

MAXPENCIL

Electrosurgical Smoke Evacuation Pencil

Product description:
Hand control handpiece with blade electrode, 10'(3.0m) cord and holster. Allows the use of Monopolar Cut, Coagulation. Single use; sterile.

Indications for Use:
MediMaxTech's smoke evacuation pencil is designed for general electrosurgical applications and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

Model	Description
EvBNH	Smoke evacuation pencil + 2.5" Ceramic coated blade + Holster

MediMaxTech's smoke evacuation pencil is designed to work with the electrosurgical generators utilizing a 3-pin monopolar connection port and smoke evacuation units utilizing the hose connector with 8 to 22 mm diameter.

Before you use:

- Please check whether there is a cracked or broken or distorted shape of the product.
- Make sure whether blade of electrode is completely linked on blade socket.

Instruction for use

- Follow the generator manufacturer's instructions to connect the device to a monopolar electrosurgical unit. A dispersive electrode should be used with the device generator to prevent burns/injury to the patient when used the monopolar handpiece. Consult with generator manual for additional instruction
- Make sure electrosurgical unit is turned off.
 - After removing the packing cover of product, you should link connector part of leadwire to electrosurgical unit.
 - Connect with hose of the device and smoke evacuator of electro surgical unit.
 - Turn on the electrosurgical unit. Then, ready to place the blade of pencil on affected part of patient. (Be careful that the top part of the blade does not contact the patient.)
 - After pushing the cutting or coagulation push button(or rocker switch), make an incision or coagulate skin tissue of patient.
 - Use the suction function to remove smoke generated during surgical procedure.
 - After using the electrosurgical unit, you should power off electrosurgical unit and then, separate connector of device from electrosurgical unit.
 - MediMaxTech's smoke evacuation pencil is single-use product. Don't reuse. It should be immediately disposed after use.
 - Disposal should be followed by regulations in your country.

Safety Tips

- Use lowest possible power setting on the associated electrosurgical unit capable of achieving desired surgical effect. Activation time should be as short as possible.
- Never allow the cables connected to these devices to be in contact with skin of the patient or operator during electrosurgical activations.
- Do not permit the cables connected to these devices to be parallel and in close proximity to the leads of other electrical devices.
- Always place unused associated electrosurgical accessories in a safe insulated location such as a holster when not in use.
- Inspect and test each device before use.
- Keep the high filtration mask to avoid harmful plume during surgical procedures. Surgical smoke contains extremely small particulate matter and may contain viable cells.
- The smoke evacuation suction tube must be held close to the tissue interaction site to remove as much plume as possible.



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2 STERILE

2 LATEX

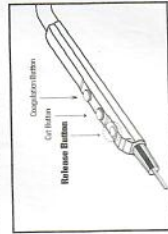


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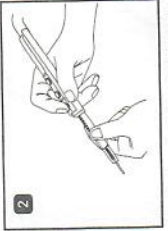
How to use Telescopic function



Press the release button first.



In order to adjust length of suction tube, press the "release" button and pull/push back on the suction tube. audible "click" will confirm that the suction tube is locked in place.



Caution

- These devices should be inspected before each use. Visually examine the devices for obvious physical damage including:
 - *Broken or significantly bent connector contacts.
 - *Damage including cuts, punctures, nicks, abrasions, unusual lumps, significant discoloration or otherwise distorted plastic parts.
 - *Verify that the electrode is fully and securely sealed in the pencil before use.
- MediMaxTech's smoke evacuation pencil is designed and intended for use only with electrosurgical generators that have been tested to the IEC60601 standard. Refer to the generator documentation to ensure compatibility.
- MediMaxTech's smoke evacuation pencil is not fluid-removal device; therefore, it should not be used for such applications.
- If the original blade is removed from the pencil, visually confirm the new blade is fully inserted and secured before activating the pencil.
- For procedures where visualization may be impaired be alert to these potential hazards:
 - *The electrode tip may remain hot enough to cause burns after the current has been deactivated.
 - *Inadvertent activation or movement of the activated electrode outside of the field of vision may result in injury to the patient.
 - *Localized burns to the patient or physician may result from electrical 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.

Warning

- Do not resterilize
- This single-use product is not designed or validated to be reused. Reuse may cause a risk of cross-contamination, or cause a malfunction as a result of the product being physically damaged.
- These devices should never be used in the presence of flammable gases, flammable prep solutions or drapes, oxidizing gases such as Nitrous Oxide(N2O), or in oxygen-enriched environments.
- To prevent shock, the pencil should be placed on the region of interest before activation.

User and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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Date 2020-12-16 Rev.002
Made in Korea.