PenEvac® Bulk, Warnings, Cautions & Instructions

Manufacturer
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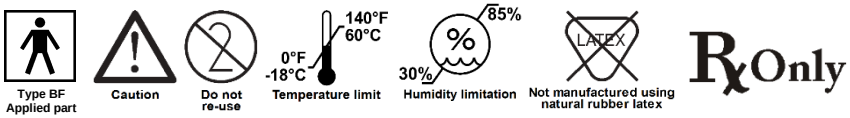
Made in the USA



Indications for Use
The PenEvac® is intended to be used as the active **Monopolar** electrode in an electrosurgery generator system and to facilitate the removal of smoke that is generated during procedures.

Technical Specification:
I.C. Medical, Inc. recommends the use of the PenEvac® with the Crystal Vision® smoke evacuators-all models, and other I.C. Medical products. The PenEvac is intended to be used with an Electrical Surgical Unit.
The maximum electrical capacity of this product is 4.5 kVp. DO NOT exceed this value under any circumstances.
The PenEvac® product family, when used as a capture device positioned at a 45-degree angle and approximately 1 cm from the smoke source, with ø10 mm transfer tubing, and without interfering with the visibility of the surgical site, meets the ISO 16571:2024 standard for plume removal efficiency when paired with the Crystal Vision® Smoke Evacuator equipped with the SAFEGUARD BLUE® Hydrophobic ULPA Filter with a built-in fluid trap, operating at flow settings of ≥75 LPM.

Transport and Storage Conditions:
Temperature limits: -18°C to 60°C (0°F to 140°F);
Relative Humidity limitation: 30% to 85%.

Safety Instructions
WARNINGS!
1. Keep active accessories away from patient when not in use and away from flammable objects, gases, and vapors at all times.
2. This is a monopolar device. BEFORE USE, a dispersive electrode must be properly attached to the patient.
3. Keep active accessories in a clean, dry, non-conductive safety container (holster) provided when not in use.
4. After using the Cut or Coagulation function on an electrosurgical pencil (PenEvac®), the tip/electrode is hot. **DO NOT** lay any active device on the patient, especially an electrosurgical pencil (PenEvac®) that has just been used on the patient. This is to prevent the patient, physician, and/or staff from accidental burns by the hot tip/electrode.
5. Electrosurgical electrodes that are activated or hot from use can cause a fire. Do not place them near or in contact with flammable materials and substances (e. g. drapes, linens, flammable gases, endotracheal tubes, etc.).
6. Keep the voltage/power as low as possible to achieve the desired end effect in order to minimize the potential for capacitive coupling and inadvertent burning at high voltages.
7. Check the product for damage before use, including all the insulation. If damaged, **DO NOT** use this product.
8. **DO NOT USE** in MR Environment!
9. **DO NOT USE** this device for the suction of liquid.
10. **DO NOT USE** in the presence of flammable anesthetics, oxidizing gases (such as nitrous oxide (N2O) and oxygen) or any potential source of ignition!
11. Protect this product from any form of mechanical damage! **DO NOT** throw! **DO NOT** use force! If there is a cable, and unless stated otherwise, **DO NOT** kink it or wrap it around the product!
12. **DO NOT** kink the tube or wrap it around the product.
13. **DO NOT USE** the telescope for lifting tissue, cracks may appear and electrical integrity may be compromised.

CAUTIONS:
1. Federal Law restricts this device to sale by or on the order of a licensed physician.
2. For all PenEvac® Accessories: Read instruction for PenEvac®, Electrosurgery Unit, and Smoke Evacuator before Use.
3. These devices are intended for single use only. Properly discard after use. Do not resterilize. ·
4. **DO NOT** operate the electrosurgical pencil if air does not flow through the smoke evacuator tube. Refer to smoke evacuator instructions.
5. **DO NOT USE** a scratch pad or other abrasive cleaner to remove eschar. This may damage the PTFE coating.
6. If the electrode or coating is damaged, discard the electrode.
7. Activate the electrodes when in contact, or in close proximity to target tissue to avoid the possibility of unintended tissue damage.
8. Electrosurgical cables should be positioned to minimize contact with the patient and avoid contact with other leads to avoid adversely influencing the operation of other electronic equipment.
9. **DO NOT USE** in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g. cardiologist), to avoid an interference with the action of the electronic implant. The implant may be damaged, which would imply a possible risk for the patient.
10. **DO NOT USE** for fluid removal, this device was not designed for such application. Aspirate fluid from the area before activating the instrument. Direct contact or near an active electrode with conductive fluids (e.g., blood or saline) may carry electrical current or heat away from target tissue, which may cause burns to the patient.
11. Localized burns to the patient or physician may result from electric currents carried through conductive objects. Current may be generated in conductive objects by direct contact with the active electrode, or by the active accessory being in close proximity to the conductive object.
12. When the visualization may be impaired, be alert, inadvertent activation or movement of the activated electrode, may result in injury to the patient.

INSTRUCTIONS:
Non-Sterile product

Non-sterile

The "Non-Sterile" product is indicated on the packaging, by Non-Sterile symbol.
I.C. Medical intends that non-sterile products for use in sterile environments, be further processed by our customers, including further packaging and/or sterilization according to their own validated processes. These products are to be sterilized by ethylene oxide only, as other sterilization methods have not been validated by I.C. Medical and may damage the product which could cause a device malfunction and/or injury to the patient.
This device has not been evaluated for reprocessing or re-sterilization. Reprocessing and/or re-sterilization may damage the device, rendering it unusable and/or may lead to device failure, which could result in patient illness, injury or death.

Warning: Malfunctions:
If the device malfunctions, immediately discontinue use.

Packaging:
Product packed **Bulk, Non-Sterile**. Check the product for handling and shipping damage before packaging, including all the insulation. If damaged, **DO NOT** pack this product! Protect this product from any form of mechanical damage! **DO NOT** throw! **DO NOT** use force!

Label ICM-001-1183 Rev. F Date:2025-02

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Follow your institutional protocol for packaging.

Operating Instructions:

1. Check the product for damage before use, including all the insulation. If damaged **DO NOT** use this product!
2. Insert electrical connector to **Monopolar** connector on ESU generator.
3. Connect the smoke tube to the smoke evacuator.
4. On the Telescopic PenEvac® loosen the locking ring ¼ turn counterclockwise, while looking into the nozzle, adjust to desired length, and tighten the locking ring on the telescopic electrode.
5. Note: When the locking ring is secure, the electrode can still be rotated to the desired orientation without loosening the ring. To change the length of the telescoping tip, you will still have to loosen the ring.

Cleaning, disinfection, sterilization

DO NOT clean, **DO NOT** disinfect, **DO NOT** re-sterilize or reuse! Reuse may result in patient injury due to contamination or dielectric failure.

PenEvac® Electrodes (All Styles) Instructions:

1. Ensure the accessory is not connected to the generator.
2. Fully insert the electrode into the accessory.
3. Adjust length of telescope and tighten locking ring.

All Items

1. Replace and dispose all items in accordance with your institutional biohazard protocol.
2. **Do Not clean, re-sterilize or reuse.** Reuse may result in patient injury due to contamination or dielectric failure.

SERIOUS ADVERSE EVENTS:

Any serious adverse event or incident that occurs in relation to the device or accessory should be reported to the manufacturer, I.C. Medical, Inc., at complaints@icmedical.com and to the FDA.