



FOLEY CATHETER TIP PUNCH

CLEANING, STERILIZATION & MAINTENANCE

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.

CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN (OR A PROPERLY LICENSED PRACTITIONER).

INTENDED USE: USED FOR PLACING AN END HOLE IN FOLEY CATHETERS SIZED 14 FRENCH OR LARGER.

CONTRAINDICATIONS: NONE KNOWN.

WARNINGS: NONE KNOWN.

PRECAUTIONS: NONE KNOWN.

INSTRUCTIONS FOR USE:

1. PLACE FOLEY CATHETER TIP ON STEM PUNCH.
2. SCREW PLUNGER COMPLETELY TIGHTEN TIP.
3. REMOVE FOLEY CATHETER AND DISCARD TIP MATERIAL.

DISASSEMBLY AND REASSEMBLY: TO DISASSEMBLE THE FOLEY CATHETER TIP PUNCH, UNSCREW THE THUMB SCREW BY TWISTING IT COUNTERCLOCKWISE UNTIL THE THUMB SCREW COMES COMPLETELY OUT OF THE BODY OF THE TIP PUNCH FIXTURE. DO NOT ATTEMPT TO REMOVE THE PUNCH FROM THE FIXTURE.

REASSEMBLY: CAREFULLY REINSERT THE THUMB SCREW BY TWISTING IT CLOCKWISE UNTIL THE THUMB SCREW SITS SECURELY WITHIN THE FIXTURE. DO NOT OVER TIGHTEN THE THUMB SCREW, AS THIS CAN DAMAGE THE DEVICE.

CLEANING, DISINFECTION AND STERILIZATION:

TO CLEAN:

1. DISASSEMBLE THE FOLEY CATHETER TIP PUNCH PER THE INSTRUCTIONS WITHIN THE IFU.
2. REMOVE ALL RESIDUAL ORGANIC MATTER, BLOOD AND IRRIGATION SOLUTION TO ALLOW THE STERILIZATION OR DISINFECTION MEDIUM TO CONTACT THE SURFACE OF THE DEVICE. **NOTE:** ETHYLENE OXIDE GAS AND DISINFECTION SOLUTIONS DO NOT EFFECTIVELY PENETRATE RESIDUAL ORGANIC MATTER.
3. PREPARE A MILD, NEUTRAL-PH ENZYMATIC DETERGENT (I.E., ENZOL USING 1 OZ. PER GALLON) AND WARM (30-43° C) TAP OR DEIONIZED (DI) WATER. IMMERSE DISASSEMBLED DEVICE AND SOAK FOR 20 MINUTES. USE A SOFT BRUSH TO REMOVE ALL RESIDUAL ORGANIC MATTER, BLOOD AND IRRIGATION SOLUTION FROM THE DEVICE.
4. PREPARE A FRESH, NEUTRAL-PH ENZYMATIC DETERGENT (I.E., ENZOL USING 1 OZ. PER GALLON) AND WARM (30-43°C) TAP OR DI WATER. IMMERSE DISASSEMBLED DEVICE AND PERFORM ULTRASONIC CLEANING FOR 20 MINUTES.
5. RINSE THOROUGHLY WITH CLEAN, RUNNING TAP OR DI WATER.
6. DRY ALL EXTERIOR SURFACES WITH A SOFT CLOTH.
7. DRY ALL OPENINGS WITH AN AIR PISTOL (COMPRESSED AIR)
8. PRIOR TO DISINFECTION / STERILIZATION AND REUSE, THIS PRODUCT SHOULD BE INSPECTED AND REASSEMBLED TO VERIFY THAT IT FUNCTIONS PROPERLY. GRASPING EDGES AND ALL SURFACES SHOULD BE SMOOTH AND FREE OF ABRASIONS. THE DEVICE MUST BE DISASSEMBLED AGAIN PRIOR TO DISINFECTION AND OR STERILIZATION.

NOTE: AUTOMATED CLEANING METHODS ARE NOT COMPATIBLE WITH THE FOLEY CATHETER TIP PUNCH.

DISINFECT

NOTE: CIDEX® SOLUTION IS A HIGH LEVEL DISINFECTION SOLUTION THAT HAS BEEN FOUND TO BE COMPATIBLE WITH THE FOLEY CATHETER TIP PUNCH.

1. DISASSEMBLE THE FOLEY CATHETER TIP PUNCH PER THE INSTRUCTIONS LISTED WITHIN THE IFU, IF THE DEVICE HAS BEEN REASSEMBLED BETWEEN CLEANING AND DISINFECTION.
2. ACTIVATE CIDEX® SOLUTION PER THE MANUFACTURER'S INSTRUCTIONS. TEST THE ACTIVATED SOLUTION PRIOR TO USE WITH CIDEX® SOLUTION TEST STRIPS.
3. IMMERSE DISASSEMBLED DEVICE COMPLETELY, FILLING ALL HARD TO REACH AREAS AND ELIMINATING AIR POCKETS IN CIDEX® ACTIVATED DIALDEHYDE SOLUTION FOR A MINIMUM OF 45 MINUTES AT 25°C.
4. RINSE THOROUGHLY IN A ROOM TEMPERATURE STERILE WATER FOR INJECTION (SWFI) WATER BATH. RINSE BY IMMERSING DEVICE COMPLETELY FOR A MINIMUM OF 1 MINUTE. MANUALLY FLUSH ALL HARD TO REACH AREAS WITH SWFI WATER.
5. AGITATE DEVICE UNDER SWFI WATER, BRING ABOVE WATER LEVEL THEN RE-IMMERSE.
6. REPEAT STEPS 4 AND 5, 2 ADDITIONAL TIMES USING FRESH SWFI FOR EACH OF THREE RINSES.

NOTE: AUTOMATED DISINFECTION METHODS ARE NOT COMPATIBLE WITH THE FOLEY CATHETER TIP PUNCH.

STERILIZE

ETO STERILIZATION

THIS DEVICE CAN BE STERILIZED BY ETHYLENE OXIDE (EO) GAS. EO STERILIZATION SHOULD BE PERFORMED IN ACCORDANCE WITH INDUSTRY STANDARDS WITH A VALIDATED STERILIZATION CYCLE. THE DEVICE MUST BE DISASSEMBLED PRIOR TO STERILIZATION. THE RECOMMENDED CYCLE FOR STERILIZING THIS DEVICE USING 100% EO IN A DOUBLE-POUCHED CONFIGURATION IS:

TEMPERATURE = 54.4°C

HUMIDITY = 50-80%RH

EO CONCENTRATION = 735MG/L EO

GAS DWELL TIME = MINIMUM 60 MINUTES

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 FORCEPS AND HANDLES, 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

**IT IS IMPORTANT THAT THE LONGEST DRYING CYCLE POSSIBLE IS EMPLOYED, TO PREVENT BUILD UP OF MOISTURE INSIDE THE INSTRUMENT. IF THE CYCLE OF YOUR AUTOCLAVE ALLOWS A 45 MIN DRY TIME, WE RECOMMEND IT. CORROSION, PITTING OR INTERMITTENT OPERATION ARE USUAL SIGNS OF A MOISTURE INDUCED CORROSION PROBLEM.*

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