

FIBER-OPTIC CABLES & FIBER-OPTIC RETRACTORS

CLEANING & STERILIZATION INSTRUCTIONS



PLEASE READ BEFORE USE: FAILURE TO FOLLOW THESE INSTRUCTIONS COULD RENDER THE DEVICE UNSTABLE AND VOID ANY WARRANTY.

DEVICE DESCRIPTION: ELMED FIBER-OPTIC CABLES ARE DESIGNED TO DELIVER MAXIMUM LIGHT WHEN COUPLED TO A MEDICAL GRADE FIBER-OPTIC LIGHT SOURCE. ELMED FIBER-OPTIC CABLES CAN BE USED WITH QUARTZ HALOGEN, METAL HALIDE, OR XENON LIGHT SOURCES. THEY ARE COMPATIBLE WITH VIRTUALLY ALL ENDOSCOPES, MEDICAL INSTRUMENTS AND MICROSCOPES.

INTENDED USE: THIS DEVICE IS DESIGNED TO ILLUMINATE A SURGICAL SITE BY RELAYING LIGHT FROM A FIBER-OPTIC LIGHT SOURCE ONTO THE DESIRED SITE. ELMED CABLES ARE MEDICAL GRADE, HIGH TRANSMITTANCE, PEAK EFFICIENCY.

CONTRAINDICATIONS: THIS DEVICE HAS NO CONTRAINDICATIONS OF WHICH WE HAVE KNOWLEDGE.

WARNINGS AND PRECAUTIONS

ELMED LIGHT CABLES & FIBER-OPTIC RETRACTORS ARE PROVIDED NON-STERILE AND MUST BE STERILIZED BEFORE USE. SEE INSTRUCTIONS FOR CLEANING AND STERILIZATION.

1. ALWAYS INSPECT CABLES & RETRACTORS FOR ANY EVIDENCE OF DAMAGE PRIOR TO USE. PAY PARTICULAR ATTENTION TO OPTICAL SURFACES LOOKING FOR SCRATCHES OR DINGS.
2. USE CAUTION TO TREAT ELMED CABLES AS YOU WOULD ANY FINE OPTICAL DEVICE.
3. THE USER OF THIS PRODUCT SHOULD BE THOROUGHLY FAMILIAR AND TRAINED IN USE AND CARE OF THE PRODUCT.

FIRE HAZARD: NEVER DRAPE OR COVER THE END OF ANY FIBER-OPTIC CABLE WITH ANYTHING FLAMMABLE.

ADVERSE EVENTS: WE HAVE NO KNOWLEDGE OF ANY ADVERSE EVENTS WITH THIS PRODUCT.

MANUAL CLEANING (CABLE): FIBER OPTIC LIGHT CABLE AND FIBER OPTIC RETRACTORS FOR ENDOSCOPES, MICROSCOPES, AND SURGICAL INSTRUMENTS ARE HIGH QUALITY OPTICAL DEVICES. THEY REQUIRE SIMILAR CARE TO THAT TAKEN FOR ANY PRECISION OPTICAL COMPONENT.

- AFTER EACH USE, THE LIGHT CABLE OR RETRACTOR SHOULD BE WASHED AND CLEANED OF ALL DEBRIS.
- A SOFT BRUSH AND MILD DETERGENT SHOULD BE USED TO CLEAN THE DEVICE.
- PAY PARTICULAR ATTENTION TO ANY CREVICES OR SEAMS.
- AVOID ANY HARSH MATERIALS OR DETERGENTS THAT CAN SCRATCH OR IN ANY WAY DAMAGE THE OPTICAL SURFACES ON EACH END OF THE LIGHT GUIDE.

WE RECOMMEND FOLLOWING THE GUIDELINES CONTAINED IN ASTM F 1518-00 "STANDARD PRACTICES FOR CLEANING AND DISINFECTION OF FLEXIBLE FIBER OPTIC AND VIDEO ENDOSCOPES USED IN THE OF THE HOLLOW VISCERA." ALTHOUGH WRITTEN SPECIFICALLY FOR ENDOSCOPES, MUCH OF IT APPLIES TO THE LIGHT CABLES + RETRACTORS.

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 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.

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 TIMES. 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

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* 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)	15 MINUTES	45 MINUTES

STERIS V-PRO LOW TEMPERATURE STERILIZATION: VALIDATED- ADHERE TO THE STERILIZATIONS INSTRUCTIONS PROVIDED BY THE MANUFACTURER. (STERIS CORPORATION)

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.

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

ELMED INC.
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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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