MODULAR SCREW-APART, 3-PIECE LAPAROSCOPIC INSTRUMENTS WITH ALL HANDLE TYPES

ASSEMBLY, CLEANING, & INSTRUCTIONS

ATTENTION:

THIS INSERT IS TO SERVE AS A GUIDANCE DOCUMENT ONLY. IT IS NECESSARY TO MAINTAIN ALL NATIONAL REGULATIONS, STANDARDS AND HEALTHCARE FACILITY PROTOCOLS REGARDING THE REPROCESSING OF SURGICAL INSTRUMENTS AND/OR DEVICES. ELMED, INC. MAKES NO CLAIMS AS TO SPECIFIC CLEANING, DISINFECTING OR STERILIZING EQUIPMENT SETTINGS OR PARAMETERS.

IMPORTANT:

THESE INSTRUMENTS ARE SHIPPED NON-STERILE AND MUST BE STERILIZED BEFORE USE. IF AN INSTRUMENT WAS USED ON/IN A PATIENT WITH OR SUSPECTED TO BE INFECTED WITH CREUTZFELDT - JAKOB DISEASE (CJD), THE INSTRUMENT CANNOT BE REUSED AND MUST BE DESTROYED DUE TO THE INABILITY TO REPROCESS OR STERILIZE TO ELIMINATE THE RISK OF PATIENT/CAREGIVER CONTAMINATION. IT IS IMPORTANT TO CLEAN AND REPROCESS ALL INSTRUMENTS/DEVICES IMMEDIATELY AFTER USE TO PREVENT THE BUILD UP OF BIOHAZARD MATERIAL ALL INSTRUMENT/DEVICES MUST BE THOROUGHLY DRY BEFORE PUTTING AWAY

INTENDED USE:

THE ELMED LAPAROSCOPIC INSTRUMENTS ARE INTENDED FOR USE IN A VARIETY OF LAPAROSCOPIC/ENDOSCOPIC, THERAPEUTIC AND MINIMALLY INVASIVE PROCEDURES FOR GRASPING, DISSECTING, MOBILIZING, RETRACTING, CUTTING, SUTURING, OCCLUDING, CLAMPING SELECTED BIOLOGICAL TISSUE. THE DEVICE IS TO BE PASSED THROUGH A LAPAROSCOPIC CANNULA. COAGULATION IS ACHIEVED USING ELECTROSURGICAL ENERGY UNDER LAPAROSCOPIC SUPERVISION IF THE SELECTED HANDLE HAS AN RF- CONNECTION. IT MUST BE CONNECTED TO THE MONOPOLAR OUTPUT OF AN ELECTROSURGICAL GENERATOR IF THE SELECTED HANDLE HAS AN RF- CONNECTION.

THIS DEVICE IS INTENDED TO BE USED WITH THE OUTPUTS OF COMPATIBLE ELECTROSURGICAL GENERATORS SUCH AS ELMED, ERBE, VALLEYLAB AND COMPARABLE GENERATORS.

WARNING & PRECAUTIONS:

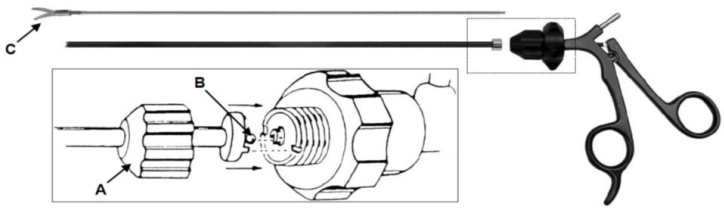
- CHECK FOR PROPER GROUNDING OF INSTRUMENT AND PATIENT PRIOR TO USE. VISUAL INSPECTION ALONE MAY NOT BE SUFFICIENT TO ENSURE THAT THE INSULATION IS INTACT. USE A ENDO TEST TO ASSURE THE INSTRUMENTS INSULATION.
- LAPAROSCOPIC PROCEDURES SHOULD BE PERFORMED ONLY BY PHYSICIANS HAVING ADEQUATE TRAINING AND FAMILIARITY WITH LAPAROSCOPIC TECHNIQUES.
- A THOROUGH UNDERSTANDING OF THE PRINCIPLES AND TECHNIQUES OF ELECTROSURGERY IS NECESSARY TO AVOID SHOCK AND BURN HAZARD TO THE PATIENT, OPERATOR, AND OPERATING ROOM PERSONNEL
- DO NOT USE IN PATIENTS WHO HAVE ELECTRONIC IMPLANTS SUCH AS CARDIAC PACEMAKERS WITHOUT FIRST CONSULTING A QUALIFIED PROFESSIONAL
- DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS OR OXIDIZING GASES (SUCH AS NITROUS OXIDE (N2O) AND OXYGEN) OR IN CLOSE PROXIMITY TO VOLATILE SOLVENTS (SUCH AS ETHER OR ALCOHOL), AS EXPLOSION MAY OCCUR.
- DO NOT PLACE INSTRUMENTS NEAR OR IN CONTACT WITH FLAMMABLE MATERIALS (SUCH AS GAUZE OR SURGICAL DRAPES). INSTRUMENTS THAT ARE ACTIVATED OR HOT FROM USE MAY CAUSE A FIRE.
- WHEN NOT USING INSTRUMENTS, PLACE THEM IN A CLEAN, DRY, HIGHLY VISIBLE AREA NOT IN CONTACT WITH THE PATIENT. INADVERTENT CONTACT WITH THE PATIENT MAY RESULT IN BURNS.
- INSPECT INSTRUMENTS AND CABLES FOR DAMAGE PRIOR TO EACH USE, ESPECIALLY THE INSULATION OF LAPAROSCOPIC/ENDOSCOPIC INSTRUMENTS. THIS MAY BE DONE VISUALLY UNDER MAGNIFICATION OR WITH A HIGH VOLTAGE INSULATION TESTING DEVICE. INSULATION FAILURES MAY RESULT IN BURNS OR OTHER INJURIES TO THE PATIENT OR OPERATOR.
- THE SURFACE OF THE ACTIVE ELECTRODE MAY REMAIN HOT ENOUGH TO CAUSE BURNS AFTER THE RF CURRENT IS DEACTIVATED
- DUE TO CONCERNS ABOUT CARCINOGENIC AND INFECTIOUS OF ELECTROSURGICAL BY PRODUCTS, PROTECTIVE EYEWEAR, FILTRATION MASK AND EFFECTIVE SMOKE EVACUATION SHOULD BE USED DURING THE PROCEDURES.
- CONNECT ADAPTORS AND ACCESSORIES TO THE ELECTROSURGICAL UNIT ONLY WHEN THE ENERGY IS OFF.
- DO NOT ACTIVATE THE INSTRUMENT WHEN NOT IN CONTACT WITH TARGET TISSUE, AS THIS MAY CAUSE INJURIES DUE TO CAPACITIVE COUPLING WITH OTHER SURGICAL EQUIPMENT.
- ASPIRATE FLUID FROM THE AREA BEFORE ACTIVATING THE INSTRUMENT. CONDUCTIVE FLUIDS IN DIRECT CONTACT WITH OR IN CLOSE PROXIMITY TO AN ACTIVE ELECTRODE MAY CARRY ELECTRICAL CURRENT OR HEAT AWAY FROM TARGET TISSUES, WHICH MAY CAUSE UNINTENDED BURNS TO THE PATIENT.
- DO NOT USE WITH HYBRID TROCAR SYSTEMS, I.E., A COMBINATION OF METAL AND PLASTIC, WHEN USING MONOPOLAR ACTIVE COMPONENTS. THIS MAY RESULT IN ALTERNATE SITE BURNS DUE TO CAPACITIVE COUPLING. USE ONLY ALL-METAL OR ALL-PLASTIC TROCAR SYSTEMS
- PRIOR TO INCREASING THE INTENSITY, CHECK THE ADHERENCE OF THE NEUTRAL ELECTRODE AND ITS CONNECTIONS. APPARENT LOW OUTPUT OR FAILURE OF THE DEVICE TO FUNCTION CORRECTLY AT THE NORMAL OPERATING SETTINGS MAY INDICATE FAULTY APPLICATION OF THE NEUTRAL ELECTRODE OR POOR CONTACT IN ITS CONNECTIONS.

CAUTIONS

- THE INTENSITY SHOULD BE SET AS LOW AS IS NECESSARY TO ACHIEVE THE DESIRED EFFECT.
- KEEP THE ACTIVE ELECTRODES CLEAN. BUILD-UP OF ESCHAR MAY REDUCE THE INSTRUMENT'S EFFECTIVENESS. DO NOT ACTIVATE THE INSTRUMENT WHILE CLEANING. INJURY TO OPERATING ROOM PERSONNEL MAY RESULT

DISASSEMBLY:

1) TURN MAIN SCREW CAP (A) COUNTERCLOCKWISE UNTIL IT DISENGAGES FROM THE HANDLE.
2) SET THE HANDLE IN THE OPEN POSITION & RELEASE THE BALL (B) OF INNER ROD OUT OF ITS FIXATION IN THE HANDLE PORT.
3) TURN THE TIP (C) COUNTERCLOCKWISE OUT OF THE TUBE.



REASSEMBLY: REVERSE STEPS OF DISASSEMBLY INSTRUCTIONS.

CLEANING AND HANDLING

IMPORTANT: OBSERVE FOR ALL CLEANING METHODS.

BE SURE TO ALWAYS CHECK THE FORCEPS TIPS. THE TIPS SHOULD BE FREE FROM ANY TISSUE OR ANY OTHER MATERIAL THAT MAY HAVE ADHERED TO IT DURING COAGULATION. UNLESS THESE TIPS ARE COMPLETELY CLEAN, THE FORCEPS WILL NOT COAGULATE PROPERTY. THE INNER TONG SHOULD BE TESTED FOR PROPER CONDUCTIVITY PRIOR TO STERILIZATION.

Immediately after each surgical procedure, clean all instruments thoroughly as follows:

1. Follow the disassembly instructions and disassembly the instrument prior to cleaning
2. Directly after use, remove any coarse soiling from the instruments with a disposable sponge moistened with water
3. Safe storage and transport of the instruments to the reprocessing room in a closed container to prevent damage to the instruments and contamination of the environment
4. Prepare enzymatic cleaner according to the prescribed direction on the container
5. Before cleaning, remove the flashing port cap
6. The device should be rinsed in deionized water and brushed to remove all visible soil
7. Immerse instruments in a cleaning solution for at least 5 minutes
8. Clean instruments with a soft brush until all visible contaminants are removed
9. Rinse out instruments for 20 seconds or, in pulsed mode, with 5 pressure surges (3 - 4 bar) using a water cleaning gun
10. Clean the jaw section of the instrument and hinge area using a brush
11. All parts should be inspected for burrs, nicks, misalignment or bent components. Insulation material should be free of nicks, gouges, scratches, and any exposed metal or breaks in the insulation

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:

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.

Function check, maintenance: Check visually for cleanliness. If necessary, repeat the reprocessing procedure until the instrument appears visually clean.

Machine Cleaning: Follow manufacturer recommendations

Automatic Washers: Follow manufacturer recommendations

STERILIZATION

Sterilization of instruments may be accomplished by steam or a chemical sterilant. Time and temperature parameters required may vary according to type of sterilizer, cycle design and packaging material. Each institution is responsible for determining the efficacy of the sterilization schedule used to sterilize this laparoscopic instrument. Please consult with the maker of your sterilizer or your facility's policy for specific guidelines and instructions. The following is provided for informational purposes:

WARNING: ELMED recommends that the instruments be sterilized dissembled. However, ELMED 3-piece laparoscopic instruments may be sterilized assembled in a steam pre-vacuum sterilizer only.

STEAM AUTOCLAVING

When Using A Wrapping Method, 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)	30 Minutes	45 Minutes

Steris V-PRO Low Temperature Sterilization

Validated- Adhere to the sterilizations instructions provided by the manufacturer. (Steris Corporation)

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

Sterrad Sterilization Process Including Sterrad NX

The 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 restriction 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 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.

Chemiclaving – Soaking: Not Recommended

This is destructive to the insulating and silicone materials of especially 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.

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