Medtronic
Engineering the extraordinary

Experience next-level performance, precision, and procedural efficiency.[1,†,‡,§]

Introducing the LigaSure™ XP Maryland jaw sealer/divider with nano-coating

Building on trusted[2] LigaSure™ technology.

Offering surgeons options.

†The LigaSure™ XP Maryland jaw device is indicated for use in general surgery and such surgical specialties as colorectal, bariatric, urologic, vascular, thoracic, and gynecologic.

‡Compared to their current preferred device; 21 of 23 surgeons agreed during clinical procedures.

§Compared to their current preferred device; 20 of 23 surgeons agreed during clinical procedures.

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Trusted technology.[2] Next-level performance.[1,†,‡]

When surgeons need to be sure of the equipment they're using, LigaSure™ technology has provided them with confidence for more than 20 years. This confidence is reflected in the use of LigaSure™ vessel sealers for 25 million procedures worldwide – and counting.[2]

The LigaSure™ XP Maryland jaw sealer/divider continues this tradition of innovation. The device delivers improved performance, precision, and procedural efficiency for diverse and complex procedures[1,†,‡,§] – all while remaining true to the foundational trusted technology[2] expected of the LigaSure™ portfolio.

The LigaSure™ XP Maryland jaw device is the latest example of our commitment to meeting the evolving needs of surgeons and their patients. Get ready to experience the next level of vessel sealing performance.[1,†,‡]

25 million

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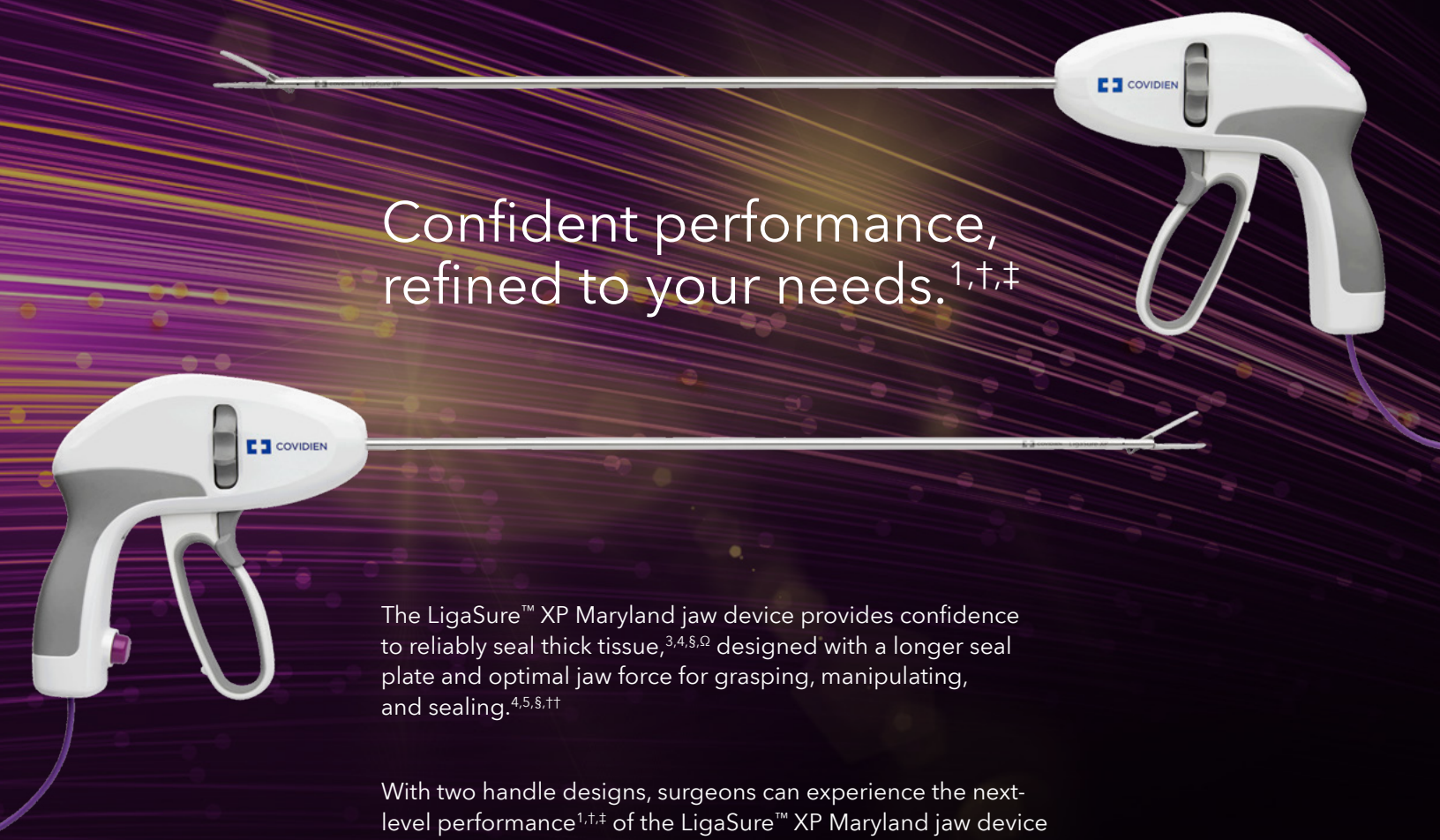

Confident performance, refined to your needs.[1,†,‡]

The LigaSure™ XP Maryland jaw device provides confidence to reliably seal thick tissue,[3,4,§,Ω] designed with a longer seal plate and optimal jaw force for grasping, manipulating, and sealing.[4,5,§,††]

With two handle designs, surgeons can experience the next-level performance[1,†,‡] of the LigaSure™ XP Maryland jaw device using the method of energy activation they prefer.[3,Ω]

- One-step sealing minimizes the number of steps required to seal and transect tissue[3,‡‡]
- Latching handle provides distinct and separate actions to grasp, seal, and cut[3,§§]

These advancements are accomplished while remaining true to the thermal performance of legacy LigaSure™ devices:

- Equivalent jaw and shaft temperatures after multiple activations[6]
- Same LigaSure™ technology standard of less than 2 mm mean lateral thermal spread[7,8]

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‡Compared to their current preferred device; 21 of 23 surgeons agreed during clinical procedures.

§Thick tissue is defined as nondissected vascular tissue or fatty tissue.

Ω29 out of 29 surgeons agree.

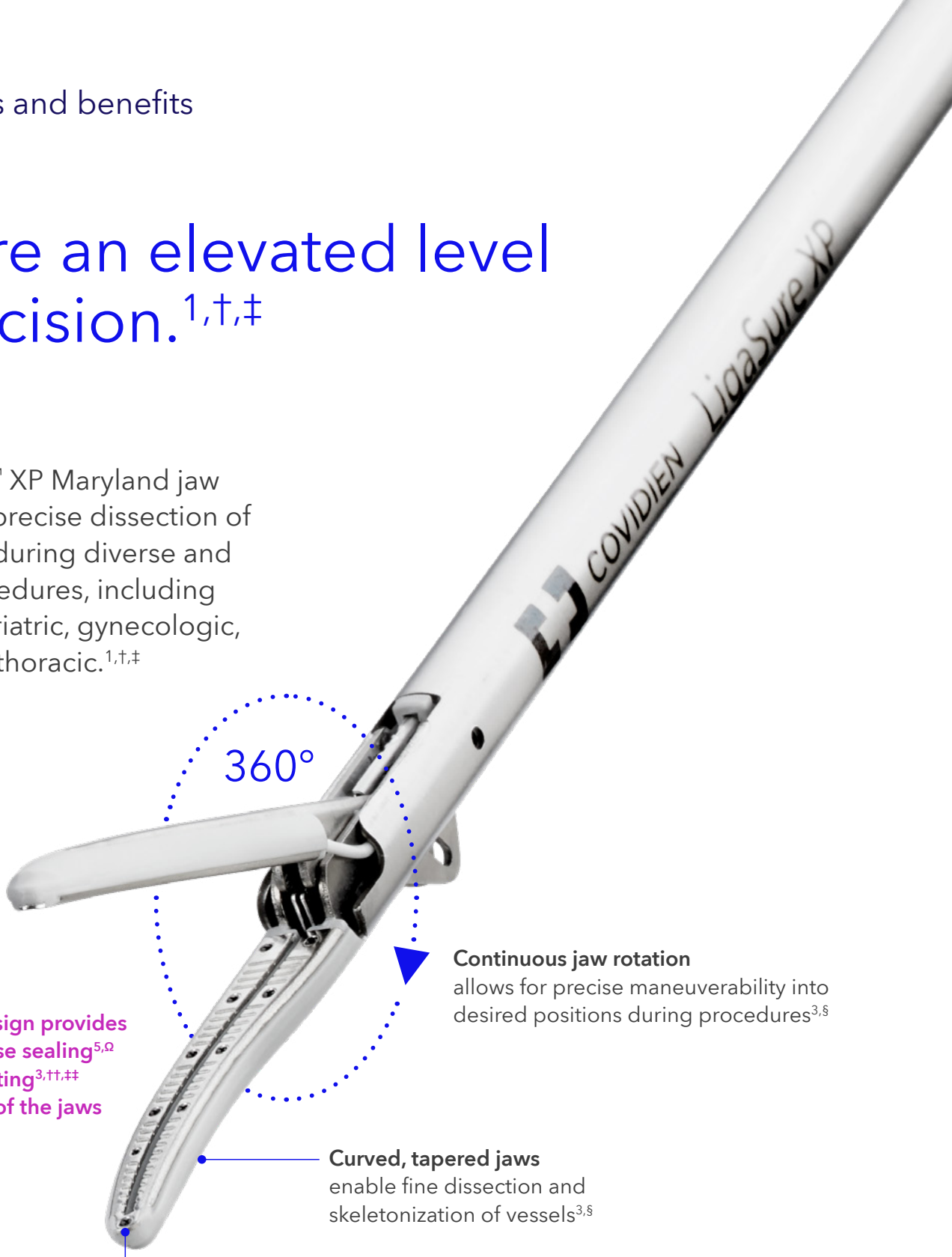
††Bench tissue may not be indicative of clinical tissue performance.

‡‡15 out of 15 surgeons agree.

§§14 out of 14 surgeons agree.

Explore an elevated level of precision.[1,†,‡]

The LigaSure™ XP Maryland jaw device offers precise dissection of tissue planes during diverse and complex procedures, including colorectal, bariatric, gynecologic, urologic, and thoracic.[1,†,‡]



Continuous jaw rotation
allows for precise maneuverability into desired positions during procedures[3,§]

Updated design provides more precise sealing[5,Ω] and cutting[3,††,‡‡] at the tip of the jaws

Curved, tapered jaws
enable fine dissection and skeletonization of vessels[3,§]

A seal plate that extends to the tip of the device
makes it easier to access tissue planes or create windows[3,††,‡‡]

†The LigaSure™ XP Maryland jaw device is indicated for use in general surgery and such surgical specialties as colorectal, bariatric, urologic, vascular, thoracic, and gynecologic.

‡Compared to their current preferred device; 21 of 23 surgeons agreed during clinical procedures.

§29 out of 29 surgeons agree.

Ω30 out of 30 surgeons agree.

††24 out of 29 surgeons agree.

‡‡Compared to legacy LigaSure™ devices.

Procedural efficiency[1,†,‡] that turns your focus to patients.

The design features of the LigaSure™ XP Maryland jaw device reduce the need for instrument exchanges and provide efficiency throughout your procedures.[3,§]

Longer jaws
provide increased seal plate and cut lengths, increasing efficiency by sealing and transecting more tissue per bite[3,Ω,††]

Continuous 360° jaw rotation
provides improved efficiency through undisrupted movement[3,§,††]

Nano-coating
performance is consistent with legacy LigaSure™ devices,[3,9,§] resulting in reduced tissue sticking compared to competing devices[9,‡‡]

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‡Compared to their current preferred device; 20 of 23 surgeons agreed during clinical procedures.

§29 out of 29 surgeons agree.

Ω28 out of 29 surgeons agree.

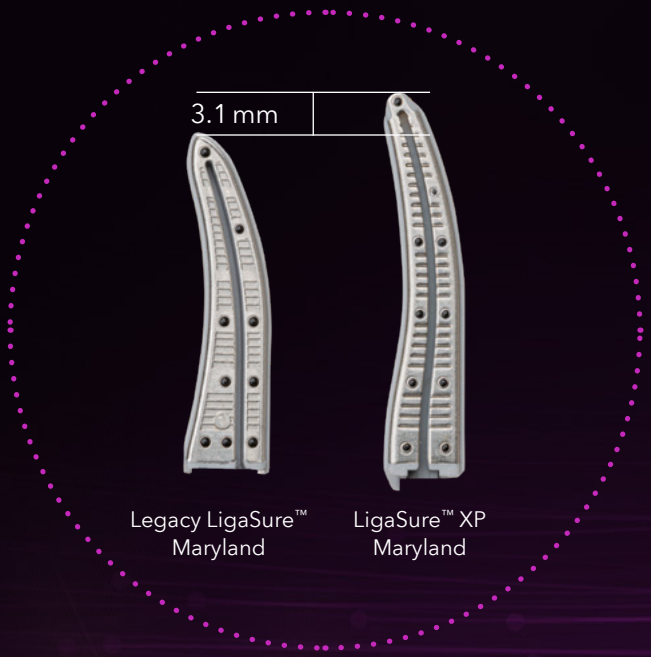
††Compared to legacy LigaSure™ devices.

‡‡Bench tissue may not be indicative of clinical tissue performance.

Achieving progress in sealing and dissection.[1,†,‡]

Compared to the legacy LigaSure™ Maryland jaw device

- The seal plate of the LigaSure™ XP Maryland jaw device is 3.1 mm (16%) longer[10]
- The LigaSure™ XP Maryland jaw device cuts closer to the device tip[10]
- Lever force provides sufficient tactile feedback to indicate when energy is about to be delivered, reducing inadvertent activation[5,§]



Compared to the legacy LigaSure™ blunt tip device

- The LigaSure™ XP Maryland jaw device pairs its longer jaw with a latching handle design option
- This latching handle design offers:
  - An improved location for the activation button[11,Ω]
  - A closer reach to the blade trigger[11,Ω]

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‡Compared to their current preferred device; 21 of 23 surgeons agreed during clinical procedures.

§15 out of 15 surgeons agree.

Ω30 out of 30 surgeons were able to actuate controls with glove sizes ranging from 5.5 to 8.5.

An ergonomic design shaped with you in mind.

With the LigaSure™ XP Maryland jaw device, you can literally feel the difference of next-level performance.[1,†,‡] Its design incorporates greater curvature, reduced handle thickness in key contact areas, and improved reach distances to controls, allowing the device to accommodate a greater range of user hand sizes.[11,§]

The one-step sealing and latching handle options both offer:

An improved mechanical advantage – increased jaw forces require similar or lower lever forces compared to legacy LigaSure™ devices[11]

Improved reach to levers, blade triggers, and activation buttons[11,§]

Larger rotation wheel features for improved usability[11,§]

Overall greater hand comfort[3,Ω]

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§30 out of 30 surgeons were able to actuate controls with glove sizes ranging from 5.5 to 8.5.

Ω29 out of 29 surgeons agree.

Ethicon Enseal™* X1 device

The LigaSure™ XP Maryland jaw device outperforms the Ethicon Enseal™* X1 device in these key measures of performance:

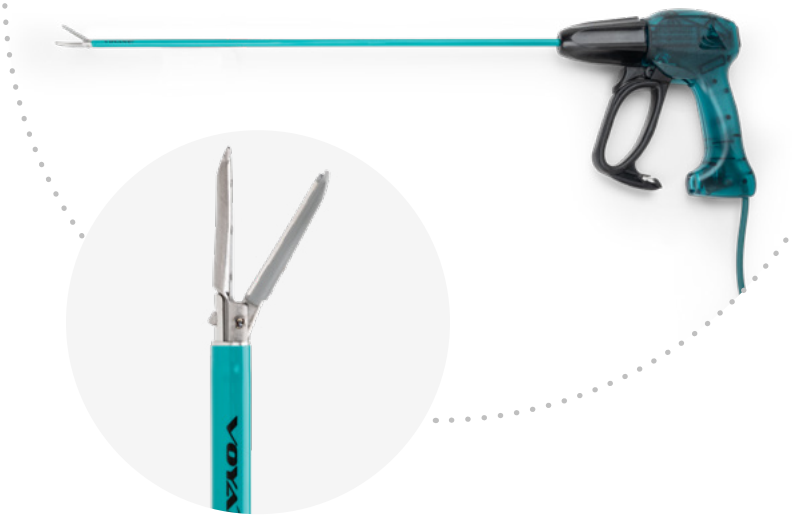
- Higher average burst pressure in thick tissue[4,†,‡]
- Greater average burst pressure on isolated large vessels (5.1–7.0 mm)[12,‡]
- Faster activation (seal) time in acute tissue[7]
- Lower mean lateral thermal spread for a single activation in acute tissue[7]
- Reduced tissue sticking[9,‡]
- Cooler average maximum distal shaft temperature after multiple activations[6]
- Cooler average hinge temperature after multiple activations[6]
- A finer jaw tip for tissue dissection, with less height and width[10]
- Transects more sealed tissue per cut[10]
- Cuts closer to the device tip[10]
- Grasps more tissue with longer jaw length and greater jaw aperture[10]

Device comparison

Device	Jaw length (measured from tissue stop to seal plate tip)	Seal plate length (measured from tissue stop to distal tip)	Cut length	Device weight
LigaSure™ XP Maryland jaw device	23.4 mm	22.6 mm	21.8 mm	262 g
Ethicon Enseal™* X1 device	22.7 mm	22.4 mm	21.1 mm	312 g

†Thick tissue is defined as nondissected vascular tissue or fatty tissue.
‡Bench tissue may not be indicative of clinical tissue performance.

Voyant™* Maryland Fusion device



The LigaSure™ XP Maryland jaw device outperforms the Voyant™* Maryland Fusion device in these key measures of performance:

- Higher average burst pressure in thick tissue[4,13,†,‡]
- Faster activation (seal) time in acute tissue[7]
- Lower mean lateral thermal spread for a single activation in acute tissue[7]
- Reduced tissue sticking[9]
- Cooler average maximum distal shaft temperature after multiple activations[6]
- Cooler average hinge temperature after multiple activations[6]
- Seals and transects more tissue per activation[10]
- Cuts closer to the device tip[10]
- Grasps more tissue with longer jaw length and greater jaw aperture[10]

Device comparison

Device	Jaw length (measured from tissue stop to seal plate tip)	Seal plate length (measured from tissue stop to distal tip)	Cut length	Device weight
LigaSure™ XP Maryland jaw device	23.4 mm	22.6 mm	21.8 mm	262 g
Voyant™* Maryland Fusion device	20.9 mm	19.9 mm	17.1 mm	268 g

†Thick tissue is defined as nondissected vascular tissue or fatty tissue.
‡Bench tissue may not be indicative of clinical tissue performance.

Aesculap Caiman™* 5 Maryland device

The LigaSure™ XP Maryland jaw device outperforms the Aesculap Caiman™* 5 Maryland device in these key measures of performance:

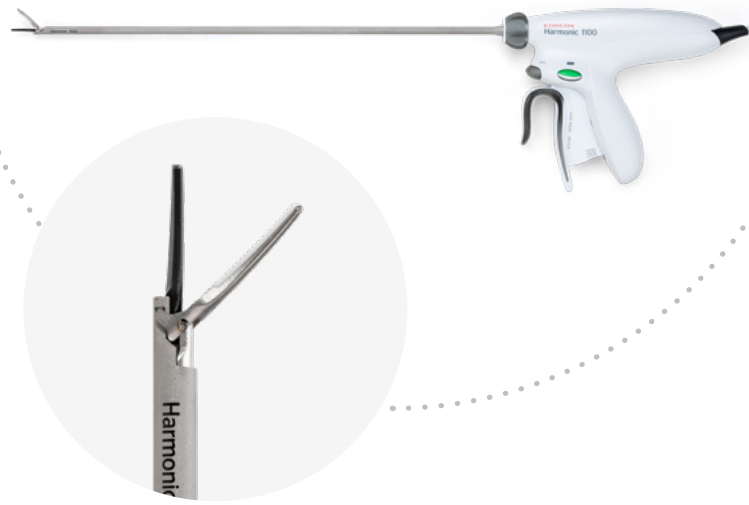
- Higher average burst pressure[12,†]
- Cooler average maximum (bottom) jaw temperature after a single activation[6]
- Cooler average distal shaft temperature after multiple activations[6]
- Reduced tissue sticking[9]

Device comparison

Device	Jaw length (measured from tissue stop to seal plate tip)	Seal plate length (measured from tissue stop to distal tip)	Cut length	Device weight
LigaSure™ XP Maryland jaw device	23.4 mm	22.6 mm	21.8 mm	262 g
Aesculap Caimen™* 5 Maryland device	20.6 mm	19.2 mm	17.7 mm	244 g

†Bench tissue may not be indicative of clinical tissue performance.

Ethicon Harmonic™* 1100 device



The LigaSure™ XP Maryland jaw device outperforms the Ethicon Harmonic™* 1100 device (an ultrasonic dissector) in these key measures of performance:

- Higher average burst pressure[12,†]
- Faster activation (seal) time in acute tissue[7]
- Lower mean lateral thermal spread for a single activation in acute tissue[7]
- Cooler average maximum (bottom) jaw temperature after a single activation[6]

Device comparison

Device	Jaw length (measured from tissue stop to seal plate tip)	Seal plate length (measured from tissue stop to distal tip)	Cut length	Device weight
LigaSure™ XP Maryland jaw device	23.4 mm	22.6 mm	21.8 mm	262 g
Ethicon Harmonic™* 1100 device	19.0 mm	NA	19.0 mm	320 g

†Bench tissue may not be indicative of clinical tissue performance.

LigaSure™ XP Maryland jaw devices

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™ XP Maryland jaw device, one-step sealing:

- ☐ **LXMJ23S** | Open Sealer/Divider, One-step Sealing, Nano-coated, 5 mm – 23 cm
- ☐ **LXMJ37S** | Laparoscopic Sealer/Divider, One-step Sealing, Nano-coated, 5 mm – 37 cm
- ☐ **LXMJ44S** | Laparoscopic Sealer/Divider, One-step Sealing, Nano-coated, 5 mm – 44 cm

LigaSure™ XP Maryland jaw device, latching handle:

- ☐ **LXMJ23L** | Open Sealer/Divider, Latching Handle, Nano-coated, 5 mm – 23 cm
- ☐ **LXMJ37L** | Laparoscopic Sealer/Divider, Latching Handle, Nano-coated, 5 mm – 37 cm
- ☐ **LXMJ44L** | Laparoscopic Sealer/Divider, Latching Handle, Nano-coated, 5 mm – 44 cm

Next-level performance[1,†,‡]

- Confidence to reliably seal thick tissue[2,3,§,Ω]
- Longer seal plate and optimal jaw force for grasping, manipulating, and sealing[3,4,§,††]

Elevated precision[1,†,‡]

- Jaw design makes it easier to access tissue planes or create windows[2,‡‡,§§]
- Curved, tapered jaws enable fine dissection and skeletonization of vessels[2,Ω]

Greater procedural efficiency[1,†,ΩΩ]

- Longer jaws seal and transect more tissue per bite[2,§§,†††]
- 360° continuous jaw rotation improves efficiency with undisrupted movement[2,Ω,§§]

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

Sincerely,

Additional comments:

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§§Compared to legacy LigaSure™ devices.

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1. Based on internal report #RE00457416 Rev A, Product introduction report: LigaSure™ XP Maryland jaw sealer/divider. May 2023.
2. Based on internal report #RE00376094 Rev A, LigaSure™ XP Maryland jaw sealer/divider surgeon validation marketing report. Dec. 7–9 and 14–16, 2021.
3. Based on internal report #RE00442444 Rev A, Comparison of the renal artery bench bundle burst pressure performance with the LigaSure™ XP Maryland jaw sealer/divider, Voyant™* Maryland Fusion, Enseal™* X1 curved jaw, and LigaSure™ LF19XX devices. Jan. 23, 2023.
4. Based on internal report #RE00372649 Rev A, Archer surgeon summative evaluation report. March 22, 2022.

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January 23, 2023

Covidien, llc
Miranda Miles
Regulatory Affairs Specialist
5920 Longbow Dr.
Boulder, Colorado 80301

Re: K223158
Trade/Device Name: LigaSure™ XP Maryland Jaw Sealer/Divider
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 21, 2022
Received: December 27, 2022

Dear Miranda Miles:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Carr -S

for Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

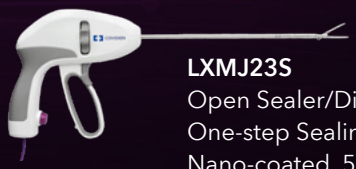
Enclosure

Next-level performance and precision[1,†,‡] are within your grasp.

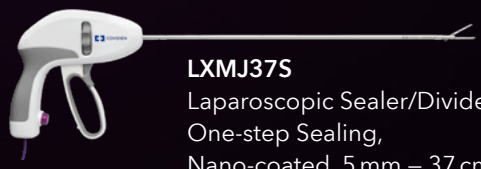
The LigaSure™ XP Maryland jaw portfolio includes two handle styles, each available in three length options. All six devices are nano-coated and compatible with 5 mm trocars, providing surgeons with an array of options to meet the needs of their individual cases.

Two handle designs. Three device lengths.

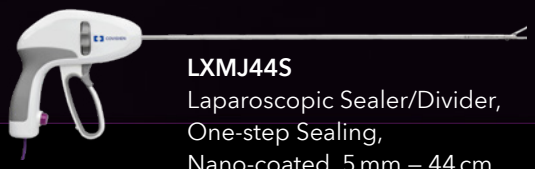
One-step sealing



LXMJ23S
Open Sealer/Divider,
One-step Sealing,
Nano-coated, 5 mm – 23 cm
6 per case

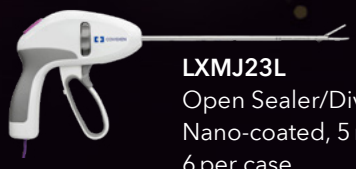


LXMJ37S
Laparoscopic Sealer/Divider,
One-step Sealing,
Nano-coated, 5 mm – 37 cm
6 per case

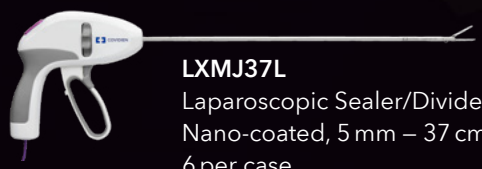


LXMJ44S
Laparoscopic Sealer/Divider,
One-step Sealing,
Nano-coated, 5 mm – 44 cm
6 per case

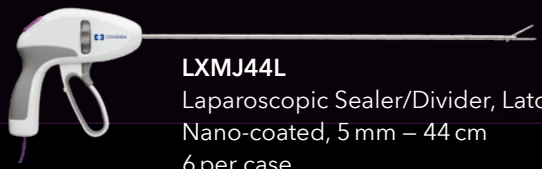
Latching handle



LXMJ23L
Open Sealer/Divider, Latching Handle,
Nano-coated, 5 mm – 23 cm
6 per case



LXMJ37L
Laparoscopic Sealer/Divider, Latching Handle,
Nano-coated, 5 mm – 37 cm
6 per case



LXMJ44L
Laparoscopic Sealer/Divider, Latching Handle,
Nano-coated, 5 mm – 44 cm
6 per case

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‡Compared to their current preferred device; 21 of 23 surgeons agreed during clinical procedures.

Bring next-level performance, precision, and procedural efficiency[1,†,‡,§] to your OR.

Contact your Medtronic representative or visit us at **medtronic.com/covidien/en-gb/products/vessel-sealing/ligasure-xp-maryland-jaw-sealer-divider-nano-coating.html** to discover more.

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‡Compared to their current preferred device; 21 of 23 surgeons agreed during clinical procedures.

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References

1. Based on internal report #RE00457416 Rev A, Product introduction report: LigaSure™ XP Maryland jaw sealer/divider. May 2023.
2. Based on COGNOS and historical sales data, FY01–FY20. October 2019.
3. Based on internal report #RE00376094 Rev A, LigaSure™ XP Maryland jaw sealer/divider surgeon validation marketing report. Dec. 7–9 and 14–16, 2021.
4. Based on internal report #RE00442444 Rev A, Comparison of the renal artery bench bundle burst pressure performance with the LigaSure™ XP Maryland jaw sealer/divider, Voyant™* Maryland Fusion, Enseal™* X1 curved jaw, and LigaSure™ LF19XX devices. Jan. 23, 2023.
5. Based on internal report #RE00372649 Rev A, Archer surgeon summative evaluation report. March 22, 2022.
6. Based on internal test report #RE00380832 Rev A, Thermal profile comparison with the LigaSure™ XP Maryland jaw sealer/divider, Aesculap Caiman™* 5 Maryland, Applied Medical Voyant™* Maryland Fusion, Ethicon Enseal™* X1 curved jaw, Ethicon Harmonic™* 1100, Sonicision™ 7 curved jaw ultrasonic, and LigaSure™ LF18XX and LF19XX devices. May 3–5, 2022.
7. Based on internal test report #RE00380826 Rev A, Acute porcine study comparison with the LigaSure™ XP Maryland jaw sealer/divider, Aesculap Caiman™* 5 Maryland, Applied Medical Voyant™* Maryland Fusion, Ethicon Enseal™* X1 curved jaw, Ethicon Harmonic™* 1100, Sonicision™ 7 curved jaw ultrasonic, and LigaSure™ LF18XX and LF19XX devices. May 9,12, and 23–24, 2022.
8. Based on internal test report #RE00366088 Rev A, LigaSure™ XP Maryland jaw sealer/divider in an acute hemostasis and thermal spread porcine study.
9. Based on internal report #RE00380835 Rev B, Sticking evaluation with the LigaSure™ XP Maryland jaw sealer/divider, Aesculap Caiman™* 5 Maryland, Voyant™* Maryland Fusion, Ethicon Enseal™* X1 curved jaw, LigaSure™ LF18XX blunt tip, and LF19XX Maryland devices.
10. Based on internal test report #RE00455509 Rev B, Competitive device analysis – LigaSure™ XP Maryland jaw sealer/divider.
11. Based on internal report #RE00279542 Rev A, LigaSure™ XP Maryland ergonomic improvements.
12. Based on internal report #RE00380822 Rev A, Comparison of the renal artery seal burst pressure performance with the LigaSure™ XP Maryland jaw sealer/divider, Caiman™* 5 Maryland, Voyant™* Maryland Fusion, Enseal™* X1 curved jaw, Sonicision™ 7 curved jaw, Harmonic™* 1100, LigaSure™ LF18XX, and LF19XX devices.
13. Based on internal report #RE00427804, LIG-48 LigaSure™ XP Maryland jaw sealer/divider (LXMJxxx) indications for use body of evidence.

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