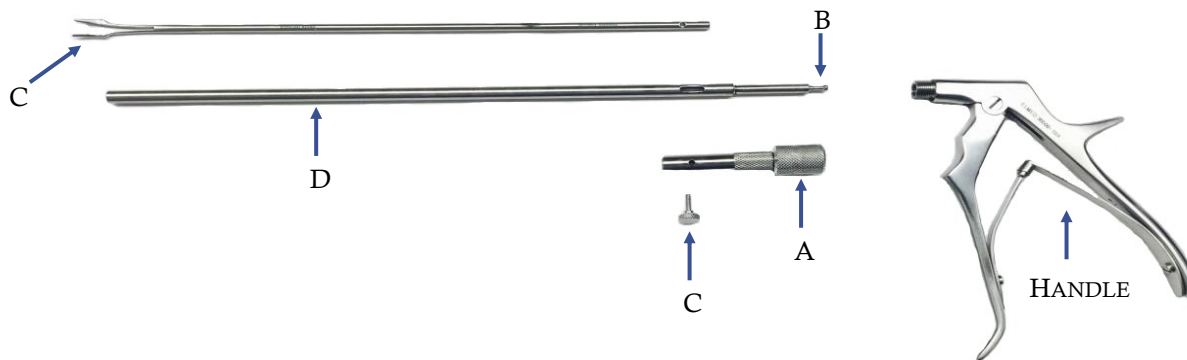


## ENDOSCOPIC CLIP APPLIER

### ASSEMBLY, CLEANING, & STERILIZATION INSTRUCTIONS



**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. CLEAN, INSPECT AND TEST ALL INSTRUMENTS THOROUGHLY, AND STERILIZE BEFORE USE. EFFECTIVE CLEANING AND MAINTENANCE WILL PROLONG SERVICE LIFE. CLEANING AND RINSING SHOULD BE DONE PROMPTLY AFTER EVERY USE WITH THE INSTRUMENT DISASSEMBLED. 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.

#### DISASSEMBLY:

1. TURN MAIN SCREW CAP (A) COUNTERCLOCKWISE UNTIL IT DISENGAGES FROM THE HANDLE.
2. SET THE HANDLE IN THE CLOSE POSITION & RELEASE THE BALL (B) OF INNER ROD OUT OF ITS FIXATION IN THE HANDLE PORT.
3. UNSCREW SET SCREW (C) FROM THE SCREW CAP (A) ASSEMBLY.
4. PULL THE TIP (C) OUT OF THE SHAFT (D).

**REASSEMBLY:** REVERSE STEPS OF DISASSEMBLY INSTRUCTIONS. MAKE SURE TIP, SHAFT AND SCREW CAP ASSEMBLY ARE ALIGNED BEFORE PLACING SET SCREW IN PLACE.

**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 HF-CABLES USED MUST FIT PERFECTLY ONTO THE CONNECTOR. THE CONNECTOR CABLE MUST BE REMOVED WHEN CLEANING AND DISINFECTING THE INSTRUMENT.

**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

**MANUAL CLEANING:** WITH THE INSTRUMENT DISASSEMBLED IN THREE PIECES; HANDLE, INSERT AND OUTSIDE SHAFT WITH LOCKING CAP. PREPARE A CLEANING BATH ACCORDING TO THE MANUFACTURERS INSTRUCTIONS.

1. RINSE ALL PARTS WITH DEIONIZED COLD TAP WATER TO REMOVE ANY DEBRIS.
2. HAND WASH ALL PARTS USING NEUTRAL OR ENZYMIC CLEANER\*<sup>1</sup> 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\*<sup>2</sup> AND FLUSHING SOLUTION THROUGH IT. **Do Not Use STEEL WOOL, WIRE BRUSHES AND/OR ABRASIVE DETERGENTS.** CLEAN\*<sup>3</sup> 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.
3. THOROUGHLY RINSE INSTRUMENT WITH DEIONIZED WATER AFTER CLEANING TO REMOVE ANY RESIDUAL DEBRIS OR CLEANING SOLUTION.

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

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

\*<sup>3</sup> RECOMMENDED ELMED WATER JET CLEANING KIT, ITEM 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 ENZYMIC 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 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.

**\*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.

#### REPLACEMENT PARTS FOR ELMED MODULAR INSTRUMENTS

INSERTS: ORDER FROM INSTRUMENT DATA SHEET BY ADDING THE LETTER “ I” TO THE NUMBERS OF THE INSTRUMENT.

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

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