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CE 1639

INSTRUCTIONS FOR USE: -
ELECTROSURGERY MONOPOLAR & BIPOLAR FORCEPS

N.B.NOTES REGARDING TERMINOLOGY MONOPOLAR VS BI-POLAR

Monopolar electrosurgery uses an active electrode and a separate dispersive pad that sends current through the patient's body, while bipolar electrosurgery uses two active electrodes in one tool, limiting the current to the tissue between them. Bipolar is generally safer for patients with pacemakers, offers more precise coagulation with less damage, and is often used when a dispersive pad is inconvenient.

MEDICAL DEVICE CLASS; 2B

INTENDED USE

- Electrosurgical (also known as diathermy) forceps are for use in the dissection or coagulation of tissue using high frequency electrical energy. They are intended for connection to an electrosurgical generator via appropriate cables and accessories.
- The device must only be used for their intended purpose.
- Refer to the documentation for the Electrosurgery Generator being used for connection and power settings.

INTENDED USER

- The device must only be used by healthcare professionals who have received appropriate training in the performance of electrosurgery procedures.

CONTRAINDICATIONS;

- Note the rated accessory voltage (RAV) stated on the label.
- Refer to the documentation for the Electrosurgery Generator being used for connection and power settings.
- These instructions are generic and will cover most forceps. If in doubt contact the manufacturer for assistance.
- Ensure the storage conditions set out on the device label are maintained. Storage outside of these conditions may compromise the sterility of the device.
- Devices supplied sterile should not be used if the packaging is damaged or wet.
- These devices cannot be dismantled.

CLEANING

Allowable reprocessing cycles = 50 See; MCI-002 Guidance for reprocessing reusable Class 2 medical devices
Reusable devices are intended to be processed to a level appropriate for the intended use at the discretion of the end user.

STERILIZATION

Moist Heat Sterilisation

STORAGE & SHELF LIFE

- Do not store at extreme temperature or humidity.
- Store in clean and dry place.
- Do not use if the package open or damaged
- Do not store in direct sunlight
- The shelf life for sterile devices is marked on the device label. The devices should not be used after this period as the sterile barrier may not maintain sterility after this time.
- For devices in sterile packaging please refer to the storage parameters on the device label.

INSPECTION

1. Examine the forceps for damage, distortion, correct alignment of tips.
2. The forceps has insulation which should be carefully examine for cuts, wear, abrasions, bubbles or any exposed metal. If the insulation is damaged, then the forceps should not be used.
3. The surfaces intended for contact with tissue may be cleaned with a light abrasive during use. Care must be taken not to abrade the insulation.
4. Check that the forceps makes a positive connection to the appropriate handle / holder by fitting the forceps into the handle / holder socket. Ensure that the handle / holder is not connected to a power source during this check.
5. The devices should not be used if their condition gives cause for concern.

MATERIALS;

- ✓ Stainless steel
- ✓ Nylon powder coating
- ✓ Polypropylene

- ✓ Devices do not contain latex or phthalates
- ✓ No animal derived substances or substances derived from blood products are used in these devices

GMDN # = 61875

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GENERAL GUIDANCE FOR THE SAFE USE OF HIGH FREQUENCY SURGICAL EQUIPMENT ACCESSORIES

The instructions below are intended as a guide when using the electrosurgical accessories supplied by Meditech Systems Ltd. They should be read in conjunction with the recommendations of the Electrosurgical Supply Unit (ESU) manufacturer's instructions AND any advice or warnings issued by regulatory authorities. Where there is any contradiction the ESU manufacturer's instructions or the Regulatory Authority warnings take precedent.

- Read the ESU manufacturer's instructions for use before using HF accessories.
- Please check warnings issued by the regulatory authorities in the region where the products are being used before using these accessories.
- The electrosurgical accessories supplied by Meditech Systems Ltd are intended for use by medical staff who have received training appropriate for the procedure being undertaken.
- If the device is labelled as being sterile it does not require any preconditioning before use.
- Reusable devices delivered non-sterile should be processed before use to the requirements of the end user.
- Avoid HF output settings where maximum output voltage may exceed rated accessory voltage.
- The entire area of the neutral electrode (aka ground plate) should be reliably attached to the patient's body and as close to the operating field as possible.
- The patient should not come into contact with metal parts which are earthed, or which have an appreciable capacitance to earth (for example operating table supports, etc.). The use of antistatic sheeting is recommended for this purpose.
- Skin-to-skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze.
- When HF surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, any monitoring forceps should be placed as far as possible from the surgical forceps. Electrosurgery devices are not recommended for use on patients with implanted neurostimulators for deep brain stimulation**.**
- In all cases, monitoring systems incorporating high frequency current limiting devices are recommended.
- Electrosurgery may not be appropriate on patients with chronic diseases/conditions that affect blood clotting/wound healing (e.g. diabetes, anaemia) and it is the user's responsibility to consider the risks.
- The cables from the ESU to the surgical forceps or active devices should be positioned in such a way that contact with the patient or other leads is avoided.
- Temporarily unused active forceps should be stored in a location that is isolated from the patient.
- For surgical procedures where the HF current could flow through parts of the body having a relatively small cross-sectional area, the use of bipolar techniques may be desirable in order to avoid unwanted tissue damage.
- The output power selected should be as low as possible for the intended purpose. Certain devices or accessories may present a safety hazard at low power settings. For example, with argon beam coagulation, the risk of gas embolism rises if there is insufficient HF power to produce a rapid, impermeable eschar on the target tissue.
- Apparent low output or failure of the HF surgical equipment to function correctly at the normal operating settings may indicate faulty application of the neutral forceps or poor contact in its connections. In this case, the application of the neutral forceps and its connections should be checked before selecting a higher output power.
- The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N2O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away.
- Non-flammable agents should be used for cleaning and disinfection wherever possible.
- Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of HF surgery. There is a risk of pooling of flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before HF surgical equipment is used. Attention is drawn to the danger of ignition of endogenous gases. Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in normal use of the HF surgical equipment.
- For patients with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the pacemaker may occur, or the pacemaker may be damaged. In case of doubt, approved qualified advice should be obtained.
- Warning - interference produced by the operation of HF surgical equipment may adversely influence the operation of other electronic equipment.
- The operator should regularly inspect the accessories, forceps, cables and endoscopically used accessories, for possible damage.

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- Where the devices are labelled for single use only no attempt should be made to reprocess the device. The EU Directive on Medical Devices 93/42/EEC, Medical Devices Regulation 2017/745 and UK MDR 2002 & UK MDR (EU Exit) 2019 states that "single use devices" means a device intended to be used once only for a single patient.
- Where the accessories have connections to other parts of the system ensure that the connection is secure and that there are no exposed metal parts.

DISPOSAL

- These devices should be disposed of following the local rules for disposal of contaminated clinical waste.
- Dispose of the device in accordance with local instruction for disposal of medical instruments / accessories. The stainless steel components of our accessories are capable of being recycled. Check if local procedures exist for the safe recycling of medical devices

Ordering information:

Meditech Systems Ltd, Unit 3 Shrublands Estate, Shearstock, Shaftesbury, Dorset, SP7 9PT, England

orders@meditechsystems.co.uk

Tel: +44(0)1747 821546 Fax: +44(0)1747 825038

Facebook: @meditechsystemslimited

LinkedIn: meditech-systems-limited

Twitter: @MeditechLtd

EU Authorised Representative

Clowrey Consultancy, White House on Bridge, Holycross, County Tipperary, Eire

+44 (0)7888744362 email; clowreyconsult@gmail.com

ADVERSE INCIDENT REPORTING

Adverse incidents may be reported to the Competent Authority in the country / region where the incident occurred.

Explanation of symbols:

= Single Use. The definition of single use is for use on a single patient for a single procedure.

= Do not reprocess / re-sterilize

= Use by date

= Lot or batch number.

= Date of manufacture.

= Device catalogue number / product code / stock

= Caution

= Device catalogue number / product code / stock

= Manufacturer

= Temperature range

= Consult instructions for use

= Keep away from sunlight

= Keep dry

= Contains latex

= Do not use of packaging is wet or damaged.

=CE mark and notified body number