



- **IMPORTANT**
THE PROBES ARE SHIPPED NON-STERILE AND MUST BE CLEANED AND STERILIZED BEFORE BEING USED THE FIRST TIME AND AFTER EVERY SUBSEQUENT USE.
- CLEAN, INSPECT THOROUGHLY AND STERILIZE BEFORE USE. EFFECTIVE CLEANING AND MAINTENANCE WILL PROLONG SERVICE LIFE.
- CLEANING AND RINSING SHOULD BE DONE PROMPTLY AFTER EVERY USE, OTHERWISE PARTICLES OR DRIED SECRETIONS MAY ADHERE TO IT, MAKING SUBSEQUENT CLEANING AND STERILIZATION DIFFICULT. INSTRUMENTS MUST BE ENTIRELY FREE OF ANY FOREIGN BODIES.

INTENDED USE

THE ELMED CLEAR VIEW DILATOR PROBES ARE INTENDED FOR VAGINAL DILATION. THESE MEDICAL GRADE DILATORS ARE MADE OF PRECISION MACHINED CAST ACRYLIC TUBING WITH GENTLE SMOOTH CURVED TIP FOR COMFORTABLE INSERTION AND GROOVED HANDLE FOR ANTI-SLIP CONTROL.

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

CLEANING

MANUAL CLEANING

ELMED CLEAR VIEW DILATOR PROBES REQUIRE SIMILAR CARE TO THAT TAKEN FOR ANY PRECISION OPTICAL COMPONENT. AFTER EACH USE, PROBES 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.

ULTRASONIC CLEANING

THE ULTRASONIC CLEANING FACILITATES THE DISLODGING OF RESIDUAL MATERIAL AND MUST BE DONE BEFORE STERILIZATION. THE ULTRASONIC CLEANING MUST LAST FOR AT LEAST 30 MINUTES.

- CLEAN THE DEVICE RIGHT AFTER ITS USE
- PUT THE INSTRUMENT IN AN ULTRASONIC CLEANING TANK
- USE ONLY TAP WATER AND THE DETERGENTS WHICH DISSOLVE ALBUMEN, ALWAYS ACCORDING TO ULTRASONIC EQUIPMENT MANUFACTURER'S INSTRUCTIONS.

AUTOMATIC/THERMAL CLEANING

ALTERNATIVELY OR ADDITIONALLY TO THE MANUAL CLEANING, THIS INSTRUMENT MAY ALSO BE CLEANED IN AUTOMATIC / THERMAL CLEANING MACHINES BY USING APPROVED ALKALINE DETERGENTS. PLEASE REFER TO RELEVANT INSTRUCTIONS OF THE CLEANING MACHINE SUPPLIER.

STERILIZATION

STEAM STERILIZATION (AUTOCLAVE)

THE CYCLE SELECTED IS DEPENDENT ON EQUIPMENT AND HOSPITAL PROTOCOL. GENERAL GUIDELINES ARE:

METHOD	CYCLE	MIN. TEMP.	STERILIZATION TIME	DRYING TIME
STEAM (WRAPPED)	PREVACUUM	270°F (132°C)	4 MINUTES	20-40 MINUTES
STEAM (WRAPPED)	GRAVITY	270°F (132°C)	10 MINUTES	20-50 MINUTES
STEAM (WRAPPED)	GRAVITY	250°F (121°C)	45 MINUTES	20-50 MINUTES

CHEMICAL DISINFECTION

IT IS RECOMMENDED THAT THE GUIDELINES BELOW PUBLISHED BY ADVANCED STERILIZATION, A JOHNSON & JOHNSON COMPANY BE FOLLOWED.

PRODUCT	HIGH LEVEL DISINFECTION	STERILIZATION
CIDEX ACTIVATED	45 MINUTES @ 25°C 77°F	10 HOURS
CIDEX PLUS 29 DAY SOLUTION	20 MINUTES @ 25°C 77°F	N/A

FLASH AUTOCLAVING (FAST HEATING/COOLING CYCLE)

WRAP DILATOR PROBES IN SURGICAL TOWEL + PLACE IN TRAY. STERILIZE FOR: 3 MINUTES 270 DEGREES F° AT (30PSI) OR 121 DEGREES C° 1 KG/CM². AVERAGE DRYING TIME IS 8 TO 15 MINUTES.

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).

GAS STERILIZATION

FOLLOW STANDARD HOSPITAL PROCEDURE FOR GAS STERILIZATION. PLACE DILATOR PROBES SEPARATELY FROM INSTRUMENTS IN A CONTAINER APPROVED FOR GENERAL USE WITH GAS STERILIZATION (SUCH AS A PERFORATED METAL TRAY), WITH GAUZE OR LOOSELY WOVEN CLOTH INSERTS FOLDED ABOUT EACH ITEM TO AVOID MOVEMENT. FOLLOWING 10:90 ETHYLENE OXIDE/OXYFUME 2002 STERILIZATION CYCLE IS VALIDATED.

IMPORTANT PARAMETERS

NOTE: THESE PARAMETERS HAVE BEEN VALIDATED TO ENSURE STERILITY. STERILIZER FUNCTIONING SHOULD BE MONITORED AT REGULAR INTERVALS WITH BIOLOGICAL INDICATORS TO ENSURE PRODUCTS HAVE BEEN SUBJECTED TO STERILIZATION CONDITIONS.

PRECONDITIONING PARAMETERS

TEMPERATURE : 55 +/-2C (131 +/- 5F)

RELATIVE HUMIDITY : >/=35%

VACUUM : 21 +/- 1 IN HG

PRE-CONDITIONING TIME : 1 HOUR

STERILIZATION PARAMETERS

ETHYLENE OXIDE CARRIER : OXYFUME 2002

TEMPERATURE : 55 +/- 2 C (131 +/- 5F)

RELATIVE HUMIDITY : >/= 35%

PRESSURE (PSIG START) : 19 +/- 1 PSIG

ETHYLENE OXIDE CONCENTRATION : 736MG/L

GAS EXPOSURE TIME (FULL CYCLE) : 4 HOURS

AERATION : 11 HOUR AT 54C (129 F) MINIMUM

WARRANTY:

- ALL ELMED INSTRUMENTS ARE WARRANTED AGAINST DEFECTS IN MATERIAL & WORKMANSHIP FOR 1 YEAR. ROUTINE RE-SHARPENING, REINSULATING, AND ADJUSTMENTS AS WELL AS REPAIR OF DAMAGED INSTRUMENTS IS AVAILABLE FOR A MOD-EST 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 SUBSE-QUENT DAMAGES THAT RESULT BY IMPROPER USAGE, IMPROPER HANDLING OR THROUGH IMPROPER PREPARATION, STERILIZA-TION 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



MADE IN THE USA

THEREFORE, WE
MANUFACTURE
REUSABLE PRODUCTS
FOR A CLEANER
WORLD

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