BIPOLAR RESECTOSCOPE

CLEANING, STERILIZATION & MAINTENANCE

PLEASE READ ALL INFORMATION CONTAINED IN THIS INSERT ATTENTIVELY.
INCORRECT HANDLING AND CARE, AS WELL AS MISUSE, CAN LEAD TO PREMATURE WEAR OR RISKS TO PATIENTS AND USERS

INTENDED USE

THE PLASMALOOP WAS DEVELOPED IN PARTICULAR FOR THE TRANSURETHRAL RESECTION (TUR). THE INSTRUMENT USED TO ABLATION IN LAYERS AND COAGULATE FROM TISSUE OF THE BLADDER OR PROSTATE GLAND. USING OF SUITABLE ELECTRODE (REF 867000XX) TISSUE CAN BE CUT OR COAGULATE.
USING OF A RESECTOSCOPE SHEATH, CONTINUOUSLY RINSING SHEATH (CH24/26; CH24/27) OR SINGLE RINSING SHEATH (CH24), THE PLASMALOOP IS INTRODUCED. THE CUTTING OR COAGULATING RESULT FROM ELECTRIC ENERGY, GENERATED BY HF GENERATORS FOR THE ELECTRIC SURGERY. THE FULLY ASSEMBLED INSTRUMENT (IF ASSEMBLY IS NEEDED) HAS TO BE CONNECTED – WITH THE APPROPRIATE CABLE - TO MONOPOLAR OR BIPOLAR OUTPUT OF AN HF GENERATOR.
ONLY THE DEFINED PARAMETERS HAS TO BE USED. WHEN INDICATED, MONOPOLAR OR ACCORDINGLY BIPOLAR COAGULATION OR CUTTING CURRENT CAN BE SELECTIVELY APPLIED.

MAXIMUM OUTPUT VOLTAGE OF THE GENERATOR: UMAX: 800 VP
APPROPRIATE CONNECTING CABLES: BISSINGER BIPOLAR CABLE REF 801 00XXX.
SUITABLE ACCESSORIES: RESECTOSCOPE SHAFT REF 867100XX CYSTOSCOPE REF 30-0XXX-XX

INSTRUMENTS FOR ELECTROSURGERY MUST ONLY BE USED BY PERSONS WHO HAVE BEEN SPECIALLY TRAINED OR INSTRUCTED IN THIS.

CONTRAINDICATIONS

INCIDENTS WHICH HAVE BEEN REPORTED IN CONNECTION WITH THE USE OF BIPOLAR SYSTEMS:

- UNINTENDED ACTIVATION WITH RESULTING TISSUE INJURY ON THE WRONG SPOT AND/ OR DAMAGE TO THE EQUIPMENT.
- FIRE IN CONNECTION WITH SURGICAL DRAPES AND OTHER INFLAMMABLE MATERIALS.
- ALTERNATING CURRENT PATHS LEADING TO BURNS ON SPOTS WHERE THE PATIENT OR USER COMES INTO CONTACT WITH COMPONENTS WITHOUT INSULATION.
- EXPLOSIONS CAUSED BY SPARKS IN THE PROXIMITY OF INFLAMMABLE GASES.
- PERFORATION OF ORGANS. SUDDEN SEVERE BLEEDINGS.

USE AND SAFETY INSTRUCTIONS

NON-OBSERVANCE OF THESE USE AND SAFETY INSTRUCTIONS MAY LEAD TO INJURIES, MALFUNCTIONS OR OTHER UNEXPECTED INCIDENTS.

- BEFORE INITIAL USE AND ANY FURTHER USE, ALL INSTRUMENTS MUST BE COMPLETELY CLEANED, DISINFECTED AND STERILIZED AND THEIR FUNCTION MUST BE CHECKED.
- IT IS VERY IMPORTANT TO CHECK EVERY SURGICAL INSTRUMENT FOR VISIBLE DAMAGE AND WEAR, SUCH AS CRACKS, BREAKS OR INSULATION DEFECTS BEFORE EACH USE. IN PARTICULAR AREAS SUCH AS BLADES, TIPS, NOTCHES, LOCKING AND BLOCKING DEVICES, AS WELL AS ALL MOVABLE PARTS, INSULATIONS AND CERAMIC ELEMENTS MUST BE CHECKED CAREFULLY.
- NEVER USE DAMAGED INSTRUMENTS.
- NEVER USE THE INSTRUMENTS IN THE PRESENCE OF FLAMMABLE OR EXPLOSIVE SUBSTANCES.
- WHEN TEMPORARILY NOT IN USE, THE INSTRUMENT MUST BE PLACED ELECTRICALLY INSULATED FROM THE PATIENT.
- RESECTION MAY ONLY BE USED IN AN ELECTRICALLY LEADING-CAPABLE PHYSIOLOGIC SALT SOLUTION.
- ACTIVATE ELECTROSURGICAL CURRENT ONLY IF THE CONTACT AREAS ARE IN FULL VIEW AND HAVE GOOD CONTACT WITH THE TISSUE THAT NEEDS TO BE TREATED. DO NOT TOUCH ANY OTHER METALLIC INSTRUMENTS, TROCAR SLEEVES, OPTICS OR SIMILAR OBJECTS DURING USE.
- ELECTRODES MUST NOTICEABLY SNAP INTO THE WORKING ELEMENT WHEN INSERTED. ELECTRODES THAT ARE NOT FULLY INSERTED CAN CAUSE ELECTRICAL PROBLEMS.
- ONLY USE PARAMETER SETTINGS SUITABLE FOR THE SPECIFIC OPERATION. IF THE STANDARD OUTPUT SETTING OF THE ELECTROSURGICAL GENERATOR DOES NOT RESULT IN THE DESIRED EFFECT, ALL COMPONENTS NEED TO BE INSPECTED FOR CORRECT CONNECTIVITY OR POTENTIAL DAMAGES BEFORE THE OUTPUT SETTING IS INCREASED.
- IF THE ELECTRODE IS LOCATED IN AN AIR- OR GAS BLADDER, DO NOT ACTIVATE ELECTROSURGICAL CURRENT.
- OBSERVE THE USE AND SAFETY INSTRUCTIONS OF THE MANUFACTURER OF THE HIGH-FREQUENCY SURGICAL DEVICE

ASSEMBLY AND OPERATION

FOR ASSEMBLY AND DISASSEMBLY OF THE INSTRUMENT FOLLOW THE PICTOGRAM, WHICH IS AVAILABLE UPON REQUEST, OR CAN BE DOWNLOADED ON WWW.BISSINGER.COM. DURING ASSEMBLY PAY ATTENTION TO COMPLETE INSERTION OF THE ELECTRODES, OTHERWISE THIS CAN LEAD TO SPARKING.
WHEN ASSEMBLED CORRECTLY, THE INSTRUMENT CAN BE HELD IN BOTH THE RIGHT AND LEFT HAND. WITH OPERATE OF THE HANDLE THE ELECTRODE IS MOVED.
WHEN INDICATED, MONOPOLAR OR ACCORDINGLY BIPOLAR COAGULATION OR CUTTING CURRENT CAN BE SELECTIVELY APPLIED.

REPROCESSING

DUE TO THE PRODUCT DESIGN, THE RAW MATERIALS USED AND THE INTENDED PURPOSE IT IS NOT POSSIBLE TO DETERMINE A PRECISE LIMIT WITH REGARD TO THE MAXIMUM POSSIBLE NUMBER OF REPROCESSING CYCLES. THE SERVICEABLE LIFE OF THE INSTRUMENTS IS DETERMINED BY THEIR FUNCTION AS WELL AS BY A CAREFUL HANDLING.
INSTRUMENTS FOR ELECTRO SURGERY ARE BY NATURE SUBJECT TO INCREASED WEAR DEPENDING ON THE TYPE AND TIME OF USE.

PREPARATION AND TRANSPORT

REMOVE COARSE DIRT FROM THE INSTRUMENTS IMMEDIATELY AFTER EACH USE. DO NOT USE FIXATION AGENTS OR HOT WATER (>40°C). STORAGE AND TRANSPORT OF THE INSTRUMENTS TO THE REPROCESSING LOCATION MUST BE ENSURED IN A SEALED CONTAINER.
COMPLEX INSTRUMENTS MUST BE TAKEN APART FOR CLEANING AND DISINFECTION IN ACCORDANCE WITH PICTOGRAM.

MANUAL PRE-CLEANING

1. IMMERSE THE INSTRUMENT IN COLD WATER FOR 5 MINUTES. IF POSSIBLE DISASSEMBLE THE INSTRUMENTS AND CLEAN WITH A SOFT BRUSH UNDER COLD WATER UNTIL ALL VISIBLE IMPURITIES ARE REMOVED. IN CAVITIES, HOLES AND THREADS FLUSH WITH A WATER JET PISTOL AT LEAST FOR 10 SEC. (PULSED PROCESS).
2. PLACE THE INSTRUMENTS IN AN ULTRASONIC BATH WITH A 0.5% ALKALINE-ENZYMATIC CLEANING DETERGENT. ULTRASOUND MUST BE APPLIED FOR 15 MINUTES AT 40°C/104°F. MAKE SURE THAT THE INSTRUMENTS ARE COMPLETELY WET.
3. REMOVE THE INSTRUMENT AND RINSE THEM COMPLETELY WITH COLD WATER TO REMOVE THE CLEANING DETERGENT.

MACHINE REPROCESSING-*CLEANING*

PLACE THE INSTRUMENTS IN A BASKET ON THE INSERT MODULE OR ON THE INSERTS OF THE MIS MODULE AND START THE CLEANING PROCESS.

1. PRERINSE FOR 1 MIN. WITH COLD WATER
2. DISCHARGING
3. PRERINSE FOR 3 MIN. WITH COLD WATER
4. DISCHARGING
5. WASH FOR 5 MIN. AT 55°C WITH A 0.5% ALKALINE OR AT 45°C WITH AN ENZYMATIC CLEANING AGENT.
6. DISCHARGING
7. NEUTRALIZE FOR 3 MIN. WITH WARM TAP WATER (>40°C) AND A NEUTRALIZING AGENT.
8. DISCHARGING
9. RINSE FOR 2 MIN. WITH WARM TAP WATER (>40°C).
10. DISCHARGING

DISINFECTION: MACHINE OPERATED THERMAL DISINFECTION HAS TO BE CARRIED OUT IN CONSIDERATION OF THE NATIONAL REQUIREMENTS WITH REGARD TO THE A0 VALUE (SEE ISO 15883).

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.

MANUAL REPROCESSING: CANNOT BE APPLIED FOR THIS INSTRUMENT.

FUNCTIONAL TEST AND PACKAGING: PERFORM VISUAL INSPECTION FOR CLEANLINESS AND INTEGRITY.; IF REQUIRED, PERFORM AN ASSEMBLY AND FUNCTIONAL TEST ACCORDING TO THE OPERATING INSTRUCTIONS.
IF NECESSARY, REPEAT THE REPROCESSING PROCESS UNTIL THE INSTRUMENT IS OPTICALLY CLEAN.
PERFORM AN ASSEMBLY AND FUNCTIONAL TEST. PACKAGING HAS TO COMPLY WITH ISO 11607 AND EN 868 STANDARDS FOR PACKAGING FOR STERILIZED INSTRUMENTS.

STERILIZATION: STERILIZATION OF THE PRODUCTS WITH FRACTIONAL PRE-VACUUM PROCEDURE (IN ACCORDANCE WITH ISO 13060 / ISO 17665) UNDER OBSERVATION OF THE RESPECTIVE NATIONAL REQUIREMENTS.

- 3 PRE-VACUUM PHASES WITH A PRESSURE OF AT LEAST 60 MBAR.
- HEATING UP TO A STERILIZATION TEMPERATURE OF MIN. 132°C AND MAX. 137°C
- EXPOSURE TIME: AT LEAST 3 MIN.
- DRYING TIME: AT LEAST 10 MIN.

STORAGE: STERILIZED INSTRUMENTS MUST BE STORED IN A DRY, CLEAN AND DUST-FREE ENVIRONMENT. THE APPLICABLE NATIONAL GUIDELINES MUST BE FOLLOWED.

REPAIRS: NEVER ATTEMPT TO PERFORM REPAIRS YOURSELF. SERVICE AND REPAIR WORK MUST ONLY BE PERFORMED BY PERSONS TRAINED AND QUALIFIED ACCORDINGLY. IF YOU HAVE ANY QUESTION REGARDING THESE MATTERS, CONTACT EITHER THE MANUFACTURER OR YOUR MEDICO-TECHNICAL DEPARTMENT.

⚠ DEFECTIVE PRODUCTS MUST COMPLETE THE ENTIRE REPROCESSING PROCESS BEFORE BEING RETURNED FOR REPAIR.

INFORMATION ON THE VALIDATION OF THE RECONDITIONING

THE FOLLOWING TESTING INSTRUCTIONS, MATERIALS AND EQUIPMENT HAVE BEEN USED FOR VALIDATION:

CLEANING AGENTS (FOR MACHINE USE):	CLEANING AGENTS (MANUAL CLEANING):	NEUTRALIZING AGENT:	CLEANING AND DISINFECTION DEVICE:
NEODISHER FA BY DR. WEIGERT (ALKALINE)	*ENZOL ENZYM, DETERGENT BY JOHNSON & JOHNSON*	*NEODISHER Z BY DR. WEIGERT*	*MIELE G 7736 CD*
ENDOZIME BY RUHOF (ENZYMATIC)	DISINFECTANTS (MANUAL DISINFECTION):		*MIELE INSERT MODULE E 327-06*
	CIDEX OPA, JOHNSON & JOHNSON		MIELE MIS MODULE E 450

IF THE CHEMICALS AND MACHINES DESCRIBED ABOVE ARE NOT AVAILABLE, THE USER HAS TO VALIDATE THE USED PROCESS ACCORDINGLY.

HANDLING

DURING TRANSPORT, CLEANING, CARE, STERILIZATION AND STORAGE, ALL SURGICAL INSTRUMENTS SHOULD BE HANDLED WITH MAXIMUM CARE. THIS APPLIES PARTICULARLY TO BLADES, FINE TIPS AND OTHER SENSITIVE AREAS.

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

SYMBOLS

BATCH CODE

UNSTERILE


REFER TO INSTRUCTIONS FOR USE

CE-MARK AND REGISTRATION NUMBER OF THE NOTIFIED BODY


MANUFACTURER PRODUCTION DATE

ATTENTION: ACCORDING TO US -LAWS, THIS DEVICE MUST ONLY BE SOLD BY A DOCTOR OR ON THE INSTRUCTION OF A DOCTOR.

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

ELMED INC.
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GLENDALE HEIGHTS, IL
60139
USA

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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