POWEREDGE

Bipolar vessel sealing and coagulation instrument

ENGLISH

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INSTRUCTIONS FOR USE

REF
82710001 - 82710601

CE 0297

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

Intended Use
The POWEREDGE bipolar vessel sealing and coagulation instrument with cutting mechanism is intended for use in minimally invasive and especially laparoscopic surgical procedures. The device is to be passed through a 5.5 mm laparoscopic cannula.
The Instrument is designed to grasp, compress, seal or coagulate selected vessels and vascular bundles or tissue so that they can then be mechanically separated with the appropriate POWEREDGE blade.
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, U_{max}:
400 V_p

Suitable Bissinger acccessoires:
Bissinger POWEREDGE-blade REF 82710300
Bissinger bipolar cable REF 80100xxx.

⚠ *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
Non-observance of these use and safety instructions may lead to injuries, malfunctions or other unexpected incidents.
- When using electrosurgery in patients with pacemakers or other active implants, special requirements apply (e.g. low HF-current, patient monitoring). In any case, a cardiologist or appropriate medical specialist must be consulted.
- Before initial use and any further use, all instruments must be completely cleaned, disinfected and sterilised and their function must be checked.
- The POWEREDGE-blade REF 82710300 is intended for one-time use and must be disposed after disassembly.
- 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 any 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.
- 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.
- Only use the cutting mechanism when the enclosed tissue or blood vessel is completely coagulated or sealed in order to avoid bleeding and post-bleeding.
- 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.
Once correctly assembled, the device may be used in either the right or the left hand.
To close jaws: compress (grip) handle.
To open jaws: release (grip) handle.
To activate the blade: depress the trigger.
To deactivate the blade: release the trigger
Only activate the knife when the jaws are closed.
Cutting or coagulation current is activated by a foot-switch that is part of the electrosurgical generator.

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.
The POWEREDGE-blade REF 82710300 is only intended for one-time use and must not be reused.
Instruments for electrosurgery are by their nature subject to increased wear depending on the type and time of use.

Preparation and transport
Disassemble the instrument following the pictogram immediately after each use. Discard the POWEREDGE blade REF 82710300. The instrument must be cleaned and disinfected in a disassembled and open condition. Remove coarse dirt from the instruments. 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.

Manual pre-cleaning
1. Immerse the instrument in cold water for 5 minutes.
2. Brush the instruments under cold water until all visible impurities are removed.
3. Flush each surface, which is not accessible with the brush, with a water jet pistol for 10 seconds (4 bar water pressure).
4. Place the instruments in an ultrasonic bath with a 0.5% alkaline-enzymatic cleaning detergent (MediClean forte, Dr. Weigert Hamburg). Ultrasound must be applied for 15 minutes at 40°C/104°F. Make sure that the instruments are completely wet. The electrode must be in an opened condition when placing in the bath.
5. Remove the instrument and rinse completely with cold tap 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 MIC module and start the cleaning process.
1. Prerinse with cold water for 4 min
2. Discharge
3. Prerinse with cold water for 3 min
4. Discharge
5. 3 min. neutralization with cold demineralized water.
6. Discharge
7. 2 min. post-rinse with cold demineralized water.
8. 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
Cannot be applied to this instrument.

Functional test and packaging
Perform visual inspection for cleanliness and integrity. If necessary, repeat the reprocessing process until the instrument is visully clean.
Use harmless medical white oil (e.g. paraffin oil acc. to DAB or Ph.Eur. or USP) to care for the thread of the instruments after cleaning and before assembling.
Assemble the instrument following the pictogram, which will require the use of an additional POWEREDGE blade REF 82710300.
Check the functionality of the instrument based on the application notes.
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.; at most 18 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 and ultrasonic):
Neodisher MediClean forte; Dr. Weigert Hamburg
Cleaning and disinfection device:
Miele G7836 CD
MIS rack E450
Steam steriliser:
Selectomat HP 666-1HR

For details, see report.

SMP GmbH # 20214-2	(machine cleaning)
SMP GmbH # 25714-2	(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.