

Instructions for Use for Bipolar Forceps

Intended Use

Bipolar forceps are used for grasping, dissection and coagulation of tissues. They have to be connected, by means of an appropriate bipolar cable, to the bipolar output of a high-frequency generator and may only be used with bipolar coagulation current.

Instruments for electrosurgery should only be used by persons who have been specially trained for the use of such instruments. These instructions do not substitute the instructions for electrosurgical and obsolete instruments must be properly disposed of in accordance to regulations.

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.
- Bipolar forceps have proved inefficient for tubular sterilization or coagulation in the context of sterilization and should therefore not be used for this purpose.

Use and Safety Instructions

The non-observance of the present use and safety instructions may lead to injuries, malfunctions or other unexpected incidents.

- Before initial use and any other use, all instruments have to be completely cleaned, disinfected, sterilized and their function checked.
- It is very important to check each 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 mobile parts, insulations and ceramic elements have to be checked carefully.
- Never use damaged instruments.
- Never use the instruments in the presence of flammable or explosive substances.
- The instrument may not be laid down on the patient.
- Frequently clean the tips from blood and debris.
- Coagulation should only be performed if the contact surfaces are visible and ensure a good contact to the tissue selected for coagulation. Do not touch any other metallic instruments, trocar sleeves, optics or the likes during use.

Prior to Use

Before connecting forceps and cables to an electrosurgical unit, make sure that the unit has been switched off or is in standby mode. Disregarding these instructions may lead to burns and electrical shock.

During use

Always use the lowest power setting available to achieve the desired surgical effect.

After use

Disconnect cable from forceps. Do not allow blood and debris to dry on forceps. Use a soft cloth or brush to remove blood and debris. Do not use aggressive/abrasive cleaners.

Rinse thoroughly with clean tap water before cleaning.

We generally recommend machine cleaning and thermal disinfection.

Machine 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. Pre-rinse for one (1) minute with cold water. Discharge.
2. Pre-rinse for three (3) minutes with cold water. Discharge.
3. Wash for five (5) minutes at 55°C with a 0.5% alkaline or at 45°C with an enzymatic cleaning agent. Discharge.
4. Neutralize for three (3) minutes with warm tap water (>40°C) and a neutralizing agent. Discharge.
5. Rinse for two (2) minutes with warm tap water (>40°C). Discharge.

Disinfection: Machine operated thermal disinfection has to be carried out in consideration of the regulation requirements with regard to the A0 value (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 Cleaning

Ultrasonic Pre-cleaning

1. The instrument must be inserted in an ultrasonic bath with 0.5% enzymatic cleaning detergent. Ultrasound must be applied for 15 minutes at 40°C.
2. Remove the instrument and rinse 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 accumulations of dirt have been removed. Remove stuck dirt by using a soft brush.
2. Place products in the prepared cleaning bath so that they are completely submerged. Observe soak 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 steps 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 distilled/desalinated water. Repeat the procedure.
5. Rinse the products thoroughly with distilled/desalinated 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 soak time. Rinse the products thoroughly with fully demineralized water to remove the disinfectant without residue.

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

Non-stick Bipolar Forceps

A certain discoloring of the tips of non-stick instruments is normal and harmless. This does not lead to any malfunction.

Bipolar Forceps with Irrigation

The wire insert included with the product should always be inserted in the irrigation channel – except during utilization and cleaning, in order to prevent any clogging. The irrigation channel has to be rinsed very thoroughly during cleaning. The passage has to be checked after cleaning.

Sterilization

- 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
- Shortest exposure time: 3 minutes.
- Drying time: at least 10 minutes.

Storage

Sterilized instruments have to be stored in a dry, clean and dust free area at moderate temperatures from 5°C to 40°C.

Repairs

Never attempt to perform repairs yourself. Service and repair work may only be performed by persons qualified and trained accordingly.

*** Note: Defect products must be sterilized before being returned for repair.