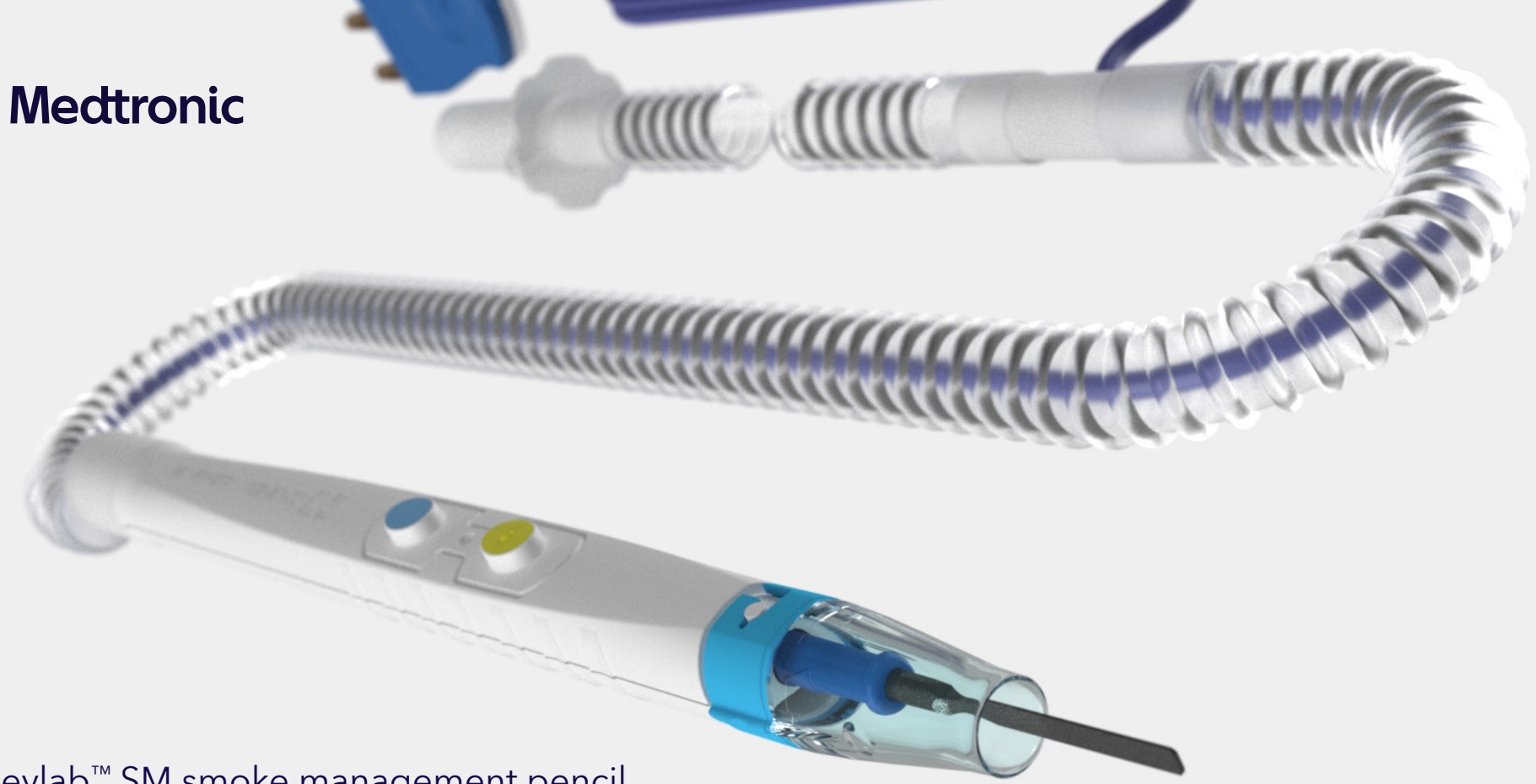
Medtronic



Valleylab™ SM smoke management pencil

Smoke safety – simplified.†,1

Product information guide

†17/17 OR staff agreed easy to setup, 17/17 surgeons agreed easy to use, and 16/17 surgeons agreed as natural to use as a standard electrosurgical pencil.

Table of contents

A complex problem.

The dangers of surgical smoke

With every surgery, you and your team work tirelessly to protect patients. But taking care of patient health shouldn't mean sacrificing your own. Protecting yourself starts with understanding the risks of surgical smoke.

The daily amount of surgical smoke is equal to

27–30

unfiltered cigarettes†,[2]

Laser plume contains

150+

hazardous chemicals[3]

Nurses exposed to surgical smoke experience

2X

more respiratory issues than the general population‡,[4]

†Average based on 44 operating days in a single elective plastic surgery theatre where porcine tissue was subject to electrocautery tissue ablation. Results may not be indicative of the average operating theatre.

‡Most frequently reported respiratory symptoms include nasal congestion, coughing, allergies, sinus infection/problems.

A simple solution.

Built on trusted Valleylab™ technology

The Valleylab™ SM smoke management pencil simplifies smoke safety with a number of enhanced features.[◊,¶,#,5] Its compact, ergonomic design has been optimized for even the most dynamic surgical environments.[Δ,∞,1,5] And with its easy-to-use interface,[†,1] smoke safety is more seamless than ever before.

Superior performance

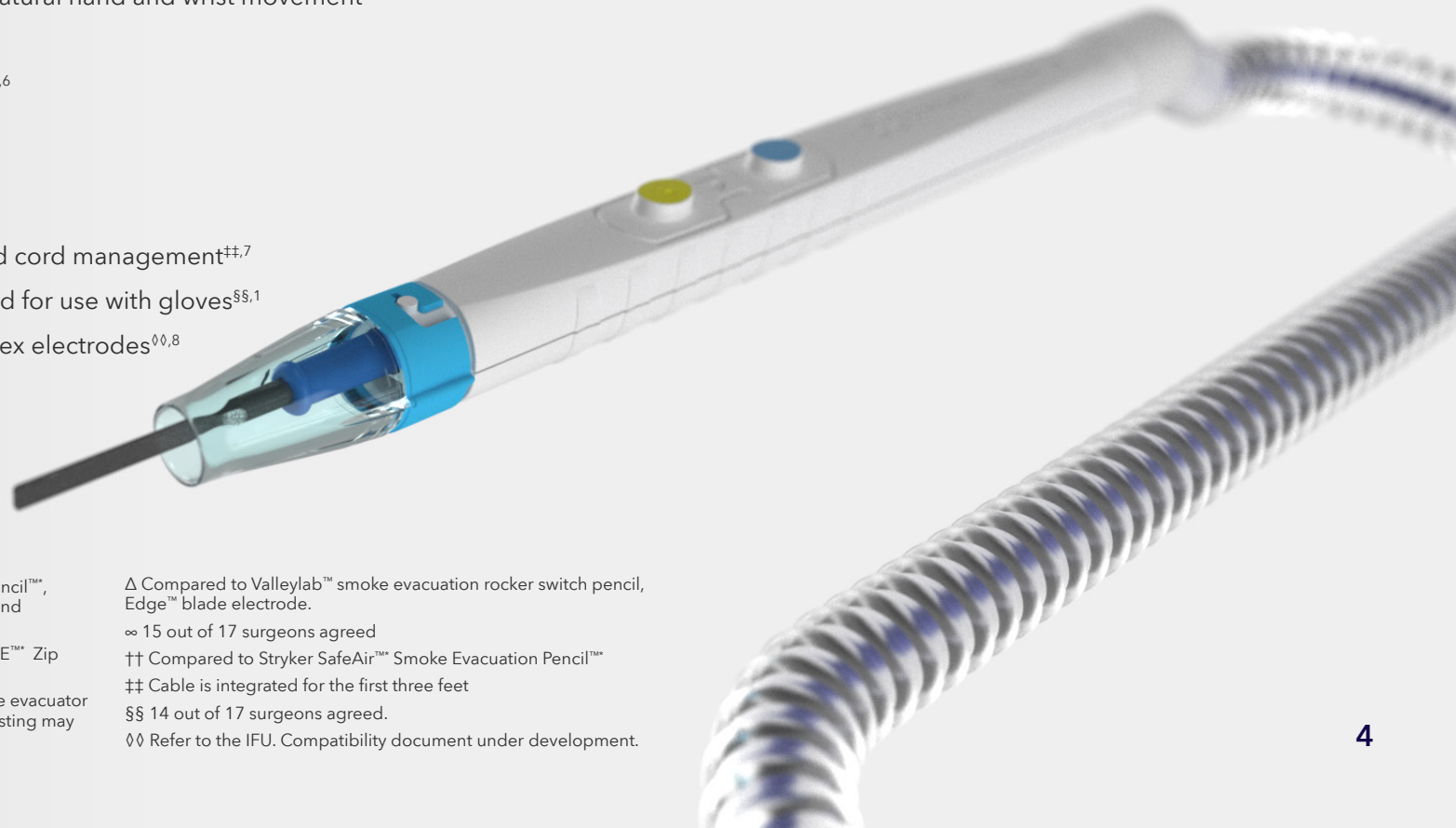
- 30 percent higher air flow[#,††,5]
- A specially designed nozzle for increased smoke removal[Δ,5]
- More efficient smoke capture[Δ,5]

Enhanced ergonomics

- A 360-degree swivel that supports natural hand and wrist movement[‡,1]
- A lightweight and natural feel[†,1]
- Optimal access to the surgical site[∞,1,6]

Ease of use

- Easy set up[§,1]
- An integrated ESU wire for simplified cord management[‡‡,7]
- Soft-touch, nonslip buttons optimized for use with gloves[§§,1]
- Compatible with both hex and nonhex electrodes[◊◊,8]



† 17 out of 17 surgeons agreed.

‡ 16 out of 17 surgeons agreed.

§ 17 out of 17 OR staff agreed.

◊ Compared to Stryker SafeAir™* Smoke Evacuation Pencil™*, MEGADYNE™* Zip Pen™*, Conmed™* PlumePen™* Pro, and Conmed™* GoldVac™* Slim Pencils

¶ Compared to ConMed PlumePen™* Elite, MEGADYNE™* Zip Pen™*, and ConMed GoldVac™* Slim Pencils.

Tested on bench tissue model with RapidVac™ smoke evacuator system at 100% (5 dots), 10 ft configurations. Bench testing may not be indicative of clinical performance.

Δ Compared to Valleylab™ smoke evacuation rocker switch pencil, Edge™ blade electrode.

∞ 15 out of 17 surgeons agreed

†† Compared to Stryker SafeAir™* Smoke Evacuation Pencil™*

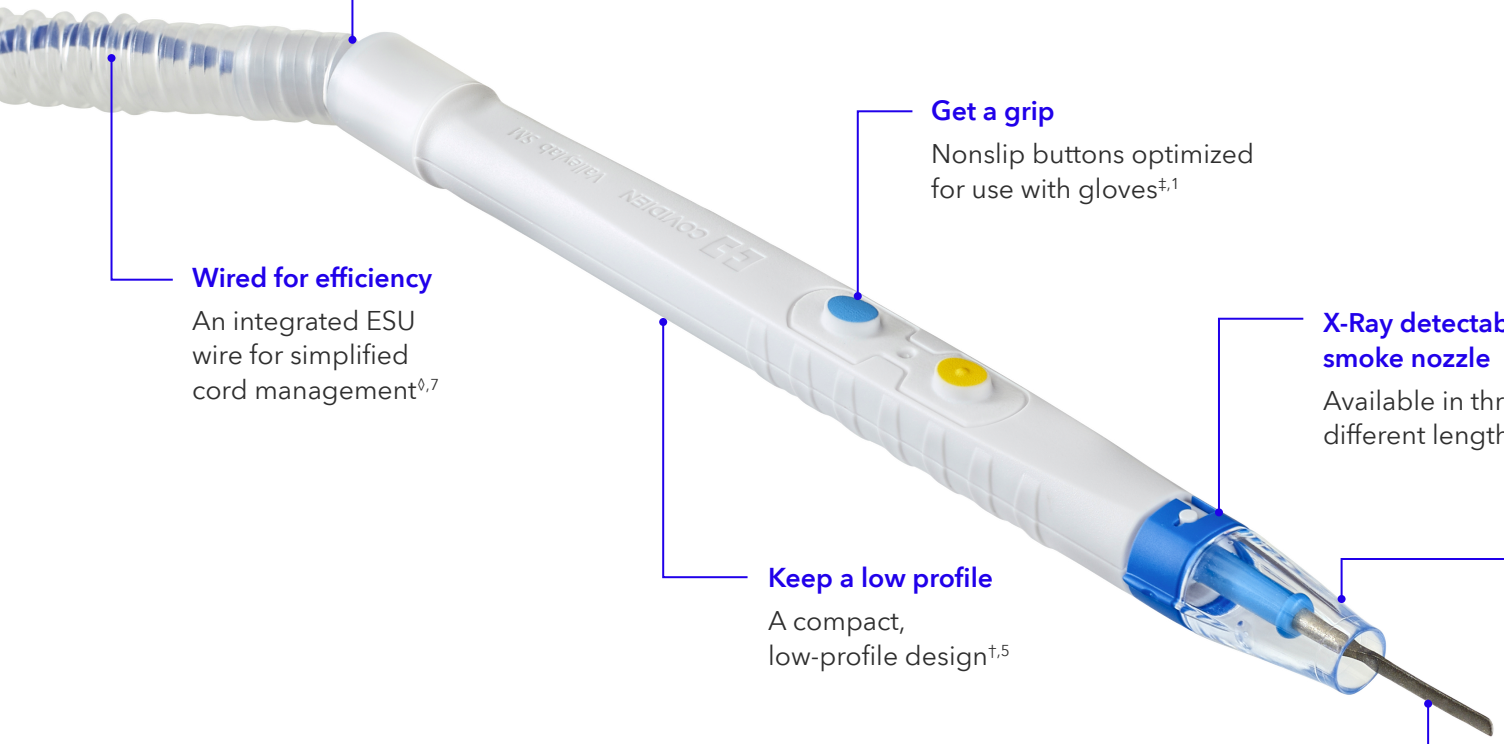
‡‡ Cable is integrated for the first three feet

§§ 14 out of 17 surgeons agreed.

◊◊ Refer to the IFU. Compatibility document under development.

Features and benefits

Improved smoke plume removal[#,Δ,5]



360 degrees of freedom

A 360-degree swivel for natural wrist movement[§,1]

Get a grip

Nonslip buttons optimized for use with gloves[‡,1]

Wired for efficiency

An integrated ESU wire for simplified cord management[◊,7]

X-Ray detectable smoke nozzle

Available in three different lengths[9]

Keep a low profile

A compact, low-profile design[†,5]

A clear vision

Transparent smoke nozzle which provides good visibility at the surgical site[§,1]

Access granted

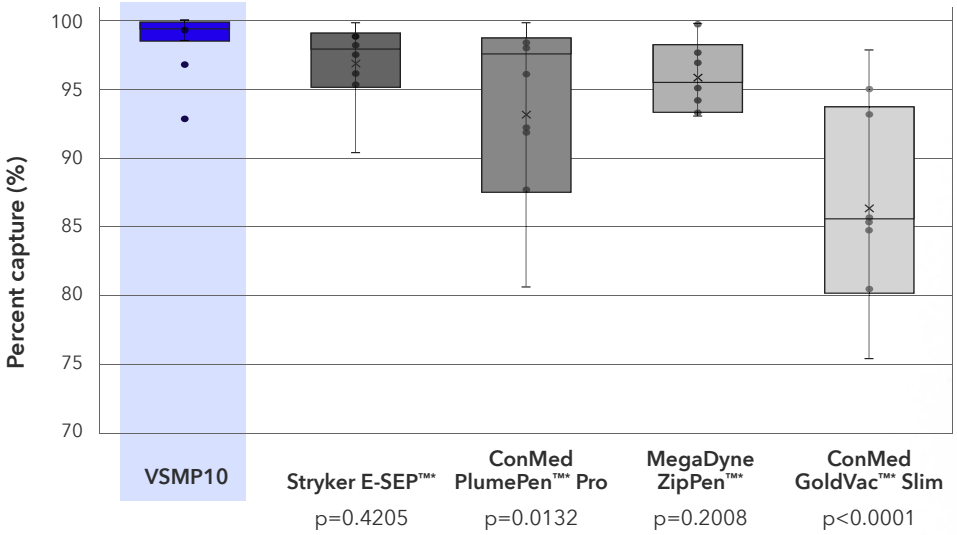
Optimal access to the surgical site[¶,1,6]

†Compared to Valleylab™ smoke evacuation rocker switch pencil, Edge™ blade electrode.
‡14 out of 17 surgeons agreed.
§16 out of 17 surgeons agreed.
◊Cable is integrated for the first three feet.
¶15 out of 17 surgeons agreed
Compared to ConMed PlumePen™* Elite, MEGADYNE™* Zip Pen™*, and ConMed GoldVac™* Slim Pencils.
Δ Tested on bench tissue model with RapidVac™ smoke evacuator system at 100% (5 dots), 10 ft configurations. Bench testing may not be indicative of clinical performance.

Competitive comparisons

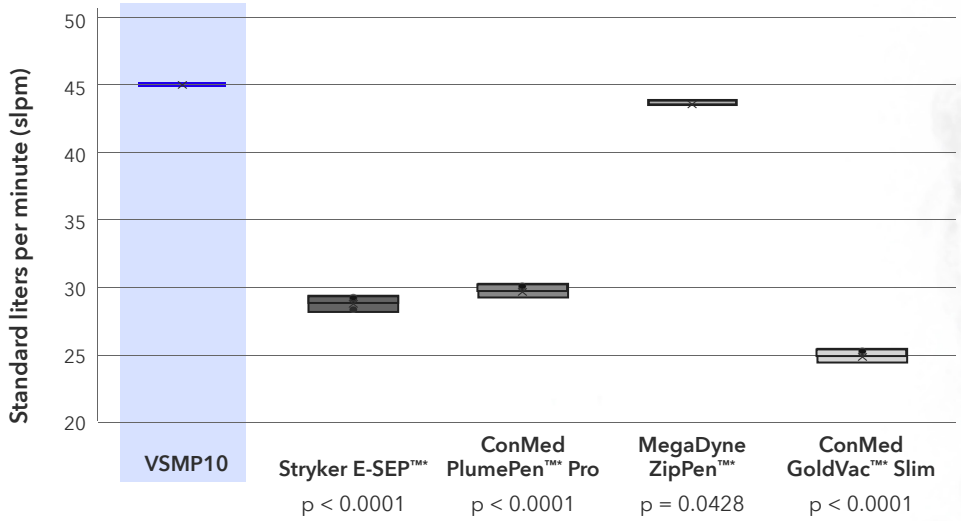
Smoke capture vs. pencil

Evacuator setting at 60% vacuum



Air flow vs. pencil

Evacuator setting at 60% vacuum



Ordering information

Order code	Material description	Units per box
Sterile		
VSMP10	Valleylab™ SM smoke management pencil with Edge™ electrode, 10 ft	20
VSMP15	Valleylab™ SM smoke management pencil with Edge™ electrode, 15 ft	20
Non-sterile		
VSMP10NSB	Valleylab™ SM smoke management pencil with Edge™ electrode, 10 ft (nonsterile bulk)	30
Extended nozzles		
VSMEN4	Valleylab™ SM smoke management extended nozzle, 4-inch electrode	80
VSMEN6	Valleylab™ SM smoke management extended nozzle, 6.5-inch electrode	80

Smoke safety – in the palm of your hand.

Ready to experience the benefits?

Scan to learn more
medtronic.com/valleylabSM

FDA 510(k) clearance letter

U.S. FOOD & DRUG ADMINISTRATION

July 1, 2024

Covidien LLC
Miranda Miles
Sr. Regulatory Affairs Specialist
200 Medtronic Dr.
Lafayette, Colorado 80026

Re: K240572
Trade/Device Name: Valleylab™ SM Smoke Management Pencil with Edge™ Blade Electrode, 10' (3m) (VSMP10); Valleylab™ SM Smoke Management Pencil with Edge™ Blade Electrode, 15' (4.6m) (VSMP15); Valleylab™ SM Smoke Management Pencil with Edge™ Blade Electrode, 10' (3m), Non-Sterile Bulk (VSMP10NSB); Valleylab™ SM Smoke Management Extended Nozzle (for use with 4" (100mm) electrode) (VSMEN4); Valleylab™ SM Smoke Management Extended Nozzle (for use with 6.5" (165mm) electrode) (VSMEN6)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 28, 2024
Received: February 29, 2024

Dear Miranda Miles:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen -S Digitally signed by Long H. Chen -S
Date: 2024.07.01 14:47:58 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices

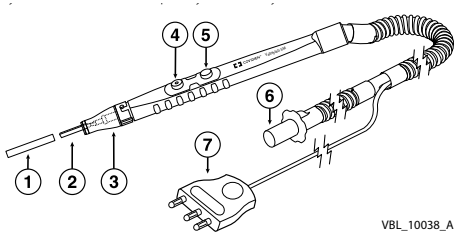
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Disclaimer: The 510(k) letter only confirms the device's legal market status in the US and should not be interpreted as an FDA approval or endorsement of the product.

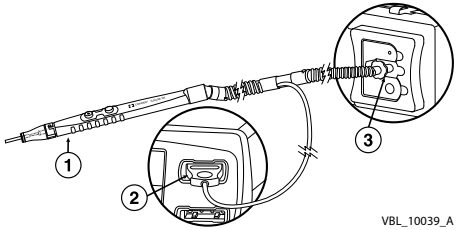
Instructions for use (IFU)

Figure 1. The Valleylab SM Smoke Management Pencil



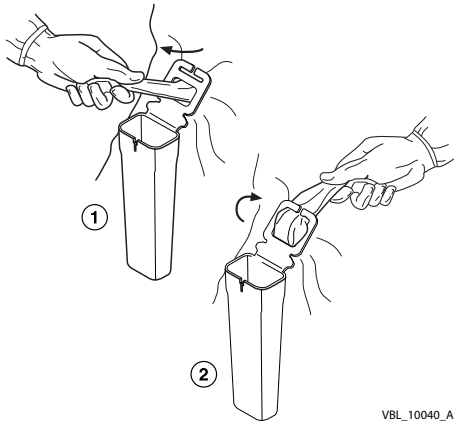
EN
1 Tip protector
2 Edge blade electrode
3 Smoke nozzle
4 CUT button (yellow)
5 COAG button (blue)
6 9.5 mm (3/8 in) port adapter
7 Monopolar plug

Figure 2. Device connected to an electrosurgical generator and a smoke evacuator



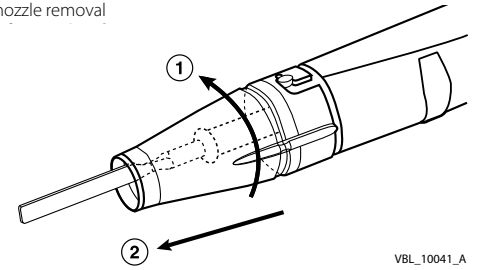
EN
1 Valleylab SM Smoke Management Pencil
2 Monopolar plug connection to electrosurgical generator
3 Port connection to evacuator, 9.5 mm (3/8 in)

Figure 3. Attaching the holster to the surgical drape



EN
1 Pull the drape material through the hole in the holster attachment tab.
2 Pull the drape material through the slot on the holster attachment tab.

Figure 4. Smoke nozzle removal



EN
1 Rotate smoke nozzle.
2 Pull smoke nozzle to remove.

Figure 5. Electrode removal

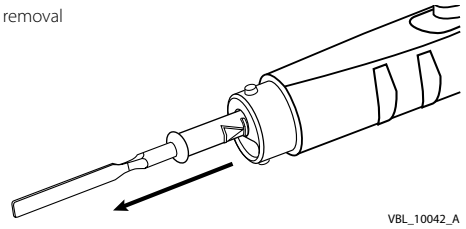
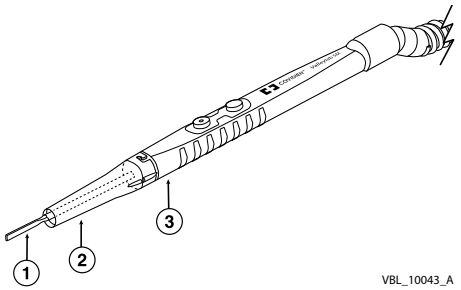


Figure 6. Device configured with VSMEN4 Smoke Management Extended Nozzle



EN
1 100 mm (4 in) electrode (sold separately)
2 VSMEN4 Smoke Management Extended Nozzle
3 Valleylab SM Smoke Management Pencil

en

Valleylab™ SM

Smoke Management Pencil with Edge™ Blade Electrode

Smoke Management Extended Nozzle

VSMP10 Smoke Management Pencil with Edge Blade Electrode, 3 m (10 ft)

VSMP15 Smoke Management Pencil with Edge Blade Electrode, 4.6 m (15 ft)

VSMEN4 Smoke Management Extended Nozzle (for use with 100 mm [4 in] electrode)

VSMEN6 Smoke Management Extended Nozzle (for use with 165 mm [6.5 in] electrode)

1 Intended Purpose

The intended purpose is to cut and coagulate tissue while removing surgical smoke.

2 Intended Users

The intended users are trained healthcare professionals using electrosurgery to cut and coagulate tissue while removing surgical smoke.

3 Intended Patient Population

The intended patient population is the general population of surgical candidates. Healthcare professionals should consider specific patient factors before deciding if the device is suitable for use.

4 Indications for Use

The Valleylab SM Smoke Management Pencil and accessories are designed for general electrosurgical applications, including cutting and coagulation, and for removing surgical smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

5 Contraindications

None known.

6 Compatible Equipment

- 2.4 mm (3/32 in) diameter hex-locking electrodes
- 2.4 mm (3/32 in) diameter non-locking electrodes
- VSMEN4 is designed for use with electrodes approximately 100 mm (4 in) in length
- VSMEN6 is designed for use with electrodes approximately 165 mm (6.5 in) in length
- Smoke evacuators with a 9.5 mm (3/8 in) port
- Covidien electrosurgical generators

For use with a maximum peak voltage of 4500 V.

7 Handling and Operating Conditions

Table 1. Environmental Conditions

Condition	Ambient temperature	Relative humidity
Operation and storage	10 °C to 40 °C (50 °F to 104 °F)	15% to 90% non-condensing
Transport	-30 °C to 60 °C (-22 °F to 140 °F)	15% to 90% non-condensing

8 Clinical Benefits

None known.

9 General Warnings and Cautions

Read all instructions, warnings, and cautions before performing any procedure using Covidien equipment or accessories.

9.1 Warnings

- **Warning:** This product cannot be adequately cleaned or sterilized by the user in order to facilitate safe reuse, and is therefore intended for single use. Attempts to clean or sterilize these devices without appropriate regulatory authorization may result in bioincompatibility, infection, or product failure risks to the patient.
- **Warning:** Do not use electrosurgery in the presence of flammable anesthetics.
- **Warning:** The sparking and heating associated with electrosurgery can provide an ignition source. To reduce the risk of ignition, do the following:
  - Keep gauze and sponges wet.
  - Keep electrosurgical electrodes away from flammable materials and environments enriched with oxygen (O_2).
  - Use of electrosurgery in oxygen-enriched environments increases the risk of fire. Therefore, take measures to reduce the oxygen concentration at the surgical site. If possible, stop supplemental oxygen at least one minute before and during use of electrosurgery.
  - Avoid enriched oxygen (O_2) and nitrous oxide (N_2O) atmospheres near the surgical site, especially during head and neck surgery. Both oxygen and nitrous oxide support combustion and may result in fires and burns to patients or surgical personnel.
  - Prevent pooling of flammable fluids and the accumulation of flammable or oxidizing gases or vapors under surgical drapes or near the surgical site.
  - Do not activate the generator until flammable vapors from skin prep solutions and tinctures have dissipated.
  - Avoid the accumulation of naturally occurring flammable gases in body cavities such as the bowel.
- **Warning:** Do not use in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (for example, cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
- **Warning:** The device is intended for use only with the equipment listed in *Section 6, Compatible Equipment, page 23*. Use of this device with other generators may not result in the desired tissue effect, may result in injury to the patient or surgical team, may cause damage to the device, or may result in electromagnetic interference.
- **Warning: Fire/Explosion Hazard** Position surgical electrode cables to avoid contact with the patient or other leads.

  Confirm proper electrosurgical generator setting before proceeding with surgery. Use the lowest power setting to achieve the desired effect.
- **Warning:** Facial and other body hair is flammable. Water soluble surgical lubricating jelly may be used to cover hair close to the surgical site to decrease flammability.
- **Warning:** Verify all oxygen circuitry connections are leak free before and during the use of electrosurgery. Verify endotracheal tubes are leak free and the cuff is properly sealed to prevent oxygen leaks. Enriched oxygen atmospheres may result in fires and burns to patients or the surgical team.
- **Warning:** Conductive fluids (for example, blood or saline) in direct contact with, or in close proximity to, the instrument may carry electrical current or heat, which may cause unintended burns to the patient. Aspirate fluid from around the instrument electrode before activating the instrument.
- **Warning:** Always place the active electrode in a clean, dry, insulated safety holster when not in use. Electrosurgical accessories that are activated or hot from use can cause unintended burns to the patient or surgical personnel. Electrosurgical accessories may cause fire or burn if placed close to or in contact with flammable materials, such as gauze, linen, or surgical drapes. Place longer electrodes away from the patient and drapes.

- **Warning:** Do not modify or add to the insulation of active electrodes. If insulated electrodes are required, use an appropriate Covidien insulated electrode.
- **Warning:** Do not modify this device without authorization of the manufacturer.
- **Warning:** This device is for use only by trained, licensed physicians. Do not use electrosurgical equipment unless properly trained in the specific procedure being undertaken. Use of this device without such training can result in serious, unintended patient injury.
- **Warning:** Use only with high-frequency surgical-mode output settings resulting in a peak output voltage not greater than the rated accessory voltage. Exceeding these settings may result in patient injury or product damage.
- **Warning:** Do not remove the active electrode from the surgical site while energy is activated. Unintended tissue effect or burns may occur.
- **Warning:** 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 use device if packaging is opened or damaged.
- **Warning:** Radiofrequency is not always confined by insulation. Current leakage does occur. To prevent unintended effects, it is recommended that:
  - Cords not be wrapped around metal instruments
  - Cords not be bundled together
- **Warning:** Leads connecting to patient should be positioned in such a way that contact with the patient or the other leads is avoided because the capacitance between the electrode cable and the patient may result in some local high current densities.
- **Warning:** The smoke nozzle tip may get hot due to the proximity of the nozzle tip to the active electrode. To prevent unintended burns:
  - Use with smoke evacuator.
  - Use the lowest power settings that achieve the desired effect.
  - Avoid extended activation times.
- **Warning:** The smoke evacuation pencil is not a fluid removal device.
- **Warning:** To address concerns about the carcinogenic and infectious potential of electrosurgical byproducts (such as tissue smoke plume and aerosols) and reduce the risks of exposure, use of the following is recommended:
  - Protective eye wear
  - Filtration masks
  - Effective smoke evacuation equipment

9.2 Cautions

- **Caution:** Do not use this device beyond its expiration date.
- **Caution:** The smoke evacuation pencil is shipped with a single-use electrode that is not designed to withstand resterilization. Safely discard after use to prevent injury to hospital personnel.
- **Caution:** The transfer bag is not a sterile barrier.
- **Caution:** The device contains nickel; use of this device could result in sensitization or an allergic reaction.

10 Product Description

The Valleylab SM Smoke Management Pencil is a hand-held electrosurgical pencil with integrated smoke evacuation. It provides monopolar electrosurgical energy to target tissues for cutting and coagulation of soft tissue. The smoke evacuation capability improves visibility of the target tissue while reducing staff and patient exposure to the hazards of surgical plume.

To select an output mode, use the following buttons on the device:

- The yellow CUT button enables a cutting function.
- The blue COAG button enables a coagulation function.

11 Before Surgery

11.1 Warnings

- **Warning:** The electrode must fit completely and securely into the device. An incorrectly seated electrode may result in burns to the patient or surgical personnel.
- **Warning:** Ensure that the patient return electrode is appropriate, properly applied to the patient, and connected to the generator. An incorrectly positioned patient return electrode may result in burns to the patient.
- **Warning:** Connect adapters and accessories to the electrosurgical unit only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.
- **Warning:** Use the lowest power settings that achieve the desired effect. If increased power settings are requested, check the patient return electrode adherence and all accessory connections before major power setting adjustments.
- **Warning:** Inspect the device and cords for breaks, cracks, nicks, or other damage before use. Failure to do so may result in injury or electrical shock to the patient or surgical team. If damaged, do not use.

11.2 Notes

Note: Using coated electrodes at high power settings may cause damage to the coating. If the coating is damaged, discard the electrode.

11.3 Setup

1. Apply the return electrode to the patient according to the manufacturer's instructions.
2. Connect the return electrode to the generator.
3. Inspect device sterile packaging.
4. Peel the pouch open.
5. Transfer the device aseptically into the sterile field. To aid in transfer of sterile product, the device has been packaged in an open transfer bag.
6. Attach the holster to the surgical drape by pulling the drape material through the hole, then through the slots (see *Figure 3*).
7. Ensure the device is not connected to the generator.
8. Remove the tip protector from the end of the electrode.
9. Inspect the device and electrode for damage.
10. If needed, change the electrode orientation. Refer to *Section 12.3* to remove the smoke nozzle and electrode, then reinsert in the preferred orientation, and reattach the smoke nozzle.

    Note: The device will also accept conventional 2.4 mm (3/32 in) hex-locking and non-locking electrodes.
11. If needed, replace the electrode according to *Section 12.3*. When using an extended electrode, use an extended smoke nozzle. See *Figure 6* and *Figure 7*.
12. Check electrode connection for secure fit.
13. Plug the 3-prong power cord connector into a compatible electrosurgical generator monopolar accessory port (see *Figure 2*). Ensure the port receptacles match the pin configuration on the plug.
14. Connect the 9.5mm (3/8 in) port adapter to the smoke evacuator. See *Figure 2*.
15. Turn on the generator and the smoke evacuator.

11.4 Electrosurgical Generators

Check the electrosurgical generator manufacturer's instructions for proper setup, use, and troubleshooting of the electrosurgical generator. Refer to the electrosurgical generator manufacturer's precautions before use.

11.5 Smoke Evacuator

Check the smoke evacuator manufacturer's instructions for proper setup, use, and troubleshooting of the smoke evacuator. Refer to the smoke evacuator manufacturer's precautions before use.

12 During Surgery

12.1 Warnings

- **Warning:** Tissue buildup (eschar) on the tip of an active electrode may create embers that pose a fire hazard, especially in oxygen-enriched environments. Keep the electrode clean and free of all debris.

- **Warning:** Some surgeons may elect to "buzz the instrument" during surgical procedures. It is not recommended, and the hazards of such a practice cannot be eliminated. Burns to the surgeon's hands may result. To minimize the risk, take these precautions:
  - Do not lean on the patient, the table, or the retractors while buzzing the instrument.
  - Activate CUT rather than COAG. CUT has a lower voltage than COAG.
  - Use the lowest power setting possible for the minimum time necessary to achieve hemostasis.
  - Ensure contact between active electrode and instrument before activating. Do not arc to the instrument.
  - Firmly grasp as much of the instrument as possible before activating. This disperses the current over a larger area and minimizes the current concentration at the fingertips.
  - "Buzz the instrument" below hand level (as close as possible to the patient) to reduce the opportunity for current to follow alternate paths through the surgeon's hands.
  - When using a coated blade electrode, place the edge of the electrode against the instrument or other metal instrument.
- **Warning:** Always use the lowest power setting that achieves the desired surgical effect. Use the active electrode for the minimum time necessary in order to reduce the possibility of unintended burn injury.
- **Warning:** Do not activate electrodes while in contact with or near other instruments, including cannulas. Localized burns to the patient or physician may result.
- **Warning:** Activate the device only when ready to deliver electrosurgical current and the active tip is in view.
- **Warning:** For coated electrodes, the electrode has a coating to reduce sticking of eschar. Cleaning the electrode with a scratch pad or other abrasive object, scraping with a sharp object, or bending beyond 90 degrees may damage the electrode. If the electrode is damaged, discard it.
- **Warning:** Before changing the electrode, turn off the generator and disconnect the device from the generator. Failure to do so may result in localized burns to surgical personnel.
- **Warning:** Do not activate the device when not in contact with target tissue. Unintended burns can happen as a result of either direct coupling with an active electrode or capacitive coupling between the active electrode and the external surface of the electrode insulation.
- **Warning:** Contact with, or close proximity to, an active electrode and any metal object (hemostats, staples, clips, retractors, and so forth) may increase the current flow and can result in unintended surgical effects such as an effect at an unintended site, insufficient energy disposition, or as localized burns to the patient or physician.

12.2 Cautions

- **Caution:** Deactivate the device before the tip leaves the surgical site.
- **Caution:** Do not activate the device while cleaning the electrode. Injury to operating room personnel may result.
- **Caution:** Wipe the electrode often with moist gauze or other material.
- **Caution:** For effective smoke evacuation, use an appropriate length smoke nozzle.

12.3 Electrode and Smoke Nozzle Exchange

Warning: Visually confirm the new electrode is fully inserted and secured and the nozzle is locked into place before activating the device.

1. Turn off the generator.
2. Unplug the device from the electrosurgical generator.
3. Remove the smoke nozzle by rotating and pulling the nozzle. See *Figure 4*.
4. Grasp the electrode by the insulating sleeve and pull it out of the device. See *Figure 5*.
5. Insert the desired electrode into the device.
6. Choose the corresponding smoke nozzle for the selected electrode. A nozzle protector may cover the locking end of the smoke nozzle. Remove and discard the nozzle protector before attaching the desired smoke nozzle.
7. Attach the smoke nozzle to the device by sliding it on and rotating the nozzle to lock it into place.
8. The included smoke nozzle is designed for use with 64 mm to 76 mm (2.5 in to 3 in) length electrodes.
   - VSMEN4 is designed for use with 100 mm (4 in) electrodes. See *Figure 6*.
   - VSMEN6 is designed for use with 165 mm (6.5 in) electrodes. See *Figure 7*.
9. A tip protector covers the end of some electrodes. If a tip protector is present, remove it before use.
10. Plug the 3-prong power cord connector on the device into a compatible electrosurgical generator monopolar accessory port. Ensure the port receptacles match the pin configuration of the plug.
11. Turn on the generator.

13 After Surgery

1. After the procedure, turn off the smoke evacuator and electrosurgical generator.
2. Disconnect the device from the electrosurgical generator and evacuator.

14 Disposal

Caution: Discard biologically contaminated devices in accordance with your institution's hazardous medical waste and sharps procedures and local regulatory requirements.

Dispose of the device, electrode, and holster after use according to hospital policy. These are not designed to withstand resterilization. **Do not resterilize.**

15 Residual Risk Summary

While every attempt has been made to reduce patient and user risks, all surgeries using this device carry some residual risk, even when used by trained physicians. The potential adverse events associated with the use of electrosurgery include, but are not limited to, the following risks:

- Allergic reaction
- Arrhythmia
- Bleeding
- Burn (including thermal and bowel)
- Cardiac arrest
- Electric shock
- Exposure to body fluids
- Fall
- Foreign body in patient
- Infection
- Inflammation
- Inhalation injury
- Perforation
- Unintended radiation exposure

Note: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and necessary regulatory authority (if European Union, the competent authority of the Member State) in which the user or patient is established.

16 Compliance Standards

16.1 California Proposition 65 Statement

For information regarding California Proposition 65, please refer to www.medtronic.com/us-en/about/corporate-governance/ca-proposition-65.html.

17 More Information

This device contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight: Cobalt; CAS No. 7440-48-4; EC No. 231-158-0.

Current scientific evidence supports that medical devices manufactured from cobalt alloys do not cause an increased risk of carcinogenicity or reproductive toxicity.

Disclaimer: IFU current as of 09/2024 when this Brochure was approved by Medtronic. For the most current IFU, please contact your sales rep.

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