

THERMO PLASTIC TROCARS & SLEEVES

CLEANING & STERILIZATION INSTRUCTIONS

IMPORTANT: BEFORE USING THESE PRODUCTS, PLEASE READ THE FOLLOWING INFORMATION THOROUGHLY!

WARNING: ALL INSTRUMENTS MUST BE CLEANED, DISINFECTED AND STERILIZED PRIOR TO EACH USE. ALL REUSABLE ELMED PRODUCTS ARE SHIPPED IN NONSTERILE CONDITION. BEFORE THE FIRST USE TRANSPORT PACKAGING, COARSE DUST/PIECES OF PAPER/PACKAGING REMAINS NEED TO BE REMOVED AND EACH PRODUCT PROCESSED AND STERILIZED ACCORDING TO THESE INSTRUCTIONS. ALL PRODUCTS HAVE BEEN PRECLEANED TO AN EXTENT WHICH ALLOW S FOR PROCESSING AND STERILIZATION BY USE OF THE EQUIPMENT STATED HERE. THIS ONLY APPLIES TO A PROCESSING METHOD ACCORDING TO THESE INSTRUCTIONS WITHIN A SYSTEM THAT HAS BEEN CONFIGURED AND VALIDATED IN COMPLIANCE WITH ISO 17665 AND IN WHICH ALL CLEANING/DISINFECTING DEVICES COMPLY WITH ISO 15883. THOROUGH CLEANING AND DISINFECTION IS CRUCIAL FOR AN EFFECTIVE STERILIZATION! *STRONG CLEANING AGENTS MAY CAUSE FADING OF MARKINGS.*

LIMITATIONS ON REPROCESSING

INSTRUMENTS MADE OF RADEL™ CAN BE CLEANED, DISINFECTED & STERILIZED FOR OVER 1,000 CYCLES WITHOUT SIGNIFICANT LOSS OF PROPERTIES, BASED ON AN AVERAGE TREATMENT. PRODUCTS THAT HAVE BEEN MARKED AS SINGLE-USE (ACC. TO EN 980 2008-11/FIGURE 5.2) MUST NOT BE REPROCESSED! WITH SUCH PRODUCTS MATERIALS ARE BEING USED THAT ARE NOT RE PROCESSABLE UNDER NORMAL CONDITIONS OR DO NOT WITHSTAND MORE THAN ONE STERILIZATION PROCESS AND, THEREFORE, MAY BREAK DURING SURGERY IF REPROCESSED! (THIS APPLIES TO PRACTICALLY ALL SINGLE-USE PRODUCTS FEATURING PLASTIC COMPONENTS).

INTENDED USE

THE ELMED TROCARS ARE DESIGNED FOR GENERAL ENDOSCOPIC/ LAPAROSCOPIC SURGERIES TO BE USED AS SEALING PORT DURING THE OBTURATORS ARE USED THROUGH THE TROCARS TO ACCESS TO THE ABDOMEN.

CONTRAINDICATIONS

NOT INTENDED FOR USE WITH PATIENTS THAT HAVE ALLERGIC REACTIONS TO NI- ; CR- STEELS OR TO BRASS OR ALUMINUM.

INSTRUCTIONS (ACC. TO ISO 17664) PLACE OF USE (IMMEDIATELY AFTER USE)

IMMEDIATELY AFTER EACH USE (WITHIN NO MORE THAN 10 MIN. OR BEFORE DRYING OF CONTAMINANTS) THE INSTRUMENTS NEED TO GET DISASSEMBLED AND IMPURITIES REMOVED UNDER RUNNING WATER, USING A SOFT BRUSH OR CLOTH WHICH ARE BEING USED SOLELY FOR THIS PURPOSE. NEVER USE A METAL BRUSH, STEEL WOOL OR OTHER CLEANING DEVICES CONTAINING METAL IN ORDER TO AVOID THE IMMINENT RISK OF CORROSION. RINSE UNDER COLD, RUNNING WATER UNTIL ALL VISIBLE IMPURITIES AND CONTAMINANTS HAVE BEEN SUCCESSFULLY REMOVED.

STORAGE AND TRANSPORT

PLACE INSTRUMENTS IN A CONTAINER; MAKE SURE THAT ASSOCIATED PARTS ARE BEING STORED TOGETHER. KEEP THE INSIDE OF THE CONTAINER MOIST/WET (NO CONTAMINANTS MAY DRY). REPROCESS ALL INSTRUMENTS AS SOON AS POSSIBLE.

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 MANUFACTURER'S INSTRUCTIONS.

1. RINSE ALL PARTS WITH DEIONIZED COLD TAP WATER TO REMOVE AND DEBRIS.
2. 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.
3. THOROUGHLY RINSE INSTRUMENT WITH DEIONIZED WATER AFTER CLEANING TO REMOVE ANY RESIDUAL DEBRIS OR CLEANING SOLUTION.

*¹ RECOMMENDED MERITZ PLUS DISINFECTANT/DECONTAMINANT: ELMED List 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.

MANUAL REPROCESSING

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 IN THE FOLLOWING WAS:

1. STEAM AUTOCLAVING: WHEN USING THE WRAP METHOD, MAKE CERTAIN THAT ALL COMPLETE INSTRUMENTS AND ALL PARTS ARE INDIVIDUALLY WRAPPED OR SEALED IN A STERILE PACK. METAL OBJECTS SHOULD NEVER COME IN CONTACT WITH THE INSULATING MATERIAL OF FORCEPS AND HANDLES, OR WITH RF-CONNECTION CABLES. SUCH POINTS OF CONTACT WILL CAUSE SEVERE MELTING.

WE RECOMMEND THE FOLLOWING VALUES/PARAMETERS, BUT ALSO SUGGEST FOLLOWING THE MANUFACTURER'S STERILIZATION UNIT INSTRUCTIONS FOR STEAM STERILIZATION:

CYCLE	STERILIZING TEMP.	STERILIZING TIME	DRYING TIME* 3
PREVACUUM/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

2. **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.
3. **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)
4. **FLASH AUTOCLAVING (FAST HEATING/COOLING CYCLE):** 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.

5. CHEMICLAVING – SOAKING: *NOT RECOMMENDED*

THIS IS DESTRUCTIVE 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 (SAME APPLIES FOR CABLES). MOISTURE WILL PREVENT PROPER ELECTROSURGICAL CONDUCTIVITY.

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



MADE IN THE USA

THEREFORE, WE
MANUFACTURE
REUSABLE PRODUCTS
FOR A CLEANER
WORLD

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