



# ELMED BIPOLAR SUBMUCOSAL TURBINATE (DENNIS) PROBE

## OPERATING RECOMMENDATIONS, STERILIZATION INSTRUCTIONS, & WARNINGS



### **\*\*IMPORTANT\*\***

THE ELMED BIPOLAR TURBINATE PROBE WAS DESIGNED TO PERFORM BIPOLAR SUBMUCOSAL COAGULATION OF THE INFERIOR ONE-HALF OF THE INFERIOR TURBINATE LONGITUDINALLY. DO NOT USE THIS INSTRUMENT FOR ANY OTHER PURPOSE OR SURGICAL PROCEDURE.

THE ELMED BIPOLAR TURBINATE PROBE IS TRULY A BIPOLAR INSTRUMENT AND MUST BE ENERGIZED ONLY BY A LOW VOLTAGE BIPOLAR GENERATOR.

THE PROBE IS EQUIPPED WITH A PLUG CONNECTOR FOR DETACHABLE BIPOLAR RF-CABLES, WHICH MUST BE CHOSEN DEPENDING ON THE BIPOLAR GENERATOR TO BE USED. THE FOLLOWING TWO CABLES ARE AVAILABLE: ITEM NO. **5302** & ITEM NO. **5230**

### ACCEPTABLE METHODS OF STERILIZATION FOR THE ELMED BIPOLAR SUBMUCOSAL TURBINATE (DENNIS) PROBE BELOW:

#### 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 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* <sup>3</sup>
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

\*<sup>3</sup> 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 30 MIN DRY TIME, WE RECOMMEND TO USE 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 AT 132°C. 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.

#### 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).

## 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.

## SELECTING THE PROPER BIPOLAR GENERATOR

**CAUTION:** NEVER PERFORM SUBMUCOSAL TURBINATE SURGERY WITH THIS INSTRUMENT USING A UNIPOLAR GENERATOR OR A HIGH-VOLTAGE BIPOLAR GENERATOR. POST-OPERATIVE BLEEDING OR EVEN BLINDNESS MAY BE THE CONSEQUENCE.

## OPERATING PARAMETER OF THE BIPOLAR GENERATOR

FREQUENCY	600 KHZ TO 2 MHZ, NON-MODULATED
ISOLATION FACTOR	THE BIPOLAR GENERATOR MUST BE ISOLATED (FLOATING) WITH A MIN. ISOLATION EFFICIENCY OF 98%.
PEAK TO PEAK VOLTAGE:	NEVER TO EXCEED 400 VOLTS PEAK TO PEAK AT MAXIMUM GENERATOR OUTPUT. OPERATING VOLTAGE (SETTINGS 3-6) SHOULD BE LESS THAN 100 VOLTS PEAK TO PEAK. THIS IS VERY IMPORTANT, AS THE SURGICAL PROCEDURE IS TO DEHYDRATE THE TISSUE AND NOT TO CHAR, OVERHEAT OR ARC ACROSS IT. SINCE SOME BIPOLAR GENERATORS ARE ENERGIZED BY HIGH VOLTAGE MODULATED CURRENT, DANGER EXISTS OF POST-OPERATIVE BLEEDING, EXCESSIVE TISSUE TRAUMA, CARBONIZATION AND OTHER COMPLICATIONS.
WATTAGE:	REQUIREMENTS RANGE FROM 15 TO 25 WATTS FOR THE PROCEDURE. ACQUAINT YOURSELF WITH THE INSTRUMENT: PRIOR TO USING THE PROBE IN SURGERY, THE COAGULATION AND POWER REQUIREMENTS SHOULD BE OBSERVED ON A FRESH PIECE OF LEAN BEEF. SETTINGS OF BETWEEN 3 & 6 ON THE ELMED BC 50 M/M (IN THE MACRO POSITION) ARE SUGGESTED.

**CAUTION:** SINCE BIPOLAR GENERATORS AVAILABLE IN CLINICS AND HOSPITALS ARE NON-UNIFORM WITH RESPECT TO OUTPUT FREQUENCY, PEAK TO PEAK VOLTAGE AND WATTAGE, WE CANNOT RECOMMEND THE USE OF THIS PROBE ON EXISTING EQUIPMENT WITHOUT ASSURANCE THAT THE ABOVE PARAMETERS HAVE BEEN MET. ALL ELMED BIPOLAR GENERATORS, PARTICULARLY THE BC 50 M/M AND THE ELMED 120 DIGITAL M/M ARE RECOMMENDED FOR BIPOLAR SUBMUCOSAL TURBINATE SURGERY AND OTHER ENT APPLICATIONS.

## FOOTSWITCHES

WHEN OPERATING THE BIPOLAR GENERATOR WITH THIS PROBE, MAKE CERTAIN THAT THE UNIT'S MODE OF SWITCHING SELECTOR IS IN THE "FOOTSWITCH" POSITION. "HAND" SWITCHING OR "AUTOMATIC" SWITCHING MUST NOT BE USED IN BIPOLAR SUBMUCOSAL TURBINATE SURGERY.

**CAUTION:** THE FOOTSWITCH MUST BE POSITIONED SO THAT ONLY THE SURGEON HAS ACCESS TO IT AND SO THAT IT WILL NOT BE ACCIDENTALLY STEPPED ON. THE FOOTSWITCH MUST ONLY BE DEPRESSED AFTER THE PROBE IS IN PLACE IN THE SURGICAL AREA AND THAT THE SURGEON IS CERTAIN THAT DEHYDRATION IS TO COMMENCE.

THE ELMED BIPOLAR TURBINATE PROBE SHOULD NOT BE USED FOR ANY OTHER PURPOSE OR SURGICAL PROCEDURE OTHER THAN WHAT IT WAS DESIGNED FOR.

IN CASE THE PROBE IS IN NEED OF REPAIR IT MUST ONLY BE GIVEN TO A QUALIFIED BIOMEDICAL TECHNICIAN FOR SERVICE. ELMED INCORPORATED PROVIDES A ONE-DAY TURN-AROUND TIME FOR ALL SERVICE, INCLUDING THIS DEVICE.

FOR ADDITIONAL INSTRUCTION AND RECOMMENDATIONS PLEASE CONSULT THE OPERATION MANUAL FOR YOUR BIPOLAR GENERATOR.

ELMED PROVIDES A VIDEO TAPE, ITEM NO. 5975, WHICH FEATURES THE CLINICAL USE OF SUBMUCOSAL TURBINATE SURGERY, FEATURING DR. DENNIS.

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

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CONTAINMENT AND  
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