

ONE DEVICE.  
FIVE FUNCTIONS.  
**BRINGING VALUE  
WITH VERSATILITY.**



**LigaSure™**

Retractable L-Hook

Laparoscopic Sealer/Divider

Product  
Information Kit



**Medtronic**  
Further, Together

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# PROVEN TECHNOLOGY & PROCEDURAL EFFICIENCY.<sup>1,†</sup>

You get the functionality of five devices in one — with the reliable performance of LigaSure™ technology and Valleylab™ monopolar energy

Reduce costs and improve clinical outcomes. Our industry demands it. Patients deserve it. And we can help you achieve both.

In your hands, our solutions have been setting the standard of patient care for nearly 50 years. And the challenges of today's healthcare system demand we go further — with technologies that bring even greater efficiency to procedures.

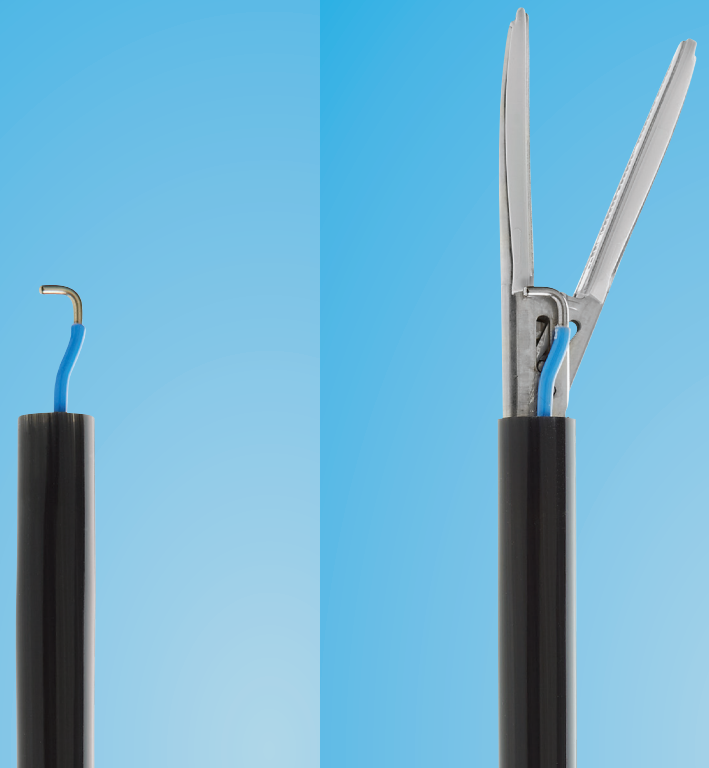
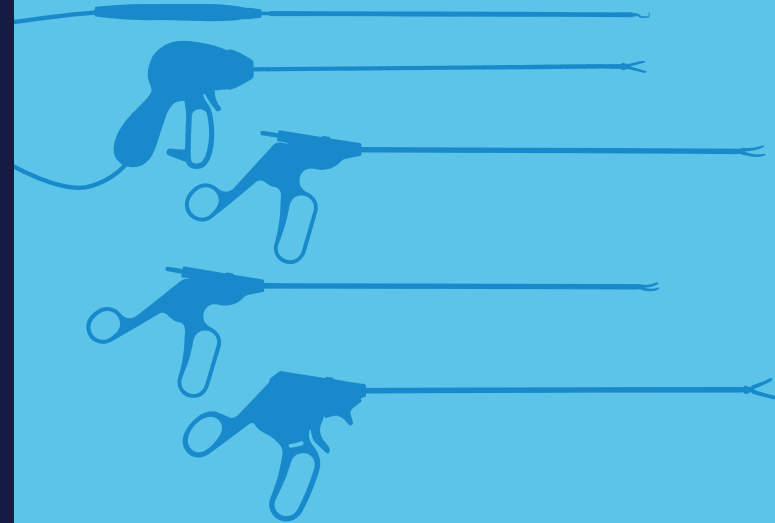
That's why we created the LigaSure™ retractable L-hook laparoscopic device.

The only instrument of its kind, it delivers the benefits of:<sup>2,‡</sup>

- Precise Valleylab™ monopolar dissection
- One-step LigaSure™ vessel sealing
- Atraumatic grasping
- Cold cutting
- Maryland-style blunt dissection

**In one device.**

COMBINING **5**  
INSTRUMENTS



# GIVING YOU VALUE BEYOND THE PRODUCT.

With the most comprehensive energy portfolio  
in the industry<sup>3</sup> and expert support for your staff

Your needs extend across the care continuum. And so do our services  
and solutions.

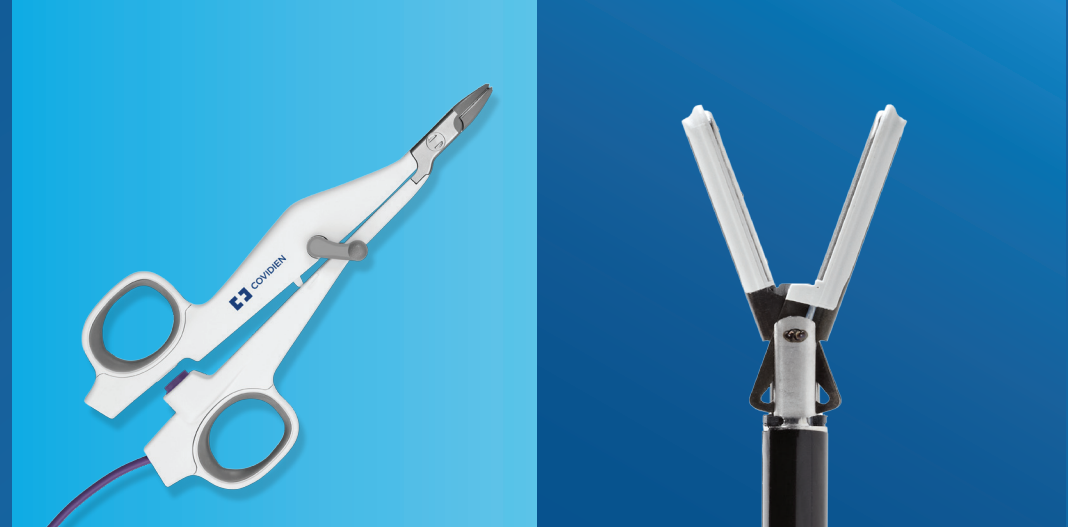
They start with offering you the most comprehensive energy portfolio  
in the industry. A suite of surgical solutions built on a half-century of  
collaboration with hospitals, surgeons, and healthcare professionals.  
From energy based hand devices to generators that power them.

The LigaSure™ retractable L-hook device is our latest innovation. And its  
groundbreaking versatility<sup>1,2</sup> brings greater efficiency to your OR<sup>1,†</sup> — on  
top of the reliability that comes with LigaSure™ technology.

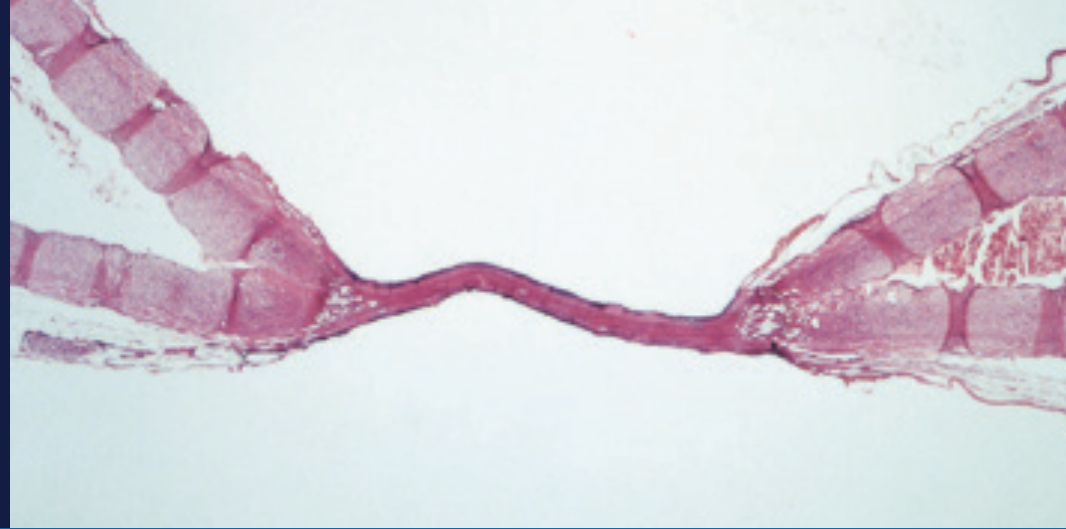
## Expert support for your staff

You're not just our customer, we're partners. And like you, we're  
committed to always doing what's best for patients. That's why our  
products come with:

- Free 24-hour clinical information hotline staffed by registered  
nurses with OR experience
- Technical support staffed by our product experts
- Access to our BioMed Connect™ information portal



# THE POWER OF **CONTROL & CONSISTENCY.**



## LigaSure™ technology has been setting the standard in vessel sealing for more than 18 years

### What is LigaSure™ technology?

LigaSure™ vessel-sealing technology uses the body's own collagen and elastin to create a permanent seal that can withstand three times normal systolic blood pressure.<sup>4,5</sup> It's supported by an ever growing body of evidence. And has been used in more than 17 million procedures worldwide.<sup>6,\*</sup>

### What does it do?

With an average seal cycle of 1-4 seconds in most surgical situations,<sup>7,‡</sup> this groundbreaking technology can seal:<sup>8</sup>

- Vessels up to and including 7 mm
- Lymphatics
- Tissue bundles

And it eliminates the guesswork with a feedback-controlled response system that automatically discontinues energy delivery when the seal cycle is complete.

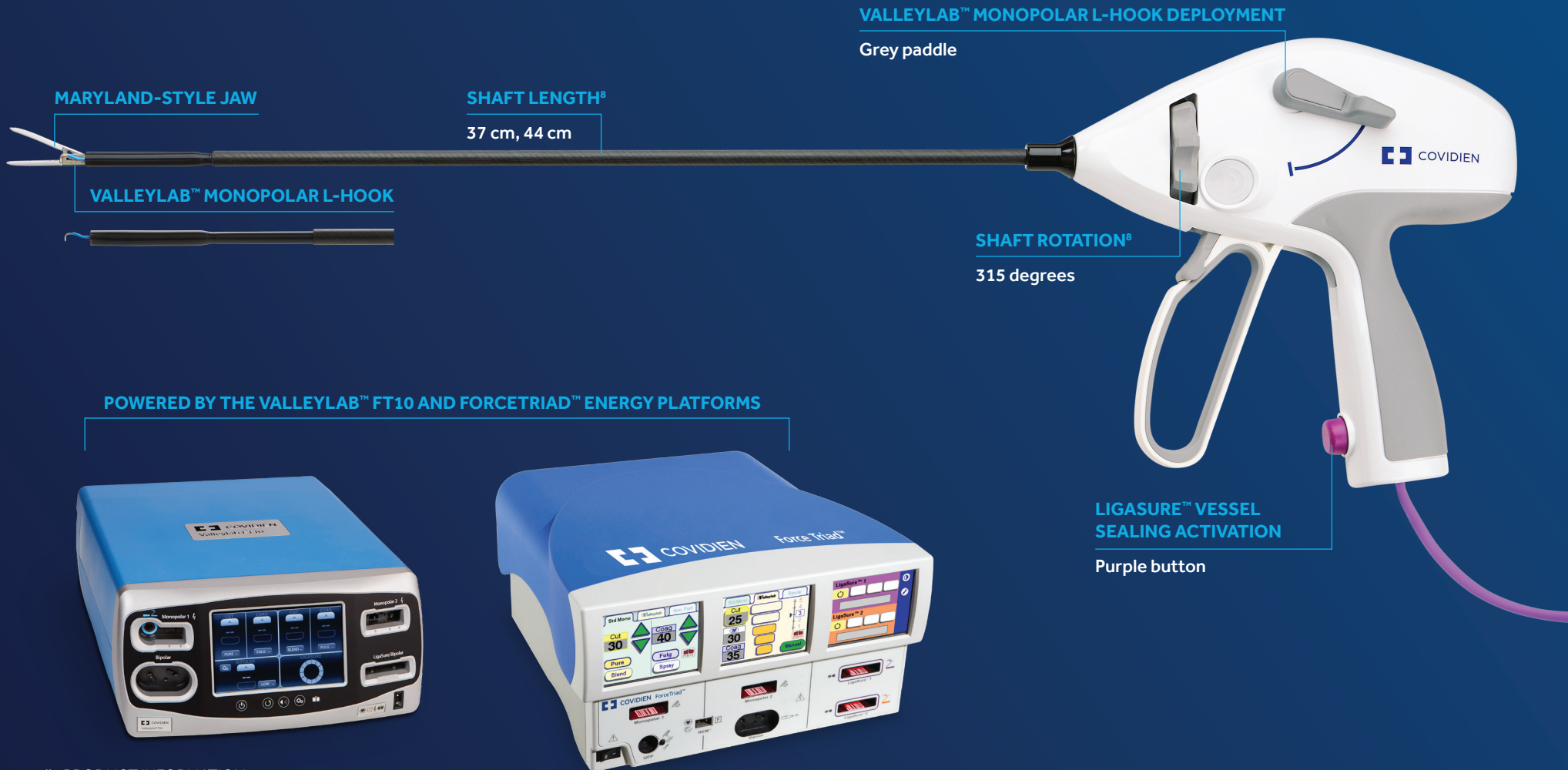
### An energy platform that enhances performance

The LigaSure™ L-hook device can be powered by the ForceTriad™ energy platform with software version 3.8. But you'll get even better performance with the Valleylab™ FT10 energy platform. Because the Valleylab™ FT10 energy platform:

- Makes LigaSure™ devices better — and faster — than ever<sup>7</sup>
- Reads tissue 434,000 times per second — and automatically adjusts energy output to maintain the desired clinical effect.<sup>9</sup>

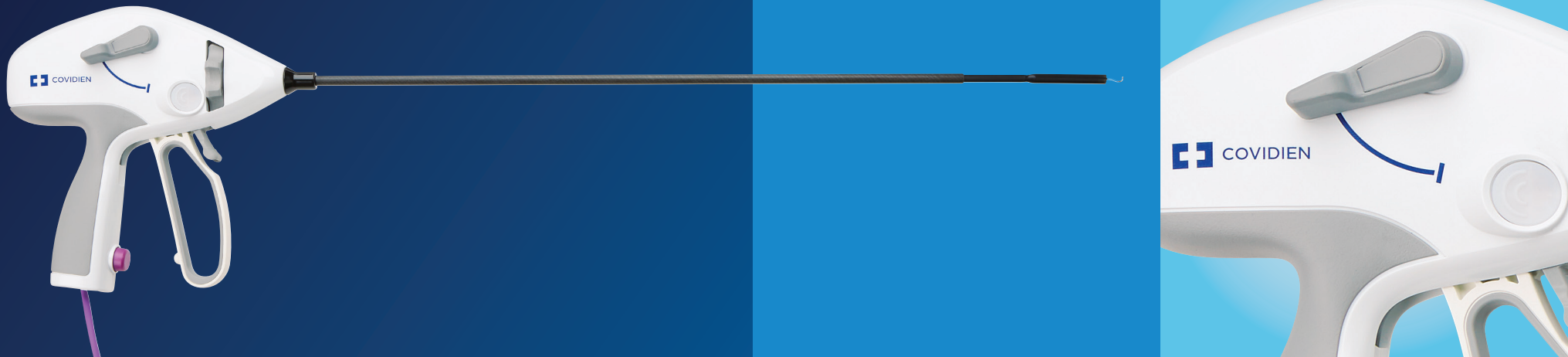


# VESSEL SEALING COLD CUTTING GRASPING AND DISSECTION **WITH ONE DEVICE.**



# CHOOSING YOUR INSTRUMENT JUST GOT A LOT EASIER.

We're redefining versatility. So you can keep your focus on the surgical site. And avoid multiple instrument exchanges, which can disrupt procedural flow and put patients at greater risk for injury.<sup>1,10,¥</sup>



## Improves surgical efficiency

The LigaSure™ L-hook device:

- Improves procedural flow<sup>1,¥</sup> and increases OR efficiency<sup>1,†</sup>
- Makes fewer instrument exchanges possible<sup>1,†</sup>
- Potentially reduces the number of instruments used in procedures<sup>2</sup>

## Easy to use

With the LigaSure™ L-hook device:

- Simply press a lever on the handle to deploy the retractable L-hook — and deliver the precision of Valleylab™ monopolar dissection<sup>8</sup>
  - You can grasp, seal, and cut independently<sup>8</sup> — the decision is in your hands
- Surgeons who tested the device say the actions to grasp, seal, cut, deploy, and retract the Valleylab™ monopolar L-hook are simple and intuitive.<sup>1,‡</sup>

# IMPROVES ACCESS<sup>1,μ</sup> VISUALIZATION<sup>1,Ω</sup> AND DISSECTION<sup>1,¥</sup>



## The LigaSure™ Retractable L-hook device:

- Provides precise, versatile, and effective energy dissection<sup>1,¥</sup>
- Delivers improved tip visualization compared to straight jaw devices<sup>1,Ω</sup>
- Provides ability to create anotomy (gastrotomy and enterotomy)<sup>2,8</sup>

## The Maryland-style jaws of the LigaSure™ retractable L-hook device:

- Deliver improved access to targeted tissues compared to straight jaw devices — even in tight spaces<sup>1,μ</sup>
- Provide the ability to follow the curvature of the uterus/stomach<sup>1,¥</sup>
- Allow for easy skeletonization of vessels<sup>1,¥</sup>





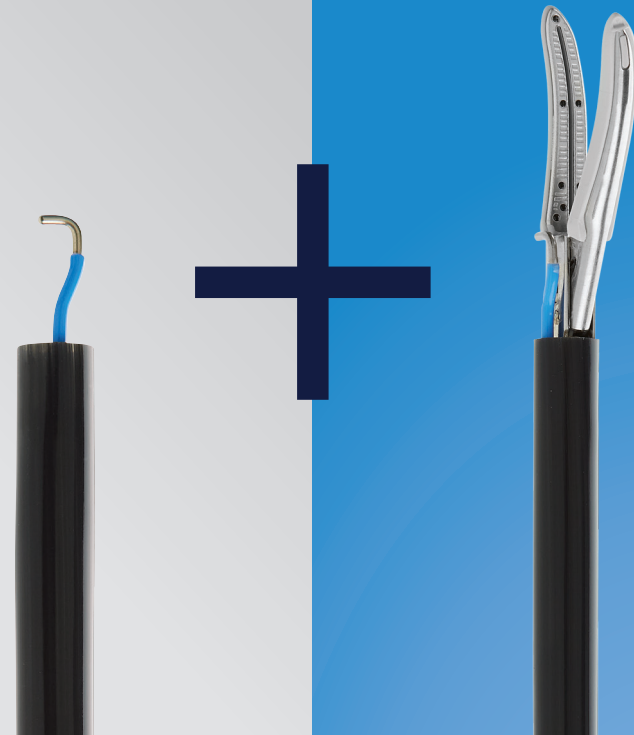
# PRECISION AT YOUR FINGERTIPS **WHEN YOU NEED IT.**

Simply press a lever on the handle to deploy the retractable L-hook— and deliver precise, versatile, and effective energy dissection<sup>1</sup>

## Compared to the LigaSure Advance™ instrument:

The retractable L-hook is there when you need it, and out of the way when you don't. The L-hook device:

- Features a more versatile monopolar tip<sup>1,¥</sup>
- Improves monopolar tip visualization<sup>1,‡</sup>
- Improves dissection<sup>1,∞</sup>



¥29 of 29 surgeons agree  
‡17 of 17 surgeons agree  
∞9 of 12 surgeons agree

# 510(k) CLEARANCE



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

September 16, 2016

Covidien  
Ms. Dawn D. Tindall  
Senior Regulatory Affairs Product Specialist  
5920 Longbow Drive  
Boulder, Colorado 80301

Re: K161804

Trade/Device Name: LigaSure™ Retractable L-Hook Laparoscopic Sealer Divider  
(LF5637, LF5644)

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device  
and accessories

Regulatory Class: Class II

Product Code: GEI

Dated: September 1, 2016

Received: September 2, 2016

Dear Ms. Tindall:

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-

Page 2 - Ms. Dawn Tindall

related adverse events) (21 CFR Part 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 Parts 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" (21 CFR 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,

**Christopher J. Ronk -S**

Binita 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

# INDICATIONS FOR USE<sup>8</sup>

The LigaSure™ retractable L-hook laparoscopic sealer/divider is a 5 mm bipolar/monopolar electro-surgical instrument intended for use in minimally invasive surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure™ sealer/divider can be used on vessels (arteries and veins) up to and including 7 mm in diameter. The Valleylab™ monopolar L-hook can be used to dissect through tissue planes and to create enterotomies or gastrotomies.

It is indicated for use in general surgery and such surgical specialties as urologic, vascular, thoracic, colorectal, bariatric, and gynecologic. Procedures may include, but are not limited to, gastric bypass, hysterectomy, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, oophorectomy, etc.

The LigaSure™ system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure™ system for these procedures.

# PRODUCT REQUEST FORM

I am requesting the following instruments be stocked in our facility so I have consistent access to these devices for my cases:

LigaSure™ 37 cm Retractable L-Hook Laparoscopic Device (LF5637)

LigaSure™ 44 cm Retractable L-Hook Laparoscopic Device (LF5644)

## Improved surgical efficiency

The LigaSure™ retractable L-hook laparoscopic sealer/divider improves procedural flow and increases OR efficiency by:

- Making fewer instrument exchanges possible<sup>1</sup> — which can reduce visceral injuries to patients<sup>2</sup>
- Potentially reducing the number of instruments used in procedures<sup>1</sup>

## Five devices in one<sup>3</sup>

The only instrument of its kind, the LigaSure™ L-hook device delivers the benefits of:

- Precise Valleylab™ monopolar dissection
- One-step LigaSure™ vessel sealing
- Atraumatic grasping
- Cold cutting
- Maryland-style blunt dissection

## Easy to use<sup>3,†</sup>

With the LigaSure™ L-hook device:

- Simply press a lever on the handle to deploy the retractable L-hook<sup>4</sup> — and deliver the precision of Valleylab™ monopolar dissection
- You can grasp, seal, and cut independently<sup>4</sup> — or perform all three at once

I am confident in using technology backed by such a significant body of evidence-based research and positive peer feedback. Thank you for reviewing this information. Please feel free to contact me if you have any questions.

Sincerely,

Additional Comments:

1. Based on internal test report #RE00041188. Independent surgeon feedback collected during cadaver and porcine labs. October 2015 and February 2016.

2. Tebala GD. Three-port laparoscopic cholecystectomy by harmonic dissection without cystic duct and artery clipping. Am J Surg. 2006;191(5):718-720.

3. Based on internal test report #RE000032739. Independent surgeon feedback collected during cadaver and porcine lab. February 2016.

4. Medtronic. Ligasure™ Retractable L-Hook Laparoscopic Sealer/Divider Indications For Use. Boulder: N.p., 2016. Print.

†17 out of 17 surgeons evaluated agreed



# ORDERING INFORMATION

## LF5644

LigaSure™ 44 cm Retractable  
L-Hook Laparoscopic Device  
Quantity: 6 each



## LF5637

LigaSure™ 37 cm Retractable  
L-Hook Laparoscopic Device  
Quantity: 6 each



Let's bring value and versatility to your OR. Call your  
local Medtronic sales representative today or visit  
[medtronic.com/ligasure-hook](https://www.medtronic.com/ligasure-hook)



# REFERENCES

1. Based on internal test report #R00041188, Independent surgeon feedback collected during cadaver and porcine labs. October 2015 and February 2016.
2. Based on internal test report #RE000032739, Independent surgeon feedback collected during cadaver and porcine lab. February 2016.
3. Based on Medtronic electrosurgery and advanced energy product catalogs compared to Ethicon's current catalog.
4. Based on internal test report #R0064457 Rev C, Verification report – LigaSure™ renal bench burst pressure evaluation of the Valleylab™ FT10.
5. Based on internal test report #R0043562 Rev B, Verification report – Emerald generator burst pressure evaluation on fresh renal and pulmonary arteries.
6. Based on internal report #US161132, Derived from data from 2001-2016 (YTD November 2016) which shows quantities sold.
7. Based on internal report #RE00025819 Rev A, LigaSure™ data sources for VLFT10 white papers. Bench testing model used to evaluate sealing time. September 2015.
8. LigaSure™ Retractable L-Hook Laparoscopic Sealer/Divider [package insert]. Minneapolis, MN: Medtronic, 2016.
9. Based on the Valleylab™ FT10 energy platform service manual, part number 1079477. Revised January 2015.
10. Tebala G. Three-port laparoscopic cholecystectomy by harmonic dissection without cystic duct and artery clipping. *Am J Surg*. 2006;191:718-710.

