

SCHREIBER[®] INSTRUMENTE **Content**

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Validity

This manual is valid for all Bipolar HF-Instruments and accessoires, sold by SCHREIBER GmbH.

Certificate of Compliance

In accordance to the MDD Directive 93/42 EC Annex II

Manufacturer's name and address:

SCHREIBER GmbH
 Chirurgische Instrumente
 Unterer Damm 15
 D-78567 Fridingen

Product name:

HF-Bipolar Instruments and accessoires according to the valid catalogues and price list.

The Schreiber GmbH confirms herewith in sole responsibility, that the above mentioned products-comply with the requirements according to annex II section 3 of the council directive 93/42/EEC. These products are permitted to carry the CE 0483 -mark

We have established a certified quality management system according to DIN/EN/ISO 13485:2003

Signature



 Armin Zepf
 Quality Manager

Schreiber HF-Instruments are reusable and meet ANSI/AAMI standards for sterilisation. We guarantee, that our HF-Instruments are withstanding a minimum of 20 sterilisation cycles, when sterilised according to the points listed below. Most devices will surpass this standard, if a protocol for proper care and inspection of medical devices is established in your facility. Steam autoclave sterilisation is recommended. For handling, cleaning storing and sterilisation the instructions for general surgical instruments are also valid.

First Check

Please check all instruments and cables on proper function before use. Especially insulations, pins, connections and cables must be checked for cracks, sharp bends and other damages. CAUTION: Damaged instruments can cause burnings in contact with persons and must not be used!

Safety Instructions

For the use of electro-surgical instruments, some precautions must be strictly observed. Improper use and ignorance of this manual may represent serious risks. Inform yourself with these instructions and the manual of the generator manufacturer about function, handling, compatibility and power consumption of your device.

- Temporary unused instruments should be placed in trays or on tables outside the surgery field.
- Cables should be held as short as possible. Contact with other instruments or wires must be avoided.
- Avoid contact of electro-surgical instruments with non insulated devices.
- These Instruments may cause malfunctions or damages of cardiac pacemakers.
- Do not use these instruments in presence of flammable or explosive liquids or gases.
- Persons using electro-surgical instruments must have the required special knowledge of the subject.

Destination

HF-generators for electro surgery which are used for the connection with these instruments have been developed to destroy tissue and can be

dangerous, used improperly. Follow the safety instructions of the device manufacturer. These instruments are used to coagulate biological tissue with high frequency electricity. The surgery fields are very various and are depending on the size and form of the instrument as well as on the planned operation. Choosing the right instrument is the surgeons job.

Compatibility

Bipolar instruments with the fitting cable can be connected to the bi-polar output of HF-generators with 100W maximum power and an output voltage of 600 V max.

Handling

- Push the plug of the cable onto the instruments pin until it is covered completely. No blank parts must be visible.
- Make sure that the cable, the switch and the generator are connected properly.
- The HF-Power is activated by operating the switch.
- The termic coagulation power is activated/available immediately.

Cleaning and Sterilisation

- To avoid damages of the insulation, these instruments must not be cleaned, sterilised and stored together with pointed instruments as scalpels or similar.
 - The lifetime of plastic insulations can be reduced by using phenol- or chloride containing detergents. We recommend to work without such liquids.
 - HF-Instruments must not be sterilised with hot air.
- For further instructions, we refer to the SCHREIBER "Instructions of use for standard Instruments", as far as there are no other indications or limits in this manual.

Maintenance

For best coagulation results, it is necessary, that the working ends of the instruments are always kept metallic pure. Incrusted blood or other debris are reducing function and power. Please do not increase power when the performance becomes low, but clean the working ends.
HF-Instruments and cables must not

be repaired, because the insulations will not be according to the rules any longer.

Guaranty

We give 12 months guaranty for material and manufacturing faults. Improper use and repair by third voids guaranty and CE-marking.

Edited by Armin Zepf QMB, SCHREIBER GmbH
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