Medtronic

Global value dossier for LigaSure™ technology

Preclinical data and summary

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1 Disclaimer and scope

1.1 Products and aliases

This document refers to devices making use of LigaSure™ technology. This technology includes, for laparoscopic procedures, the LigaSure™ 5mm blunt tip device (37 cm and 44 cm), the LigaSure™ Maryland jaw device (37 cm and 44 cm), the LigaSure Advance™ Pistol Grip device, the LigaSure Atlas™ device and the LigaSure™ dolphin tip device. For open surgeries, applicable devices include the LigaSure Precise™ device, the LigaSure Impact™ device, the LigaSure™ Small Jaw device, the LigaSure™ 5mm blunt tip device (23 cm), the LigaSure™ Maryland jaw device (23 cm), the LigaSure Atlas™ device (20 cm), the LigaSure™ dolphin tip device (20 cm), the LigaSure™ curved jaw device, the LigaSure™ Exact device, and other reusable LigaSure™-branded instruments. LigaSure™ devices are available with uncoated jaws or with nonstick jaws coated with hexamethyldisiloxane (HMDSO).

LigaSure™ Exact is the only LigaSure™ device cleared for breast procedures, and only in the USA. Indications, contraindications, warnings, precautions and procedure steps may vary between products and models, and availability may vary by jurisdiction. Please always refer to indication labeling for your jurisdiction and read all applicable instructions for use provided with the products. An overview of all LigaSure™ devices, their indications and the countries/regions where these indications apply is provided in chapter 6 Overview: Indications of LigaSure™ devices.

1.2 Data sources

Data regarding the clinical application of LigaSure™ devices were derived from searches of literature published within the last 14 years in PubMed (last searches performed in September 2021 and January 2022) and EMBASE (last search performed in March 2022). General text searches for LigaSure™ device references were performed in EMBASE to include all published instances of the use of the technology without restriction of time of publication. These results provide an overview of the extent of usage of the technology.

For clinical evidence data of LigaSure™ technology usage, structured searches were performed using PubMed for peer-reviewed literature applying consistent exclusion criteria across searches for specific surgical indications (see Section 5, Structured literature search details). Results were restricted to publications based on data obtained within the most recent 14 years of the search (2007 and onwards), and excluded editorials/commentaries, articles with no abstract, those that did not report

relevant clinical data (such as animal or ex vivo studies), those that reported data on fewer than 20 patients, those which were not focused on outcomes related to the technology (that is, no mention of vessel sealing or hemostasis), and articles which did not reference LigaSure™ devices or generic LigaSure™ technology (electrosurgical or radiofrequency bipolar vessel sealing).

1.3 Analysis

Clinical results from individual studies are presented as reported (including indication of statistical significance where determined). Where data are amalgamated from multiple reports, please note that the individual studies will vary in terms of design, protocol, surgical technique and patient population, which may limit conclusions drawn from direct comparison and relevant analysis of statistical significance. The resulting figures, however, provide insight into clinical outcomes that have been achieved using LigaSure™ devices in vessel sealing during surgical procedures.

2 Introduction to LigaSure™ technology

2.1 Overview

Summary and key messages

1. **Answers unmet surgical need:** Blood loss is still a major concern during surgical procedures[1,2] and LigaSure™ technology enables efficient, electrosurgical division and sealing of tissues where the control of blood loss is required.[3]
2. **History of development:** LigaSure™ devices span more than 20 years of continuous development and improvement to meet current healthcare needs.
3. **Nano-coating:** Nonstick coating on the jaws of the LigaSure™ device reduces eschar build-up and sticking, and increases cleanability compared to uncoated or reprocessed LigaSure™ devices.[a] Nano-coated LigaSure™ device jaws also show a significantly lower sticking rate than similar competitive devices.[b]
4. **Extensive worldwide usage:** LigaSure™ technology has over 1,700 published reports of its use in a broad range of surgical procedures spanning 66 countries around the world.[G1-G401]
5. **Excellent preclinical performance data:** LigaSure™ devices have been tested in preclinical animal[4-9] and ex vivo human tissue[10,11] models, demonstrating sealing times of 10 seconds or faster with the LVS generator,[3,12-14] or 2-4 seconds with the ForceTriad™ energy platform.[13,14] The applicator provides seal quality resistant to supraphysiological burst pressures for vessels ranging from small (2-3 mm)[7,10,12,14] to large (up to and including 7 mm).[4,5,7,8,14]

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[a] *Based on internal test report #RE00065124, LF4418 Report Marketing Claims for Reprocessed Jaws. Oct. 4 to Oct. 7, 2016 and internal test report #RE00065374, LF18XX Product Claims Report for Reprocessed Jaws. Sep. 22 to Sep. 29, 2016. Bench test data may not be indicative of clinical results.*

[b] *Based on internal test report #RE00073194, Market Research - Report – Tissue Sticking Comparison of the Ethicon® G2, Voyant® 5 mm Fusion, LigaSure™ LF1737, and LigaSure™ LF1937 Devices. Jan. 18, 2017.*

2.2 Prelude

LigaSure™ technology is used in surgical procedures to divide and seal vessels up to and including 7 mm in diameter. The devices are electrosurgical in nature, using current delivered to patient tissues to effect tissue sealing. The complete LigaSure™ vessel sealing system comprises the vessel sealing device (the LigaSure™ sealer/divider), and the energy platform (such as the ForceTriad™ energy platform, the Valleylab™ LS10 generator or the Valleylab™ FT10 energy platform). The vessel sealing device delivers a combination of pressure and electrical current to tissues, the current is provided in a smart algorithm by the energy platform, using tissue-sensing technology (TissueFect™ technology[c]) to control energy delivery. The technology is suitable for use wherever the division and ligation of vessels is desired during general open or minimally invasive surgical procedures. This document presents background information, and associated dossiers provide clinical evidence demonstrating the application of LigaSure™ technology in improving surgical procedures and patient outcomes.

2.3 The surgical application: Hemostasis

In surgery, for the patient's health, as well as to ensure maintenance of adequate visualization, the operative field must stay free of excess blood and other fluids. This is accomplished by hemostatic techniques, whereby dissection is only carried out in blood-vessel-free planes, and when necessary, hemostatic devices are used.

2.3.1 Various methods of controlling blood loss

Methods for controlling bleeding during surgery vary in terms of the immediacy and desired length of action of their effect. A general, non-comprehensive overview of some hemostatic methods is shown in Figure 2-1. The more durable means of preventing excessive blood loss include making use of intrinsic components from the patient's own tissues, from providing a matrix to support the natural clotting process, to electrosurgical techniques which alter the vessel collagen to collapse or fuse the vessel lumen to create a permanent seal. In the case of some electrosurgical instruments, tissue/vessel division is performed simultaneously to ligation, thereby preventing blood loss from the separated vessel.

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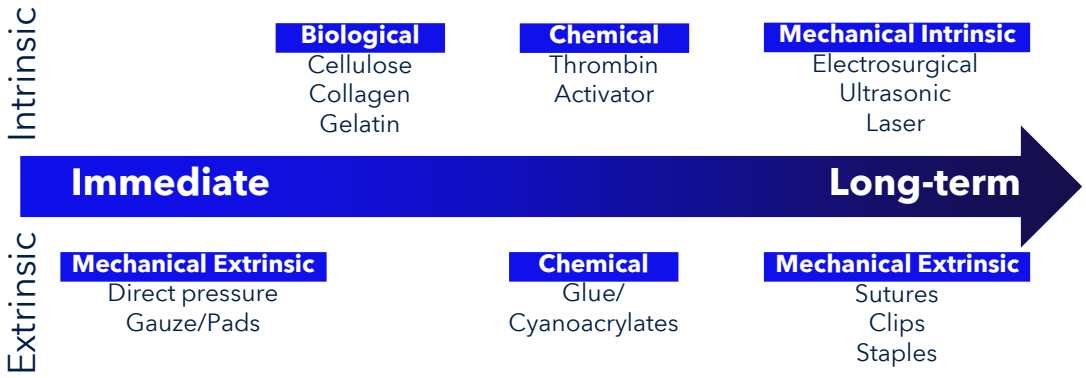
[c] *White paper, Valleylab™ FT10 Energy Platform TissueFect™ Technology. McHenry J, Dunning J and Wagle K (2015) 10/2015 US150755 [REF#479324]. Bench test data may not be indicative of clinical results.*

Figure 2-1 Methods of surgical hemostasis



Shown are several options (a non-comprehensive list) for hemostasis that can be intraoperatively deployed. Placement along the timeline indicates a typical expected duration of effect, assuming no failure. The intrinsic methods make use of body components, such as the natural clotting process captured in the matrix of the biological agents indicated, or the fusion of tissues/structures for the mechanical. Extrinsic methods rely on external structures to provide the seal, which may be subsequently removed (such as pads) or may be absorbed (as in the case of some biologics). Adapted from references.[1,2]

2.3.2 Electrosurgery

As mentioned (section 2.3.1), electrosurgery is one method of hemostasis. These technologies create an electrical current through the patient to generate localized bursts of heat to coagulate tissue. The electricity oscillates at radiofrequencies (hence sometimes referenced as radiofrequency or RF electrocoagulation), which are well above frequencies for normal nerve function, preventing devices from triggering muscle stimulation.

The waveform of energy delivery determines the function of the device:

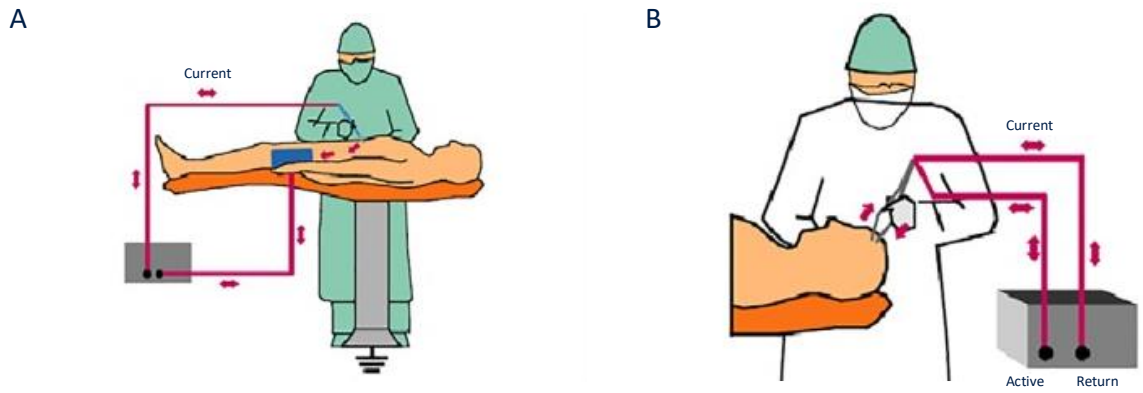
- Cut mode: dissects tissue and uses a low voltage with a long duty cycle
- Coagulation mode: cauterizes tissue using a higher voltage with a shorter duty cycle
- Blend mode: uses intermediate voltage and duty cycle length to achieve both dissection and coagulation of the tissues simultaneously with dissection.

The energy from these waveforms is delivered to patient tissues via:

- Monopolar delivery: the electric circuit passes from the generator through the patient, and back to the source via a separately positioned return electrode (Figure 2-2A)

– Bipolar delivery: the electric circuit passes only through tissue positioned between graspers of the device, obviating potential issues of return electrode misplacement or detachment (Figure 2-2B)

Figure 2-2 Monopolar and bipolar electrosurgery



Monopolar and bipolar forms of electrosurgery differ in the paths taken by the current. In the schematic on the left (A) monopolar electrosurgery with monitoring of the return electrode is shown. Current flows along the magenta arrows from the source (lower left) and through the patient, returning via the patient return electrode (PRE, blue rectangle). In contrast, for bipolar surgery (B), the current passes only through tissue grasped between the forceps, reducing risks to the patient, including from misplaced or detached PREs. Illustration adapted from Golpaygani et al. 2016.[15]

2.4 LigaSure™ technology

LigaSure™ technology is based on bipolar electrosurgery, commonly referenced as electrothermal bipolar vessel sealing (EBVS). The complete system for the sealing of vessels during surgery (previously known as the LigaSure™ Vessel Sealing System, or LVSS) comprises the bipolar device, the energy platform (including the ForceTriad™ energy platform, the Valleylab™ LS10 generator, or the Valleylab™ FT10 energy platform), and the TissueFect™ sensing system, which, using data from the applicator device analyzed at 3,333 to 434,000 data points per second (dependent on the generator), senses the properties of the tissue being grasped to optimize vessel sealing performance[d]. The LS10 generator and the ForceTriad™ and FT10 energy platforms include the TissueFect™ technology. The sealing occurs through the application of a potential difference between the electrodes of the grasping device, which denatures collagen and elastin within the vessel wall and surrounding connective tissue. The addition of extreme pressure applied by the instrument causes

[d] *White paper, Valleylab™ FT10 Energy Platform TissueFect™ Technology. McHenry J, Dunning J and Wagle K (2015) 10/2015 US150755 [REF#479324].* Bench test data may not be indicative of clinical results.

the denatured and reformed collagen and elastin in the tissue bundle or blood vessel to form a hemostatic plug or seal. As a method engaged for hemostasis (section 2.3.1), use of the system is intended to provide an alternative to clips or suture for vessel closure during and after surgery.

2.4.1 Energy platform

The current required for the tissue dividing and vessel sealing functions of LigaSure™ devices is provided by generators designed to provide multiple waveforms for any type of electrosurgery. LigaSure™ device-compatible systems include the ForceTriad™ energy platform and the newer generation Valleylab™ LS10 generator and Valleylab™ FT10 energy platform. These devices (ForceTriad™ and FT10 energy platforms) provide modes to deliver monopolar, bipolar, and LigaSure™ technology-specific waveforms (the LS10 generator provides only the LigaSure™ technology waveform). In its contact with tissue, the LigaSure™ device provides energy delivery and acts as a sensor. The device provides data to the energy delivery platform and is subjected to feedback regulation via the TissueFect™ system. The system provides data to the instrument regarding the resulting effects on the tissue. In LigaSure™ technology mode, the system can be set to automatically complete the sealing, registering an auditory signal when the cycle is complete. A preclinical comparison of a LigaSure™ device as part of the older generation LVSS and the same device with the ForceTriad™ energy platform in blood vessels of various type and size from a porcine model found the use of the ForceTriad™ energy platform to be associated with statistically significantly shorter sealing times ($p < 0.05$) and higher burst pressures ($p < 0.01$), although for both power sources, the LigaSure™ device achieved supraphysiological burst strengths.[13] The latest version of the power generator, the FT10 energy platform, demonstrates still further improvements on the ForceTriad™,[d] energy platform.

2.4.2 Preclinical and laboratory data

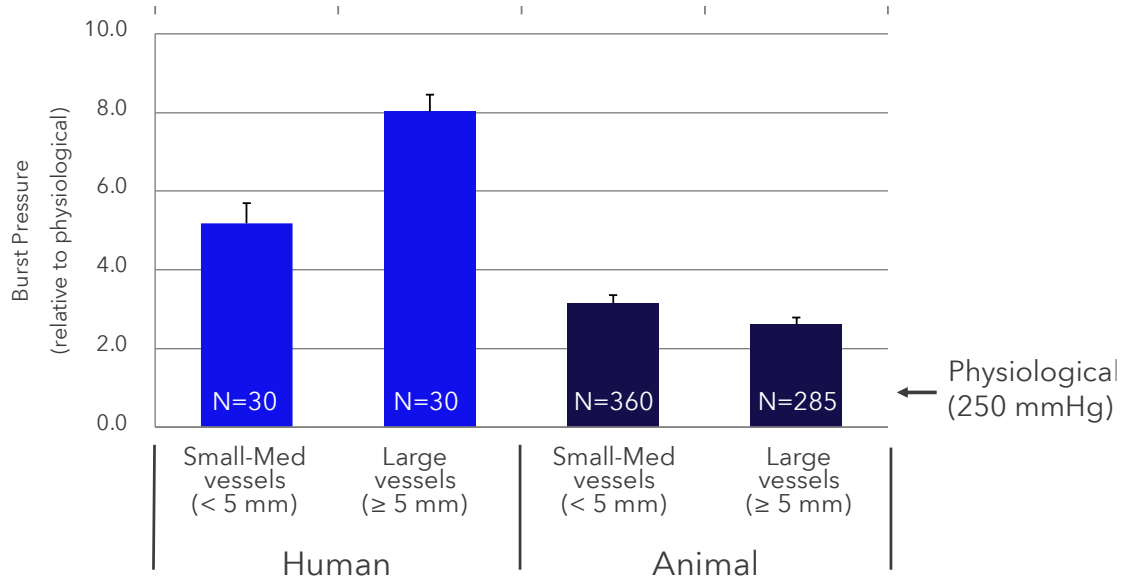
To minimize patient risk, and to enable analysis of parameters that would not be possible in the live patient, experimental studies to assess instrument performance have been performed. These consist of animal studies (mostly porcine) of various types of vessels, and ex vivo human tissue, immediately after tissue removal or post-fixation.[e] Details of studies can be found in Table 4-1.

[e] *These studies may not be indicative of clinical performance.*

2.4.2.1 Burst pressure

A key parameter not readily measurable in vivo in patients is the pressure to which newly divided and sealed vessels can be subjected before seal failure, or the burst pressure Figure 2-3. Across numerous analyses, in vessels extracted from human patients perioperatively (mesenteric vessels)[10] and in animal studies of vessels (porcine,[4,5,7-9,14,16] bovine[3] and ovine[17]), LigaSure™ devices have achieved burst pressures well above normal physiological pressures.

Figure 2-3 LigaSure™ device supraphysiological burst pressure measurements



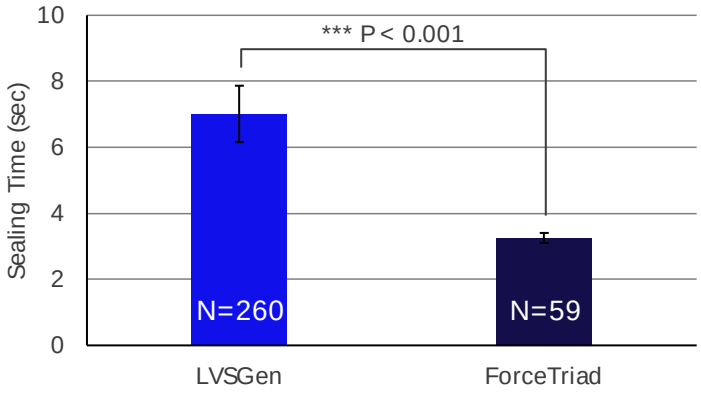
Data are compiled from several comparable studies in animal and tissue and one study in human tissue removed during surgery (mesenteric vessels[10]) and examined ex vivo. Animal data for small vessels are all from porcine models,[5,7-9,14] while animal large-vessel data consist of porcine,[4,5,7,8,14] bovine[3] and ovine.[17] Bars represent weighted means across studies of the ratio of the mean reported burst pressure as a multiple of physiological pressure (taken as 250 mm for blood vessels), N is shown for the total number of individual measurements, and error is indicated as standard error of the mean (SEM).

2.4.2.2 Sealing time

In addition to the security of the created seal, the average time for the device to complete the sealing cycle is another operative parameter for a user to consider. The latter is in part dependent on the power generator used, where across different sizes of vessels tested in animal models from 2-7 mm, shorter sealing times have been observed using the ForceTriad™ energy platform[13,14] with LigaSure™ devices in comparison to the original LigaSure™ Vessel Sealing System Generator[3,9,13,14,17] (Figure 2-4). Direct comparisons in the same study of the ForceTriad™ energy platform and

the earlier version generator, statistically significantly shorter ($p < 0.05$) seal times were observed. Even given the performance improvement observed with the ForceTriad™ energy platform over the original generator, the newer version FT10 demonstrates still further reductions in seal time over the ForceTriad™ energy platform, illustrating the continued improvement in performance in the LigaSure™ technology energy platform[f].

Figure 2-4 Vessel sealing times in experimental models



Although multiple factors will influence the vessel seal time, the power generator used can also have a significant impact on the time to complete the vessel seal using LigaSure™ devices. In animal models, the ForceTriad™ energy platform[13,14] has demonstrated shorter sealing times than with the original version LigaSure™ Vessel Sealing System generator (LVSGen)[3,9,13,14,17] ($p<0.001$, two-tailed t-test), although both have mean times under 10 seconds. Data aggregated from animal studies (LVSGen: porcine,[9,12-14] ovine,[17] and bovine[3]; ForceTriad™ technology, porcine[13,14]) only where the generator used was described. In direct head-to-head comparisons of the LVSGen and ForceTriad™ technology in porcine vessels of various sizes, a significant reduction in seal time was also observed[13,14] ($p < 0.05$). Total counts of individual measurements are indicated on the bars, and error bars represent the standard error of the mean (SEM).

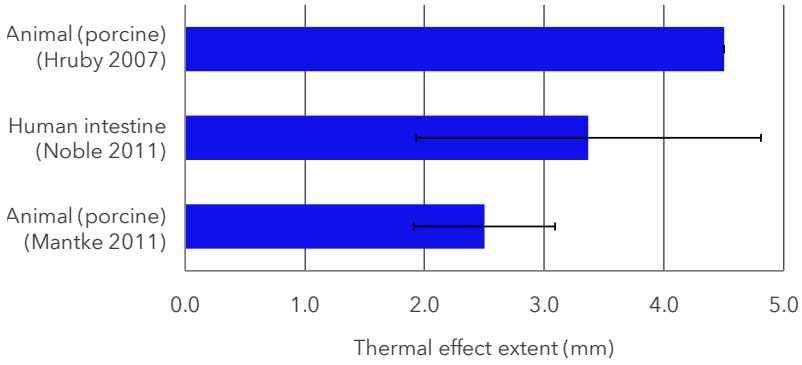
2.4.2.3 Thermal damage

A further consideration for use of LigaSure™ devices in clinical applications is the extent of thermal changes caused by the device to assess the potential for unintended damage that may occur in patient tissues. In the preclinical setting, the temperatures generated by the grasping jaws of the LigaSure™ device and the extent of tissue necrosis have been measured. At the point of sealing, mean maximum temperatures (T_{max}) of the instrument (measured by thermal camera imaging of the jaw surface at 85 ± 3°C[8]) and of the cutting blade (103.1°C[12]) have been measured in porcine models, while 2 mm from the device, a mean T_{max} of 55.5 ± 2.4°C has been determined in bovine tissue.[3] Separately from temperatures, histological examination of tissue samples have been used to measure the range of effect (Figure 2-5) in human

[f] *White paper, Valleylab™ FT10 Energy Platform TissueFect™ Technology. McHenry J, Dunning J and Wagle K (2015) 10/2015 US150755 [REF#479324].* Bench test data may not be indicative of clinical results.

(mesenteric vessels from intestine[10]) and animal models (porcine carotid artery segments[9] and multiple vessel types[12]). The weighted mean distance of tissue changes from the sealing point across these studies is 2.9 ± 0.3 mm.

Figure 2-5 Histological measures of extent of effect for LigaSure™ devices



Reported tissue effects (lateral surface spread and full thickness through all vessel layers) from histological examinations from different studies. Study identifier is indicated in parentheses beneath the model system: Hruby 2007,[12] Noble 2011,[10] and Mantke 2011.[9] Error bars correspond to standard deviation (no error value reported for Hruby 2007)

2.4.3 Nano-coating

LigaSure™ devices are available with uncoated jaws or with hexamethyldisiloxane (HMDSO) coating applied to the jaw and seal plate surfaces. This nonstick nano-coating enhances the performance of the LigaSure™ device.

Eschar build-up causes the jaws of the device to stick to the tissue. It can affect the performance of the device and require multiple cleanings of the device jaws, which affects procedural flow. LigaSure™ devices with nonstick coating help to prevent eschar build-up: the average eschar build-up is reduced by 15% in nano-coated devices compared to uncoated devices, and nonstick-coated device jaws can also be cleaned more effectively.[g] The improved cleanability and ease of cleaning enable greater procedural efficacy.[g]

The nano-coated LigaSure™ devices are intended for single-use only, and the results in the previous paragraph are based on tests according to the expected conditions of a single surgical procedure. However, it is conceivable that third-party reprocessed devices have possibly been subjected to process steps, tools, and/or chemicals that may negatively affect the device's HMDSO nano-coating, which may result in an increase in tissue sticking force in reprocessed jaws compared to nano-coated jaws. In

[g] Based on internal test report #RE00071599, LF19XX MJC marketing claims report conducted on porcine tissue. Feb. 7 to Feb. 22, 2017. Bench test data may not be indicative of clinical results.

fact, the HMDSO nano-coating of nonstick-coated LigaSure™ device jaws is degraded during standard reprocessing procedures, resulting in a significant increase in eschar build-up and sticking as well as reduced cleanability compared to LigaSure™ device jaws with intact nonstick coating.[h] Finally, it has been shown that the rate of sticking is significantly lower in LigaSure™ devices with HMDSO coating, not just compared to uncoated LigaSure™ devices, but also compared to similar competing devices such as the Curved EnSeal® G2 and the Voyant™ 5mm Fusion device.[i]

2.4.4 A history of innovation

Since the introduction of the first LigaSure™ device in 1998, continual development has seen the release of multiple devices employing LigaSure™ technology for open and laparoscopic electrosurgical applications, spanning a wide array of indicated surgeries (Figure 2-6).

Figure 2-6 Timeline of introduction of LigaSure™ devices and supporting technology

[h] *Based on internal test report #RE00065124, LF4418 Report Marketing Claims for Reprocessed Jaws. Oct. 4 to Oct. 7, 2016 and internal test report #RE00065374, LF18XX Product Claims Report for Reprocessed Jaws. Sep. 22 to Sep. 29, 2016. Bench test data may not be indicative of clinical results.*

[i] *Based on internal test report #RE00073194, Market Research - Report – Tissue Sticking Comparison of the Ethicon® G2, Voyant® 5 mm Fusion, LigaSure™ LF1737, and LigaSure™ LF1937 Devices. Jan. 18, 2017.*

2.4.5 Surgical indications

The LigaSure™ vessel sealing system (including the devices and energy delivery) is designed for use in minimally invasive (laparoscopic) or open procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. Note that different devices have different specific surgical indications, and these should always be confirmed in the instructions for use accompanying the device according to the local jurisdiction. Please refer to chapter 6 for an overview of all LigaSure™ devices and their indications.

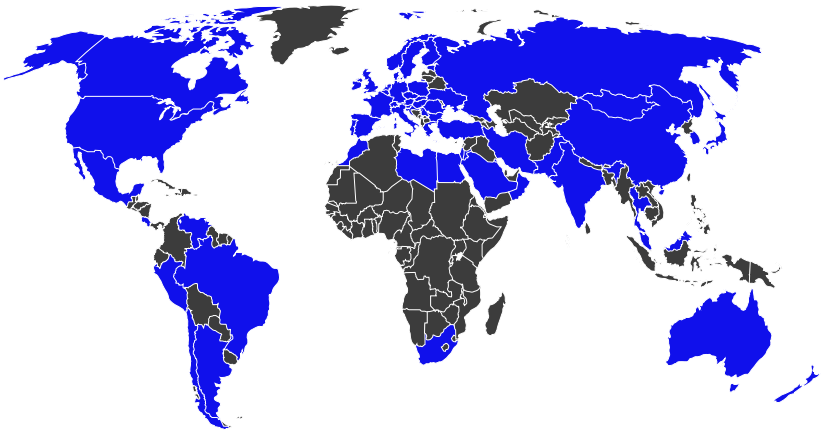
2.5 Extensive worldwide usage

Publications referencing LigaSure™ devices demonstrating good performance in surgical settings originate from a wide range of countries (Figure 2-7). LigaSure™ technology was also included among medical supplies ("ligasure vessel sealing equipment, a steam sterilizer, obstetric labor table and intensive care ward beds") provided by the World Health Organization to a camp in Damascus, Syrian Arab Republic in 2013 as part of its health response to the situation at the time[j]. Overall, there is published evidence of LigaSure™ device use in:

Argentina,[G1,G2] Australia,[G3-G18] Austria,[G19-G27] Bahamas,[G28] Belgium,[G29-G34] Brazil,[G35-G37] Bulgaria,[G38] Canada,[G39-G47] Chile,[G48,G49] China,[G50-G64] Costa Rica,[G65] Croatia,[G66,G67] Czech Republic,[G68-G71] Denmark,[G72-G76] Egypt,[G77-G92] Estonia,[G93] Finland,[G94-G96] France,[G97-G115] Germany,[G116-G127] Greece,[G128-G133] Hong Kong,[G134,G135] Hungary,[G136] India,[G137-G143] Iran,[G144-G153] Iraq,[G154,G155] Ireland,[G156-G160] Israel,[G161-G167] Italy,[G113,G168-G187] Jamaica,[G188] Japan,[G189-G209] Jordan,[G210-G212] Kuwait,[G213] Lebanon,[G34,G214-G216] Lybia,[G217]Malaysia,[G218] Mexico,[G219-G224] Mongolia,[G225] Morocco,[G226] Netherlands,[G227-G232] New Zealand,[G233] Norway,[G234-G237] Oman,[G238] Pakistan,[G239-G241] Peru,[G242] Poland,[G243-G250] Portugal,[G251,G252] Romania,[G253-G260] Russia,[G261-G267] Saudi Arabia,[G268-G271] Serbia,[G272-G274] Singapore,[G275-G280] Solvakia,[G281] Slovenia,[G67] South Africa,[G282,G283] South Korea,[G284-G298] Spain,[G299-G313] Sweden,[G314,G315] Switzerland,[G316,G317] Taiwan,[G318-G330] Thailand,[G331,G332] Trinidad and Tobago,[G333] Turkey,[G334-G362] Ukraine,[G363,G364] United Kingdom,[G18,G365-G377] United States of America[G16,G378-G398] and Venezuela.[G399-G401]

[j] *World Health Organization, Health Situation Report, Syrian Arab Republic, Jordan, Lebanon, Iraq, Issue 16, reporting period 21 June – 9 July, 2013; available at* http://www.who.int/hac/crises/syr/sitreps/syria_regional_sitrep_21june_9july2013.pdf

Figure 2-7 LigaSure™ devices have been applied in clinical settings globally



Highlighted in blue are countries of origin for publications demonstrating the successful use of LigaSure™ technology in clinical settings across all surgeries for which the devices have been indicated.

2.6 Dossiers regarding LigaSure™ devices in procedures

In this series of dossiers, use of LigaSure™ devices in hysterectomy, colectomy, thyroidectomy, bariatric surgery, and breast surgery is discussed. An overview of the indications of the different LigaSure™ devices is detailed in chapter 6. It should be noted that breast surgery is only indicated for LigaSure™ Exact and only in the USA.

3 Key messages for LigaSure™ devices in clinical applications[k]

LigaSure™ technology has also demonstrated excellent outcomes for patients in clinical settings. Key, common findings from analyses across hysterectomy, colorectal procedures (colectomy), thyroidectomy, breast surgery and gastric surgery are indicated below (Table 3-1). Individual dossiers for each surgery are available for further details.

Table 3-1 General LigaSure™ technology outcomes across five indications (colectomy, hysterectomy, thyroidectomy, breast surgery and gastric surgery)

General

- **Extensive worldwide usage:** LigaSure™ technology has over 1,300 published reports of its use in a broad range of surgical procedures spanning 66 countries around the world.[G1-G401]

Compared with conventional ligation:

- **Decreased operative time compared with conventional ligation:** Across studies reporting operating time (total 35 in the search window for the five procedures), LigaSure™ devices have on average reduced procedure time by 16.6% (±3.0% SEM[l]) compared to conventional ligation.[18-52] Time differences (difference in mean times within these studies) range from longer procedures by 17.9 minutes (of 85.6 min axillary lymph node dissection procedures)[50] to time reductions of 106 min (of 349 min radical hysterectomy procedures).[36]
- **Reduced intraoperative blood loss compared with conventional ligation:** Across studies reporting volumetric blood loss (total 22 in the search window for the five procedures), the use of LigaSure™ devices has reduced these losses by an average of 28.9% (±3.9% SEM[l]) compared to conventional ligation.[18,19,25,27-39,41,44-46,48,52] Difference in mean blood loss within these studies have ranged from a non-significant increase of 28 ml (of 260 ml in open radical gastrectomy)[28] to a reduction of 1,025 ml (of 4,223 ml in radical hysterectomy procedures).[39]

k Always refer to product labeling for indications for use of the associated LigaSure™ device (see section 1.1 for more details and chapter 6 for an overview of indications of the different LigaSure™ devices).

l SEM, standard error of the mean. Source data used in calculation available on request MED2154_LigaSure_background

- **Rates of operative complications are similar or reduced with LigaSure™ technology:** LigaSure™ devices have reduced or had equivalent risks of complications compared to conventional ligation in several procedures. These include statistically significant reductions in infections after hysterectomy,[43] and transient hypocalcemia[53] and hypoparathyroidism[35] after thyroidectomy. In breast surgery, LigaSure™ devices have achieved a significant reduction in both drainage duration[23,26,34,40,42,44,50] and volume.[23,34,44,50,54]
- **Potential to reduce costs due to complications:** Interventions and additional operating room usage required to treat complications can considerably increase costs.[38,55-57] Improvement of patient safety endpoints could potentially decrease complication-related cost burdens.
- **Substantial cost savings reported with LigaSure™ devices:** In comparison to suture ligation, LigaSure™ devices have been reported to reduce hospital,[38] staffing,[38] and per-procedure costs.[18,48,58,59]

Compared with other energy devices:

- **Faster or equivalent operative time compared to other energy devices:** In comparison to other energy devices, LigaSure™ technology has shown similar [29,60-65] and significantly reduced operative time for monopolar scissors[48,66] and ultrasonic technology.[67-69]
- **Reduced or equivalent intraoperative blood loss:** Compared to other energy devices, LigaSure™ technology has achieved similar[29,60,61,64] and significantly lower blood loss.[67-69]
- **Equivalent complication rates:** There have been no increased risks of complications with LigaSure™ technology compared to other energy-based methods of hemostasis.[29,47,48,53,62,63,66,69-74]
- **Lowers the cost of care:** Substantial savings with LigaSure™ technology have been achieved when compared to reusable monopolar scissors,[66,75] even when specifically including costs of disposal of the single-use device,[75] and costs were comparable to ultrasonic technology device costs.[58,73,76]

4 Source data tables

Refer to section 1.2 for scope of literature presented in the following data tables.

4.1 Data table summary: LigaSure™ technology preclinical data[m]

Table 4-1 Publication data on LigaSure™ technology in preclinical settings

Source	Model	Device	Generator	Measure	Detail	N	Value	Error
Chekan EG, et al., 2015[4]	porcine	LS Blunt tip	NR	BP	5-7mm	66	823.05	NR
				Sticking	5-7mm	66	0.133	NR
Timm RW, et al., 2014[5]	porcine	LS Blunt tip	NR	BP	<5mm	40	836	NR
					5-7mm	40	591	NR
Lesser TG, et al., 2013[77]	human lung	LS Blunt tip	ForceTriad™ generator	BP	small arteries	15	315	213.1
					thick arteries	15	156	42.5
Takebayashi K, et al., 2013[6]	porcine lymph	NR	NR	BP	NR	NR	290	NR
				Leakage	NR	NR	0.133	NR
Milsom J, et al., 2012[7]	porcine	LS V	ForceTriad™ generator	BP	2-3mm	20	822.6	131
					4-5mm	20	740.9	124
					6-7mm	20	788.9	492
				TS (mm)	2-7mm	41	1.3	0.4
					4-5mm	20	2.1	1
					6-7mm	20	2.1	0.7

m Data from preclinical studies may not be indicative of clinical performance.

Source	Model	Device	Generator	Measure	Detail	N	Value	Error
Seehofer D, et al., 2012[8]	porcine	LS V	ForceTriad™ generator	BP	2-4mm	50	800	NR
					5-7mm	50	615	NR
				TS (degC), thermosensor	max T	8	86	NR
				TS (degC), thermocamera	max T	8	85	NR
Klar M, et al., 2011[17]	ovine	LS Atlas	LVSGen	BP	5.35mm	40	484	229
				SF	5.35mm	44	0.091	NA
				Time (s)	5.35mm	40	9.1	2.5
Mantke R, et al., 2011[9]	porcine	LS Dolphin	LVSGen	BP	<5mm	37	965	364
				Time (s)	<5mm	37	11.7	2
				TS (mm)	depth	37	2.5	0.59
Noble EJ, et al., 2011[10]	human intestine	LS Atlas	NR	BP	arteries	9	2005	NR
					veins	21	1295	NR
				TS (mm)	depth	30	3.37	1.44
Pick DL, et al., 2011[16]	porcine	NR	NR	BP	NR	24	518.2	244.7
Katsuno G, et al., 2010[13]	porcine	LS Atlas	ForceTriad™ generator	Time (s)	3.8mm	20	3.5	0.7
			LVSGen	Time (s)	3.7mm	20	7.6	1.9
Tsunezuka Y, et al., 2010[11]	human lung	LS V	NR	BP	thick PA (>5mm)	12	399	147
					thin PA (<5mm)	13	604	82

Source	Model	Device	Generator	Measure	Detail	N	Value	Error
Newcomb WL, et al., 2009[14]	porcine	LS V	ForceTriad™ generator	BP	2-3mm	13	999.43	NR
					4-5mm	13	884.67	NR
					6-7mm	13	386.53	NR
				Device failure (%)	2-3mm	13	0	NR
					4-5mm	13	0	NR
					6-7mm	13	0	NR
				Time (s)	2-3mm	13	2.85	1.54
					4-5mm	13	3	2.36
					6-7mm	13	3.54	2.62
			LVSGen	BP	2-3mm	13	744.43	NR
					4-5mm	13	1261.45	NR
					6-7mm	13	645.16	NR
				Device failure (%)	2-3mm	13	13.3	NR
					4-5mm	13	0	NR
					6-7mm	13	0	NR
				Time (s)	2-3mm	13	4.07	1.56
					4-5mm	13	7.2	2.38
					6-7mm	13	6.77	2.62
Lamberton GR, et al., 2008[3]	bovine	LS V	LVSGen	BP	5mm	10	385	76
				Time (s)	5mm	20	10	0.9
				TS (degC)	max T, 5mm vessels	10	55.5	2.4

Source	Model	Device	Generator	Measure	Detail	N	Value	Error
Hruby GW, et al., 2007[12]	porcine	LS V	LVSGen	BP	< 3mm	73	569.4	NR
					3-5mm	38	557.8	NR
					5-7mm	3	533.7	NR
				Time (s)	< 3mm	73	4.1	NR
					3-5mm	38	5.7	NR
					5-7mm	3	8	NR
				TS (degC)	max T	10	103.14	NR
				TS (mm)	depth	2	4.5 (arterial)	NR

degC, degrees Celsius; NR, not reported; LVSGen, LigaSure™ vessel sealing system generator; PA, pulmonary artery; s, seconds. Measures: BP, burst pressure; SF, seal failure rate; Sticking, tissue sticking rate; Time, cycle completion time seconds; TS, thermal spread.

5 Structured literature search details

5.1 Searches performed

Structured searches were performed to identify literature reporting on clinical applications of LigaSure™ technology. The searches were divided into two streams: one to identify the most recent clinical evidence of the use of LigaSure™ devices (within the last 10 years), and a second parallel search to identify all clinical applications of LigaSure™ technology, regardless of time, to identify settings in which the devices have been used in patient care. The searches for hysterectomy and colorectal procedures were originally performed on February 27, 2017(Table 5-1). Specifically, for thyroid surgery, the search was composed to capture any reference to LigaSure™ technology. On full text screening, only those publications were retained that applied to the LigaSure™ Small Jaw device. The PubMed search for peer-reviewed clinical evidence in thyroidectomy was originally performed on March 17, 2017 (Table 5-1). New searches for hysterectomy, colorectal and thyroidectomy procedures were undertaken in September 2021, using the same inclusion and exclusion criteria and search strings to identify any publications since the original search up to August 31, 2021. Further PubMed searches for clinical evidence on LigaSure™ technology in two additional procedures (breast surgery and gastric surgery) were performed on January 7, 2022 (Table 5-2).

Table 5-1 Structured searched in PubMed to identify relevant LigaSure™ technology data (original searches in 2017)

Index	Aim	Search string	Hits
#1	LigaSure™ devices by product name	ligasure*[tiab] OR LigaSure™[tiab] OR ligasurev*[tiab]	614
#2	Generic names for LigaSure™ devices	EBVS[tiab] OR BVSS[tiab] OR ((bipolar[tiab] OR ((high[tiab] OR advanced[tiab]) AND energy[tiab]) OR radiofrequency[tiab]) AND (diathermy[tiab] OR cautery[tiab] OR electrocautery[tiab] OR electrocauterization[tiab] OR electrocauterisation[tiab] OR cauterization[tiab] OR cauterisation[tiab] OR coagulation[tiab] OR ((vessel[tiab] OR tissue[tiab]) AND (sealing[tiab] OR sealer[tiab])))) OR electrosurgical[tiab] OR electrocoagulation[tiab] OR electrocoagulation[MeSH]	16,742
#3	Publication years of interest – original search	"2007/01/01"[PDat]:"2018/12/31"[PDat]	9,418,446

Index	Aim	Search string	Hits
#4	Invalid publication types	"Case Reports" [ptyp] OR "Clinical Conference" [ptyp] OR "Comment" [ptyp] OR "Editorial" [ptyp] OR "Letter"[ptyp] OR "Retracted Publication"[ptyp] OR "Congresses"[ptyp] OR "Duplicate Publication"[ptyp]	3,240,780
#5	Non-clinical data	"ex vivo"[tiab] OR cadaver[tiab] OR "deceased donor"[tiab]	78.271
#6	Animal data	Search terms for animal studies[78]	6,291,401
#7	LigaSure™ devices (by name or generic), restricted to publication years, excluding animal, non-clinical, and non-primary data	(#1 OR #2) AND #3 NOT (#4 OR #5 OR #6)	3,656
#8	All hysterectomy procedures	(hysterectomy[tiab] OR hysterectomy[MeSH] OR "hysterectomy,vaginal"[MeSH]) AND (surgery[tiab] OR "surgical procedure"[tiab] OR "General Surgery"[Mesh] OR "Surgical Procedures, Operative"[Mesh])	34,056
#9	All colorectal procedures	colectomy[tiab] OR sigmoidectomy[tiab] OR hemicolectomy[tiab] OR "colon resection"[tiab] OR "bowel resection"[tiab] OR colectomy[MeSH] OR ((colon[tiab] OR colorectal[tiab]) AND (polyp[tiab] OR polyps[tiab] OR polypectomy[tiab])) OR hemorrhoidectomy[tiab] OR haemorrhoidectomy[tiab] OR Hemorrhoids[MeSH] OR hemorrhoidectomy[MeSH] OR colostomy[MeSH] OR "Colorectal Surgery"[MeSH] OR "colorectal cancer"[tiab]	120,805
#10	All thyroidectomy procedures	Thyroidectomy[MeSH] OR thyroidectomy[tiab]	26,518
#11	LigaSure™ device + hysterectomy	#7 AND #8	136
#12	LigaSure™ device + colorectal	#7 AND #9	164
#13	LigaSure™ device + thyroidectomy	#7 AND #10	102

The original searches designed above revealed few relevant comparative studies reporting on LigaSure™ device usage in colectomy, although broader searches indicated wider use of the technology. For colectomy surgeries only then, the above searches were supplemented with hand searches, manual screening of article contents (to confirm usage of a LigaSure™ device when not otherwise mentioned in the abstract) and the inclusion of publications after 2007, which may also have referenced pre-2007 data.

Table 5-2 Structured searched in PubMed to identify relevant LigaSure™ technology data (searches for new indications in 2022)

Index	Aim	Search string	Hits
#1	LigaSure™ devices by product name	ligasure*[tiab] OR LigaSure™[tiab] OR ligasurev*[tiab]	802
#2	Generic names for LigaSure™ devices	EBVS[tiab] OR BVSS[tiab] OR ((bipolar[tiab] OR ((high[tiab] OR advanced[tiab]) AND energy[tiab]) OR radiofrequency[tiab]) AND (diathermy[tiab] OR cautery[tiab] OR electrocautery[tiab] OR electrocauterization[tiab] OR electrocauterisation[tiab] OR cauterization[tiab] OR cauterisation[tiab] OR coagulation[tiab] OR ((vessel[tiab] OR tissue[tiab]) AND (sealing[tiab] OR sealer[tiab])))) OR electrosurgical[tiab] OR electrocoagulation[tiab] OR electrocoagulation[MeSH]	19,818
#3	Publication years of interest – original search	"2010/12/31"[PDat]:"2022/01/04"[PDat]	12,752,634
#4	Invalid publication types	"Case Reports" [ptyp] OR "Clinical Conference" [ptyp] OR "Comment" [ptyp] OR "Editorial" [ptyp] OR "Letter"[ptyp] OR "Retracted Publication"[ptyp] OR "Congresses"[ptyp] OR "Duplicate Publication"[ptyp]	4,049,793
#5	Non-clinical data	"ex vivo"[tiab] OR cadaver[tiab] OR "deceased donor"[tiab]	112,219
#6	Animal data	Search terms for animal studies[78]	7,468,331
#7	LigaSure™ devices (by name or generic), restricted to publication years, excluding animal, non-clinical, and non-primary data	(#1 OR #2) AND #3 NOT (#4 OR #5 OR #6)	4,369

Index	Aim	Search string	Hits
#8	All breast surgery procedures	"Breast surgery"[tiab] OR (breast[tiab] AND (surgery[tiab] OR reduction[tiab] OR augmentation[tiab] OR implant[tiab] OR reconstruction[tiab] OR DIEP[tiab] OR flap[tiab] OR lymphadenectomy[tiab] OR "Lymph Node Excision"[MeSH] OR (lymph[tiab] AND node[tiab] AND (dissection[tiab] OR excision[tiab] OR biopsy[tiab])))) OR mastectomy[MeSH] OR mastectomy[tiab] OR lumpectomy[tiab]	103,885
#9	All gastric surgery procedures	Gastrectomy[tiab] OR gastrectomies[tiab] OR Gastrectomy[MeSH] OR Pyloromyotomy[MeSH] OR Pyloromyotomy[tiab] OR pyloroplasty[tiab] OR ((stomach[tiab] OR gastric [tiab] OR bariatric[tiab]) AND surgery[tiab]) OR gastroplasty[tiab] OR "Bariatric surgery"[MeSH] OR "Gastric Bypass"[MeSH] OR "gastric bypass"[tiab] OR Roux-en-Y[tiab] OR RYGB[tiab] OR "sleeve gastrectomy"[tiab] OR Billroth[tiab] OR BPD/DS[tiab] OR (BPD[tiab] AND DS[tiab]) OR ((biliopancreatic[tiab] OR bilio-pancreatic[tiab]) AND diversion[tiab] AND duodenal[tiab] AND switch[tiab])	109,521
#10	LigaSure™ device + breast surgery	#7 AND #8	63
#11	LigaSure™ device + gastric surgery	#7 AND #9	76

The second search, to reveal all clinical instances of LigaSure™ device use, including incidental mentions of use of the technology even if not the focus of the study, was performed using EMBASE. This database includes coverage of non-PubMed-indexed journals and congress reports to thus provide a comprehensive survey of LigaSure™ device use (Table 5-3). A differential search was performed May 2017 to retrieve new records from 2017 and updated or added from 2016, yielding 166 publications to screen for additional settings where LigaSure™ technology has been used. An additional differential search was performed in March 2022 to retrieve records that were added since the last search, yielding 810 publications to screen for additional settings where LigaSure™ technology has been used.

Table 5-3 Structured search in EMBASE to identify use of LigaSure™ devices

Index	Aim	Search string	Hits
1	LigaSure™ technology (referenced by name) excluding ex vivo data and select animals	((ligasure or ligasurev or LigaSure™) not (preclinical or "ex vivo" or cadaver or animal or dog or cat or pig or veterinary or veterinarian)).mp.	1,390

Results from the various searches were exported from their respective databases as search strings (PubMed) and.RIS files (EMBASE) for integration into the Sourcerer software utility for literature screening and review. Duplicate articles returned from the different sources were automatically removed.

5.2 Screening literature results

5.2.1 Screening general search (EMBASE) results

The purpose of the EMBASE search as described (Section 5.1) was to capture as many references (by name) of LigaSure™ device use in both peer-reviewed and non-peer-reviewed literature. As such, the results were not screened for exclusion criteria, but for surgery type and geographical location to verify clinical application of the technology.

5.2.2 Screening returned results for evidence (PubMed)

The articles returned from the PubMed searches were subjected to screening to identify articles relevant to the targeted indication (hysterectomy) for further deeper analysis. The criteria, and rationale are presented in Table 5-4.

Table 5-4 Description of exclusion criteria

Criterion	Explanation
Data pre-2007	Although the article was published after 2007 according to the search terms, the data referenced within cover a range prior to 2007
Articles with no abstract	At the level of top level screening, no informed decision regarding evidence or quality can be made without an abstract
Editorial/commentary	Articles that are commentaries or letters responding to other articles are not included for evidence recovery
Non-clinical	Articles which do not present any relevant clinical data, including patient surveys and experimental/ex vivo studies which were captured
Fewer than 20 patients	For higher quality evidence, studies of fewer than 20 patients are excluded
Non-targeted surgery	For a given surgical search area, if the focus of surgery of the article is for another, the study is excluded. Examples include the capture of mention of "bariatric procedures" for a study of appendectomy
Not vessel sealing focused	The mention of LigaSure™ technology or related technology is incidental and not the focus of the study with no data relevant to the performance of the technology
Not LigaSure™ technology	The reference by generic name to the technology cannot be conclusively identified as LigaSure™ technology at abstract level, or the reference to generic terms in the search such as electrocautery catches technology not relevant to bipolar vessel sealing

6 Overview: Indications of LigaSure™ devices

Table 6-1 gives an overview of the indications for use of all LigaSure™ devices as well as related BiZact™ bipolar devices and in which regions/countries these indications are applicable. This table was accurate at the time of writing. Indications, contraindications, warnings, precautions, and procedure steps may vary between products and models, and availability may vary by jurisdiction. Please always refer to indication labeling for your jurisdiction and read all applicable instructions for use provided with the products.

Table 6-1 LigaSure™ devices and their indications

Device Name	Reorder Code	Indications for Use	Region
BiZact™ Tonsillectomy Device	BZ4212	The BiZact™ device is a bipolar instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The tissue fusion function of the device can be used on vessels (arteries and veins) and lymphatics up to and including 3 mm diameter. The BiZact™ device is indicated for use in general open surgical procedures. It is also indicated for ENT procedures, including adult, children and adolescent tonsillectomies for the ligation and division of vessels, tissue bundles and lymphatics 2-3 mm away from unintended thermally-sensitive structures. The BiZact™ device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use for these procedures.	OUS
BiZact™ Tonsillectomy Device	BZ4212A	The BiZact™ device is a bipolar instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The tissue fusion function of the device can be used on vessels (arteries and veins) and lymphatics up to and including 3 mm diameter. The BiZact™ device is indicated for use in open general surgical procedures. It is also indicated for adult, children, and adolescent ENT procedures (3 years of age and above), including tonsillectomy, for the ligation and division of vessels, tissue bundles, and lymphatics 2–3 mm away from unintended thermally-sensitive structures. The BiZact™ device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use for these procedures.	US Only

Device Name	Reorder Code	Indications for Use	Region
LigaSure Impact™ Instrument	LF4418	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.	Global
LigaSure™ Curved, Small Jaw	LF1212	The LigaSure™ Curved, Small Jaw, Open Sealer/Divider is a bipolar electrosurgical instrument intended for use in open general surgical procedures where ligation and division of vessels (up to 7 mm in diameter), tissue bundles, and lymphatics is performed, such as urologic, thoracic, plastic, and reconstructive. Procedures may include, but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, and adhesiolysis. 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.	OUS
LigaSure™ Curved, Small Jaw	LF1212A	The LigaSure™ Curved, Small Jaw, Open Sealer/Divider is a bipolar electrosurgical instrument intended for use in open general surgical procedures where ligation and division of vessels (up to 7 mm in diameter), tissue bundles, and lymphatics is performed, such as urologic, thoracic, plastic, and reconstructive. Procedures may include, but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, and adhesiolysis. The instrument is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, parotidectomy, and tonsillectomy) for ligation and division of vessels, lymphatics and tissue bundles 2-3 mm away from unintended thermally-sensitive structures such as nerves and parathyroid glands. 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.	US Only

Device Name	Reorder Code	Indications for Use	Region
LigaSure™ Exact Dissector	LF2019	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 and veins) up to and including 7 mm. It is indicated for use in general surgery and in such surgical specialties as urologic, thoracic, plastic, and reconstructive. Procedures may include, but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, and adhesiolysis. The instrument is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, parotidectomy, and tonsillectomy) for ligation and division of vessels, lymphatics and tissue bundles 2-3 mm away from unintended thermally-sensitive structures such as nerves and parathyroid glands. 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.	OUS
LigaSure™ Exact Dissector	LF2019	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 and veins) up to and including 7 mm. It is indicated for use in general surgery and in such surgical specialties as urologic, thoracic, plastic, and reconstructive. Procedures may include, but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, breast procedures, and adhesiolysis. The instrument is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, parotidectomy, and tonsillectomy) for ligation and division of vessels, lymphatics and tissue bundles 2-3 mm away from unintended thermally-sensitive structures such as nerves and parathyroid glands. 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.	US only
LigaSure™ Maryland Jaw	LF1923, LF1937, LF1944	The LigaSure™ Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or 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 and 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. These may include, but are not limited to, such procedures a 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.	Global

Device Name	Reorder Code	Indications for Use	Region
LigaSure™ Maryland Jaw Thoracic	LF1930T	The LigaSure™ sealer/divider is a bipolar electrosurgical instrument intended for use in minimally invasive or 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.	Global
LigaSure™ Blunt Tip	LF1823, LF1837, LF1844	The LigaSure™ Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or 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 and 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.	Global

OUS, Outside of the US

This table was accurate at the time of writing. Indications, contraindications, warnings, precautions, and procedure steps may vary between products and models, and availability may vary by jurisdiction. Please always refer to indication labeling for your jurisdiction and read all applicable instructions for use provided with the products.

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