT THEY ARE COMPLETELY SUBMERSED. OBSERVE RESIDENCE TIME ACCORDING TO THE MANUFACTURER'S INSTRUCTIONS.
3. CLEAN THE INSTRUMENT IN THE BATH MANUALLY USING A SOFT BRUSH. BRUSH ALL SURFACES SEVERAL TIMES.
4. THE FOLLOWING STEP ONLY APPLIES TO CHANNELS AND THE INSIDE OF TUBES: PUSH THE BRUSH IN AND OUT OF THE TUBES AT LEAST SIX TIME. RINSE THE TUBES WITH DI WATER. REPEAT THE PROCEDURE.
5. RINSE THE PRODUCTS THOROUGHLY WITH DI WATER TO REMOVE THE CLEANING AGENTS WITHOUT RESIDUE.

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:

MANUAL DRYING IS CARRIED OUT USING A LINT FREE CLOTH AND IN PARTICULAR, FOR DRYING CAVITIES AND CHANNELS, STERILE COMPRESSED AIR.

FUNCTIONAL TEST AND PACKAGING:

PERFORM A VISUAL INSPECTION FOR CLEANLINESS. IF REQUIRED, PERFORM AN ASSEMBLY AND FUNCTIONAL TEST ACCORDING TO THE OPERATING INSTRUCTIONS. IF NECESSARY REPEAT THE REPROCESSING PROCESS UNTIL THE INSTRUMENT IS OPTICALLY CLEAN.

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 WITH PREVACUUM AND GRAVITY STERILIZERS

IF A WRAPPING METHOD IS USED, MAKE CERTAIN THAT THE INSTRUMENTS ARE INDIVIDUALLY WRAPPED OR SEALED IN A STERILE PACK. OTHER 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

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/1 ETHYLENE OXIDE, 30-70% RELATIVE HUMIDITY AND 120-135°F TEMPERATURE. TEMP. 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.

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.

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

SPARE PARTS

ITEM NO.	DESCRIPTION	ITEM NO.	DESCRIPTION
52205-96-01	SPRING HANDLE	52105-67-01	SPRING HANDLE
52205-96-10	C1 32CM OUTER SHAFT	52105-67-10	C1 45CM OUTER SHAFT
52205-96-11	C2 32CM INNER SHAFT	52105-67-11	C1 45CM INNER SHAFT
52205-44	32CM STD TIP INNER TONG	52105-70	45CM STD TIP INNER TONG
52205-91	32CM FLAT TIP INNER TONG	52105-71	45CM FLAT TIP INNER TONG
52205-47	32CM MICRO TIP INNER TONG	52105-72	45CM MICRO TIP INNER TONG

BIPOLAR RF-CONNECTION CABLES

52005-19	BIPOLAR RF-CABLE WITH ELMED INSTRUMENT CONNECTOR AND ELMED/WOLF UNIT CONNECTOR
52005-20	BIPOLAR RF-CABLE WITH ELMED INSTRUMENT CONNECTOR AND DUAL BANANA UNIT CONNECTOR

INSTRUMENT CLEANING KIT FOR ENDOSCOPIC INSTRUMENTATION

THE ELMED INSTRUMENT CLEANING KIT IS AN EFFECTIVE AND EASY-TO-USE SOLUTION TO YOUR LAPAROSCOPIC INSTRUMENTATION CLEANING NEEDS. IT WAS DESIGNED WITH YOUR CONVENIENCE IN MIND. THE ELMED INSTRUMENT CLEANING KIT CONSISTS OF:

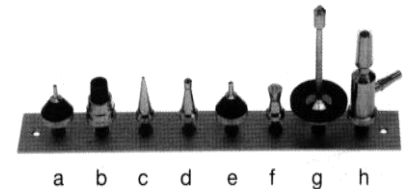


52003-80

WATER JET CLEANING
GUN FOR CONNECTION TO
WATER FAUCET OR AIR

52003-81

SET OF ADAPTERS FOR
CLEANING GUN



52003-31: 6MM DIA. BRUSH FOR 5MM & 6MM
CANNULAS, PKG OF 10

52003-41: NYLON BRISTLE BRUSH WITH

CLEANERS DISINFECTANTS AND LUBRICANTS

ITEM NO.	DESCRIPTION
52003-90	MERITZ PLUS DISINFECTANT / DECONTAMINANT (1GAL)
52003-39	LUBRICATION OIL FOR SURGICAL INSTRUMENTS (PKG OF 10)

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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60139
USA

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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