

LESS
STICKING.
EASIER
CLEANING.
**GREATER
EFFICIENCY.**



The reliable performance of
LigaSure™ technology — now
with nonstick coated jaws



LigaSure Impact™ Curved Large
Jaw Open Sealer/Divider
Nano-Coated
Product Information Kit

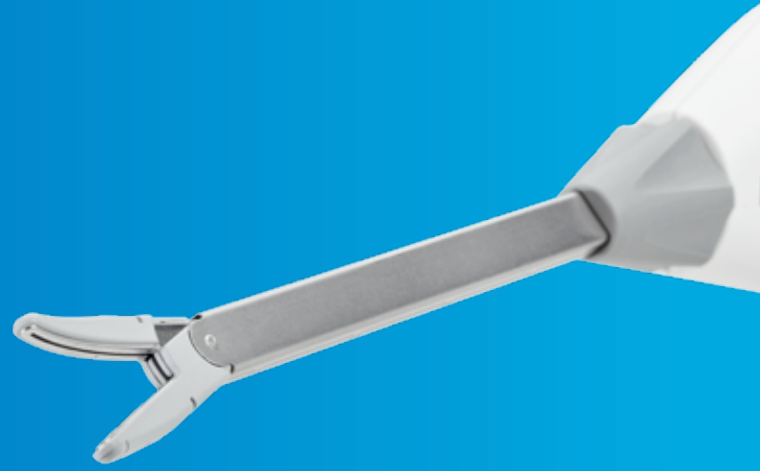
Medtronic
Further, Together

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HEALTHCARE
IS EVOLVING.
SO ARE OUR
SOLUTIONS.



We're focused on the challenges you face today — and tomorrow

In your hands, our surgical solutions have been setting the standard of patient care for nearly 50 years. But the challenges of our healthcare system demand we go further — and we believe we can always do better.

That's why we're building on the reliable performance of our technologies and nearly 50 years of experience working alongside healthcare professionals. Introducing solutions that deliver value across the continuum of care and help you overcome clinical challenges.

Solutions like the LigaSure Impact™ device with nonstick nano-coated jaws. A versatile instrument, it delivers our vessel sealing technology backed by 18 years of clinical use — now with even more benefits.



GIVING YOU VALUE BEYOND PRODUCT

With the most comprehensive energy portfolio in the industry¹ — and expert support for your staff

Your needs extend across the care continuum. So do our solutions.

They start with offering you the most comprehensive energy portfolio in the industry.¹ 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 Impact™ device with nonstick coated jaws is our latest innovation. And it's designed to bring greater efficiency² to your OR — 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

SPEED VERSATILITY AND COMFORT.

Grasp, seal, and cut tissue — with one device



The LigaSure Impact™ device is designed to optimize performance across a range of specialties, including:

- Urology
- Colorectal
- General surgery
- Gynecology

The curved jaw also allows you to hug the curve of the stomach and uterus.³



Greater procedural efficiency

Compared to the LF4318, the nonstick coating on the LigaSure Impact™ jaws:

- Reduces sticking and eschar buildup^{2,4}
- Results in fewer cleanings^{2,†}
- Makes cleaning more efficient^{2,†}
- Enables greater procedural efficiency^{2,†}

The large jaw of the LigaSure Impact™ device also:

- Enables fast transection and procedural efficiency³
- Minimizes the need for multiple activations³



COATING IMPROVES PERFORMANCE

Key findings from our benchtop testing using porcine tissue

Compared to the LF4318, the LigaSure Impact™ device (LF4418) improves LigaSure™ performance with:

67%
LESS STICKING⁴

50%
LESS ESCHAR
BUILDUP^{2,†}

Compared to the EnSeal™* G2 super jaw, the LigaSure Impact™ device:

39%
LESS STICKING⁴

IMPORTANT:

Standard reprocessing methods will degrade the nonstick coating and lead to an increase in sticking, eschar buildup, and cleanings.⁵

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. It's supported by an ever-growing body of clinical evidence. And has been used in more than 10 million procedures worldwide.

What does it do?

With an average seal cycle of 1-4 seconds in most surgical situations,⁶ this groundbreaking technology can seal:

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

It also eliminates the guesswork — by automatically discontinuing energy delivery when the seal cycle is complete.

**LESS
BLOOD LOSS.
FASTER
PROCEDURES.
SHORTER
HOSPITAL
STAYS.**



LigaSure™ vessel sealing technology:

- Has the highest burst pressure, fastest sealing time, and highest overall rating compared to Gyrus PKS™*, Harmonic Ace™*, and Enseal™*⁷
- Reduces blood loss compared to sutures and clips^{8,9}
- Reduces procedure time compared to sutures^{8,9}
- Reduces patient length of stay compared to sutures⁸

Compared to mechanical ligation techniques, LigaSure™ technology has been shown to:

- Significantly reduce operative blood loss in colorectal, gynecologic, and urologic surgery⁸⁻¹³
- Significantly reduce perioperative blood transfusions in gynecologic, urologic, and general surgery^{12,14}
- Significantly reduce procedure time in colorectal, gynecologic, and urologic surgery^{8-10,13,15}
- Significantly reduce length of hospital stay in gynecologic and urologic surgery⁸

Compared to other energy-based modalities, LigaSure™ technology has been shown to:

- Significantly reduce operative blood loss in colorectal and gynecologic surgery¹⁶⁻¹⁹
- Significantly reduce procedure time in colorectal and gynecologic surgery¹⁶⁻¹⁹

An energy platform that enhances performance

The LigaSure Impact™ device can be powered by the ForceTriad™ energy platform with 3.6 software.

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^{6,20}
- Monitors tissue impedance 130 times faster than the ForceTriad™ energy platform and automatically adjusts energy output to maintain the desired clinical effect

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 15, 2016

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

Re: K162047

Trade/Device Name: LigaSure Impact Curved, Large Jaw, Open Sealer/divider, 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: August 31, 2016
Received: September 1, 2016

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 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

510(k) CLEARANCE

Page 2 - Mr. Celso Duran

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,

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

INDICATIONS FOR USE

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LigaSure Impact™

REF LF4418 **Curved, Large Jaw, Open Sealer/Divider, Nano-coated**
36 mm jaw length,
18 cm shaft length

The LF4418 is designed for use with Covidien electrosurgical generators that include vessel sealing capability. Please refer to the cover page for details on compatible generator models and software versions. If the software version on your generator is lower than required, contact Covidien about software updates.

These instructions assume that the operator is knowledgeable about correct setup and operation of the associated Covidien generator. Refer to the generator user's guide for setup information and for additional warnings and cautions.

The instrument creates a seal by application of radiofrequency (RF) electrosurgical energy to vascular structures (vessels and lymphatics) or tissue bundles interposed between the jaws of the instrument. A blade within the instrument is surgeon actuated to divide tissue.

Maximum rated voltage: 288 V_{peak}



Not made with natural rubber latex



Do not use if package is opened or damaged



Type CF applied part.

Indications for Use

The LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/Divider can be used on vessels (arteries, veins, pulmonary arteries, pulmonary veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialties as urologic, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, 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.

General Warnings

Warning

This product cannot be adequately cleaned and/or sterilized by the user in order to facilitate safe reuse, and is therefore intended for single use. Attempts to clean or sterilize these devices without appropriate regulatory authorization may result in bio-incompatibility, infection, or product failure risks to the patient.

This instrument is intended for use ONLY with the Covidien equipment listed on the cover of this document. Use of this instrument with other generators may not result in the desired tissue effect, may result in injury to the patient or surgical team, or may cause damage to the instrument.

Do not use the LigaSure system unless properly trained to use it in the specific procedure being undertaken. Use of this equipment without such training may result in serious unintended patient injury.

Use the system with caution in the presence of internal or external pacemakers, or other implanted devices. Interference produced by electrosurgical equipment can cause a pacemaker or other device to enter an unsafe mode or permanently damage the device. Consult the device manufacturer or responsible hospital department for further information when use is planned in patients with implanted medical devices.

The safe and effective use of RF energy depends on many factors solely under the control of the operator. There is no substitute for properly trained and vigilant personnel. It is important that the operating instructions supplied with this or any other medical equipment be read, understood, and followed.

Contact between an active instrument electrode and any metal object (hemostats, staples, clips, retractors, etc.) may increase current flow and may result in unintended surgical effects, such as an effect at an unintended site or insufficient energy deposition.

INDICATIONS FOR USE

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- Open the jaws by squeezing the lever until it unlocks, then push the lever completely forward.

Wipe jaw surfaces and edges with a wet gauze pad as needed.

Cleaning the Instrument During Use

Warning

Inspect the instrument jaws prior to cleaning to ensure the blade is not deployed.

Do not activate the instrument or the cutting trigger while cleaning the jaws. Injury to operating room personnel may result.

Notice

Do not attempt to clean the instrument jaws by activating the instrument on wet gauze. Product damage may occur.

Remove any embedded tissue from blade track and jaw hinge area.

Do not clean the instrument jaws with a scratch pad or other abrasives.

Troubleshooting

The following is a list of troubleshooting suggestions for situations encountered when using the instrument with compatible Covidien vessel sealing generators. For details on specific situations, refer to the corresponding generator user's guide or the generator quick reference guide.

Alert Situations

When an alert condition occurs, energy delivery stops. After the alert condition has been corrected, energy delivery will be immediately available.

Troubleshooting information	
The following is a list of troubleshooting suggestions for situations encountered when using the instrument with compatible Covidien vessel sealing generators. For details on specific situations, refer to the corresponding generator user's guide or the generator quick reference guide.	
Alert situations	When an alert condition occurs, energy delivery stops, the generator produces a sequence of pulsed tones, and an alert will be displayed on the generator. Do Not Cut the Vessel. The user should inspect the seal site and instrument before proceeding. After the alert condition has been corrected, energy delivery will be immediately available.
Troubleshooting steps	<ol style="list-style-type: none"> Release the footswitch pedal or activation button, if still engaged. Open the instrument jaws and inspect for a successful seal. Follow the suggested corrective actions on the generator screen, the generator quick reference card, or in the generator user's guide. If possible, reposition the instrument and regrasp tissue in a location that overlaps the previous seal, then reactivate the seal cycle.
Reasons for alert	<p>Too little tissue between the jaws – The user is grasping thin tissue or not enough tissue; open the jaws and confirm that a sufficient amount of tissue is inside the jaws. If necessary, increase the thickness of tissue that is grasped and reactivate the seal cycle.</p> <p>Too much tissue between the jaws – The user is grasping too much tissue; open the jaws, reduce the amount of tissue that is grasped, and reactivate the seal cycle.</p> <p>Activating on a metal object – Avoid grasping objects, such as staples, clips, or encapsulated sutures in the jaws of the instrument.</p> <p>Dirty jaws – Use a wet gauze pad to clean surfaces and edges of instrument jaws.</p> <p>Excess Fluids in the Surgical Field – Minimize or remove excess fluids from around the instrument jaws.</p> <p>Activation switch released before seal complete tone – The footswitch or activation button was released before the seal cycle was complete.</p> <p>Maximum seal cycle time has been reached – The system needs more time and energy to complete the seal cycle.</p>

PRODUCT REQUEST FORM

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

LigaSure Impact™ Curved Large Jaw Open Sealer/Divider (LF4418)

Improves procedural flow

Compared to the LF4318, the nonstick coating on the LigaSure Impact™ jaws:

- Reduces sticking and eschar buildup^{1,2}
- Results in fewer cleanings^{2,†}
- Makes cleaning more efficient^{2,†}
- Enables greater procedural efficiency^{2,†}

Delivers the value of versatility and speed

The LigaSure Impact™ device can grasp, seal, and cut tissue independently. The device also:

- Enables fast transection and procedural efficiency³
- Minimizes the need for multiple activations³

Proven performance

The LigaSure Impact™ device comes with the reliable performance of LigaSure™ vessel sealing technology, which:

- Has the highest burst pressure, fastest sealing time, and highest overall rating compared to Gyrus PKS™*, Harmonic Ace™*, and Enseal™**4
- Reduces blood loss compared to sutures and clips^{5,6}
- Reduces procedure time compared to sutures^{5,6}
- Reduces patient length of stay compared to sutures⁵

I'm confident using technology backed by such a significant body of evidence-based research — and I'm sure it will add value for our patients and our hospital.

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 #RE00034755, LF4418 design verification report: benchtop testing using porcine abdominal aorta, mesentery, and renal arteries, with average (lbs.) sticking force. Feb. 24, 2016 and March 25, 2016.

2. Based on internal test report #RE00057355, Lig-40 report product claim LF4418: benchtop testing using porcine uterine tissue. Eschar buildup assessed using optical imaging analysis after 20, 40, and 60 seal and divide cycles. July 29, 2016.

3. Based on internal test report #RE00052321, Lig-40 marketing report surgeon evaluation of LigaSure Impact™ LF4418: independent surgeon feedback collected during porcine labs. June 21-22, 2016.

4. Targarona EM, Balague C, Marin J, et al. Energy sources for laparoscopic colectomy: A prospective randomized comparison of conventional electrosurgery, bipolar computer-controlled electrosurgery and ultrasonic dissection. Operative outcome and cost analysis. *Surg Innov.* 2005;12(4):339-344.

5. Manouras A, Filippakis G, Tsekoura D, et al. Sutureless open low anterior resection with total mesorectal excision for rectal cancer with the use of the electrothermal bipolar vessel sealing system. *Med Sci Monit.* 2007;13(5):CR224-230.

6. Ding Z, Wable M, Rane A. Use of LigaSure bipolar diathermy system in vaginal hysterectomy. *J Obstetrics Gynaecol.* 2005; 25(1):49-51.

† Using a wet gauze cleaning fixture, and optical imaging analysis. Cleaning effectiveness assessed after each of two cleaning cycles.



LigaSure Impact™ Curved Large Jaw Open Sealer/Divider Nano-Coated

Product Code: LF4418
Quantity: 6 per box

ORDERING INFORMATION

Let's bring proven performance and greater efficiency to your OR.
Call your local Medtronic sales representative today
or visit medtronic.com/covidien

REFERENCES

1. Based on Medtronic electrosurgery and advanced energy product catalogs compared to Ethicon's catalog.
2. Based on internal test report #RE00057355, Lig-40 report product claim LF4418: benchtop testing using porcine uterine tissue. Eschar buildup assessed using optical imaging analysis after 20, 40, and 60 seal and divide cycles. July 29, 2016.
3. Based on internal test report #RE00052321, Lig-40 marketing report surgeon evaluation of LigaSure Impact™ LF4418: independent surgeon feedback collected during porcine labs. June 21-22, 2016.
4. Based on internal test report #RE00034755, LF4418 design verification report: benchtop testing using porcine abdominal aorta, mesentery, and renal arteries, with average (lbs) sticking force. Feb. 24, 2016 and March 25, 2016.
5. Based on internal test report #RE00065124, Lig-40 LF4418 product claims report for reprocessed jaws: benchtop testing conducted with reprocessed device jaws using porcine tissue, porcine blood, and average (lbs) tissue sticking force. Oct. 4-7, 2016.
6. Based on internal test report #RE00025819 Rev A, LigaSure™ device data sources for VLFT10 white papers. September 2015.
7. 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.
8. Ding Z, Wable M, Rane A. Use of LigaSure™ bipolar diathermy system in vaginal hysterectomy. *J Obstetrics Gynaecol*. 2005; 25(1):49-51.
9. Levy B, Emery L. Randomized trial of suture versus electrosurgical bipolar vessel sealing in vaginal hysterectomy. *Obstet Gynecol*. 2003;102(1):147-151.
10. Targarona EM, Balague C, Marin J, et al. Energy sources for laparoscopic colectomy: A prospective randomized comparison of conventional electrosurgery, bipolar computer-controlled electrosurgery and ultrasonic dissection. Operative outcome and cost analysis. *Surg Innov*. 2005;12(4):339-344.
11. Manouras A, Filippakis G, Tsekoura D, et al. Sutureless open low anterior resection with total mesorectal excision for rectal cancer with the use of the electrothermal bipolar vessel sealing system. *Med Sci Monit*. 2007;13(5):CR224-230.
12. Tamussino K, Afschar P, Reuss J, Perschler M, Ralph G, Winter R. Electrosurgical bipolar vessel sealing for radical abdominal hysterectomy. *Gynecol Oncol*. 2005;96(2):320-322.
13. Leonardo C, Guaglione S, De Carli P, Pompeo V, Forastiere E, Gallucci M. Laparoscopic nephrectomy using LigaSure system: preliminary experience. *J Endourol*. 2005;19(8):976-978.
14. Daskalopoulos G, Karyotis I, Heretis I, Delakas D. Electrothermal bipolar coagulation for radical prostatectomies and cystectomies: a preliminary case-controlled study. *Int Urol Nephrol*. 2004;36(2):181-185.
15. Cronjé HS, de Coning EC. Electrosurgical bipolar vessel sealing during vaginal hysterectomy. *Int J Gynaecol Obstet*. 2005;91(3):243-245.
16. Araki Y, Noake T, Kanazawa M, et al. Clipless hand-assisted laparoscopic total colectomy using LigaSure Atlas. *Kurume Med J*. 2004;51(2):105-8.
17. Campagnacci R, de Sanctis A, Baldarelli M, Rimini M, Lezoche G, Guerrieri M. Electrothermal bipolar vessel sealing device vs. ultrasonic coagulating shears in laparoscopic colectomies: a comparative study. *Surg Endosc*. 2007; 21(9):1526-1531.
18. Takada M, Ichihara T, Kuroda Y. Comparative study of electrothermal bipolar vessel sealer and ultrasonic coagulating shears in laparoscopic colectomy. *Surg Endosc*. 2005;19(2):226-228.
19. Demirturk F, Aytan H, Caliskan AC. Comparison of the use of electrothermal bipolar vessel sealer with harmonic scalpel in total laparoscopic hysterectomy. *J Obst Gynaecol Res*. 2007;33(3):341-345.
20. Based on internal test report #RE00005401 Rev A, Product validation of Valleylab™ FT10: Surgeon and nurse evaluation in simulated use. Jan. 27-30, 2015; Feb. 24-27, 2015.
† Using a wet gauze cleaning fixture, and optical imaging analysis. Cleaning effectiveness assessed after each of two cleaning cycles.
‡ Eschar build-up assessed using optical imaging analysis after 60 seal and divide cycles.