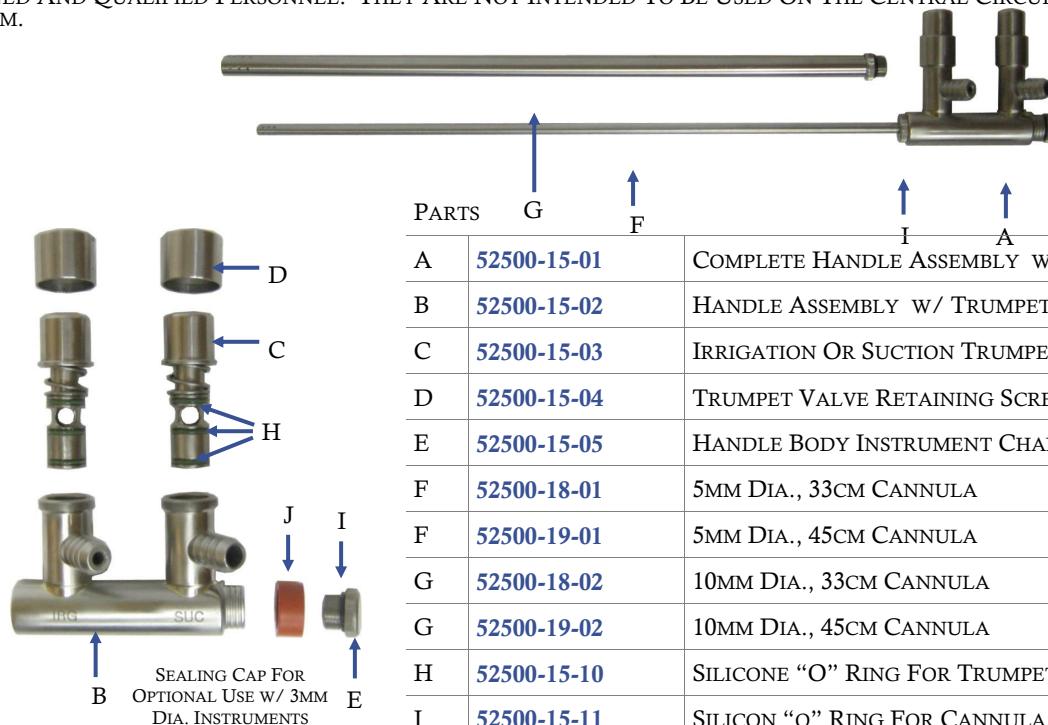


LAPAROSCOPIC IRRIGATION / SUCTION SYSTEM

CLEANING AND STERILIZATION INSTRUCTIONS
INSTRUMENT LIST NO: **52500-15** & **52545-15**, HIGH FLOW HANDLE

IMPORTANT: THESE INSTRUMENTS ARE FOR MINIMAL INVASIVE SURGERY. THEY ARE NON-STERILE, REUSABLE. THIS ELMED LAPAROSCOPIC IRRIGATION SUCTION SYSTEM SHOULD ONLY BE HANDLED BY QUALIFIED PERSONNEL FAMILIAR WITH THEIR OPERATION, ASSEMBLY AND DISASSEMBLY. THE INSTRUMENT IS INTENDED FOR USE ONLY FOR ENDOSCOPIC MINIMAL INVASIVE SURGERY.

IMPORTANT: WHEN IN USE, IT SHOULD NEVER COME IN CONTACT WITH RF-ENERGIZED LAPAROSCOPIC INSTRUMENTS. 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.



PARTS		
A	52500-15-01	COMPLETE HANDLE ASSEMBLY W/ TRUMPET VALVE W/OUT CANNULA
B	52500-15-02	HANDLE ASSEMBLY W/ TRUMPET VALVE W/OUT CANNULA
C	52500-15-03	IRRIGATION OR SUCTION TRUMPET VALVE (REQUIRES 2)
D	52500-15-04	TRUMPET VALVE RETAINING SCREW CAPS (REQUIRES 2)
E	52500-15-05	HANDLE BODY INSTRUMENT CHANNEL SCREW PLUG
F	52500-18-01	5MM DIA., 33CM CANNULA
F	52500-19-01	5MM DIA., 45CM CANNULA
G	52500-18-02	10MM DIA., 33CM CANNULA
G	52500-19-02	10MM DIA., 45CM CANNULA
H	52500-15-10	SILICONE "O" RING FOR TRUMPET VALVE (PKG. OF 12)
I	52500-15-11	SILICON "O" RING FOR CANNULA & INSTRUMENT CHANNEL
J	52003-15	SEALING CAP FOR OPTIONAL USE OF INSTRUMENT CHANNEL

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 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.

DISASSEMBLING & CLEANING:

- UNSCREW THE CANNULA – CHECK CONDITION OF "O" RING (G). REPLACE IF BROKEN OR IN HARD, BRITTLE CONDITION.
- UNSCREW TRUMPET VALVE RETAINING SCREW CAPS (C)
- PULL OUT TRUMPET VALVES (C)
- UNSCREW BOTTOM SCREW (D) & REMOVE SPRING (H)
- REMOVE REAR INSTRUMENT CHANNEL SCREW (E). INSPECT CONDITION OF "O" RINGS (E) (G). REPLACE IF BROKEN OR IN HARD, BRITTLE CONDITION.

RINSE WITH DEIONIZED WATER AFTER CLEANING TO REMOVE ANY DEBRIS, HAND WASH THE COMPLETE OUTSIDE OF HANDLE BODY, TRUMPET VALVES AND CANNULA USING NEUTRAL pH DETERGENT OR ENZYMATIC CLEANER*¹ AND SOFT BRUSH*². CLEAN ALL INSIDE LUMENS ON VALVE BODY USING ROUND CLEANING BRUSHES, BEING SURE TO WASH AND FLUSH ALL LUMENS AND CHANNELS WITH SOLUTION. THOROUGHLY CLEAN THE OUTSIDE AND INSIDE CANNULA USING A ROUND CLEANING BRUSH*² AND WASHING SOLUTION AND/OR ABRASIVE DETERGENT.

*¹ RECOMMENDED MERITZ PLUS DISINFECTANT/DECONTAMINANT: ELMED LIST NO. **52003-90**.

*² RECOMMENDED ELMED CLEANING BRUSHES, ITEM NO. **52003-42, 52003-25, 52003-27**.

RE-ASSEMBLING: REVERSE STEPS OF DISASSEMBLY.

NOTE: THE IRRIGATION/TRUMPET VALVES ARE THE SAME AND CAN BE INTERCHANGED DURING REASSEMBLY.

IMPORTANT: WE RECOMMEND THAT THE TRUMPET VALVE "O" RINGS ARE LUBRICATED WITH INSTRUMENT OIL*¹ OR INSTRUMENT SPRAY LUBRICANT*², WHEN BEING REASSEMBLED AND PRIOR TO STERILIZATION

*¹ RECOMMENDED ELMED NO. **52003-39** - LUBRICATION OIL FOR SURGICAL INSTRUMENTS

*² RECOMMENDED MILTEX NO. **3-700** – MILTEX INSTRUMENT SPRAY LUBRICANT

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.

ULTRASONIC PRE-CLEANING:

1. THE INSTRUMENT MUST BE INSERTED IN AN ULTRASONIC BATH WITH 0.5% ENZYMATIC CLEANING DETERGENT. ULTRASOUND MUST BE APPLIED FOR 15 MINUTES AT 40° C/104° F.
2. REMOVE THE INSTRUMENT AND RINSE COMPLETELY WITH COLD WATER TO REMOVE THE CLEANING DETERGENT.

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 FORCEPS & HANDLES, 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
GRAVITY DISPLACEMENT	250° -254°F (121° -123°C)	30 MINUTES	20-50 MINUTES
	270° -274°F (132° -134°C)	20 MINUTES	20-50 MINUTES
GRAVITY/WRAPPED	270° -274°F (132° -134°C)	5-10 MINUTES	20-40 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 30 MIN DRY TIME, WE RECOMMEND USING IT. CORROSION, PITTING OR INTERMITTENT OPERATION ARE USUAL SIGNS OF A MOISTURE INDUCED CORROSION PROBLEM.

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 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.

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

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

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WE SUBSCRIBE TO COST
CONTAINMENT AND
PROTECTION OF THE
ENVIRONMENT



THEREFORE, WE
MANUFACTURE
REUSABLE PRODUCTS FOR
A CLEANER WORLD

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