INSTRUCTIONS FOR USE

RE-USABLE FINGERSWITCHES & FOOTSWITCH HANDLES

These instructions for use do not replace the user manual of the electrosurgical unit used. Read the user manual of each and ask Prima Medical or your distributor in case of doubt.

Product Specifications

PMS651	100 Use Footswitch Handle for: 4mm Aesculap, Berchtold, Erbe T Series, Eschmann TD300, TD311, DS302 Sutter BM780, 3m cable
PMS652	100 Use Footswitch Handle for: 8mm Bard, Birtcher, Bovie, Bowa, Conmed, Eschmann, Medtrex, Valleylab, 3m cable
PMS653	100 Use Footswitch Handle for: 4mm (female) Aesculap/Berchtold/Erbe T Series/Huttinger/Martin/Micromed/Siemens/Sutter BM780, 3m
PMS654	100 Use Footswitch Handle for: 5mm ACC (standard) ICC, Erbe V10, Karl Storz, 3m cable
PMS750	100 Use fingerswitch with blade electrode, AUTOClabel and punch, 3m cable (5m cable models available)
PMS950	60 Use fingerswitch with blade electrode, AUTOClabel and punch, 3m cable (5m cable models available)

INTENDED USE

The Fingerswitch is intended to be used as the active **Monopolar** electrode in an electrosurgery generator system. It is a re-usable instrument designed to effect cutting, coagulation & ablation of soft tissues by means of targeted delivery of RF current.

INDICATIONS

The device is indicated for any application that requires the cutting, coagulation, ablation or excision of soft tissues according to the surgeon's preference and habit.

Prima, as a manufacturer, do not recommend a specific procedure.

CONTRAINDICATIONS

Any use of this instrument for tasks other than for which is it indicated, can lead to premature wear, which may result in damage which may cause potential hazards to patients and users.

These devices should never be used when:

- The device fails the instructions for use inspection
- In the presence of flammable materials or gases
- When electrosurgical techniques are contraindicated.
- If the labelled expiry date has been exceeded
- If, during use, the performance or characteristics of the device change suddenly.
- No non-conductive holster is present to isolate active electrodes from the patient.

INSPECTION

These devices should be inspected before each use. Visually examine the devices for obvious physical damage. Including:

- Cracked, broken or otherwise distorted plastic parts/ insulations/coatings.
- Broken or significantly bent connector contacts.
- Damage including cuts, punctures, nicks, abrasions, unusual lumps, discoloration.
- Damage or perforation to the sterile packaging

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SETUP AND USE

1. Insert the electrode into the receptacle of the fingerswitch and remove the plastic cap. Ensure that the connection is firm and that there is no play and that there is no exposed metal.
2. Connect the instrument and cord to the generator/footswitch only while it is in the "**OFF**" or "**STANDBY**" mode. Failure to do so may result in injury or electrical shock to the patient or operating room personnel.
3. The device is equipped with a standard 4mm male plug connector. To operate the monopolar electrosurgical features, the buttons are used. For fingerswitch models, yellow activates CUT functions and blue activates COAG function, as indicated in the diagram below. Footswitch models vary dependent on the footswitch being used – refer to the manufacturer's instructions.
4. Test the functions of the device once connected through brief activation before patient introduction.
5. During use, ensure that the device is not left on or near the patient when not active, as portions of the device may still pose a risk of burns.
6. Check the active portion of the device regularly for soft tissue residues (eschar). Eschar has a high electrical impedance and failure to remove it from the device may result in increased patient scarring.

CAUTION

- This device is provided NON-STERILE. Ensure that it has been sterilised prior to use.
- A thorough understanding of the techniques and principles involved in electrosurgical procedures is necessary to avoid burn or shock hazard to patient and/ or operator.
- Modification, including bending, is not recommended. In the event of the electrode bending, Prima Medical electrode models whose product code is suffixed with "A" will accept gentle modification up to 60 degrees, but the use of mechanical or metal instruments to do this may cause damage and affect subsequent product performance.
- Always refer to the generator manufacturers' operating instructions for the correct use of this equipment. Always use the lowest power setting possible to achieve the intended clinical effect and use brief, intermittent activation of the device.
- Always be mindful of the presence of EM fields in the operating theatre. NEVER use the device in proximity to any active implants. This may cause severe patient injury.
- If at any time the performance of the device changes suddenly, stop usage immediately.
- Keep the desired voltage/power as low as possible and use only brief intermittent activation in order to minimize the potential for capacitive coupling and inadvertent burn injuries whilst working at high voltages.
- Activate only when in contact / proximity to target tissue to avoid the possibility of unintended tissue damage.
- Do not activate in close proximity to other active instruments, as this may cause insulation breakdown.
- This product may be used only by trained medical staff, who use it according to the instructions for use. A thorough understanding of the techniques and principles of electrosurgery is ESSENTIAL for patient safety.

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ADVERSE REACTIONS or SIDE-EFFECTS

The use of these devices may generate harmful “surgical” smoke. The presence of a suitable smoke evacuation system during theatre use is recommended to minimise the risk of harm.

SAFETY TIPS

- Use lowest possible power settings on the electrosurgery generator capable of producing the desired surgical affect and use brief, intermittent activation of the device.
- Never allow the cable to come in to contact with the skin of the patient or the operator during electrosurgical activations.
- Do not permit the cable to be parallel and/ or in close proximity to the cables of other electrosurgical devices.
- Always place unused electrosurgical accessories in a safe, insulated location such as a holster/ quiver when not in use.
- Do not lay any device on the patient, especially one that has just been used. After using the Cut or Coagulation function on an electrosurgical pencil, the tip/electrode is hot. This is to prevent the patient, physician and/or staff from accidental burns and to prevent the possible incidence of fires

WARNING

CONNECT BIPOLAR ACCESSORIES TO THE BIPOLAR RECEPTACLE AND MONOPOLAR ACCESSORIES TO THE MONOPOLAR RECEPTACLE. DO NOT ATTEMPT TO INTERCHANGE BIPOLAR AND MONOPOLAR ACCESSORIES AS IMPROPER CONNECTION OF ACCESSORIES MAY RESULT IN HAZARDOUS CONDITIONS.

CLEANING & DISINFECTION

Never use an ultrasonic cleaning device! Use a soft bristle brush or damp cloth with mild detergent to thoroughly wash and remove any foreign material and debris. Always follow the detergent manufacturer recommendations for use. Then, use a disinfectant solution suitable for the disinfection of surgical instruments. Finally, the device should be rinsed using warm water and dried with a lint free cloth, with visual checks to ensure all material, detergent and disinfection residues have been removed.

STERILISATION

DO NOT USE GAMMA TO STERILISE THIS DEVICE. DOING SO RISKS PRODUCT FAILURE, ELECTRICAL BREAKDOWN AND SERIOUS INJURY.

Moist Heat Sterilisation
134 º C to 137 º C for > 3 minutes or
121 º C to 124 º C for > 15 minutes, depending on sterilisation equipment cycles

EtO Sterilisation
Follow manufactures recommendations appertaining to the sterilisation equipment used.
Only use validated equipment/processes according to national/international standards.

LIMITED WARRANTY

Prima Medical Ltd warrants that this product will be free from material and workmanship defects. The warranty is void should Prima Medical Ltd determine that damage has occurred as a result of improper handling, misuse, unauthorised repair or accident.

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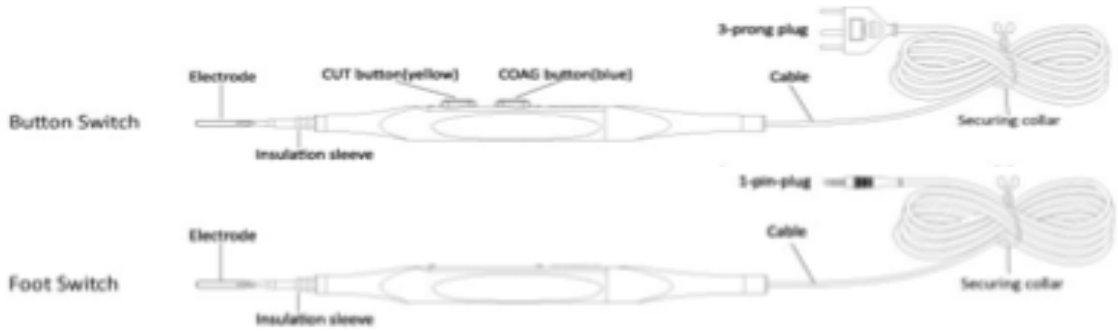
DIAGRAM



SYMBOLS AND MEANINGS

Temperature limit - Indicates the upper and lower limits of temperature to which the medical device can be safely exposed. The temperature is indicated adjacent to the horizontal line

Caution - Indicates that the instructions for use contain important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

LATEX

No Latex - Indicates that natural rubber latex was not used in the manufacturing of the product, its container, or its packaging.

Keep away from sunlight - Indicates a medical device that needs protection from light sources

Manufacturer - Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.

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CE Mark - Indicates manufacturer declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation. Notified body 0120.

Manufacture date - Indicates the date when the medical device was manufactured.

LOT

Batch code - Indicates the manufacturer's batch code so that the batch or lot can be identified.

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