



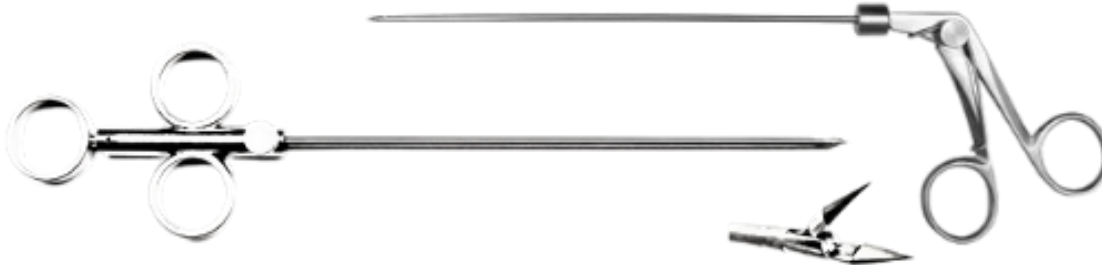
## LAPAROSCOPIC TROCAR PORT-SITE CLOSURE INSTRUMENT

SYRINGE/SCISSOR STYLE CLEANING AND  
STERILIZATION

ITEM No.'s **52203-41/52213-41/52203-00**

### IMPORTANT:

EVERY INSTRUMENT MUST BE CLEANED AND STERILIZED BEFORE BEING USED FOR THE FIRST TIME AND AFTER EVERY SUBSEQUENT USE. THESE INSTRUMENTS ARE FOR MINIMAL INVASIVE SURGERY. THEY ARE NON-STERILE, REUSABLE.



### 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.

### CLEANING:

THE INSTRUMENT IS CLEANED THROUGH THE FLUSH PORT " USE THE APPROPRIATE CONNECTIONS; WE SUGGEST THE ELMED CLEANING GUN. THE ELMED WATER JET CLEANING GUN USES EITHER WATER OR PRESSURIZED AIR THIS MEANS THE CLEANING PROCESS IS QUICK, EFFICIENT AND INEXPENSIVE. THE SELECTA SPRAY GUN FEATURES A NEW TYPE OF INTERNAL FLOW CONTROL MECHANISM. IT PERMITS THE SMOOTH AND SIMPLE ADJUSTMENT OF THE WATER OR AIR FLOW ACROSS THE ENTIRE RANGE OF THE TRIGGER MOVEMENT. RINSING, SUCTION OR DRYING IN EVERY AREA OF APPLICATION IS MADE POSSIBLE THROUGH THE SET OF 8 ATTACHMENTS.

RINSE WITH DEIONIZED WATER TO REMOVE ANY DEBRIS. HAND-WASH THE COMPLETE OUTSIDE, HANDLE AND SHAFT USING NEUTRAL pH DETERGENT OR ENZYMATIC CLEANER\*<sup>1</sup> AND A SOFT BRUSH, BEING SURE TO FLUSH ALL LUMENS AND CHANNELS WITH SOLUTION. THOROUGHLY CLEAN THE OUTSIDE SHAFT USING A SOFT BRUSH\*<sup>2</sup> AND FLUSHING SOLUTION. AVOID THE USE OF STEEL WOOL, WIRE BRUSHES, AND/OR ABRASIVE DETERGENTS.

CLEAN\*<sup>3</sup> ENTIRE SURFACE OF INSERT, 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.

\*<sup>1</sup> RECOMMENDED MERITZ PLUS DISINFECTANT/DECONTAMINANT: ELMED LIST No. **52003-90**.

\*<sup>2</sup> RECOMMENDED ELMED CLEANING BRUSHES, LIST No. **52003-31 & 52003-42**.

\*<sup>3</sup> RECOMMENDED ELMED WATER JET CLEANING KIT, LIST 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 RF-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.

**IMPORTANT:** THE FLUSHPORT OR RINSING CHANNEL CAP **MUST BE REMOVED** WHEN THE INSTRUMENT IS BEING STERILIZED TO

## STEAM AUTOCLAVING

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 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* <sup>3</sup>
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)	15 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.

\*<sup>3</sup> **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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