TRUSTED PRECISION.
A HISTORY OF INNOVATION.

Valleylab™ FT10 Energy Platform
Product Information Kit
A HERITAGE YOU CAN TRUST

The Valleylab™ energy portfolio

You can have confidence in almost 50 years of quality energy-based products and innovation in the surgical space. Confidence delivered in surgical arenas, around the globe, day after day. Confidence in our unwavering commitment to positive patient outcomes.

The Valleylab™ energy portfolio offers the most comprehensive suite of energy-based surgical hand devices in the industry¹ — ranging from a series of trusted electrosurgical tools to advanced vessel-sealing instruments with LigaSure™ technology and generator equipment that powers it all.

Now we are excited to offer the latest advancements in energy-based surgical devices: the Valleylab™ FT10 energy platform.
The Valleylab™ FT10 energy platform not only drives our full portfolio of energy-based devices, it makes them better than ever. ²,³

Improving all our devices’ performance with faster sealing and cutting times — for example, LigaSure™ vessel sealing is up to 50% faster⁴ — the Valleylab™ FT10 energy platform delivers precise amounts of energy.³
The Valleylab™ energy portfolio’s best-in-class advanced energy and electrosurgery devices are all powered by smart generators that manage energy delivery with precision-enabling algorithms. The Valleylab™ FT10 energy platform’s technology improves all surgical applications for the entire portfolio. ²,³

**Next-generation changes**

**LigaSure™ technology** is improved with:

- **Up to 50% faster** sealing times⁴
- **Lower** jaw temperatures⁵

**Electrosurgical performance** is more precise³:

- Autobipolar has a **faster** activation time⁶
- Monopolar performance is **improved**³
The built-in smart TissueFect™ tissue sensing technology in the Valleylab™ FT10 energy platform improves the speed and consistency of hand-held devices by reading tissue composition in real time.\textsuperscript{7}

TissueFect™ technology examines device performance 434,000 times per second, monitoring tissue impedance and allowing effective and efficient energy delivery.\textsuperscript{7} This technology is only available on Valleylab™ generators and drives all electrosurgical and advanced bipolar functions.
Our LigaSure™ portfolio has faster vessel-sealing speed\(^4\)

- **51% FASTER\(^8\)**
  - 1 – 3 mm vessels

- **26% FASTER\(^8\)**
  - 4 – 5 mm vessels

- **11% FASTER\(^8\)**
  - 6 – 7 mm vessels

Our energy platform is more precise\(^3\)

- The Valleylab™ FT10 energy platform provides more precise monopolar energy delivery than the ForceTriad™ energy platform.\(^5\)
- Autobipolar has a faster activation time.\(^6\)
- Monopolar performance is improved.\(^3\)
## GENERATOR COMPARISON

<table>
<thead>
<tr>
<th>Features</th>
<th>Valleylab™ FT10 Energy Platform</th>
<th>ForceTriad™ Energy Platform</th>
</tr>
</thead>
<tbody>
<tr>
<td>TissueFect™ Tissue Sensing Technology</td>
<td>Reads tissue: 434,000 times per second</td>
<td>Reads tissue: 3,333 times per second</td>
</tr>
<tr>
<td>Software Upgradeable</td>
<td>Ethernet connection (has WiFi capabilities that are not yet enabled)</td>
<td>Serial port connection</td>
</tr>
<tr>
<td>Bipolar Cable Compensation</td>
<td>Reads cable length and width for consistent ES output</td>
<td>Not available</td>
</tr>
<tr>
<td>Touch Screen</td>
<td>Single, simplified touch screen²</td>
<td>Three touch screens for each mode</td>
</tr>
<tr>
<td>New ES Settings</td>
<td>Soft coag</td>
<td>Existing ES settings</td>
</tr>
<tr>
<td>Performance</td>
<td>▪ Lower max jaw temperatures⁵</td>
<td>▪ Performance that set the standard against competitive devices</td>
</tr>
<tr>
<td></td>
<td>▪ Faster sealing times (1-4 seconds vs. 3-6 seconds with ForceTriad™ energy platform)¹⁰</td>
<td></td>
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<tr>
<td></td>
<td>▪ Automatic power settings require minimal setup and minimize need for further handling during surgery⁹</td>
<td></td>
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<tr>
<td></td>
<td>▪ Simple, intuitive controls and information displays⁷</td>
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## Dimensions

<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>10.1</td>
<td>13.6</td>
</tr>
<tr>
<td>Width (cm)</td>
<td>35.8</td>
<td>45.8</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>17</td>
<td>25.25</td>
</tr>
<tr>
<td>Depth (cm)</td>
<td>46.25</td>
<td>50.8</td>
</tr>
</tbody>
</table>
SIMPIFIED SOLUTION

Nurses and surgeons agree\textsuperscript{11}:
The Valleylab\textsuperscript{™} FT10 energy platform is simple to use, improves performance and takes up less room in the OR.

- **95\%** of nurses surveyed agree that the Valleylab\textsuperscript{™} FT10 energy platform makes their jobs easier in the OR.

- **91\%** of nurses surveyed agree that the Valleylab\textsuperscript{™} FT10 energy platform reduces the number of generators in the OR.

- It's easy to train others on the Valleylab\textsuperscript{™} FT10 energy platform.

- More useful combination of devices in procedures.
91% of surgeons surveyed agree that the Valleylab™ FT10 energy platform provides improved bipolar performance and provides you with improved control during your procedures.\textsuperscript{11}

94% of surgeons surveyed agree that increased clip detection speed instills more confidence in the system.\textsuperscript{11}

97% of surgeons surveyed agree that the Valleylab™ FT10 energy platform provides an improved surgical experience.\textsuperscript{11}

100% of nurses surveyed would be confident using the Valleylab™ FT10 energy platform in their next procedure.\textsuperscript{11}

The Valleylab™ FT10 energy platform has an average fusion cycle time of 1 to 4 seconds.\textsuperscript{10}
Covidien
Ms. Sharon McDermott
Senior Regulatory Affairs Product Specialist
5920 Longbow Drive
Boulder, Colorado 80301

Re: K151649
Trade/Device Name: Valleylab™ FT10 Electrosurgical Platform
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 17, 2015
Received: June 18, 2015

Dear Ms. McDermott:

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 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 Federal Regulations, Title 21, Parts 800 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 contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21CFR Part 807.97). 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/ReportaProblem/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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S
for
Binna S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
The Valleylab™ energy portfolio offers the largest suite of energy-based surgical hand devices in the industry — ranging from a series of trusted electrosurgical tools to advanced vessel-sealing devices with LigaSure™ technology and generator equipment that powers it all.1

As compared to the ForceTriad™ energy platform, the new Valleylab™ FT10 energy platform delivers improved speed and consistency for my procedures with:

- Faster LigaSure™ vessel sealing performance4
- More precise electrosurgery energy delivery3

It also offers a simplified platform with:

- A single touch screen5
- A small operating footprint9
- Easy-to-train functionality11

I am confident in using a platform of technology that has powered a portfolio of devices that has been used in millions of procedures globally. Thank you for reviewing this information. Please feel free to contact me if you have any questions.

Sincerely,
1. Based on ES and Advanced energy product catalogs compared to Ethicon’s current catalog.
5. Ex-vivo porcine bench testing model used to evaluate device temperature. Based on Covidien verification report: “LigaSure Thermal Profile Valleylab FT10”.

IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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