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CE 1639

GUIDANCE FOR THE SAFE USE, REPROCESSING & INSPECTING OF HIGH FREQUENCY SURGICAL EQUIPMENT ACCESSORIES MANUFACTURED BYMEDITECH SYSTEMS Ltd.

Instructions for use.

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.

1. Read the ESU manufacturer's instructions for use before using hf accessories.
2. Please check warnings issued by the regulatory authorities in the region where the products are being used before using these accessories.
3. 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.
4. Unless the device is labeled as being sterile it should be cleaned before use and sterilized if required. Cleaning and sterilization guidance is provided below.
5. Avoid hf output settings where maximum output voltage may exceed rated accessory voltage.
6. The entire area of the neutral electrode should be reliably attached to the patient's body and as close to the operating field as possible.
7. 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.
8. Skin-to-skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze.
9. When hf surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended.
10. In all cases, monitoring systems incorporating high frequency current limiting devices are recommended.
11. The cables from the ESU to the surgical electrodes or active devices should be positioned in such a way that contact with the patient or other leads is avoided.
12. Temporarily unused active electrodes should be stored in a location that is isolated from the patient.
13. 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.
14. 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.
15. 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 electrode or poor contact in its connections. In this case, the application of the neutral electrode and its connections should be checked before selecting a higher output power.
16. The use of flammable anesthetics 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.
17. Non-flammable agents should be used for cleaning and disinfection wherever possible.
18. 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.
19. 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.
20. Warning - interference produced by the operation of hf surgical equipment may adversely influence the operation of other electronic equipment.
21. The operator should regularly inspect the accessories, in particular, electrode cables and endoscopically used accessories, for possible damage.
22. Where the devices are labeled for single use only no attempt should be made to reprocess the device. The EU Directive on Medical Devices 93/42/EEC states that "single use devices means a device intended to be used once only for a single patient".
23. 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.
24. 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.
25. Intended Use is 100 times.

WARNINGS - Monopolar and Bipolar Instrumentation

1. For devices that incorporate suction, do not extend suction tube while energy is applied to avoid accidental burns.
2. Do not place the instrument on the patient when not in use. Place the instrument in an insulated support or on a clean, dry surface, very visible and non-conductive, so as to avoid accidental electrical injuries.
3. Do not try to modify the instrument. Do not try to repair the electrical insulation. Do not "buzz" the instrument during the surgical procedure to reduce the risk of burning the patient or the physician.

4. The pathways of the current through conductive elements like metal instruments and endoscopes can cause local burns to the patient, the physician or another member of the care team. Contacting conductive elements with the active cautery area may cause undesired tissue heating and burns.
5. The temperature of the instrument in the active cautery area can remain high enough after use that it burns the patient, the physician or another person, even when the electrical current is turned off.
6. To avoid alternate site burns, ensure hinges, handles and proximal un-insulated portions of the electrosurgical instruments do not inadvertently contact patient.
7. Extreme care should be taken when handling instruments with a dielectric coating.
8. Damage to the dielectric coating may result in patient/user injury
9. Begin procedure at the lowest possible electrosurgical power setting to reduce the risk of patient burns at high voltages.

ADDITIONAL WARNINGS - Monopolar Instrumentation

1. Apply the patient return electrode according to the recommendations of the generator manufacturer.
2. The entire surface of the neutral electrode should be securely connected to the patient's body and as close as possible to the surgical field.
3. The patient should not be in contact with grounded metal parts or parts having an appreciable capacity with respect to the ground (for example operating table, supports, etc.). Antistatic wrapping is recommended in this case.
4. Skin to skin contact (for example between the patient's arms and body) must be avoided, for example by separation with dry gauze.

ADDITIONAL WARNINGS - Bipolar Instrumentation

1. Do not apply a patient return electrode for bipolar procedures.

PRECAUTIONS- Monopolar and Bipolar Instrumentation

2. Make a visual inspection of the instrument and the cable to ensure that the electrical insulation is in good condition.
3. The use of trocars made entirely of plastic or metal is recommended with electrosurgical devices in order to avoid thermal injuries in the surgical access zones.

ADVERSE EVENTS - Monopolar Instrumentation

1. Localized burns to the patient or physician may result from electrical current carried through conductive objects (such as trocar cannulas). Electrical current may be generated in conductive objects by direct contact with the active electrode, or by the active accessory (electrode or cable) being in close proximity to the conductive object.

ADVERSE EVENTS - Bipolar Instrumentation

2. Adverse events reported while using bipolar electrosurgical devices include inadvertent activation with resultant tissue damage at the wrong site and/or equipment damage.
3. Fires involving surgical drapes and other combustible materials have been reported.
4. Alternate pathways resulting in burns where the patient or physician or assistant is in contact with exposed metal.

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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-sterilise


= Use by date


= Lot or batch number.


= Date of manufacture.

= Device catalogue number / product code / stock


= Caution


= Device catalogue number / product code / stock


= CE mark and notifiedbody number


= Manufacturer


= Temperature range


= Consult instructions for use


= Keep away from sunlight


= Keep dry


= Contains latex


= Do not use of packaging is wet or damaged.


= Contains or Presence of Phthalates.

This is an explanation of the symbols that may be found on Meditech Systems Ltd's products.

For any enquires please contact:-


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Instructions for Reprocessing Reusable Medical Devices Manufactured By Meditech Systems Ltd

Device(s): The following instructions are for all reusable medical devices supplied by Meditech Systems Ltd., unless stated otherwise with the packaging of the product. These instructions are intended for use only by persons with the required specialist knowledge and training.

WARNINGS	1. Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid use of mineral acids and harsh, abrasive agents. 2. No Part of the process shall exceed 137^{O}C. 3. Some sensitive materials (e.g. Aluminium) are damaged by high alkaline solutions (pH>10). 4. Devices with long, narrow cannula, hinges and blind holes require particular attention during cleaning. 5. Care must be taken when handling thin sections such as wire and needle electrodes. 6. Do not use metallic or abrasive cleaning mediums on insulation coatings. 7. Do not permit sharp instruments or edges to contact insulation coatings or cable covers. 8. When handling fibre optic light cables do not allow them to be bent in a tight radius. **Note: when reprocessing medical devices, always handle with care, wearing protective clothing, gloves and eyewear in accordance with local Health & Safety procedures.**
LIMITATIONS ON PROCESSING	1. Non-insulated stainless steel instruments - Repeated reprocessing has minimal effect on these instruments 2. Insulated instruments – Repeated reprocessing of these instruments may cause deterioration of the insulation over a prolonged period. 3. Devices made of plastic – repeated reprocessing may degrade the material over a long period. 4. End of life is normally determined by wear and damage in use. 5. Any specific limitations on the number of reprocessing cycles shall be made available with the instrument.
INSTRUCTIONS	
FROM POINT OF USE	1. Wherever possible, do not allow blood, debris or bodily fluids to dry on instruments. For best results and to prolong the life of the medical device reprocess immediately after use. If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner to help prevent soil from drying. 2. It is important that thin tubes and lumens, and difficult to access areas are cleaned immediately after use before the debris had adhered to the surfaces otherwise it may not be possible to obtain a satisfactory degree of cleanliness prior to sterilisation. 3. Where deposits are burnt on to the device i.e. electrosurgical electrodes, these should be removed as soon as possible using a light abrasive medium (see also Warnings above). 4. Where possible flush through any small bore tubes or fine lumens with warm water (<30^{O}C) and cleaner, if required.
PREPERATION FOR DECONTAMINATION	1. Reprocess all instruments as soon as it is reasonably practical following use. 2. Disassemble only where intended, without the use of tools unless specifically provided by the manufacturer. Where instructions for disassembly are required, these are available with the product. 3. Use suitable autoclavable pipe cleaning apparatus to clean small bore tubes and fine lumens. These areas should be thoroughly flushed through before being placed in the washer-disinfector as they are particularly difficult for automated cleaning. 4. Burnt on deposits may have to be removed before automated cleaning.

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CLEANING: AUTOMATED	**1. Use only either CE marked or validated washer-disinfector machines and low-foaming, non-ionising cleaning agents and detergents following the manufacturers' instructions for use, warnings, concentrations and recommended cycles.** 2. Load instruments carefully, with any box joints and hinges open and so that any fenestrations in instruments can drain. 3. Care must be taken when loading the instruments to prevent damage to fine needles, wires and delicate instruments. 4. Place heavy instruments with care in the bottom of containers, taking care not to overload wash baskets. 5. Place instruments with concave surfaces facing down to prevent pooling of water. 6. Where available, use appropriate attachments to flush inside reamers and devices with lumens or cannula. 7. Ensure that soft, high purity water, which is controlled for bacterial endotoxins, is used in the final rinse stage. **Note:** *automated cleaning may not be suitable for all lumens and cannula, in which case clean manually with a water gun, if available, and an appropriate brush (and stilette if provided) that reaches the depth of the feature. After manually cleaning, pass all devices through an automatic cleaning cycle to achieve disinfection.* **Note:** *these instructions have been validated using a washer-disinfector cycle validated to include two cold rinses at <35^{O}C, a detergent cycle and a rinse cycle both at >50^{O}C, a disinfection cycle operating at a temperature of between 90oC and 95oC for a minimum holding time of 1 minute (actual holding time in excess of 2 minutes 50 seconds) and a 20 minute drying cycle. The detergent used was a low foaming, non-ionising spray wash detergent cleaner (max 12pH) and the rinse aid neutral pH low foaming, non-ionic surfactant with isopropyl alcohol.*
CLEANING: MANUAL	**1. Manual cleaning is not advised if an automatic washer-disinfector is available. If this equipment is not available, use the following process: -** Use a double sink system (wash/rinse) dedicated for instrument cleaning (not used for hand washing). Ensure that the water temperature does not exceed 35^{O}C. In the first sink, keeping the instrument submerged, with an autoclavable brush, apply CE marked cleaning solution to all surfaces until all soil has been removed. Pay particular attention to serrations, teeth, ratchets and hinges, always brushing away from the body and avoiding splashing. Ensure rongeurs and hinged instruments are thoroughly cleaned in both open and closed positions. In the second sink, rinse instruments thoroughly with soft, high purity water which is controlled for bacterial endotoxins, so that the water reaches all parts of the instrument, then carefully hand dry or use a drying cabinet. **2. Note:** *manual cleaning is NOT a disinfection process: when manual cleaning is used it may not be possible to disinfect prior to further handling.*
CLEANING: INSPECTION	**3. After cleaning, visually inspect all surfaces, cannulations, ratchets, joints, holes and lumens for complete removal of soil and fluids. Visually inspect active devices for signs of burnt on debris. If ANY soil, debris or fluid is still visible return the instrument for repeat decontamination.**
MAINTENANCE	1. Where stipulated in the instructions for use of the device apply surgical grade lubricants to hinges, joints and moving parts as per the lubricant manufacturer's instructions. **2.** Where stipulated replace worn parts especially seals, blades etc. It is recommended that only manufacturers approved be used.
INSPECTION AND FUNCTION TESTING	1. Refer to the instruction supplied with the device for device specific details. 2. Visually inspect and check: - all instruments for damage and wear; cutting edges are free of nicks and present a continuous edge; jaws and teeth align correctly; all articulated instruments have a smooth movement without excess play; locking mechanisms (such as rackets) fasten securely and close easily; long, slender instruments are not distorted; any component parts fit and assemble correctly with mating components. 3. Remove for repair or replacement any blunt, worn out, flaking, fractured or damaged instruments. 4. Remove from service any active device or electrosurgical power cable where there is any doubt as to the integrity of the insulation. 5. The dielectric strength of the insulation may be tested using suitable equipment and with reference to BS EN 60601-2-2. 6. Devices do not have any special disposal requirements other than those for the disposal of used medical instruments. 7. **Note:** *if an instrument is returned to the manufacturer / supplier, the instrument **must** be decontaminated and sterilised and be accompanied with the relevant documented evidence.*
PACKAGING	8. All instruments to be packed following local protocol in accordance with BS Standards.

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STERILISATION	1. **Forceps/Loops and Balls - Either CE marked or validated vacuum autoclave operating at 134-137^0 C 2.25 bar for a minimum holding time of 3 minutes – always following the instructions of the machine manufacturer.** 2. **Cables Monopolar/Bipolar – autoclave operating at 134 C 2.25 bar For a minimum 3 minutes to maximum 15 minutes** 3. When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser manufacturer's stated maximum load is not exceeded. 4. Ensure all instruments are dry before sterilisation.
STORAGE	1. Ensure instruments are cool and dry before storage, and stored in dry clean conditions at an ambient room temperature. **2.** Refer to the packaging manufacturer's specifications for limitations on storage conditions and packaging life.
ADDITIONAL INFORMATION	1. Other forms of **cleaning** (i.e. ultrasonic) and **sterilisation** (i.e. Low temperature steam and Formaldehyde, Ethylene Oxide and Gas Plasma) *are* available. However, always follow the instructions for use as issued by the manufacturer and *always* consult with them if in any doubt over the suitability of any process used. 2. Cleaning and sterilising guidelines are available in HTM 01-01 Part C and HTM 01-01 Part D. Contact: The NHS Estates Stationary Office Publications Centre for details at www.tsonline.gov.uk . For further information contact: NHS Estates Information Centre, Department of Health, 1 Trevelyan Square, Boar Lane, Leeds, LS1 6AE, England or visit www.nhsestates.gov.uk
MANUFACTURERS CONTACT	1. For assistance please contact +44(0)1 747 821 546 2. Meditech Systems Ltd, Unit 3 Shrublands Estate, Shearstock, Shaftesbury, Dorset SP7 9PT, England

UNLESS STATED OTHERWISE DEVICES MANUFACTURED BY MEDITECH SYSTEMS Ltd ARE LATEX FREE, DO NOT CONTAIN PHTHALATES OR SUBSTANCES DERIVED FROM HUMANS OR ANIMALS.

NOTE: THE INSTRUCTIONS PROVIDED BY THE MANUFACTURER HAVE BEEN VALIDATED AS BEING CAPABLE OF PREPARING A DEVICE FOR REUSE. IT IS THE RESPONSIBILITY OF THE REPROCESSOR TO ENSURE THAT THE REPROCESSING AS ACTUALLY PERFORMED USING EQUIPMENT, MATERIALS AND PERSONNEL IN THE REPROCESSING FACILITY ACHIEVE THE DESIRED RESULTS. THIS REQUIRES VALIDATION AND ROUTINE MONITORING OF THE PROCESS. LIKEWISE, ANY DEVIATION BY THE REPROCESSOR FROM THE INSTRUCTIONS PROVIDED MUST BE PROPERLY EVALUATED FOR EFFECTIVENESS AND POTENTIAL ADVERSE CONSEQUENCES

ELECTROSURGERY FORCEPS INSPECTION

Figure 1 Examples of forceps

Top = monopolar forceps Bottom = bipolar forceps

1. Forceps cannot be dismantled.
2. Care must be taken not to damage the insulation coating during handling and reprocessing. Avoid contact with sharp or heavy objects and do not use abrasives on the coated areas.
3. Inspect the coating for damage and wear, especially on the grip section. Any damage or wear to the coating will render the device unfit for service. For some instruments the manufacturer may offer a repair service on the coating.
4. Check that the tips of the forceps meet when closed together. Any misalignment of the tips may render the forceps unfit for use
5. Check the action of the 'spring'. The forceps should be neither too hard nor too easy to close. There is no exact figure for the force required to operate forceps and it is very much a subjective assessment by the user.
6. Check the tip faces are in good condition. Plain tips should be smooth and flat. Serrated tips must have undamaged serrations. For specialist tips refer to the manufacturer for information.
7. Check that the connection on monopolar forceps is a secure fit in an appropriate size cable socket. If the connector is too loose it may be possible to insert a thin screwdriver into the slots in the connector and gently splay the connector out until a good connection is obtained. If this is not possible the device must be removed from service and either discarded or returned to the manufacturer for possible repair.
8. For forceps with bipolar UK or USA connections, Aeshculap or 'Olsen' screw connections should be checked by fitting them to an appropriate socket connection. The connection should be secure but not difficult to fit into or remove from the socket.

NOTE; The above illustration is for guidance only. Forceps vary in size, shape, tip type, tip size and connection configuration.

ELECTROSURGERY ELECTRODES INSPECTION

Figure 2 Loop Electrode

Figure 3 Ball Electrode

Figure 4 Blade or Spatula Electrode

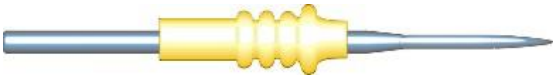


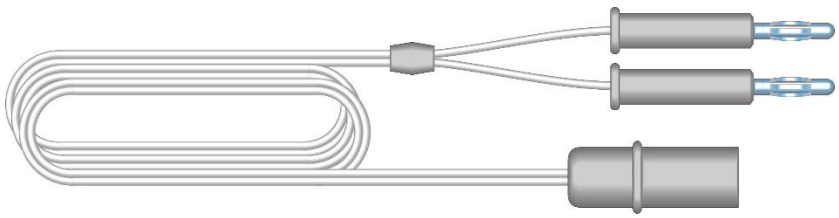
Figure 5 Needle Electrode

1. Electrosurgical (also known as diathermy) electrodes 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.
2. The examples shown above are the most commonly used but there are many other styles. These instructions are generic and will cover most electrodes. If in doubt contact the manufacturer for assistance.
3. These devices cannot be dismantled.
4. Reprocessing may be carried out following the general reprocessing instructions available from the manufacturer.

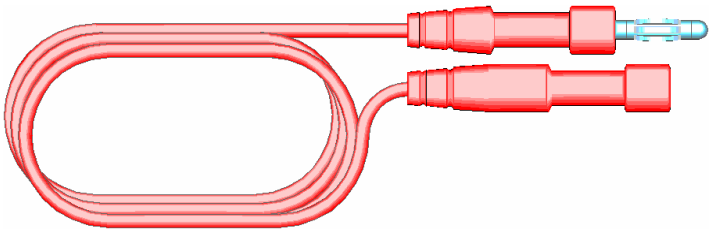
INSPECTION

1. Examine the electrode for damage, distortion, broken or kinked loop wire.
2. Where the electrode has insulation, either nylon coating or plastic tube, carefully examine the insulation for cuts, wear, abrasions, bubbles or any exposed metal. If the insulation is damaged then the electrode should be withdrawn from service. Some electrodes can be re-insulated (refer to manufacturer).
3. The surfaces intended for contact with tissue may be cleaned with a light abrasive during use and when being reprocessed. Care must be taken not to abrade the insulation.
4. Check the security of the ball (ball electrodes) and loop wires (loop electrodes) by gently pulling on the ball / wire.
5. Check that the grip (where fitted) is secure on the shaft.
6. Check that the electrode makes a positive connection to the appropriate handle / holder by fitting the electrode into the handle / holder socket. Ensure that the handle / holder is not connected to a power source.
7. The devices do not have a prescribed life but should be withdrawn when their condition gives cause for concern.

ELECTROSURGERY CABLES INSPECTION



Picture 1 - Bipolar electrosurgical power cable (example)



Picture 2 Monopolar electrosurgical power cable (example)

1. Electrosurgical power cables are used to connect active electrosurgical devices to an energy generator. They cannot be dismantled.
2. Inspect the cable connection for damage or distortion.
3. Check the integrity of the machine end connection(s) by inserting them into the sockets of an electrosurgical generator or a suitably sized test socket. The plugs must provide a positive and secure connection to the machine. If in doubt withdraw the cable from service. When using a generator ensure that the generator is switched off before insert the cable plugs.

4. Check the integrity of the instrument connection by inserting a suitable instrument into the connection. The connector must provide a positive and secure connection to the instrument. If in doubt withdraw the cable from service. Before connecting the test instrument ensure that the cable is not connected to a power source.
5. For dispersive / patient plate cables check the action of the patient plate clamp connector. The clamp must lock down positively and provide a secure grip onto a patient plate.
6. Inspect the cable cover for cuts, abrasion or other damage. Look also for kinks in the cable especially at the points where the cable exits the moulded end connectors. Kinks and bulges in the cable cover, especially if the cable appears to be floppy in the area of the damage, indicates that the internal conductor may be damaged. If in doubt withdraw the cable from service.
7. Inspect the cable cover for aging. This will be seen as surface cracking of the cover. This is unlikely to be present in cables that have been reprocessed in accordance with our cleaning instructions < 200 times.
8. Carry out an electrical continuity test. Cable resistance should be <2.0 ohms/metre.
9. When storing the cable do not coil it on a diameter less then 75mm and avoid storing it in direct sunlight or in temperatures above 160^{o}C.