USA

Instructions for use
Modular Monopolar Instrument System:
Insulated Metal Handels

B|BRAUN
SHARING EXPERTISE

Technical alterations reserved

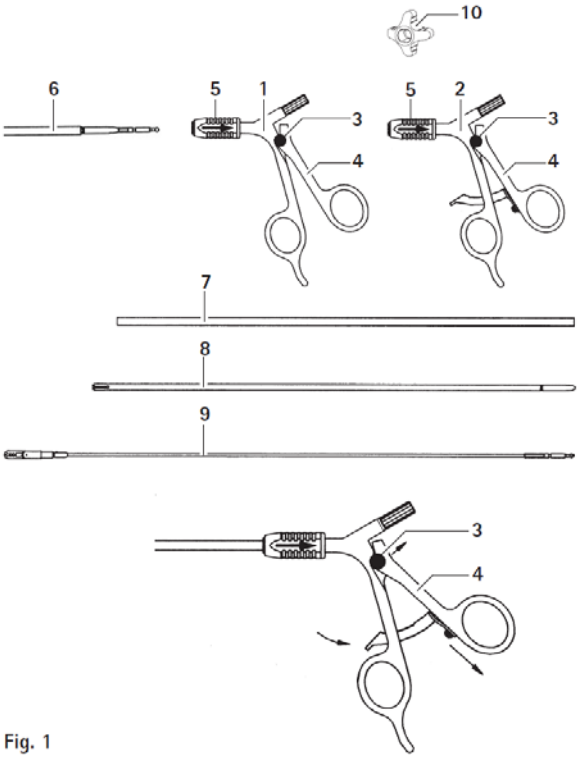

Fig. 1

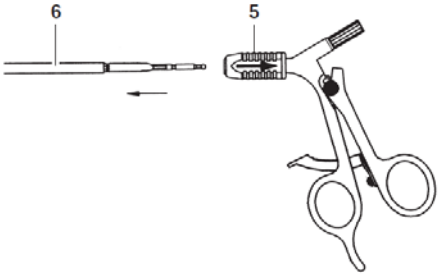

Fig. 2

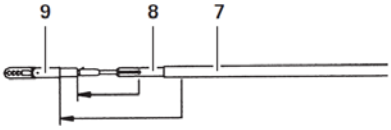

Fig. 3

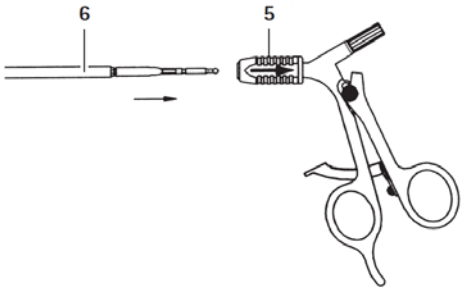

Fig. 4

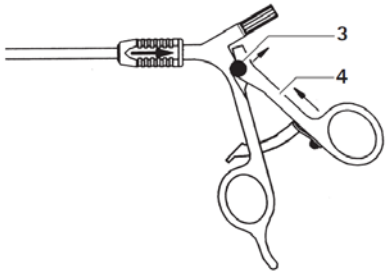

Fig. 5

USA

Modular Monopolar Instrument System: Insulated Metal Handle

Legend

1 Handle without lock
2 Handle with lock
3 Button
4 Moveable ring
5 Spring mechanism
6 Sheath, complete
(Outer tube, inner tube, working insert)
7 Insulated outer tube
8 Inner tube
9 Working insert
10 Star wheel

Applications

All endoscopic disciplines:

- Cutting, preparation, and grasping of tissues
- Biopsies
- Suturing

Safe handling and preparation

CAUTION

Federal law restricts this device to sale by or on order of a physician!

- Read, follow and keep the instructions for use.
- Use the product only in accordance with its intended use, see Intended use.
- Clean the new product either manually or mechanically prior to initial sterilization.
- Store any new or unused products in a dry, clean and safe place.
- Inspect the product after each cleaning and disinfecting cycle to be sure it is clean, functioning properly, not damaged, has intact insulation and does not have any loose, bent, broken, cracked, worn, or fractured components.
- Do not use the product if it is damaged or defective. Set aside the product if it is damaged.
- Replace any damaged components immediately with original spare parts.
- To avoid damage to the working tip: Exercise caution when passing products through the working channel (e.g. trocars).
- Prior to each use, inspect the product for: loose, bent, broken, cracked, worn, or fractured components.

WARNING

Danger of injury from burns and/or explosion of flammable gases! Application of the HF device according to its intended use can involve spark formation.

- **Follow the safety notes in the instructions for use of the HF device.**

- Adjust the HF power output to the intended operation. Take into account clinical experience or reference values.
- Select the lowest possible HF power output.
- Keep the product's contact surfaces clean during the operation. Wipe off encrusted tissue residues or body fluids, using a moistened swab.

The plug end of the product is fitted with the following connector: Pin 4 mm, unscrewable.

The compatible cable can be found in our brochures.

The insulation of the product is rated for a maximum recurrent peak voltage of 2.3 kVp in coagulation mode.

The insulation of accessories (e.g. HF cable, instruments) must be adequate for the maximum peak output voltage, see IEC 60601-2-18.

To avoid HF burns:

- Only use the product if its rated voltage is the same as, or greater than, the maximum power output setting of the HF device.
- The product's working tip must be in the user's field of vision whenever HF power is activated.
- Prior to switching on the HF device, make sure that the product's working tip is not touching any accessory or fluid that conducts electricity.
- Prior to each use, visually check the product for: damage to, or surface changes on, the insulation.
- Deactivate the automatic "On" function of the HF device.
- Follow the instructions for use of the HF device.

Safe operation

- To open and close a distal jaw piece: Open and close moveable ring **4**.

Disassembling

The instrument can be disassembled into five components:

- Handle **1** or **2**
- Insulated outer tube **7**
- Inner tube **8**
- Working insert **9**
- Star wheel **10**

Removing the ring from the handle

see Fig. 1

- Remove star wheel **10**.
- If the handle is fitted with a lock: Open the handle all the way.
- Hold down button **3** while removing moveable ring **4** from its anchoring.

Removing the sheath from the handle

see Fig. 2

- Pull back rotatable spring mechanism **5** on handle **1** or **2** in the direction of the arrow as far it will go and hold it against the stop.
- Remove sheath **6**.

Disassembling the sheath

- First remove insulated outer tube **7** , then inner tube **8** from insert **9**.

Assembling

Assembling the sheath

see Fig. 3

- Slide the end of inner tube **8** with its flexible tongues over insert **9** until the flexible tongues snap into place.
- Slide outer tube **7** over inner tube **8** with insert **9** as far as it will go.

Mounting the sheath on the handle

see Fig. 4

- Pull back rotatable spring mechanism **5** on handle **1** or **2** as far it will go and hold it against the stop.
- Grasp sheath **6** at the closed working tips and, rotating the sheath slightly, slide it into handle **1** or **2**.
- Let rotatable spring mechanism **5** slide forward.
  Sheath **6** must be firmly in place in handle **1** or **2** so that it will not come loose even under traction.

Mounting the ring on the handle

see Fig. 5

- Fully open the handle with lock **2**.
- Hold down button **3** while pushing moveable ring **4** onto the handle.
- Make certain that the moveable ring **4** is firmly in place in the handle.
- Slide the star wheel **10** onto the handle.

Processing

Note

Observe all relevant national regulations and standards concerning processing.

Note

For patients with Creutzfeldt-Jakob Disease (CJD), suspected CJD or possible variants of CJD, observe the relevant national regulations with regard to processing of the products.

Preparations

- Carry out non-fixating/NaCl-free pre-cleaning immediately after use.
- Disassemble separable products (see section Disassembling).
- Open jointed products.
- Reprocess the product immediately after use.
- Put away the product in dry condition.
- Use suitable cleaning/disinfecting agents if the product is put away in wet condition. Prior to mechanical cleaning and disinfecting, rinse the product thoroughly with running water.
- If necessary, clean the product through ultrasound treatment (see section Cleaning/Disinfecting).

Cleaning/Disinfecting

CAUTION

Damage to the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!

- **Only use a cleaning/disinfecting agent that is approved for CJD, and follow the manufacturer's instructions.**

- Use cleaning/disinfecting agents that are suitable for the product. Always follow the manufacturer's instructions regarding concentration, temperature and exposure time.
- Avoid encrustation of residues/proteins (e.g. caused by aldehyde/alcohol).
- Only use bactericidal, fungicidal and virucidal disinfecting agents.
- Carry out ultrasound cleaning:
  - as an effective mechanical supplement to manual cleaning/disinfecting.
  - to prepare products with encrusted debris for mechanical cleaning/disinfecting.
  - as an integrated mechanical support measure for mechanical cleaning/disinfecting.
  - as an aftertreatment for products that are still dirty after mechanical cleaning/disinfecting.
- Preferably apply thermal disinfecting processes.
- After chemical disinfection, rinse the product thoroughly under running water. Always adhere to the manufacturer's instructions.
- Manually clean and disinfect products with fine working tips.
- Providing the microsurgical products can be securely fixed in machines or in storage devices in such a way that they will be thoroughly cleaned, clean and disinfect them mechanically.

Note

Immersion treatment in a 3 % H_2O_2 solution for approx. 5 minutes is a particularly effective and gentle method for etching off encrustations from HF instruments. Encrustations can be removed by hand, with a soft brush and/or in an ultrasound bath. After that treatment, proceed through the normal steps

Mechanical cleaning/disinfecting

Pre-cleaning

- Thoroughly pre-rinse under running water.
- Carry out ultrasound treatment.
- Use special cleaning brush (art. no. PM995R).
- Carry out the final rinse under running water.

Cleaning

- Place the product on a tray that is suitable for cleaning (avoid rinsing blind spots).
- Connect components with lumens and channels directly to the injector carriage attachment.
- Store any products with hinges or joints on the tray in such a way that the joints are open.
- Ensure that water can flow out of openings.
- Process the product in a cleaning/disinfecting machine. Follow the instructions provided by the manufacturer of the machine.

- Processing cycle:
  - Use a suitable neutral/mildly alkaline cleaning/disinfecting agent according to the manufacturer's instructions.
  - Do not exceed the maximum cleaning temperature of 55 °C.
  - Clean for at least 10 min.
  - Neutralize if necessary.
  - Apply intermediate rinse for at least 1 min.
  - Carry out intensive final rinse with distilled, demineralized or fully desalinated water.
  - For thermal disinfection: Rinse for 10 min at 93 °C with distilled, demineralized or fully desalinated water.
  - Complete the program with a drying phase of at least 20 min at a temperature of not more than 110 °C.
- After completion of the mechanical cleaning/disinfecting cycle, inspect all surfaces, cavities, lumens, and openings for visible debris.
- Carry out additional manual cleaning if necessary.

Manual cleaning/disinfecting

- Use a suitable neutral/mildly alkaline cleaning/disinfecting agent according to the manufacturer's instructions.
- Immerse the product in the cleaning/disinfecting agent in such a way that all surfaces, cavities, lumens, and openings are covered.
- After the end of the disinfection period, thoroughly rinse the product under running water, ensuring that water flows through every lumen and channel, and all blind holes are repeatedly filled and drained.
- Clean hinged or jointed products in open and closed positions.
- Remove encrusted debris with a soft nylon brush. Do not use harsh cleaning agents or metal brushes.

- Clean lumens, channels and blind holes with soft round plastic brushes of fitting diameter.
- Carry out an intensive final rinse with distilled, demineralized or fully desalinated water.
- Inspect surfaces, cavities, lumens and openings for visible debris. If necessary repeat the cleaning/disinfection process.
- Use a lint-free cloth or a compressed-air gun for drying the product.
- Make certain that lumens, channels and blind holes are dried too.

Control, care and inspection

- Allow the product to cool down to room temperature.
- Lightly lubricate moving parts such as hinges and joints with a sterilizable, steam-permeable and tissue-compatible maintenance oil (e.g. Aesculap STERILIT® spray JG600 or maintenance oil JG598).
- Assemble any separable product (see section Assembling).
- Inspect the product after each cleaning and disinfecting cycle to be sure it is clean, functioning properly, and not damaged (e.g. insulation), and does not have any loose, bent, broken, cracked, worn, or fractured components.
- Check for compatibility with associated products.
- Set aside the product if it is damaged.

Packaging

- Appropriately protect products with fine working tips.
- Secure product with retractor in the first notch.
- Sort the product into its appropriate storage device or put it on a suitable tray. Make certain that all cutting edges are protected. Observe the weight limit for each tray/container.
- Package trays appropriately for the sterilization process (e.g. in Aesculap sterile containers).
- Ensure that the packaging will prevent recontamination of the product in the period between reprocessing and reuse.

Sterilization method and parameters

Note

The product can be sterilized either in disassembled or in assembled condition.

- Make certain that all external and internal surfaces will be exposed to the sterilizing agent (e.g. by opening all valves and faucets).
- Apply steam sterilization, observing the following rules:
  Sterilization has to be performed in a validated steam sterilization process (e.g. in a sterilizer according to EN 285/ANSI/AAMI/ISO 11134-1993, ANSI/AAMI ST46-1993, validated according to EN 554/ISO 13683). For the fractionated vacuum process, sterilization has to be carried out running the 134 °C/ 2-bar program for a minimum holding time of 5 minutes.
- When sterilizing several products at the same time in one steam sterilizer: Make certain that the maximum load capacity of the steam sterilizer, as specified by the manufacturer, is not exceeded.

Sterilization for the US market

- Sterilization of the device may be accomplished by steam.
- Aesculap does not recommend the device be sterilized by "Flash" or chemical sterilization.
- Surgical instruments may also be placed within an Aesculap rigid sterilization container (sterile container) for processing under generally accepted hospital in-use conditions.

The recommended sterilization parameters are as follows:

Sterilization method	Temp.	Minimum exposure time	
		Wrapped	In a sterile container system
Pre-vacuum	270/275 °F	4 min	4 min

WARNING for the US market

If this device is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination!

Storage

- Store processed products under conditions as germ-free as possible, in a dry, dark, cool and dust-protected room.

Technical Service

Modifications carried out on medical technical equipment may result in loss of guarantee/warranty rights and forfeiture of applicable licenses.

Service address

Aesculap Inc.
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Fax: +1 314 895-4420
Other service addresses can be obtained from the address indicated above.

Distributor in the US/Contact in Canada for product information and complaints

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