BISSINGER CABLES FOR ELECTROSURGERY

ENGLISH

Bissinger Cables for electrosurgery

INSTRUCTIONS FOR USE

REF

801xxxxx, 8550010x
8550040x, 8550050x
855301xx, 8910xxxx

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⚠ 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
Cables for electrosurgery are designed either to conduct electrical power from the output of a high-frequency generator to the instrument or to connect a neutral electrode with the generator.
When combining with other electrosurgical devices, ensure that the output parameters of the electrosurgical generator do not exceed the rated voltage of the cable. Use only with compatible electrosurgical generators and instruments. The connectivity depends on the specific types of connectors, both on the generator side and the instrument side.

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

Use and safety instructions
Non-observance of these use and safety instructions may lead to injuries, malfunctions or other unexpected incidents.
- All cables have to be completely cleaned, disinfected and sterilised before initial use and any other use.
- The cables have to be submitted to a visual inspection and a functional test before each use.
- Ensure that the correct connector both on the generator side and the instrument side has been chosen and that the connector has been fully inserted.
- Never use damaged cables.
- Do not kink to avoid cable break.
- To avoid damages, grasp plug to remove cable, do not pull cord.
- Never use the instruments in the presence of flammable or explosive substances.

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.

Preparation and transport
Remove coarse dirt from the cables immediately after each use. Do not use fixation agents or hot water (>40°C).

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 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
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. 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 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.; 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. 15min.) may apply.

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 (man. cleaning/disinfection)
Nelson Labs # 200432706-02 (sterilisation)
MDS GmbH Testbericht 084183-10 (sterilisation)

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

Handling
Store the cables in a clean, cool and dry place. During transport, cleaning, care, sterilisation and storage, all cables should be handled with maximum care. Coil cables loosely, do not kink or fold them.

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	Serial number
	Attention!
	Refer to Instructions for Use
CE	CE-mark
	Manufacturer Production date Year-Month
LATEX	Not made with natural rubber latex
Rx ONLY	Attention: According to US-laws, this device must only be sold by a doctor or on the instruction of a doctor.