GET MORE.
WITH LESS.

Less sticking.[1,†]
Less cleaning.[2,‡]
Less eschar buildup.[2,§]
More benefits.

LigaSure™ Maryland jaw device
with nano-coated jaws

† Instances of tissue sticking to jaws measured over 110 seals per device.
‡ Cleaning effectiveness assessed after each of two cleaning cycles.
§ Eschar buildup assessed using optical imaging analysis after 60 seal and divide cycles.

Medtronic
Further, Together

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The Valleylab™ Energy Portfolio

ADVANCING OUR TECHNOLOGIES TO ADVANCE HEALTHCARE.

For more than 50 years, the surgical solutions that make up our Valleylab™ energy family have inspired confidence. Solutions like our LigaSure™ Maryland jaw device.

In a single device, it delivers[3]:

- A one-step vessel sealer
- A dissector
- A grasper
- Cold scissors

Now, that reliable technology is better than ever because we've added a nonstick nano-coating to the jaws.

It's part of our commitment to helping you overcome your clinical challenges so that — together — we can provide the best possible patient care.

ENHANCED DISSECTION.[4,†] INTUITIVE CONTROL.[4,‡] GREATER EFFICIENCY.[2,§]

We engineered our multifunctional LigaSure™ Maryland jaw device to provide efficiency throughout the procedure.[5,Ω] Now, we've taken that efficiency to the next level — by putting nonstick nano-coating on the jaws.[2,§]

Multifunctional flexibility

With the LigaSure™ Maryland jaw device you get the benefits of:

- A one-step vessel sealer[3]
- A Maryland dissector for enhanced blunt dissection[4,‡]
- An atraumatic grasper to securely grasp tissue[4,††]
- Cold scissors to leave the critical decision to cut in your hands[3,5]

Multifunctional performance[4]

The LigaSure™ Maryland jaw device delivers:

- Improved access compared to straight jaws[‡]
- Improved tip visualization compared to straight jaws[‡‡]
- A jaw designed to follow the curvature of the uterus or stomach[‡‡]
- Easy skeletonization of vessels[‡‡]
- A nonstick nano-coating for improved efficiency[§]

† When compared to the surgeon's primary device, 23 out of 32 surveyed agreed.

‡ 31 out of 33 surgeons surveyed agreed.

§ Compared to the legacy device. Cleaning effectiveness assessed after each of two cleaning cycles.

Ω 32 out of 32 surgeons surveyed agreed.

†† 33 out of 33 surgeons surveyed agreed.

‡‡ 30 out of 33 surgeons surveyed agreed.

A SMOOTHER, MORE EFFICIENT[2,†] PROCEDURE.

All the advantages of the LigaSure™ Maryland jaw device. Now made even better by nonstick nano-coating.

Less sticking[1,‡]

97% less
than our legacy device

97% less
than the EnSeal™* G2 5 mm device

97% less
than the Voyant™* 5 mm Fusion

More effective cleaning

The LigaSure™ Maryland jaw device with nano-coating delivers[2,§]:

- Fewer cleanings during the procedure than the legacy device
- Greater procedural efficiency than the legacy device because of less eschar buildup and fewer jaw cleanings
- Potentially fewer instrument exchanges due to fewer jaw cleanings needed

Less eschar buildup[2,Ω]

13% less
than our legacy device

Standard reprocessing methods will degrade the nonstick coating and lead to an increase in sticking, eschar buildup, and cleanings.[6]

† Compared to the legacy device.
‡ Instances of tissue sticking to jaws measured over 110 seals per device.
§ Cleaning effectiveness assessed after each of two cleaning cycles.
Ω Eschar buildup assessed using optical imaging analysis after 60 seal and divide cycles.

THREE LENGTHS FOR **MULTIPLE PROCEDURES AND APPROACHES.**[3]

The nano-coated LigaSure™ Maryland jaw device delivers the same excellent benefits in three different lengths

Made even better by the Valleylab™ FT10 energy platform

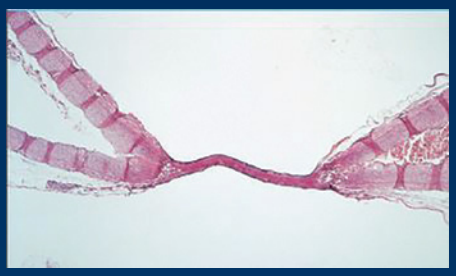
The LigaSure™ Maryland jaw portfolio works great when powered by the ForceTriad™ energy platform with 3.6 software and higher. For optimal performance, use it with the Valleylab™ FT10 energy platform.

The Valleylab™ FT10 energy platform makes LigaSure™ devices better than ever.[7,8]

CONTROL. CONSISTENCY. **CONFIDENCE.**

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.[9] It's been used in more than 19 million procedures worldwide[10,†] and is supported by an ever-growing body of clinical evidence.



Our groundbreaking technology uses the body's collagen and elastin to create a permanent seal.

What does it do?

With an average seal cycle of 1 to 4 seconds in most surgical situations,[7] LigaSure™ technology can seal:

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

It also eliminates the guesswork — and minimizes thermal spread[11] — by automatically discontinuing energy delivery when the seal cycle is complete.

† Based on data from 2001 through FY17.

PRODUCT REQUEST FORM

I'm requesting the following instruments be stocked in our facility so that I have consistent access to them for my cases:

- ☐ LigaSure™ Maryland jaw 23 cm open sealer/divider (LF1923)
- ☐ LigaSure™ Maryland jaw 37 cm laparoscopic/sealer/divider (LF1937)
- ☐ LigaSure™ Maryland jaw 44 cm long laparoscopic/sealer/divider (LF1944)

Improves procedural flow

Compared to the legacy device, the nonstick coating on the LigaSure™ Maryland jaws:

- Reduces sticking[1,†] and eschar buildup[2,‡]
- Results in fewer cleanings[2,§]
- Makes cleaning more efficient[2,§]
- Enables greater procedural efficiency[2,§]

Multifunctional flexibility

LigaSure™ Maryland jaw devices:

- Securely and atraumatically grasp tissue[3,Ω]
- Provide enhanced blunt dissection[3,‡‡]

Proven technology

LigaSure™ Maryland jaw devices deliver the reliable performance of LigaSure™ vessel-sealing technology, which has the highest burst pressure, fastest sealing time, and highest overall rating[4] compared to Gyrus PKS™*, Harmonic ACE™*, and Enseal™*.

I'm confident in using a technology that has been used in more than 19 million cases[5] and is backed by a significant body of evidence-based research.

Thank you for reviewing this information. Please feel free to contact me if you have any questions.

Sincerely,

Additional comments:

References

1. Based on internal test report #RE00073194 , Tissue sticking comparison of the Ethicon G2™*, Voyant™* 5 mm Fusion, LigaSure™ LF1737, and LigaSure™ LF1937 devices conducted on porcine tissue using the Force Triad™ energy platform. Jan. 18, 2017.
2. Based on internal test report #RE00071599, LF19XX MJC marketing claims report conducted on porcine tissue. Feb. 7 to Feb. 22, 2017.
3. Based on internal test report #R0035742, Maryland validation labs: Independent surgeon feedback collected during porcine labs in Houston and Los Angeles. April 16 to 18 and April 30 to May 3, 2013.
4. Lamberton GR, Hsi RS, Jin DH, Lindler TU, Jellison FC, Baldwin DD. Prospective comparison of four laparoscopic vessel ligation devices. *J Endourol.* 2008;22(10):2307–2312.
5. Based on internal report #US161132(2), Sales data from FY01-FY17. July 2017.

† Instances of tissue sticking to jaws measured over 110 seals per device.

‡ Eschar buildup assessed using optical imaging analysis after 60 seal and divide cycles.

§ Cleaning effectiveness assessed after each of two cleaning cycles.

Ω 33 out of 33 surgeons surveyed after use agreed.

†† When compared to surgeon's primary device, 23 out of 32 surgeons surveyed agreed.

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For more information, please visit
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IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

17-weu-ligasure-maryland-lf19xx-vab-2074558

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

April 21, 2017

Covidien
Mr. Celso Duran
Senior Specialist, Regulatory Affairs
5920 Longbow Drive
Boulder, Colorado 80301

Re: K170869
Trade/Device Name: LigaSure Maryland Jaw Sealer/Divider One-step Sealing, Nano-coated
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 22, 2017
Received: March 23, 2017

Dear Mr. Duran:

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

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" (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,

For 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

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

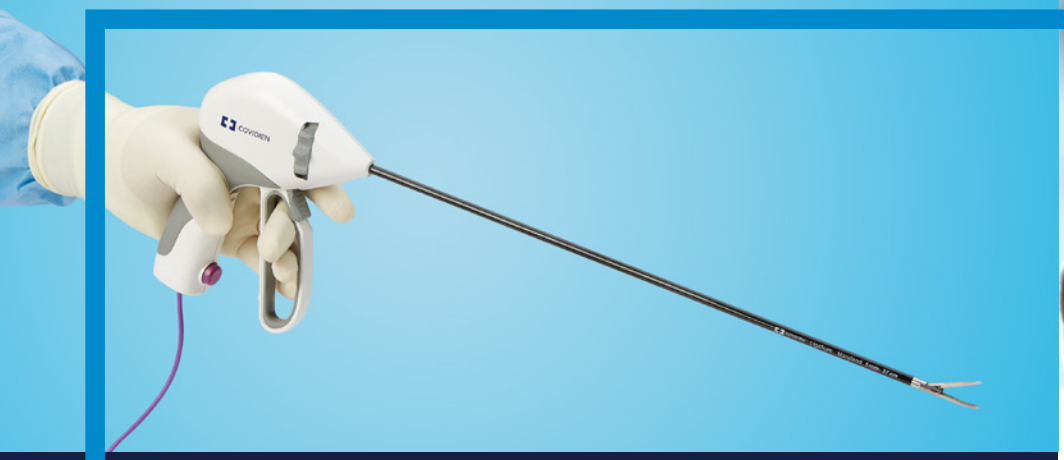
EC Certificate — **CE 00500**

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

Place, Date of Issue — Boulder, Colorado, USA, August 18, 2017

Signature — Nancy Sauer Aug 18, 2017
Nancy Sauer **date**
Manager, Regulatory Affairs

Catalog Number	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)
LF1923 LigaSure™ Maryland Jaw Open Sealer/Divider Onestep Sealing, Nanocoated	IIb	Rule 9		Annex II	56296, Open-surgery electrosurgical handpiece/electrode, bipolar, single-use.	Open-surgery electrosurgical handpiece/electrode, bipolar, single-use.
LF1937 LigaSure™ Maryland Jaw Laparoscopic Sealer/Divider Onestep Sealing, Nanocoated	IIb	Rule 9		Annex II	57944, Endoscopic electrosurgical handpiece/electrode, bipolar, single-use	Endoscopic electrosurgical handpiece/electrode, bipolar, single-use
LF1944 LigaSure™ Maryland Jaw Laparoscopic Sealer/Divider Onestep Sealing, Nanocoated	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) ISO 10993-1: 2009 + AC: 2010; ISO 10993-7:2008 + AC:2009; IEC 60601-1:2005 + A1:2012; IEC 60601-1-2:2014; IEC 60601-2-2:2009; IEC 60601-2-18:2009; EN 1041:2008; ISO 15223-1:2016; ISO 11607-1:2006; ISO 11607-2:2006; ASTM F 1980:2007 (R):2011; ISTA 2A:2011; ISO 14971:2007; ISO 11135-1:2007; ISO 11135:2014; ISO 11737-1:2006 ; ISO 11737- 2:2009; EN 556-1:2001 + AC 2006; ANSI AAMI ST67:2011; IEC 62366:2014; IEC 60601-1-6:2013; ISO 18000- 3:2010; ISO 29160:2012						



Introduce the benefits of LigaSure™ technology with nano-coating to your OR.

Call your local Medtronic sales representative

References

1. Based on internal test report #RE00073194 , Tissue sticking comparison of the Ethicon G2™*, Voyant™* 5 mm Fusion, LigaSure™ LF1737, and LigaSure™ LF1937 devices conducted on porcine tissue using the Force Triad™ energy platform. Jan. 18, 2017.
2. Based on internal test report #RE00071599, LF19XX MJC marketing claims report conducted on porcine tissue. Feb. 7 to Feb. 22, 2017.
3. LigaSure™ Maryland Jaw Sealer/Divider, Nano-Coated [instructions for use]. Boulder, CO: Medtronic; 2016.
4. Based on internal test report #R0035742, Maryland validation labs: Independent surgeon feedback collected during porcine labs in Houston and Los Angeles. April 16 to 18 and April 30 to May 3, 2013.
5. Based on internal test report #RE00071598, Maryland validation labs: Independent surgeon feedback collected during porcine labs in Houston and Los Angeles. April 16 to 18 and April 30 to May 3, 2013.
6. Based on internal report #RE00045785 , LF19XX Waiver of sticking testing postreprocessing. Jan. 19, 2017.
7. Based on internal test report #RE00025819 Rev A, LigaSure™ device data sources for VLFT10 white papers. September 2015.
8. Based on internal test report #RE00005401 Rev A, Product validation of Valleylab™ FT10 energy platform: surgeon and nurse evaluation in simulated use. Jan. 27 to 30, 2015 and Feb. 24 to 27, 2015.
9. Based on internal test report #R0064457, LigaSure™ device renal bench burst pressure evaluation of the Valleylab™ FT10 energy platform. May 3, 2015.
10. Based on internal report #US161132(2), Sales data from FY01 to FY17. July 2017.
11. Based on internal test report #RE00005503, Verification report: GLP acute animal lab: LigaSure™ device preclinical evaluation of Valleylab™ FT10 energy platform. May 19, 2015.

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

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