

IN ORDER TO MINIMIZE HAZARDS FOR PATIENTS AND USERS THESE DIRECTIONS MUST BE FOLLOWED. APPLICATION, MAINTENANCE AND TEST OF THE INSTRUMENTS MAY ONLY BE CARRIED OUT BY SPECIFICALLY SKILLED STAFF. REUSABLE SURGICAL INSTRUMENTS FROM ELMED ARE, IF NOT STATED OTHERWISE, SUPPLIED NON STERILE AND NEED TO UNDERGO A COMPLETE CLEANING/DISINFECTION CYCLE BEFORE THE FIRST AND EACH FOLLOWING USE.

**INTENDED USE:** THIS MANUAL, IF NOT STATED OTHERWISE, IS VALID FOR ALL ELMED REUSABLE SURGICAL INSTRUMENTS OF RISK CLASS L, WITH ARTICLE NUMBERS STARTING WITH:

4XXX-XX; 5XXX-XX; 6XXX-XX; 7XXX-XX; 8XXX-XX; 9XXX-XX; 10XXX-XX; 11XXX-XX; 12XXX-XX; 13XXX-XX; 14XXX-XX; 15XXX-XX; 16XXX-XX; 17XXX-XX; 18XXX-XX; 19XXX-XX; 20XXX-XX; 21XXX-XX; 22XXX-XX; 23XXX-XX; 24XXX-XX; 25XXX-XX; 26XXX-XX; 28XXX-XX; 29XXX-XX; 30XXX-XX; 31XXX-XX; 32XXX-XX; 34XXX-XX; 35XXX-XX; 36XXX-XX; 37XXX-XX; 38XXX-XX; 39XXX-XX; 40XXX-XX; 48XXX-XX; 49XXX-XX; 50XXX-XX; 51XXX-XX; 52XXX-XX; 53XXX-XX; 55XXX-XX; 54XXX-XX; 55XXX-XX; 56XXX-XX; 70XXX-XX; 71XXX-XX; 72XXX-XX; 73XXX-XX; 75XXX-XX; 79XXX-XX; 83XXX-XX; 6XX-XXX; 7XX-XXX; 8XX-XXX; Z0000XXXXXX.

- THESE INSTRUCTIONS FOR USE ARE VALID FOR SURGICAL INSTRUMENTS MADE OF STAINLESS STEEL, SUCH AS DENTAL INSTRUMENTS, EXTRACTING FORCEPS, INSTRUMENTS FOR BONE SURGERY, SCALPELS, KNIVES, SCISSORS, FORCEPS, CLAMPS, RETRACTORS, PROBES, SPATULAS, SUTURE INSTRUMENTS ALSO.
- DISMANTLABLE INSTRUMENTS OR INSTRUMENTS MADE OF OTHER MATERIALS WILL BE DISTRIBUTED WITH SPECIAL INSTRUCTIONS.
- INSTRUMENTS MADE OF TITANIUM OR TITANIUM ALLOYS ARE TO BE TREATED EXACTLY AS STAINLESS STEEL INSTRUMENTS. NO SPECIAL ADVICE NEED TO BE OBSERVED.
- INSTRUMENTS MADE OF ALUMINUM NEED TO BE CLEANED/DISINFECTED WITH NON-ALKALINE, NEUTRAL CLEANING/DISINFECTION DETERGENTS AND FULLY DESALINATED WATER, IN ORDER TO AVOID DAMAGES TO ANODIZED SURFACES. ALKALINE CLEANING PROCEDURES WILL VERY QUICKLY HAVE NEGATIVE EFFECTS ON COLOR ANODIZED SURFACES.

**TESTS:** PRIOR TO EACH USE, THE INSTRUMENTS MUST BE TESTED TO THEIR CORRECT WORKING ORDER. SURFACE DAMAGE SUCH AS SCRATCHES, CRACKS, NICKS, DENTS AS WELL AS BENT PARTS INDICATE THAT THE INSTRUMENT MUST NOT BE USED. DEFECTIVE PRODUCTS SHOULD BE REPAIRED OR DISPOSED OF AS SPECIFIED BY THE HOSPITAL.  
**DAMAGED PRODUCTS MAY NOT BE USED!**

**HANDLING:** THE INSTRUMENTS MUST NOT BE OVER STRESSED BY TWISTING OR LEVERING AS THIS MAY LEAD TO DAMAGES OR CRACKING OF THE INSTRUMENTS.

**PURPOSE:** THE OPERATING INSTRUCTIONS ARE VALID FOR STANDARD SURGICAL INSTRUMENTS OF THE PRODUCTION OF ELMED. THE USER DECIDES ACCORDING TO THEIR SPECIALIZED KNOWLEDGE WHETHER THE INSTRUMENT MAY BE SUITABLE FOR THE INTENDED PURPOSE.



**CAUTION:** USE OF SELF-RETAINING RETRACTORS MUST NOT EXCEED 60 MINUTES CUMULATIVELY.  
**CAUTION:** SUCTION AND IRRIGATION CANNULAS ARE NOT SUITABLE CONNECTION TO AN ACTIVE MEDICAL DEVICE

**MATERIALS:** THE MATERIALS USED, IF NOT OTHERWISE STATED, ARE STAINLESS STEEL ACCORDING TO DIN EN ISO 7153-1.

**REPROCESSING DIRECTIONS:** SURGICAL INSTRUMENTS MAY IN GENERAL ONLY BE PROCESSED BY SPECIFICALLY SKILLED STAFF POSSESSING THE SPECIFIC KNOWLEDGE FOR THIS KIND OF WORK. DETAILED INFORMATION TO THE MAINTENANCE OF INSTRUMENTS ARE AVAILABLE IN THE "RED BROCHURE" OF THE AKI. UNDER [WWW.A-K-I.ORG](http://WWW.A-K-I.ORG) LINKS TO LAWS, NORMS AND SPECIALIZED MAINTENANCE COMMITTEES CAN BE FOUND.

**ADVICE:** INSTRUMENTS MADE OF STAINLESS STEEL MUST NOT BE PUT IN PHYSIOLOGICAL SALINE SOLUTIONS (NACL), AS LONGER CONTACT MAY LEAD TO CORROSION DAMAGES.

INSTRUMENTS MAY ONLY BE STERILIZED AFTER A PREVIOUS CLEANING AND DISINFECTION.

**INSTRUCTION:** DUE TO THE DESIGN OF SURGICAL INSTRUMENTS AND THE USED MATERIALS, IT IS NOT POSSIBLE TO DETERMINE A LIMITED NUMBER OF REPROCESSING CYCLES. THE LIFETIME OF SURGICAL INSTRUMENTS IS THEREFORE DETERMINED BY THE FUNCTION/WEAR OF THE DEVICE. \*\*IN CASE OF DAMAGE THE DEVICE MUST BE REPROCESSED BEFORE SENDING BACK TO THE MANUFACTURER FOR REPAIR.

### REPROCESSING INSTRUCTIONS

**PREPARATION AT THE POINT OF USE:** REMOVE GROSS SOILING BY SUBMERGING THE INSTRUMENT INTO COLD WATER (<40°C) IMMEDIATELY AFTER USE. DON'T USE A FIXATING DETERGENT OR HOT WATER (>40°C) AS THIS CAN CAUSE THE FIXATION OF RESIDUALS WHICH MAY INFLUENCE THE RESULT OF THE REPROCESSING PROCESS.

**TRANSPORTATION:** SAFE STORAGE AND TRANSPORTATION IN A CLOSED CONTAINER TO THE PROCESSING AREA TO AVOID ANY DAMAGE AND CONTAMINATION TO THE ENVIRONMENT.

**PREPARATION FOR DECONTAMINATION:** THE DEVICES MUST BE REPROCESSED IN AN OPENED OR DISASSEMBLED STATE. INSTRUMENTS MUST BE PLACED ON ADEQUATE SUPPORTS OR TRAYS. THE NATURE OF THE SUPPORTS OR TRAYS MUST NOT HAVE ANY NEGATIVE INFLUENCE ON THE RESULT OF THE FOLLOWING CLEANING AND DISINFECTION BY RISING OR ULTRASONIC TREATMENT.

### MANUAL PRECLEANING:

- IMMERSE THE INSTRUMENT INTO COLD TAP WATER FOR AT LEAST 5 MINUTES. DISMANTLE THE INSTRUMENTS IF POSSIBLE AND BRUSH UNDER COLD TAP WATER UNTIL ALL VISIBLE RESIDUES ARE REMOVED.
- INNER LUMENS, THREADS AND HOLES ARE FLUSHED EACH WITH A WATER JET PISTOL FOR MINIMUM 10 SECONDS IN THE PULSED MODE.
- IMMERSE THE INSTRUMENT INTO AN ULTRASONIC
- BATH WITH AN ALKALINE OR ENZYMATIC DETERGENT (0.5%) AND TREAT WITH ULTRASOUND FOR 15 MINUTES AT 40°C.
- REMOVE THE INSTRUMENTS FROM THE BATH AND RINSE AGAIN WITH COLD TAP WATER.
- THE CLEANING BATH MUST BE CHANGED AT LEAST ONCE A DAY, OR IF REQUIRED. ANY POLLUTION MAY INFLUENCE THE RESULT OF CLEANING / DISINFECTION AND MAY FAVOR CORROSION.

**AUTOMATED CLEANING:** PUT THE INSTRUMENTS OPENED ON AN INSTRUMENT TRAY. DISMANTLABLE INSTRUMENTS MUST BE TAKEN APART AS FAR AS POSSIBLE. PUT THE TRAY ON AN INSTRUMENT RACK IN THE WASHER DISINFECTOR AND START THE CYCLE:

- 1 MIN. PRE-CLEANING WITH COLD WATER
- DRAINING
- 3 MIN. PRE-CLEANING WITH COLD WATER
- DRAINING
- 5 MIN. CLEANING AT 55°C WITH 0.5 % ALKALINE; OR AT 45°C WITH AN ENZYMATIC DETERGENT.
- DRAINING

- 3 MIN. NEUTRALIZATION WITH WARM WATER (>40°C) AND NEUTRALIZER
- DRAINING
- 2 MIN. RINSING WITH WARM DESALINATED WATER (>40°C)
- DRAINING

**AUTOMATED DISINFECTION:** AUTOMATED THERMAL DISINFECTION WITH DESALINATED WATER IN WASHER DISINFECTOR UNDER CONSIDERATION OF NATIONAL REQUIREMENTS IN REGARDS TO A0-VALUE (SEE ISO 15883).

**AUTOMATED DRYING:** DRYING OF THE OUTER SIDES OF THE INSTRUMENTS BY THE DRYING CYCLE OF WASHER/DISINFECTOR. IF NECESSARY, ADDITIONAL MANUAL DRYING CAN BE PERFORMED WITH A LINT FREE TOWEL. INSUFFLATE CAVITIES OF INSTRUMENTS BY USING STERILE COMPRESSED AIR.

**MANUAL CLEANING:** IN CASE OF MANUAL CLEANING, THE CLEANING PROCESS NEEDS TO BE ADAPTED TO THE PRE-TREATMENT. THE USED DETERGENTS MUST BE COMPATIBLE, IN ORDER TO AVOID ANY NEGATIVE INFLUENCE ON THE CLEANING/DISINFECTION RESULT.

- THE DETERGENT MUST BE SUITABLE FOR THE TREATMENT OF SURGICAL INSTRUMENTS.
- THE MANUFACTURE'S INSTRUCTIONS REGARDING CONCENTRATION AND REACTION TIME MUST BE STRICTLY OBEYED.
- USE ONLY SOFT BRISTLES, NOT METAL BRUSHES.
- CHANNELS AND HOLLOW PATS MUST BE RINSED THOROUGHLY. IF NECESSARY, A HIGH PRESSURE HOSE MUST BE USED.
- RINSE THE INSTRUMENTS WITH RUNNING CLEAR WATER.
- **DRY THE INSTRUMENTS THOROUGHLY.**
- THE CLEANING BATH MUST BE CHANGED AT LEAST ONCE A DAY, OR IF REQUIRED.

**CHEMICAL DISINFECTION:** THE CHEMICAL DISINFECTANT FOLLOWS THE MANUAL CLEANING. A DETERGENT, SUITABLE FOR SURGICAL INSTRUMENTS MADE OF STAINLESS STEEL MUST BE USED.

**DRYING:** MANUAL DRYING MUST BE PERFORMED WITH A LINT FREE TOWEL. INSUFFLATE CAVITIES OF INSTRUMENTS BY USING STERILE COMPRESSED AIR

**FUNCTIONAL TESTING, MAINTENANCE:** VISUAL INSPECTION FOR CLEANNESS, ASSEMBLING AND FUNCTIONAL TESTING ACCORDING TO INSTRUCTIONS OF USE. IF NECESSARY REPROCESS AGAIN UNTIL THE INSTRUMENTS ARE VISIBLY CLEAN. INSTRUMENTS WITH MOVABLE PARTS MUST BE TREATED WITH A SPECIAL INSTRUMENT OIL, E.G. TK95100-00. INSTRUMENTS WITH A RATCHET MUST BE CLOSED IN THE FIRST POSITION. DEFECTIVE OR DAMAGED INSTRUMENTS MUST BE IMMEDIATELY SORTED OUT.

**PACKAGING:** APPROPRIATE PACKAGING FOR STERILIZATION ACCORDING ISO 11607 AND EN 868.

**STERILIZATION:** STERILIZATION OF INSTRUMENTS BY APPLYING A FRACTIONATED PRE-VACUUM PROCESS (ACCORDING. ISO 13060 / ISO17665) UNDER CONSIDERATION OF THE RESPECTIVE COUNTRY REQUIREMENTS.

#### PARAMETERS FOR THE PRE-VACUUM CYCLE:

- 3 PRE-VACUUM PHASES WITH AT LEAST 60 MILLIBAR
- HEAT UP TO A MINIMUM STERILIZATION TEMPERATURE OF 132°-134°C; MAXIMUM TEMPERATURE 137°C
- MINIMUM HOLDING TIME: AT LEAST 5 MINUTES AT 134°C
- DRYING TIME: MINIMUM 10 MINUTES
- A SAL (STERILITY ASSURANCE LEVEL) OF 10<sup>-6</sup> MUST BE ACHIEVED.
- ANY CHANGE OF THE STERILIZATION PROCESS IS BEYOND OUR RESPONSIBILITY

**STORAGE:** STORAGE OF STERILIZED INSTRUMENTS IN APPROPRIATE PACKAGING IN A DRY, CLEAN AND DUST FREE ENVIRONMENT AT MODEST TEMPERATURES 0 5°C TO 40°C, AND AT A CONSTANT HUMIDITY. THE DISTANCE BETWEEN SHELF AND FLOOR SHOULD BE AT LEAST 30CM. STORAGE DURATION TIMES IS TO BE DETERMINED BY THE USER.

#### REPROCESSING VALIDATION STUDY INFORMATION:

THE FOLLOWING TESTING DEVICES, MATERIALS & MACHINES HAVE BEEN USED IN THE VALIDATION STUDY; DETERGENT: NEODISHER FA; DR. WEIGERT; HAMBURG  
 ENDOZIME, FA. RUHOF (ENZYMATIC)  
 NEUTRALIZER: NEODISHER Z; DR. WEIGERT, HAMBURG  
 WASHER/DISINFECTOR: MIELE 7735 CD  
 INSTRUMENT RACK: MIELE E 327-06  
 KEY HOLE SURGERY RACK MIELE E 450  
 DETAILS: CLEANING: 01707011901-2 SMP GMBH

**ADDITIONAL INSTRUCTIONS:** IF THE DESCRIBED CHEMISTRY AND MACHINES ARE NOT AVAILABLE, IT IS THE DUTY OF THE USER TO VALIDATE THEIR PROCESS. IT IS THE DUTY OF THE USER TO ENSURE THAT THE REPROCESSING PROCESS INCLUDING RESOURCES, MATERIALS AND PERSONNEL ARE CAPABLE TO REACH THE REQUIRED RESULTS. STATE OF THE ART AND OFTEN NATION LAW REQUIRING THESE PROCESSES AND INCLUDED RESOURCES TO BE VALIDATED AND MAINTAINED PROPERLY.

#### 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.  
 35 N. BRANDON DR.  
 GLENDALE HEIGHTS, IL  
 60139  
 USA

WE SUBSCRIBE TO COST  
 CONTAINMENT AND  
 PROTECTION OF THE  
 ENVIRONMENT



MADE IN THE  
 USA

THEREFORE, WE  
 MANUFACTURE  
 REUSABLE PRODUCTS FOR  
 A CLEANER WORLD

PH (224) 353-6446  
 FAX (224) 653-8178  
 EMAIL  
 MEDICAL@ELMED.COM  
 WWW.ELMED.COM