The Valleylab® Smoke Evacuation Pencil

EXCEPTIONAL PERFORMANCE

POSITIVE OUTCOMES

ECONOMICAL VALUE

in perfect accord
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Because you’ve come to expect exceptional from us

The right balance creates maximum value

Value is critical in today’s healthcare environment. While patient care is priority #1, increasing economic pressures urge us all to share the responsibility to ensure quality and performance while lowering costs. Creating the right balance—positive outcomes and exceptional performance at a fair price—ensures success that everyone can share.

The most trusted name in electrosurgery

Covidien Electrosurgery is in more than 100 million surgeries a year. For over 40 years, our Valleylab brand has been synonymous with innovation and reliability.

Performance, Outcomes, Cost—in perfect accord

From the most trusted name in electrosurgery comes a uniquely designed smoke evacuation pencil that’s comfortable, effective and convenient to use. The Valleylab Smoke Evacuation Pencil delivers the performance, quality and service you’ve come to expect from Covidien.

Designed, tested and endorsed by surgeon users, the Valleylab Smoke Evacuation Pencil satisfies your perioperative staff and supports the health of your facility’s bottom line.

• Advanced, streamlined functionality for confident, simple use
• Ergonomic enhancements for comfortable utilization
• Engineered for versatility to preserve surgeon choice
Uniquely designed pencil from a brand you trust

Features & Benefits

Free and easy turning—
360° swivel minimizes “drag” on the wrist

Smooth and precise—
CUT/COAG button activation is modeled after the most popular ESU pencils

Balanced, comfortable feel with enhanced grip
- Subtle texture on handle
- Overall narrow/compact design
- Low-profile front end enhances visibility of surgical field

Overall compact design—
low-profile front end enhances visibility of the surgical field

Capture smoke where it begins
- Transparent cannula provides clear vision of the target tissue
- Telescoping feature accommodates different lengths of ESU blades
- Adjust the capture tube securely without the need to lock/unlock

Stable, safe blade attachment
- Plastic collar feature protects staff from injury when attaching blades
- Pencil can be fitted with almost any available blade (nonstick or standard options)

All-in-one, pre-assembled construction
- Integrated suction tubing and ESU wire—optimizes cord management over the surgical field
- Corrugated tubing optimizes flexibility and range of movement

EXCEPTIONAL PERFORMANCE

“In hindsight, will health-care professionals be embarrassed about their cavalier attitudes toward surgical smoke as they once were with cigarette smoke?”

1
The dangers of surgical smoke have been known for 30 years.

Each year, an estimated 500,000 workers, including surgeons, nurses, anesthesiologists, and surgical technologists, are exposed to laser or electrosurgical smoke. Surgical smoke evacuation is strongly recommended by regulatory bodies and industry associations alike, such as OSHA, JCAHO, NIOSH, and AORN, to name a few. Smoke composition, particle size, and particulate concentration are key components to understanding the potential long-term hazards of surgical smoke exposure.

<table>
<thead>
<tr>
<th>PROBLEM: Irritant, carcinogenic and neurotoxic compounds exist in surgical smoke.</th>
<th>PROBLEM: Electrosurgical smoke compounds pose a health risk to exposed perioperative staff and patients.</th>
<th>PROBLEM: Current practices/protective measures do not adequately safeguard staff and patients against the dangers of exposure to surgical smoke.</th>
</tr>
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<tr>
<td>Researchers were able to quantify the presence of toluene, ethylbenzene and xylene present in the smoke, which appeared in quantities similar to cigarette smoke.</td>
<td>Potential risks of surgical smoke inhalation include: acute and chronic inflammatory changes (emphysema, asthma, chronic bronchitis), hypoxia/dizziness, eye irritation, nausea/vomiting, headache, sneezing, weakness, light-headedness, carcinoma, dermatitis, cardiovascular dysfunction, throat irritation, lacrimation, colic, anxiety, anaemia, leukaemia, nasopharyngeal lesions, human immunodeficiency virus, and hepatitis.</td>
<td>Standard OR ventilation is ineffective at removing smoke directly where it is generated.</td>
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<td>In one particular study, researchers identified Furfural present in the composition of surgical smoke. The solvent (a strong irritant affecting the eyes, mucous membranes, lungs and central nervous system) was found at a level of 12 times higher than the recommended occupational exposure limit.</td>
<td>On average, in order to produce the same level of mutagenicity, 27-30 cigarettes would need to be smoked in the OR on a daily basis.</td>
<td>Staff in the OR should take any available precaution to protect themselves from surgical smoke, including using smoke evacuators and high-filtration masks.</td>
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<tr>
<td>A laser surgeon contracted laryngeal papillomatosis after treating patients with anogenital condylomas. Research findings suggest the surgeon may have contracted the disease by inhaling the laser plume, which was likely laden with virus particles.</td>
<td>A well-functioning smoke evacuator is of greatest importance to the surgical team.</td>
<td></td>
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</table>
With the hazards of surgical smoke so clearly defined, Covidien would like to partner with you in your efforts to safeguard your perioperative staff and patients from these potential health risks. We invite you to consult with your local Covidien representative to learn more about our smoke evacuation eletrosurgery products and how they can benefit your facility.

When evaluating over a 44-day period, the following chemicals were found in surgical smoke

<table>
<thead>
<tr>
<th>Chemical 1</th>
<th>Chemical 2</th>
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<tbody>
<tr>
<td>Acetonitrile furfural (aldehyde)</td>
<td>Carbon monoxide phenol</td>
</tr>
<tr>
<td>Acetylene hexadecanoic acid</td>
<td>Reosol propene</td>
</tr>
<tr>
<td>Acroloin hydrogen cyanide</td>
<td>1-decene (hydrocarbon)</td>
</tr>
<tr>
<td>Acrilonitrile indole (amine)</td>
<td>2-propylene nitrile</td>
</tr>
<tr>
<td>Alkyl benzene isobutene</td>
<td>2,3-dihydro indene pyridine</td>
</tr>
<tr>
<td>Benzalddehyde methane benzene</td>
<td>Ethane pyrrole (amine)</td>
</tr>
<tr>
<td>3-methyl butenal (aldehyde)</td>
<td>Ethene styrene</td>
</tr>
<tr>
<td>Benzonitrile 6-methyl indole</td>
<td>Ethylene toluene (hydrocarbon)</td>
</tr>
<tr>
<td>(amine)</td>
<td>Ethyl benzene 1-undecene (hydrocarbon)</td>
</tr>
<tr>
<td>Butadiene 4-methyl phenol,</td>
<td>Ethynyl benzene xylene</td>
</tr>
<tr>
<td>Butane 2-methyl propanol</td>
<td>Formaldehyde</td>
</tr>
<tr>
<td>(aldehyde)</td>
<td></td>
</tr>
<tr>
<td>3-butenenitrile methyl pyrazine</td>
<td></td>
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</table>

References
Leverage the benefits of Covidien’s extensive portfolio

The Valleylab Smoke Evacuation Pencil is an exceptional stand-alone value. Additionally, when using the full array of complimentary products within Covidien’s extensive electrosurgery and advanced energy portfolio, you enhance the cost-to-value advantages for your facility. Realize these potential cost savings and operational efficiencies:

- As our Covidien electrosurgery portfolio grows deeper, your GPO-contracted facility can realize compliance cost-savings
- With preferred status among many primary distributors, Covidien products will be available on-demand
- Reducing part numbers and minimizing the number of vendors you work with allows you to enjoy time, money and staff efficiencies
- Join our System Standardization Program for additional benefits
  - Free continuing education programs, biomed training and in-service videos
  - Support hotlines for clinical information or tech assistance
  - Loaner units available during equipment downtime
Appendix A: 510K approval letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

MEDTEK DEVICES, INC., dba Buffalo Filter
5% Regulatory Technology Services LLC

Mr. Mark Job
1394 25th Street NW
Buffalo, MN 55313

Re: K103375
Trade/Device Name: PLUMEPEN® Integrated Smoke Evacuation Pencil
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GFI
Dated: February 28, 2011
Received: March 1, 2011

Dear Mr. Job:

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 (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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration. Please note: CDER 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 Federal Regulations, Title 21, Parts 600 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CenterforCompliance/CDRHCDCDEOffices/ucm112895.htm for the Center for Devices and Radiological Health's (CDRH) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 897.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportsProblems/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYourIndustry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic And Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Appendix B: Valleylab Smoke Evacuation Pencil Instructions for Use

**Valleylab™**

**CVPLP2000 Smoke Evacuation Pencil**

For use with maximum voltage of 10 kV P.P.

**Caution**

- Do not use if package is opened or damaged.
- Does not contain natural rubber latex components.

**Caution**

- Sterility is guaranteed unless packaging is damaged or any seal is broken.
- Do not use electrosurgery in the presence of flammable anesthetics or other flammable gases, fluids or objects, or in the presence of oxidizing agents, as fire may result.
- Place active accessories in a holster or in a clean, dry, non-conductive and highly visible area away from the patient when not in use. Inadvertent contact with the patient may result in burns. Contact with drapes or linens may cause a fire.

The Valleylab Smoke Evacuation Pencil is designed and intended for use only with electrosurgical generators that have been tested to the IEC 60601 standard. Refer to the generator documentation to ensure compatibility.

The Valleylab Smoke Evacuation Pencil is not a 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.

**Valleylab Smoke Evacuation Pencil**

1. Blade
2. Smoke-evacuation tube
3. Cut button
4. Coag button
5. 3-prong connector
The right balance creates maximum value

Patient care is priority #1. As economic pressures increase, we share a responsibility to ensure quality while lowering costs. Creating the right balance—positive outcomes and exceptional performance at a fair price—creates success everyone can share.

The Valleylab Smoke Evacuation Pencil product brochure

EXCEPTIONAL PERFORMANCE

Advanced, streamlined functionality for confident, simple use
- Compact design and low-profile front end enhance visibility of the surgical field
- Transparent tube minimizes any obstruction of the blade’s tip or target tissue
- Spinal blade attachment provides a steady approach and interaction with the tissue
- 360° swivel feature enables free and easy turning to minimize “drag” on the wrist
- Corrugated tubing optimizes flexibility and range of movement
- ESU wire encapsulated within tubing improve cord management over the sterile field
- Plastic collar feature protects staff from injury when changing/attaching blades
- All-in-one, pre-assembled construction simplifies set up and reduces troubleshooting efforts

Ergonomic enhancements for comfortable utilization
- Subtle texture on handle enhances grip
- Smooth and precise CUT/COAG button activation (modeled after the most popular ESU pencils)

Engineered for versatility to preserve surgeon choice
- Pencil can be fitted with almost any available blade (nonstick or standard options)
- Extendable/retractable smoke capture tube accommodates different lengths of ESU blades (1½”/38mm – 6”/152mm)

Stable, safe blade attachment
- Telescoping transparent smoke-capture cannula
- Advanced, streamlined functionality for confident, simple use
- Compact design and low-profile front end enhance visibility of the surgical field
- Transparent tube minimizes any obstruction of the blade’s tip or target tissue
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The most trusted name in electrosurgery, Covidien Electrosurgery is by your side every day in more than 100 million surgeries a year. For over 40 years, our Valleylab brand has been synonymous with innovation and reliability. From the most trusted name in electrosurgery comes a uniquely designed smoke evacuation pencil that’s comfortable, effective and convenient to use. The Valleylab Smoke Evacuation Pencil delivers the performance, quality and service you’ve come to expect from Covidien.
EXCEPTIONAL PERFORMANCE

- Advanced, streamlined functionality for quick, effective use
- Compact design and ergonomic profile reduce fatigue and enhance visibility of the surgical field
- Transparent tube enhances any obstruction of the blade's tip and reduces drag on the wrist
- Telescoping transparent smoke capture tube accommodates different lengths of ESU blades (1in/25mm – 6in/152mm) (nonstick or standard options)
- Extendable/retractable smoke capture tube accommodates almost any available blade
- Smooth and precise CUT/COAG button activation
- Subtle texture on handle enhances grip
- All-in-one, pre-assembled construction simplifies set up and reduces troubleshooting efforts
- Plastic collar feature protects staff from injury when changing/attaching blades
- ESU wire encapsulated within tubing improves cord management
- Corrugated tubing optimizes flexibility and range of movement
- 360° swivel feature enables free and easy turning to minimize "drag" on the wrist
- Stable blade attachment provides a steady approach and interaction with the tissue
-易滑的纹理增强了握持

POSITIVE OUTCOMES

- Smoke evacuation in the OR is strongly recommended by many healthcare authorities including OSHA1, JCAHO2, NIOSH3 and AORN4. Though scientific consensus is lacking, virtually all healthcare providers agree the vital importance of smoke evacuation in the OR is well documented. 41
- Enhanced suction volume and port 20% better flow rate than some other smoke-capture pencils on the market. The Valleylab Smoke Evacuation Pencil provides better suction quality in the OR. The adjustable capture port allows the user to position the system and smoke capture point.

ECONOMICAL VALUE

- Not only is the Valleylab Smoke Evacuation Pencil an exceptional stand-alone value, but switching from the competitor’s pencil enhances your cost-to-value advantages. Working within Covidien’s broad electrosurgery and advanced energy portfolio allows you to realize potential cost savings and operational efficiencies.
- Your GPO-contracted facility is entitled to reduce part numbers and minimize your number of suppliers.
- Covidien’s electrosurgery portfolio has preferred status with many primary distributors ensuring products will be available on demand.
- Reduce part numbers and minimize your number of suppliers.
- Further maximize your benefits — join the Covidien System Standardization Program.
- Free continuing education programs, licensed training and in-service videos
- Support hotline for clinical information or tech assistance
- Customer service available during equipment downtime

Product | Name | Order Code | Description |
--- | --- | --- | --- |
CVPLP2000 | Valleylab Smoke Evacuation Pencil | CVPLP2000 | Smoke Evacuation Pencil |

References
3. NIOSH3 and AORN4. Though scientific consensus is lacking, virtually all healthcare providers agree the vital importance of smoke evacuation in the OR is well documented.
4. COVIDIEN, COVIDIEN with logo, ValleyLab, and "positive results for life" are trademarks of Covidien Ag.
5. The hardest thing to doing anything is to start. — Henry Ford
6. COVIDIEN, COVIDIEN with logo, ValleyLab, and "positive results for life" are trademarks of Covidien Ag.
15. Glenfield Hospital Foundation, Glenfield Hospital Foundation, Recommendation X and XI. Denver (CO): Association of PeriOperative Registered Nurses (US); 2013.
Appendix D: Surgeon request sample letter

I am requesting the Valleylab Smoke Evacuation Pencil (Item # CVPLP2000) be stocked in our facility so that I have consistent access to this instrument for my cases.

The Valleylab Smoke Evacuation Pencil provides the perioperative staff with reliable, state-of-the-art performance as well as simple set-up and utilization. The pencil’s universal attachment feature preserves surgeon preference of blades.

As we aim to gain control over smoke in the OR, the Valleylab Smoke Evacuation Pencil is an ideal tool in support of our efforts. This pencil’s unique adjustable capture port allows for easy and secure positioning at the optimum smoke-capture point.

Not only is the Valleylab Smoke Evacuation Pencil an exceptional stand-alone value, but switching from the competitor’s pencil enhances our cost-to-value advantages.

I am confident in using a product developed by a trusted brand renowned for innovation where products are developed in partnership with surgeon users. Thank you for reviewing this information. Please contact me if you have any questions.

Sincerely,

Additional Comments:

<table>
<thead>
<tr>
<th>Product</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>CVPLP2000</td>
<td>ValleyLab™ Smoke Evacuation Pencil</td>
</tr>
<tr>
<td>PACKAGING</td>
<td>UOM Case, 5/each per box, 4 boxes per case.</td>
</tr>
</tbody>
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