Bipolar and Monopolar Electrodes

ENGLISH

Bipolar and Monopolar Electrodes

INSTRUCTIONS FOR USE

REF

856204xx, 856370xx
85904000, 85904001
85600100 – 85600700
85630100 – 85630900
85900000 – 85902403
85907000 – 85907007

CE 0297

Günter Bissinger Medizintechnik GmbH
Hans-Theisen-Str.1
79331 Teningen
Germany

Tel.: +49 7641 9 14 33 0
Fax: +49 7641 9 14 33 33
Email: info@bissinger.com
www.bissinger.com

⚠ Please read all information contained in this insert attentively.
Incorrect handling and care, as well as misuse, can lead to premature wear of surgical instruments or risks to patients and users.

Intended Use
Bipolar electrodes for open surgery
The bipolar electrodes (REF 856204xx, 856370xx) are used for cutting and coagulation of biological tissue. The fully assembled instrument (if assembly is needed) has to be connected – with the appropriate cable - to the bipolar output of an HF generator.
Only the defined parameters have to be used. The product is a prescription device and is designed exclusively for use by trained medical personnel.

Maximum output voltage of the generator, U_{max}:
500 Vp , 250 Vp (depending on the type, see catalogue)

Appropriate connecting cables for bipolar electrodes for open surgery:
Bissinger bipolar cable REF 801 00xxx.

Bipolar and monopolar electrodes for MIS
The bipolar electrodes for MIS (REF 85600100-85600700 und 85630100-85630900) are intended to be used for coagulation of biological tissue.
The monopolar electrodes (REF 85900000-85902403) are intended to be used for coagulation of biological tissue.
The electrodes are intended for use in minimally invasive and especially laparoscopic surgical procedures. The instrument has to be inserted through a trocar sleeve with the appropriate diameter. The monopolar hysterectomy loop (REF 85902xxx) electrode is intended to be used for removal of the uterus in supracervical hysterectomies.
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. When indicated, monopolar or accordingly bipolar coagulation or cutting current can be selectively applied.

Maximum output voltage of the generator, U_{max}:
for bipolar electrodes for MIS:
500 Vp , 300 Vp , 250 Vp (depending on the type, see catalogue)

for monopolar electrodes for MIS:
2kV

Suitable cables for bipolar electrodes for MIS:
Bissinger bipolar cable REF 801 00xxx.

Suitable cables for monopolar electrodes for MIS:
Bissinger Monopolar Cable REF 801 00xxx.

⚠ *Instruments for electrosurgery must only be used by persons who have been specially trained or instructed in this.*

Contraindications
- Do not use the instrument if, in the opinion of the attending physician, the risks to the patient outweigh the benefits.

Incidents that have been reported in connection with the use of electrosurgical systems
- Unintended activation with resulting tissue injury in the wrong location 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
Before initial use and any further use, all instruments must be completely cleaned, disinfected and sterilised and their function must be checked.
- DO NOT USE in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
- DO NOT USE in the presence of flammable anaesthetics 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 and wear 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. Additionally, areas such as blades, tips, notches, locking and blocking devices, as well as all movable parts and ceramic elements must be checked carefully.
- The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.
- 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
- 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.
- Never use any damaged instruments.
- Observe the use and safety instructions of the manufacturer of the high-frequency surgical device.

⚠ Applies for monopolar mode of operation:
Ensure correct application of the neutral electrode on the patient; otherwise, there is a danger of burns.

⚠ Applies for monopolar mode of operation:
Ensure correct application of the neutral electrode on the patient; otherwise, there is a danger of burns.

Assembly
For assembly and disassembly of the instrument follow the pictogram, which is available upon request, or can be downloaded on www.bissinger.com.

Special instructions for the hysterectomy loop electrode
- Insert the instrument through the cannula with the loop pulled inside the shaft.
- Thoroughly check correct placement of the loop around the uterus prior to activation of the electrical current; the entire tissue surrounded by the loop will be cut.
- After correct placement, maintain tension of the loop to avoid uncontrolled slip of the loop. Maintain some safety distance to the ligature.
- During electrosurgical cutting, pull the loop continuously inside the shaft. Cutting will start at the uninsulated part of the loop wire.
- The loop wire is a replaceable, sterilisable product for single use that should be replaced following each procedure.

Reprocessing
Due to the product design, the materials used and the intended purpose, it is not possible to define a 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 electrosurgery are by their nature subject to increased wear depending on the type and time of use.

Preparation and transport
Immediately after each use, clean the instruments with a soft brush under cold tap water until all visible contamination is removed. Do not use fixation agents or hot water (>40°C). Storage and transport of the instruments to the reprocessing location must take place in a sealed container.
Complex instruments must be taken apart for cleaning and disinfection in accordance with pictogram.

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 with cold water for 1 min
2. Discharge
3. Prerinse with cold water for 3 min.
4. Discharge
5. Wash at 55°C with a 0.5% alkaline or at 45°C with an enzymatic cleaning agent for 5 min.
6. Discharge
7. Neutralise with warm tap water (>40°C) and a neutralising agent for 3 min.
8. Discharge
9. Rinse with warm tap water (>40°C) for 2 min.
10. Discharge

Disinfection
Machine-operated thermal disinfection must be carried out under observation of the national requirements regarding 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
Ultrasonic pre-cleaning
1. The instruments are placed in an ultrasonic bath with 0.5% enzymatic cleaning detergent and treated with ultrasound for 15 minutes at 40°C/104°F.
2. Remove the instrument and rinse them completely with cold water to remove the cleaning detergent.

Cleaning
Prepare a cleaning bath according to the manufacturer's instructions.
1. Rinse products with cold tap water (<40°C) until all visible contamination has been removed. Remove adhering 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.
4. *The following step only applies to channels and the insides of tubes:* Push the brush into and out of the tubes at least six times. Rinse the tubes with DI water. Repeat the procedure.
5. Rinse the products thoroughly with DI water to remove the cleaning agents without residue.

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 very thoroughly with DI water to remove the disinfectant without residue.

Drying
Manual drying is carried out using a lint-free cloth and sterile compressed air, in particular for drying cavities and channels.

Functional test and packaging
Perform visual inspection for cleanliness and integrity; if required, perform an assembly and functional test.
If necessary, repeat reprocessing until the instrument is visually clean. Packaging must comply with the ISO 11607 and EN 868 standards for packaging for sterilised instruments.

Sterilisation
Sterilisation 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 sterilisation temperature of at least 132°C and at most 137°C
- Exposure time: at least 3 min.
- Drying time: at least 10 min.

⚠ If contamination with prions (CJD) is suspected, differing national guidelines are to be followed and longer holding times (i.e. 15 min.) may apply.

Storage
Sterilised 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):
Neodisher FA by Dr. Weigert (alkaline)
Endozime by Ruhof (enzymatic)
Cleaning agents (manual cleaning):
Cidezyme, Enzol Enzym detergent, Johnson&Johnson
Disinfectants (manual disinfection):
Cidex OPA, Johnson&Johnson
Neutralising agent:
Neodisher Z by Dr. Weigert
Cleaning and disinfection device:
Miele Desinfector G 7735 CD
Miele insert module E 327-06
Miele MIS module E 450

For details, see report.
SMP GmbH # 01707011901 (machine cleaning)
MDS GmbH # 135196-10 (manual cleaning, sterilisation)
Nelson Labs # 200432706-02 (sterilisation)
MDS GmbH Testbericht 084183-10 (sterilisation)

If the chemicals and machines described above are not available, the user has to validate the used process accordingly.

Handling
During transport, cleaning, care, sterilisation and storage, all surgical instruments should be handled with maximum care.
This applies particularly to blades, fine tips and other sensitive areas.

Disposal
Disposal must be carried out in accordance with the respective applicable local and national laws and regulations.

Warranty
Günter Bissinger Medizintechnik GmbH exclusively supplies tested and faultless products to its customers.
All products are designed and manufactured to comply with maximum quality requirements. We refuse any liability for products which have been modified as compared to the original product, misused or handled or used improperly.

Explanation of symbols

LOT	Batch code
NON STERILE	Unsterile
REF	Reference number
⚠	Attention
	Refer to instructions for use
CE 0297	CE-Mark and registration number of the Notified Body DQS Medizinprodukte GmbH August-Schanz-Straße 21 60433 Frankfurt, Germany
	Manufacturer Production date
Rx ONLY	Attention:According to US-laws, this device must only be sold by a doctor or on the instruction of a doctor.
MD	Indicates that the product is a medical device