

# **REUSABLE MONOPOLAR ELECTRODES**

MAINTAINING, CLEANING & STERILIZATION

EVERY INSTRUMENT MUST BE CLEANED AND STERILIZED BEFORE BEING USED FOR THE FIRST TIME AND AFTER EVERY SUBSEQUENT USE. ALL ELECTROSURGICAL INSTRUMENTS AND ELECTROSURGICAL ACCESSORIES MUST BE ONLY USED FOR ITS INTENDED PURPOSE AND ONLY UTILIZING MONOPOLAR OR BIPOLAR RF CURRENT AS SPECIFIED.

THESE ELECTROSURGICAL INSTRUMENTS AND ELECTROSURGICAL ACCESSORIES ARE ONLY FOR USE BY A QUALIFIED PHYSICIAN FULLY TRAINED IN BOTH ELECTROSURGERY AND THE OPERATION OF ELECTROSURGICAL UNITS (ESU).

THESE ELECTROSURGICAL INSTRUMENTS AND ELECTROSURGICAL ACCESSORIES MUST BE INSPECTED PRIOR TO EACH USE TO MAKE CERTAIN THEY ARE IN PROPER WORKING ORDER.

ALL REMOVABLE ELECTROSURGICAL INSTRUMENTS AND ELECTROSURGICAL ACCESSORIES MUST BE STERILIZED BEFORE EACH USE. SELECTING THE PROPER TECHNIQUE WILL HELP TO PRESERVE THE FUNCTION AND EXTEND THE LIFE OF YOUR SURGICAL INSTRUMENTS.

## CLEANING YOUR ELECTROSURGICAL MONOPOLAR ELECTRODES

PLEASE ADHERE TO SPECIFIC CLEANING INSTRUCTIONS FOR ELECTROSURGICAL INSTRUMENTS AND ELECTROSURGICAL ACCESSORIES. ALL ACCESSORIES MAY BE CLEANED BY CONVENTIONAL PROCEDURES, INCLUDING ULTRASONIC CLEANING. THE ONLY EXCEPTION TO ULTRASONIC CLEANING ARE HANDSWITCHING (BI-CO-MATIC) BIPOLAR FORCEPS, AND HANDSWITCHING UNIPOLAR HANDLES, WHICH MUST NOT BE IMMERSED IN AN ULTRASONIC CLEANER, TO PROTECT THEIR RF-SWITCHING DEVICES. ALSO, IT SHOULD BE NOTED THAT ULTRASONIC CLEANING OVER EXTENDED PERIODS OF TIME CAN DETERIORATE THE DELICATE JOINTS OF MICRO FORCEPS. AGAIN, IT IS IMPORTANT THAT ELECTROSURGICAL ACCESSORIES BE DRY WHEN PUT INTO USE, OTHERWISE INTERMITTENT PERFORMANCE WILL BE OBTAINED.

## **CLEANING**

# **IMPORTANT:** OBBSERVE FOR ALL CLEANING METHODS

Re-inspect all internal chamber and crevices after cleaning to verify that all surfaces are clean of all foreign materials included tissue particles

### 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 ITH 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.

### **AUTOMATIC WASHERS:** FOLLOW MANUFACTURER RECOMMENDATIONS

### **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  $40^{\circ}$ C /  $104^{\circ}$ 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.

## **AUTOCLAVING METHODS**

**ETO STERILIZATION:** WITH A PRESSURE READING NOT TO EXCEED 12 PSI, AND A TEMPERATURE NOT TO EXCEED 68.3°C (155°F), THE ELECTROSURGICAL ACCESSORIES CAN BE STERILIZED BY ETHYLENE OXIDE IN ANY STANDARD CYCLE. CONCERNING HUMIDIFICATION, VACUUM, CYCLE TIME, GAS CONCENTRATION AND TEMPERATURE, WE RECOMMEND FOLLOWING THE MANUFACTURER'S INSTRUCTIONS FOR THE ETO STERILIZATION UNIT.

STEAM AUTOCLAVING WITH PRE VACUUM 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)	30 MINUTES	45 MINUTES

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

#### FLASH AUTOCLAVING (FAST HEATING/COOLING CYCLE)

FLASH STERILIZATION: MINIMUM EXPOSURE TIME – 4 MINUTES. 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.

#### **COLD SOAKING**

THERE IS NOTHING DETRIMENTAL ABOUT THE USE OF GLUTARALDEHYDE OR OTHER COLD SOAKING SOLUTIONS, AS LONG AS THE ACCESSORIES ARE DRIED COMPLETELY PRIOR TO USE.

### 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).

### CHEMICLAVING

THIS IS THE MOST DESTRUCTIVE METHOD TO THE INSULATING AND SILICONE MATERIALS OF ELECTROSURGICAL ACCESSORIES AND CAN CAUSE RAPID DETERIORATION AND FAILURE.

#### **TESTING AND MAINTENANCE**

IT IS MOST IMPORTANT THAT ALL ELECTROSURGICAL INSTRUMENTS AND ELECTROSURGICAL ACCESSORIES BE INSPECTED PRIOR TO EACH SURGICAL PROCEDURE, FOR SIGNS OF DETERIORATION. ALSO, ALL ACCESSORIES MUST BE THOROUGHLY INSPECTED AND TESTED BY A QUALIFIED BIOMEDICAL TECHNICIAN TO INSURE PROPER PERFORMANCE. HAVING AN EXTRA SET OF ACCESSORIES ON HAND IS ALWAYS RECOMMENDED.

ELECTROSURGICAL CABLES PARTICULARLY ARE CONSIDERED WEAR AND TEAR ITEMS, AND DURING HEAVY USAGE. ELECTROSURGICAL CABLES WHICH HAVE ANY CRACKS OR BREAKS IN THEIR INSULATION SHOULD BE REPAIRED OR REPLACED UPON ANY OBSERVATION OF CRACKED OR PEELING INSULATION, INTERMITTENT PERFORMANCE, OR WHEN ANY CORROSION IS PRESENT. ANY SUCH INSTRUMENT SHOULD BE IMMEDIATELY FORWARDED FOR REPAIR OR REPLACED.

WHEN UNPLUGGING CABLES FROM EQUIPMENT OR INSTRUMENTS, GRAB THE JACKET OF THE PLUG AND DO NOT PULL ON THE WIRE. THE LATTER WILL BREAK THE UNION BETWEEN THE PLUG AND THE CABLE.

#### \*\*\* WARNING \*\*\*

MANY ELECTROSURGICAL ACCIDENTS HAVE BEEN CAUSED BY FAULTY ACCESSORIES, BY FAILURE TO CHECK FOR AND IDENTIFY THESE ACCESSORIES PRIOR TO EACH PROCEDURE AND BY CARELESS USE.

THE USE OF THE DEVICE WITH SAFELY FUNCTIONING AND COMPATIBLE HANDLES, CORDS, ELECTROSURGICAL GENERATORS AND ACCESSORIES IS THE USER'S RESPONSIBILITY. READ AND UNDERSTAND ALL PRECAUTIONS AND INSTRUCTIONS BEFORE ATTEMPTING TO USE ANY ELECTROSURGICAL DEVICE.

ELMED SPECIALIZES IN THE DESIGN AND MANUFACTURE OF NEW INNOVATIVE INSTRUMENTS AND EQUIPMENT, THE REPAIR OF ALL COMPETITIVE PRODUCTS AND A ONE-DAY TURN AROUND TIME ON REPAIRS.

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

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