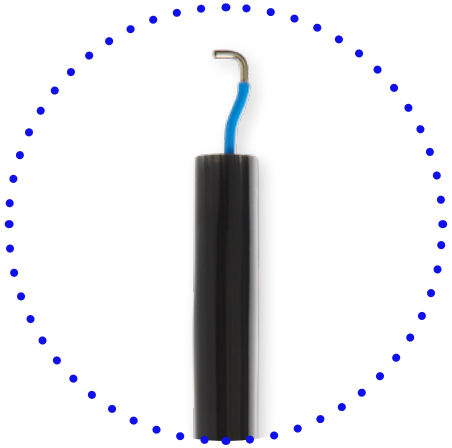
Medtronic

LigaSure™ retractable L-Hook
laparoscopic sealer/divider



One device.
Five functions.
Bringing value with versatility.

Product information kit

Table of contents

Proven technology & procedural efficiency.[1,†]

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.

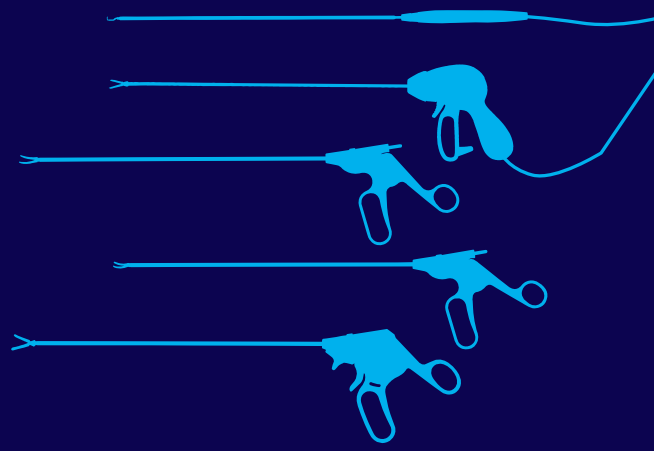
The only instrument of its kind, it delivers the benefits of:[2,‡]

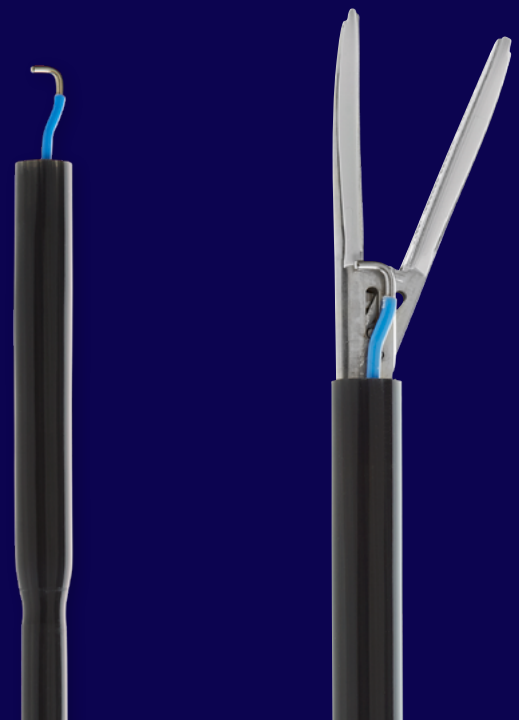
- Precise Valleylab™ monopolar dissection
- One-step LigaSure™ vessel sealing
- Atraumatic grasping
- Cold cutting
- Maryland-style blunt dissection

In one device.

† 27 of 29 surgeons agreed
‡ 17 of 17 surgeons agreed

Combining 5 instruments





Giving you value beyond the product.

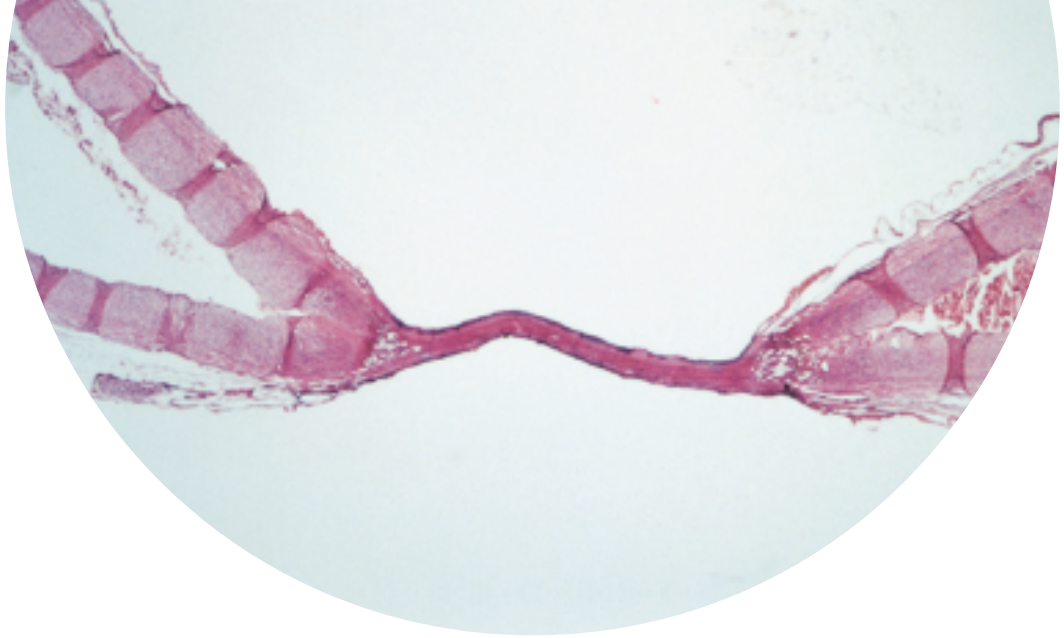
Your needs extend across the care continuum. And so do our services and solutions.

They start with offering you 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 and its versatility[1,¥] brings greater efficiency to your OR[1,†] – on top of the reliability that comes with LigaSure™ technology.

¥29 of 29 surgeons agree
†27 of 29 surgeons agree

The power of control & consistency.



LigaSure™ technology has been setting the standard in vessel sealing for more than 25 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.[3,4] It's supported by an ever growing body of evidence. And has been used in more than 25 million procedures worldwide.[5,*]

What does it do?

With an average seal cycle of 1–4 seconds in most surgical situations,[6,£] this groundbreaking technology can seal:[8]

- 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.[8]

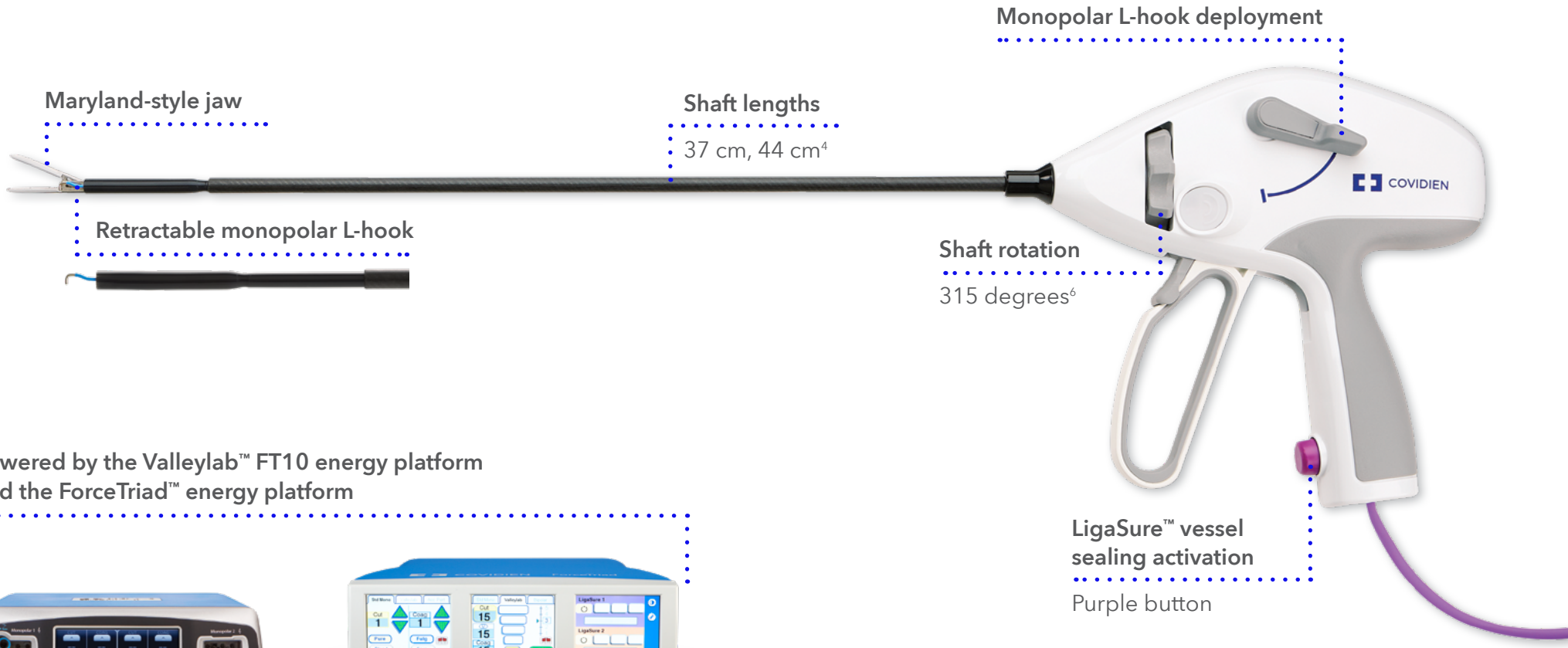
An energy platform that enhances performance

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[6]
- Reads tissue 434,000 times per second – and automatically adjusts energy output to maintain the desired clinical effect.[8]

*Based on data from 2001-FY2016
£When used with the Valleylab™ FT10 energy platform

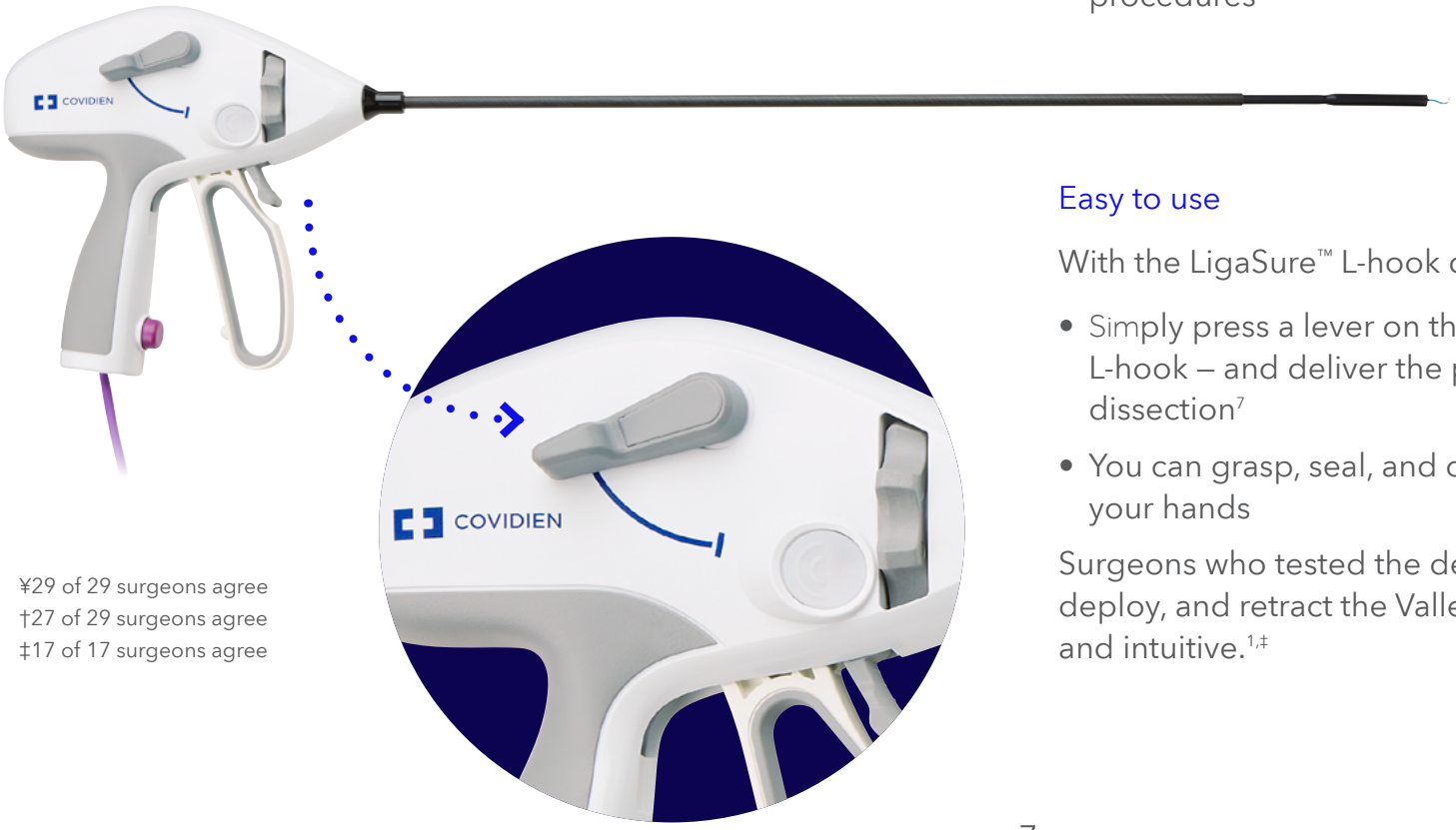
Vessel sealing cold cutting grasping and dissection with one device.[2]



Powered by the Valleylab™ FT10 energy platform and the ForceTriad™ energy platform

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.[1,9,¥]



¥29 of 29 surgeons agree
†27 of 29 surgeons agree
‡17 of 17 surgeons agree

Improves surgical efficiency

The LigaSure™ L-hook device:

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

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[7]
- You can grasp, seal, and cut independently[7] – 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.[1,‡]

Improves access[1,µ] Visualization[1,ω] And dissection[1,¥]

The LigaSure™ Retractable L-hook device:

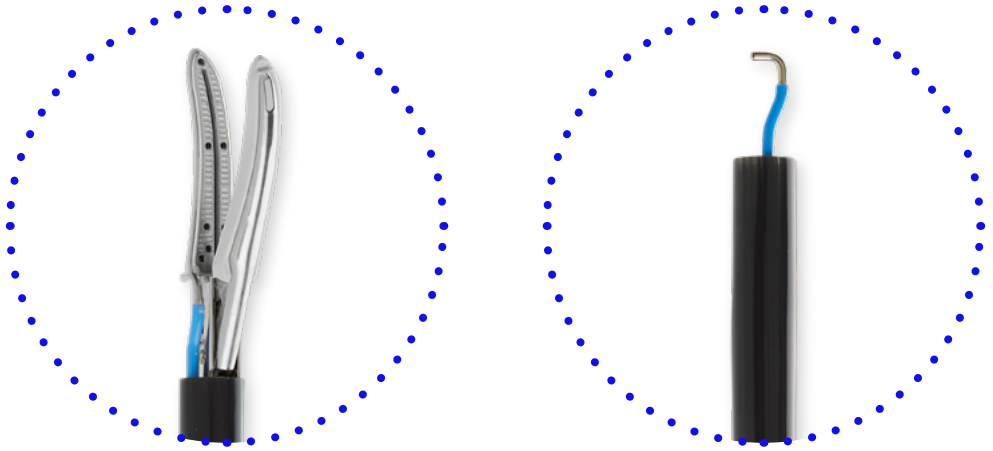
- Provides precise, versatile, and effective energy dissection[1,¥]
- Delivers improved tip visualization compared to straight jaw devices[1,Ω]
- Provides ability to create anatomy (gastrotomy and enterotomy)[2,7]

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[1,µ]
- Provide the ability to follow the curvature of the uterus/stomach[1,¥]
- Allow for easy skeletonization of vessels[1,¥]

µ28 of 29 surgeons agree
Ω25 of 29 surgeons agree
¥29 of 29 surgeons agree

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[1]

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[1,¥]
- Improves monopolar tip visualization[1,‡]
- Improves dissection[1,∞]

¥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-

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

DOC certificate

Declaration of Conformity
DOC # 416

COVIDIEN

Legal Manufacturer
Covidien llc
15 Hampshire Street
Mansfield, Massachusetts 02048
USA

European Representative
Covidien Ireland Limited
IDA Business and Technology Park
Tullamore
Ireland

Product — **Electrosurgical Vessel Sealing Devices**

Classification (MDD) — **Class IIb**
Conformity Assessment Route — **European Medical Device Directive 93/42/EEC amended by 2007/47/EC, Annex II**

Reorder Codes / GMDN Codes — **Refer to Appendix**

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacture. Covidien is exclusively responsible for the Declaration of Conformity.

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principals, the classification rules and the full quality assurance procedures at each stage, from the design of the device until its final inspection before being supplied, in accordance with Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods Regulations.

Notified Body — **BSI Group**
Kitemark Court, Davy Avenue,
Knowlhill,
Milton Keynes, MK5 8PP UK
Number: 0086

EC Certificate — **CE 00500**

Standards to which Conformity is Declared — **Refer to Appendix**

Place, Date of Issue — Boulder, Colorado, USA, March 13, 2017

Signature — Nancy Sauer Mar. 13, 2017
Nancy Sauer **date**
Manager, Regulatory Affairs

DOC Revision Date: March 13, 2017 Supersedes: February 3, 2017 Page 1 of 9

Declaration of Conformity
DOC # 416

COVIDIEN

Catalog Number	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)
LF5637 LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider	IIb	Rule 9		Annex II	57944, Endoscopic electrosurgical handpiece/electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/electrode, bipolar, single-use
LF5644	IIb	Rule 9		Annex II	57944, Endoscopic electrosurgical handpiece/electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/electrode, bipolar, single-use

Standards: These standards are applicable to the above listed products. (standard: version) EN ISO 13485: 2012/ AC: 2012; EN ISO 14971: 2012 + Annex Z; EN ISO 10993-1 2009 AC: 2010; EN ISO 10993-7: 2008 AC: 2009; EN ISO 11135-1: 2007; ISO 11135: 2014; EN ISO 11737-1: 2006/AC: 2009; EN ISO 11737-2: 2009; EN 556-1: 2001/ AC: 2006; ANSI AAMI ST67: 2011; EN 60601-1-6: 2010; EN 62366: 2008; ENISO 11607-1: 2009; EN ISO 11607-2: 2006; EN 1041: 2008; ISO 15223-1: 2012; EN 60601-1: 2006/ A1: 2013; AAMI ANSI ES 60601-1: 2005/(R) 2012, A1: 2012 C1: 2009/(R)2012 A2: 2010/(R)2012(MOD); EN 60601-2-2: 2009; EN 60601-1-2: 2007/ AC: 2010; ASTM F1980: 2007(R2011); EN 60601-2-18: 1996/ A1: 2000(MOD); IEC 60601-2-18: 2009; CSA C22.2 No. 60601-1-08: 2008; ISTA 2A: 2011; ISO 18000-3: 2010; ISO 29160: 2012; IEC 60601-1-2: 2014;

Indications for use[7]

The LigaSure™ retractable L-hook laparoscopic sealer/divider is a 5 mm bipolar/monopolar electrosurgical 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[1] – which can reduce visceral injuries to patients[2]
- Potentially reducing the number of instruments used in procedures[1]

Five devices in one[3]

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[3,†]

With the LigaSure™ L-hook device:

- Simply press a lever on the handle to deploy the retractable L-hook[4] – and deliver the precision of Valleylab™ monopolar dissection
- You can grasp, seal, and cut independently[4] – 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,

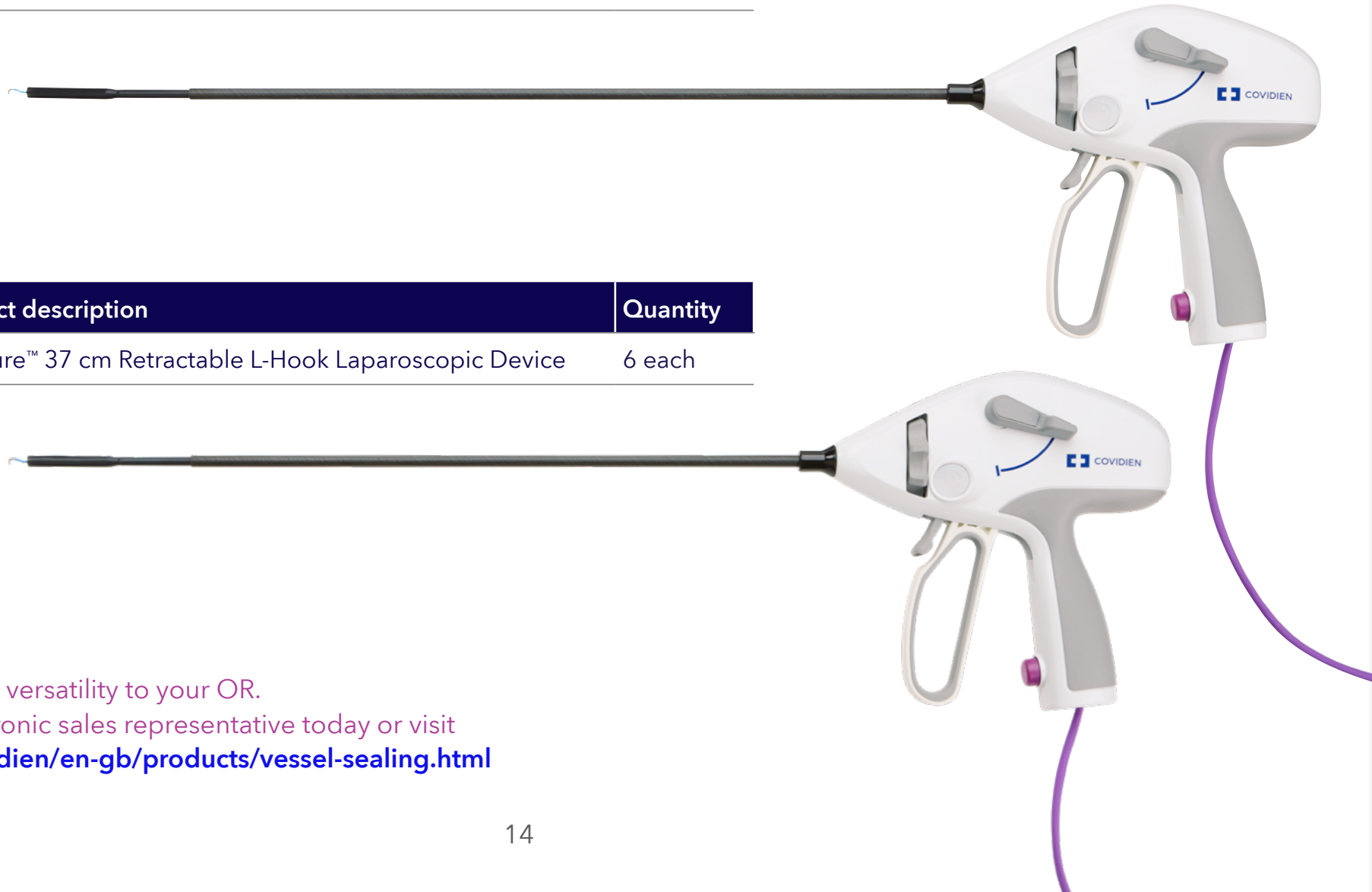
Additional Comments:

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.
5. †17 out of 17 surgeons evaluated agreed

Ordering information

Product code	Product description	Quantity
LF5644	LigaSure™ 44 cm Retractable L-Hook Laparoscopic Device	6 each

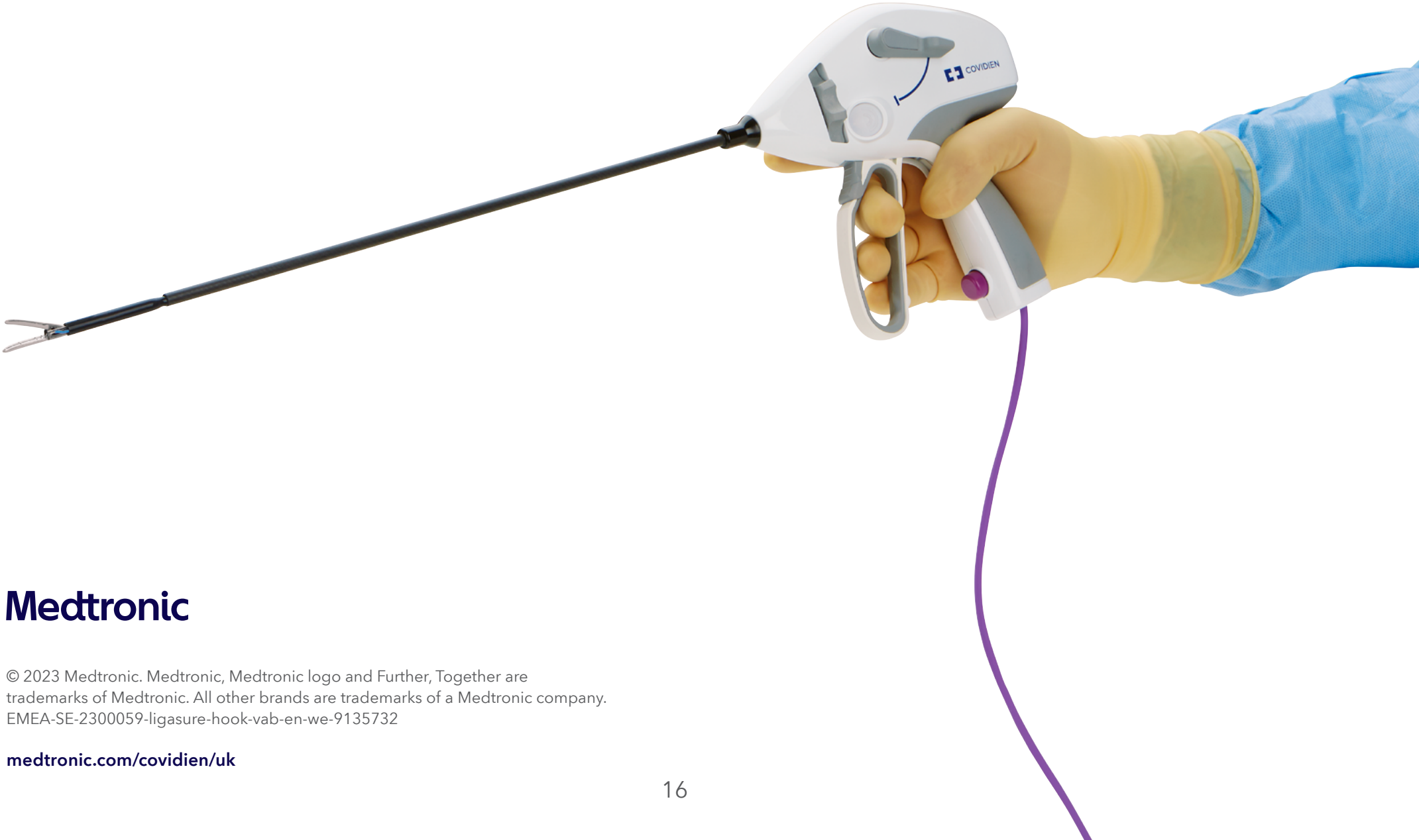
Product code	Product description	Quantity
LF5637	LigaSure™ 37 cm Retractable L-Hook Laparoscopic Device	6 each



Let's bring value and versatility to your OR.
Call your local Medtronic sales representative today or visit
medtronic.com/covidien/en-gb/products/vessel-sealing.html

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



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EMEA-SE-2300059-ligasure-hook-vab-en-we-9135732

medtronic.com/covidien/uk