

Special REPORT

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Optimizing Outcomes Using LigaSure™ Small Jaw Instrument in Vessel Sealing Procedures

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Introduction

Despite the great variety in surgical procedures performed every day, the need to reliably and consistently seal and cut blood vessels of all sizes is essential. Since 1998, Covidien has provided surgeons with an alternative to clamps, ties, and cautery with LigaSure technology. The latest instrument to join the LigaSure family, the small jaw instrument, was designed with feedback from surgeons who described what they found lacking in their current vessel sealing devices and what they wanted out of an energy-based vessel sealing instrument.

The small jaw instrument, intended for open procedures, reliably seals and cuts vessels, lymphatics, and tissue bundles up to and including 7 mm, and also can be used for blunt dissection and grasping, which reduces the need for multiple instruments in many procedures.¹ It performs its sealing function at a low temperature compared with other vessel sealing devices, thus reducing the risk for inadvertent burns to nearby tissues and structures while confining lateral thermal spread. It has an integrated blade that can be activated independent of sealing, and its short jaws make it easier to use in tightly confined areas. The small jaw instrument is indicated for use in general surgery and can be used in head and neck surgeries outside the United States (Figure 1).²

Clinical Experience

When Y. Etan Weinstock, MD, assistant professor of head and neck surgery and chief of otorhinolaryngology-head and neck surgery at LBJ Hospital in Houston, Texas, first encountered LigaSure technology and the small jaw instrument in February 2011, he was a bit resistant to the idea of shifting away from the instrument he was currently using.

"I had been using the Harmonic [FOCUS], and had grown very comfortable with the Harmonic, having done a few hundred cases with that device in the neck. But I agreed to use the [small jaw], albeit selectively—only on a very straightforward case," Dr. Weinstock said. After confirming his initial positive experience with a second case, another straightforward treatment for a benign condition, he changed his preference for energy-based sealing devices.

"After just a couple of cases, I liked [the small jaw] and I started implementing it in every open case I do," he said. Dr. Weinstock practices the full spectrum of head and neck surgeries from routine thyroidectomies and neck dissections to significant resections in the treatment of cancer that require reconstructions with free flaps. He currently uses the small jaw instrument for neck dissections, thyroidectomy, parathyroidectomy, parotidectomy, lymph node biopsy, and submandibular gland resection.

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Figure 1. LigaSure™ Small Jaw Instrument with ForceTriad™ Energy Platform.

In his experience with more than 200 cases using the small jaw instrument, hemostasis has been so consistent that it has changed not only his surgical technique, but also his preference cards for the operating room. “Since I’ve grown completely confident in its ability to seal vessels permanently and efficiently, I no longer ask for suture ties in any of my cases because I generally don’t use them. If I do need one, I’d rather open it for a particular case,” Dr. Weinstock said. “Whenever you remove steps from a surgery, your surgery is inherently more efficient, and when you’re efficient in the operating room, the cases tend to move faster.”

Oscar Vidal, MD, general and endocrine surgeon at the Hospital Clinic of Barcelona and professor at the University of Barcelona Medical School in Spain, who has been using LigaSure instruments since his residency, finds it difficult to imagine surgery being completely free of traditional suturing but acknowledges that use of sealing devices makes it possible and that this could benefit both patients and hospitals. “Sutureless surgery would help to avoid leaving foreign materials in the patient’s body, improving and shortening recovery periods,” he said. “The postoperative stay reduction also is an advantage for the hospital because of the reduced costs.”

Avoiding suture ties also may reduce concerns about complications that may arise when sharing the operating table with residents whose skills are not fully developed. “Sutures can slide and fall off the end of the vessel,” Dr. Weinstock said. “When a junior resident ties down a knot imperfectly, it can come off, either during the surgery itself or worse, when the patient is in the recovery room or a day later, and then you have a bleeding scenario where you have to go back to the operating room.”

Although suture tying is a skill that all residents have the opportunity to develop throughout their training, Ovunc Bardakcioglu, MD, section chief of colorectal surgery and assistant professor of surgery at St. Louis University

Hospital in Missouri, prefers to use the most up-to-date tools available training residents in colorectal surgery.

“Thirty years ago, when we did a low rectal resection, we had to do a hand-sutured anastomosis which was technically very difficult. Since the invention of the [surgical] staple, that’s gone,” Dr. Bardakcioglu said. “It takes residents a long time to learn how to suture and tie a tiny vessel in a deep cavity. When I see a resident using a LigaSure device to accomplish that task, in just 1 or 2 applications they know how to do it. This tells me that it is a better technology.”

Franco DiFilippo, MD, chief of the Department of Surgical Oncology at Regina Elena Cancer Institute in Rome, Italy, was first attracted to the small jaw instrument because of its multifunctionality, which he suspected would reduce his operating time. “The possibility of carrying out axillary node dissection with a single instrument was very appealing,” he said. He now uses it for axillary node dissection in breast surgery and surgical treatment of melanoma and soft tissue sarcoma.

“I have found [the small jaw instrument] very effective for the treatment of soft tissue sarcoma because the ability to seal and cut is very effective,” Dr. DiFilippo said. “You can have a fast operation without hemorrhage.” The reduction in operating time serves many different ends. Patients benefit by spending less time under anesthesia, and with increased efficiency in the operating room, doctors can see and treat more patients.³ A reduction in operating time may provide benefit to the hospital as well. “If you shorten your operation time, you can increase the number of patients you operate on during your session,” Dr. DiFilippo said.

The benefits of LigaSure to patients and hospitals are many, but there is another quality of this technology that often goes unsung: the comfort it provides to the surgeon. “When we ask 5 or 6 experts from different countries in Europe what is the [No. 1] positive point of LigaSure technology, they all answer: ‘the surgeon’s comfort,’” Dr. Pigot said. “But this is very important; it makes the surgery much quicker, much easier—this is a big improvement in the quality of surgery.”

Hemorrhoid Surgery

When Francois Pigot, MD, head of the proctological unit at Maison de Santé Protestante Bagatelle in Talence, France first began using LigaSure technology 5 or 6 years ago, he found the only problem to be one of overconfidence in surgeons not familiar with its use. “I think in the beginning it requires some learning because it is so easy to use,” he said. Once a surgeon has crested that slight learning curve, however, “everything is positive.”

Dr. Bardakcioglu was first introduced to LigaSure technology during his residency, about 10 years ago, and it is one technology he intends to hold onto. “Of all the new technologies out in the last 10 years, this would be the only one I would not give up; if I could pick one device that I could say has helped me the most, it would be the LigaSure [technology],” he said.

Dr. Bardakcioglu had been using the Harmonic [Ace]. But he found it had limitations when it came to sealing some of the larger vessels he came across in colorectal surgery. “The Harmonic is not meant for all vessel sizes—it needs to be combined with either a stapler or clips,” he said. “If I have one instrument that works reliably in all cases, it doesn’t make sense to me to use more instruments to perform a procedure.”

The small jaw instrument first drew Dr. Bardakcioglu’s attention at a major surgical conference. From the moment a Covidien representative laid the instrument in his hands, he knew what he wanted to do with it. “A lot of times you need someone to explain to you what the indication for a new instrument is, but for me the small jaw was the missing LigaSure [instrument] for the procedures I was doing,” he said.

Before the small jaw was introduced, Dr. Bardakcioglu had been using the LigaSure Impact, a long jaw open instrument, for hemorrhoid surgery. “But the Impact is a big device” he said, and was not particularly suited for hemorrhoidectomies.

He quickly found the small jaw instrument ideal for hemorrhoid surgery. “Traditionally we would use scissors or electrocautery to dissect a hemorrhoid out, which makes it a fairly bloody procedure.” In hemorrhoidectomy, blood loss is less a problem for the patient than it is for the surgeon, for whom it can be a major inconvenience. “If you have a bloody field, it’s less precise. LigaSure, particularly with the small jaw, makes the procedure bloodless, quick, and efficient.”^{4,5}

It is hard to estimate how much blood loss occurs with more traditional hemorrhoidectomy using scissors and/or

electrocautery. “I would say [blood loss] affects [visibility] enough that you have to use suction devices to get blood out of the area,” Dr. Bardakcioglu said, adding that this also may result in the need for more monopolar energy.⁵

“The more you bleed, the more you have to control and the longer the procedure takes. With the small jaw, once the tissue is sealed you don’t have bleeding to deal with. I would say I don’t see any blood loss with any LigaSure device.”

In Dr. Bardakcioglu’s opinion, the characteristics of the small jaw that make hemorrhoidectomy so efficient in experienced hands may have the potential to make hemorrhoid surgery technically easier for surgeons who are learning the procedure.

Ideally, Dr. Bardakcioglu would like to see LigaSure technology, which may be more readily available at teaching institutions such as the university hospital for which he works, gain a toehold in more far-flung areas. “The United States is very large—there’s a lot of ground to cover. A lot of patients don’t want to go into a big city. So I feel that accessibility will be important in the next 5 to 10 years—that technology, not just with LigaSure, gets everywhere so that every one has access to it there.”

Dr. Bardakcioglu envisions this happening as up-and-coming surgeons disperse after residency and fellowship. “It may be possible, because the same way I got exposed to [new technology], residents are getting exposed through me and the university and residency programs,” he said. “A lot of the chief residents here in St. Louis go 100, 150 miles away to private centers and they take what they learn from me and from other surgeons and apply it.”

Table 1. Comparison of Outcomes in Hemorrhoidectomy

Parameter	LigaSure (n=24)	Harmonic (n=25)	P-Value
Operating time (min)	11 (8-16)	18 (11-27)	<0.001 ^a
Blood loss (mL)	0 (0-20)	2 (0-64)	0.008 ^a
Pain score (0-10), median	2.6 (1.8-4.8)	4.8 (1.3-6.1)	<0.001 ^a
Patient satisfaction score (-3 to +3)	1 (-2 to +2)	0 (-3 to +1)	0.548 (NS) ^a
Hospital stay (d)	2 (2-3)	3 (2-6)	0.138 (NS) ^a
Dologesic [®] (no.)	5 (2-29)	13 (2-28)	0.001 ^a
Patients who required pethidine	16.70%	24.00%	0.266 (NS) ^b
Patients who had bowel movement on or before postoperative day 1	50.00%	44.00%	0.890 (NS) ^b

Values are the median and range unless specified.

NS, not significant.

^a Mann-Whitney U test.

^b χ^2 test.

Adapted from reference 7.

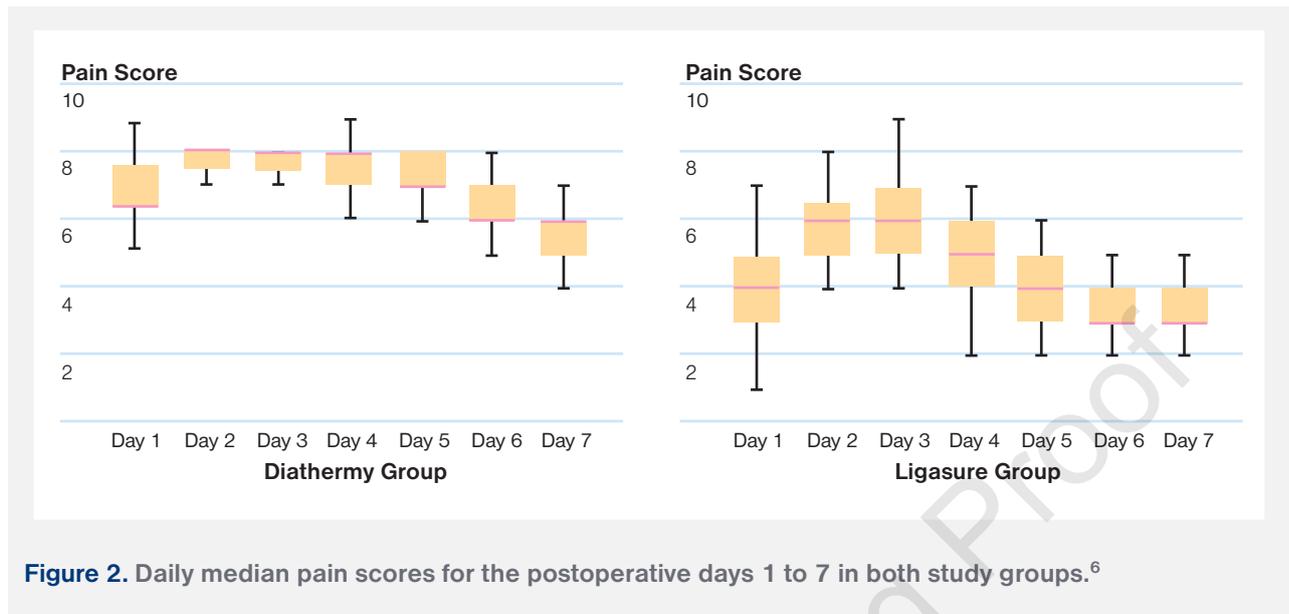


Figure 2. Daily median pain scores for the postoperative days 1 to 7 in both study groups.⁶

While both Dr. Bardakcioglu and Dr. Pigot have experienced shortened operating times using LigaSure and the small jaw instrument for hemorrhoidectomy, an easily quantifiable measurement, it is more difficult to gauge what effect this technology has had on patient comfort and recovery in what is widely regarded as one of the most painful surgical procedures.

Dr. Pigot corroborates that it is difficult to tell if patients are actually experiencing a reduction in pain when surgeons use LigaSure and the small jaw instrument. “You cannot see it with your eyes. Actually, randomized studies have demonstrated a reduction in pain versus diathermy dissection.^{6,7} My feeling is that both the simplification of surgical dissection and the gentle fusion of tissues may decrease discomfort and pain in the postoperative period.”

Studies have shown that along with reduced operating time and blood loss, use of LigaSure has resulted in less postoperative pain and analgesic consumption, shorter hospital stay, and a faster return to work and other activities, compared with conventional diathermy and other approaches to hemorrhoidectomy (Table 1; Figure 2).⁴⁻⁷

For Dr. Pigot, the availability of the small jaw instrument was timely in the sense that it supports advances toward less invasive procedures. “We are performing less aggressive surgery for hemorrhoidectomy and all surgery, thinking about less resection and less coagulation,” he said. “The small jaw has been the right instrument for this way of operating, the right instrument at the right time.”

In Dr. Bardakcioglu’s opinion, the same qualities the small jaw instrument brings to the procedures he performs—speed and efficiency and a dry field—are applicable to many types of surgeries. “The first time I saw it, I thought it would be great for precise dissection,” he said. “I’m a colorectal surgeon, but I know the head and neck surgeons are using it more and more. We’re at opposite parts of the body, but the underlying technology is the same.”

Head and Neck Surgery

The small jaw instrument provides consistent, high-quality hemostasis, which is one of Dr. Weinstock’s concerns when performing head and neck surgical procedures.⁸ “I need to know that any device I’m using will seal the vessel I want to seal and that it will stay sealed—that it is not going to open up and develop a hematoma after I close the neck.”

In Dr. Vidal’s opinion, the LigaSure small jaw instrument met his expectations for an energy-based vessel sealing device in that “it offers safe and precise tissue and vessel coagulation and is really easy to use. [The small jaw] offers a really good coagulation of the tissues and reduces bleeding, thus saving time and improving patients’ surgical safety.”

Dr. Weinstock, too, has great confidence in the device’s vessel sealing capacity. “I use it for practically every single blood vessel I encounter,” he said. In terms of vessel size, he has different thresholds for comfort with the small jaw instrument depending on whether the vessel is a vein or an artery. “Venous systems are lower pressure, but thinner walled. If the seal works, I’m not worried that a higher pressure is going to blow the seal,” he said.

“But with arterial vessels, that’s more of a concern because of the higher pressure. I would say I’ve grown confident enough with the device that there are very few instances where I don’t try to use it as my first line,” Dr. Weinstock said. When he encounters a large vessel branching from another vessel, he will dissect a bit farther so that he has more vessel left to work with. “Then I’ll try the LigaSure. If it works, I am completely confident that it will hold. If it is not going to hold, which I haven’t really had a problem with, I still have a healthy stump of tissue that I can then clamp and tie.”

There are only 2 vessels to which Dr. Weinstock does not apply LigaSure and the small jaw. “I still rely on suture

ties for [the internal jugular]," he said. "I also have not used [the small jaw] on the external carotid artery itself, but I have used it on every major branch of the arterial and venous systems in the head other than the great vessels."

He also uses the small jaw instrument for sealing small lymphatics in the head and neck and for sealing the thoracic duct. "If that's not sealed well during surgery, it can create a significant complication—patients could experience a chyle leak. I use the device for sealing those vessels and have not had any postoperative complications or chyle leaks as a consequence," Dr. Weinstock said.

Both Drs. Weinstock and Vidal are pleased by the small jaw's ability to perform multiple functions.⁸ "The most important [feature] is that it is possible to dissect and then seal and cut with the same instrument," Dr. Vidal said.

Dr. Weinstock finds that the multifunctional characteristics of the small jaw instrument have increased his efficiency. "I don't have to continually swap instruments out of my hand or spend extra time tying off blood vessels for hemostasis," he said. "The net result for me is increased efficiency in the operating room. I've noticed that my case length has diminished, which affords me the ability to expedite surgeries, perform more surgeries, and reduce anesthesia time for patients."

Dr. Weinstock appreciates the fact that the integrated blade of the small jaw instrument allows him to cut independently of sealing and that the vessel sealing activation button is conveniently located in the handle. But the feature he likes most is the fact that the instrument is symmetrical—there is no hot or cold side. "Both tines are shielded and protected, so I can use the device either way"

Dr. Vidal, too, finds the small jaw's cool thermal profile clinically beneficial.⁹ "This device offers the possibility to decrease the chance of injuring critical nerves or even its degree of injury. This is obviously very important for our patients, because the injury to the recurrent laryngeal nerve or the facial nerve can produce voice and breathing problems or facial palsy, respectively," he said.

Dr. Weinstock observed that he can approach vessels from any direction with the small jaw instrument and that he doesn't worry about heat transfer to other tissues or about burning any nearby anatomy.¹⁰ "That allows me the opportunity to use the device close to very sensitive structures, such as nerves and other vessels," he said, noting that this may reduce the risk for error and injury to the patient in the hands of surgeons in training. "It gives me confidence to know that it's a very safe device before, during, and after use, so if I'm observing residents, I'm more comfortable with their use of the instrument at all 3 stages."

According to Dr. Weinstock, the reduced risk for excess heat damaging surrounding nerves and tissues makes him comfortable using the small jaw within the tight confines of certain head and neck procedures.¹¹ "I feel very confident using this device in narrow, tight spaces and in close proximity to other structures. In the past, these sensitive areas would require longer time for dissection using multiple techniques, which would require a change of instruments and a need for more items and actions, such as tying sutures, which prolonged the case."

The concern about excess heat is not confined to inadvertent burns to the patient; drapes, surgeons, and anything or anyone within proximity of the instruments can be affected by the heat.¹¹

"Other vessel sealing devices generate substantial heat at their active portion during use. The active tip stays very hot after use and can remain so for some time," he said. "When using a heat generating device, it is imperative that the surgeon doesn't allow the tip to come in contact with any adjacent tissues when removing it from the wound. If those devices are used again before they have completely cooled, it is critical to ensure that the tip doesn't contact any surrounding tissues when inserting and positioning it in the wound. To me, that meant that there were limitations in minimal wound size because I had to ensure an adequate corridor to pass the heated instrument," he said.

Dr. Weinstock noted, "With the Ligasure device I do not have those same concerns and can readily pass the instrument via a narrow or small wound without fear of inadvertent thermal injury to adjacent tissue."

Breast Surgery

As a breast surgeon for more than 40 years, Elissa Santoro, MD, of St. Barnabas Hospital Health Care System in Livingston, New Jersey, has witnessed a sea change in the care of breast cancer patients, of whom she estimates she's seen about 28,000. "When I started, there were no mammograms. All women came in with lumps, and 4 out of 5 patients were dead within 5 years," she said. Today, with early detection and screening surveillance, most of her patients "go on to lead a wonderful life."

Although the improvements in screening and cancer treatment that led to increased longevity and better quality of life have been progressive over the past 4 decades, Dr. Santoro experienced a fairly sudden change in her own practice when her institution adopted LigaSure and the small jaw instrument earlier last year.

"Using the LigaSure small jaw instrument energized by the Force Triad energy platform has been such a breakthrough, especially in a difficult dissection, [such as] cancer in the lymph nodes," she said. "This instrument makes it so easy."

Prior to using LigaSure and the small jaw, Dr. Santoro and her colleagues were using the usual: "knife, Bovie, and ties," she said. "Now all I'm using is 1 instrument, almost without exception. I haven't tied a vessel since I've had this. I'm almost using the small jaw as a forcep, which is amazing; it actually does what it purports to do."

Dr. DiFilippo finds that the scissor-like shape of the small jaw instrument allows him to isolate tissue that needs to be sealed and cut. "It is very useful in the preparation of vessels and nerves, and it reduces the [duration] of the operation," he said. "Moreover, the tissue can be immediately cut by pushing the trigger instead or using the scissors, and last but not least, the instrument is very light and easy to handle."

Table 2. Characteristics of the Patients Randomized to the LigaSure™ Group or the Conventional Axillary Dissection Group

Variable	Axillary Dissection	
	LigaSure™ (n=50)	Conventional (n=50)
Surgical Procedure	n (%)	n (%)
Modified radical mastectomy	24 (48)	23 (46)
Conservative procedure	26 (52)	27 (54)
Immediate reconstruction	0	0
Axillary Surgery	n (%)	n (%)
Intraoperative blood loss >200 mL (n=52)	16 (30.8)	36 (69.2)

Adapted from reference 12.

Dr. Santoro finds the small jaw ideal for the axilla, and capable of executing all surgical tasks she needs to complete when operating on the breast.¹² “I’m able to do blunt dissection, pick up tissue, divide tissue, seal tissue, and have less postoperative drainage at the end,” she said. “This has cut down on operating time, which means it has cut down on anesthesia time, and the patients seem more comfortable.”

Although it is difficult to gauge patient comfort, a recent study comparing LigaSure with conventional techniques for axillary dissection found that patients who underwent LigaSure procedures experienced statistically fewer drainage days (4.3 vs 5.7), shorter hospital stays (5.1 vs 6.5 days), and shorter procedure times (48 vs 63.2 minutes) than those who received conventional surgical treatment.¹²

Dr. Santoro is confident in the capacity of the small jaw’s to seal and cut vessels without further reinforcement. “It allows us in the axilla to seal and cut vessels up to 7 mm, which is quite large; I don’t have to tie any blood vessels in the axilla.”

According to Dr. Santoro, patients’ drainage after surgery with the small jaw instrument is now negligible compared with what she saw before bringing in that technology. “The sealing with the small jaw has been dramatic. When you’re cutting close to lymphatics with a Bovie, you get a seal, but with the small jaw it is enhanced.”

Dr. DiFilippo has also noticed a reduction in drainage since he switched from cutting with electrocautery and sealing with titanium clips to performing both functions with the small jaw. “I have operated on 40 patients, and in my experience it seems that the instrument allows for [both] a reduction of drainage and in the formation of seromas,” he said.

The sealing capability of the small jaw also keeps blood loss at a minimum during axillary dissection (Table 2).¹² “When you go around the cancer and withdraw tissue, it’s dramatic how dry it is; the blood loss is absolutely negligible,” Dr. Santoro said.

Thermal injury, too, has been reduced or even eliminated since Dr. Santoro started using the small jaw, which has become especially critical as breast surgery becomes increasingly refined.¹³ “Because the instrument stays cool, we haven’t had any thermal injury, which is a very important thing now because we are doing skin-sparing procedures close to the nipple, where a lot of tissue was lost when we were using a regular Bovie,” Dr. Santoro said. “Now our work is more delicate, we’re using small amounts of area for dissection, and we’re not getting the thermal injury we saw with a Bovie, which is exciting. There is no burn on the skin from the instrument touching it.”

Use of the small jaw also has made needle localization for biopsy easier. “A Bovie would cut right through the guide wire going into the breast, and so would a scissor, so we always had to use the knife, which would slow us down because of bleeding,” Dr. Santoro said. “With the small jaw, you cannot cut through the needle—it won’t work because it cuts through the signal if you are near the needle. You can use this without fear that you’re going to cut the guide wire, and that’s another blessing.”

Just as LigaSure and the small jaw instrument have made procedures easier for Dr. Santoro, it has eased the learning curve for her residents. “My interns are quickly able to learn how to use this; they’re actually in awe of the multiple capabilities of the LigaSure small jaw instrument,” she said. “All the residents tell the other attendings about it, and I think it’s become quite popular.”

"We're using it because it works," Dr. Santoro said. "It really does deliver on everything that's in the brochure."

Financial Considerations

Like any sophisticated technology, LigaSure comes at a cost that may incur scrutiny from materials managers and other economic decision makers.¹³ LigaSure may be on par or even less costly than competitor products, but no energy-based vessel sealing device will cost less up front than a titanium clip.

For Dr. Pigot, financial scrutiny has kept his use of LigaSure and the small jaw device to cases where he knows the reduction in operating time makes the small jaw a sensible choice.

"The hospital is paid the same whatever device I use; if the hemorrhoids are small and it will be easy to use the cautery device, which costs about \$3, that's what I use. With large hemorrhoids when I know there will be much bleeding and I want to stay under 10 minutes [of]

operating, I use the small jaw. But I do not use the small jaw for every patient. It is a compromise," he said.

Dr. Vidal notes that his hospital was concerned about the cost of introducing new technology and that he and his colleagues had to argue the potential cost versus benefit. "It's a normal issue nowadays." In situations in which cost is a hospital concern, Dr. Vidal recommends asking a representative to help prepare a plan for the financial director.

Largely, the cost of LigaSure is offset by the efficiency they create, including a reduction in surgeon fatigue, which allows for a greater number of cases to be seen. "We don't have an ambulatory care center, so we are doing ambulatory cases in the main operating room," Dr. Bardakcioglu said. "Time in the operating room is very important. The sooner I finish a case, the better—I can either book more cases, or I can finish and make room for a surgeon who is doing something bigger, like a liver transplant. We've cut a 35-minute procedure down to 10 or 15 minutes, which I think is unheard of in any other surgical procedure. That's where the cost savings are."

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Disclosures

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