Clinical Advancements Using The ENSEAL® G2 Articulating Tissue Sealer

Despite the advances associated with laparoscopic surgery (eg, reduced blood loss and pain and a shorter hospital length of stay), its integration into practice continues to present challenges for surgeons performing general, colorectal, and gynecologic procedures.1-3 In particular, compromised access and visualization, as well as reduced tactile feedback with instrumentation, jeopardize the surgeon’s ability to seal vessels securely without potential risk for internal bleeding or damage to other tissues.3 Traditional vessel-sealing methods rely solely on compression through sutures, staples, and clips to maintain hemostasis.

Energy-based sealing devices were developed specifically to use heat and compression to provide a secure seal while decreasing the risk for bleeding.4 Of the available options, bipolar energy devices enable the current to only pass through tissue located between the instrument’s electrodes thus providing a high degree of precision in execution while minimizing the risk for damaging neighboring tissue; however, some of these devices have proven to yield more adequate compression force and offer more control in delivering energy to the tissue. The ENSEAL® portfolio, marketed by ETHICON was developed to provide surgeons with bipolar energy-based...
vessel-sealing devices that provide reliable hemostasis while reducing the risk for thermal spread and vessel damage. Additionally, the ENSEAL® devices are multifunctional and can be used to grasp, cut, dissect, spot coagulate, and to create an otomy. Since receiving FDA clearance in 2003, the ENSEAL® product line has evolved to include a portfolio of dynamic devices, each with modifications based on surgeons’ feedback.

As the most recent addition to the ENSEAL® family, the ENSEAL® G2 Articulating Tissue Sealer is the first advanced energy device that allows surgeons to use a perpendicular approach to vessel sealing when operating in challenging anatomy, which improves access and visualization, facilitates greater control during the procedure, and reduces the risk for internal bleeding and postoperative complications.

ENSEAL® Vessel-Sealing Technology

ENSEAL® devices were developed to provide surgeons bipolar energy-based instruments that can seal vessels up to 7 mm in diameter, as well as lymphatics. With proprietary features such as the I-Blade® (a unique cutting mechanism that delivers uniform compression across the length of the jaw), Positive-Temperature Coefficient technology, and the offset electrode configuration, the ENSEAL® system ensures reliable vessel sealing while minimizing thermal spread. The ENSEAL® also allows surgeons to use different shaft lengths and jaw configurations (ie, straight and curved) based on procedure needs.

The ENSEAL® G2 platform expands the ENSEAL® portfolio to include devices that further enhance the sealing experience through improved ergonomics, tactile feedback, and safety. The latest addition, the ENSEAL® G2 Articulating Tissue Sealer, encompasses the ENSEAL® features while offering a flexible tool that allows for a perpendicular approach to vessel sealing. Having this ability improves visualization and access to targeted tissues, ensuring a strong seal that could reduce the risk for bleeding during gynecologic, colorectal, and general surgery procedures (Figure 1).

ENSEAL® G2 Articulating Tissue Sealer

As part of the ENSEAL® portfolio, the G2 articulating device features both the I-Blade® and the Positive Temperature Coefficient to ensure uniform compression, reduce thermal spread, and minimize sticking. Compression begins once the I-Blade® advances to the tissue, delivered uniformly along the length of the jaw. “I can actually see the I-Blade® as it slides forward. Consequently, I know exactly where I am in the cutting process, and I can stop halfway through the procedure if I want because I know how far the device has traveled. This is not possible with [other energy-sealing] devices,” explained Ira Stanley Frye, MD, associate professor at Michigan State University College of Human Medicine and Temple University School of Medicine. To achieve superior vessel sealing with minimal thermal spread, the Positive-Temperature Coefficient technology regulates the temperature as it reaches 100°C and controls the flow of electric current. “This is actually one of the great advantages of the [ENSEAL®] devices,” said Alan M. Gillespie, MD, FRCCOG, consultant gynaecological surgeon and gynaecological oncologist at Sheffield Teaching Hospital. “When the tissue reaches 100°C, carbon fibers within the jaw of the device deactivate it to stop thermal transmission. Consequently, the opportunity for damage to nearby organs and surrounding tissue is greatly reduced. Also, the temperature at which the device functions is low compared with [other energy-sealing devices]. This is a feature that gives surgeons confidence that they are less likely to cause inadvertent thermal tissue damage.”

With the ENSEAL® G2 Articulating Tissue Sealer, surgeons are equipped with the latest vessel-sealing device possessing the latest advancements toward optimal vessel sealing. The ENSEAL® G2 Articulating Tissue Sealer allows surgeons to take a perpendicular approach to sealing vessels up to 7 mm in diameter using 5-mm ports by means of 110 degrees of articulation with full 360-degree shaft rotation. Its articulating design facilitates access to tissues in deep or tight anatomical spaces and maneuvering around corners of organs and behind structures, resulting in greater control and stronger sealing.

The ability of the ENSEAL® G2 Tissue Sealer to articulate and thereby work around a curve is just one of several features that distinguish it from other surgical technologies (Figure 2). “The articulating feature allows me to reach around organs or follow their contours while dissecting, as with a bulky uterus,” Dr. Frye said. “Additionally, I can perform more difficult surgeries, perform more through a single incision, and even remove larger masses.” By giving surgeons more control in visualizing and accessing the anatomy, the G2 Tissue Sealing Device maintains hemostasis and minimizes the risk for complications. “This device provides consistent and reliable hemostasis. But it is its capacity to create a seal at a perpendicular angle to ensure that blood flow is completely interrupted what I find really innovative,” Dr. Gillespie said. “It really results in a significant reduction in the potential for bleeding.”

Because the ENSEAL® G2 Articulating Tissue Sealer also provides tactile feedback, surgeons are able to assess the placement of the instrument with confidence. “The G2 device provides feedback similar to what I experience when I actually have an instrument in my hand. The articulation point is pliable, yet rigid, and that actually adds to the instrument’s safety. With this device, I can actually feel the tissue,” Dr. Frye explained. “It has a little ‘play’ so if I were to push in a bit too hard on the uterus with the tip, the potential for back bleeding is reduced and yet I’m still far away from the ureters because of the articulation.”

Benefits of a Perpendicular Approach To Vessel Sealing

In laparoscopic procedures—general, colorectal, and gynecologic—the perpendicular approach to vessel sealing can play a significant role in reducing the amount of tissue manipulation needed to access a targeted area. In a recent white paper evaluating retroperitoneal tissue dissection and hemostasis, the authors concluded that applying a perpendicular approach to coagulation could improve visualization of the anatomy and provide strong vessel sealing with greater precision. Using the ENSEAL® G2 Articulating Tissue Sealer, the perpendicular approach to vessel sealing is more than 28% stronger than vessels sealed at a 45-degree angle. Laboratory studies have shown that a perpendicular seal as opposed to a seal...
made by an oblique angle is much stronger,” said Matthew Kalady, MD, an associate professor of surgery at the Cleveland Clinic. “When tissue is crossed at an oblique angle, the distance required to seal the vessel is also greater and requires more firings of the device.”

**Efficient Operating Time**

The perpendicular approach has proven to be advantageous in optimizing vessel sealing. Using the ENSEAL® G2 Articulating Tissue Sealer has resulted in faster operating times. “A perpendicular approach takes less time because less tissue is crossed and less tissue manipulation is needed,” Dr. Kalady explained. Additionally, a strong seal can help minimize the risk for postoperative complications. “A strong seal means better hemostasis, reducing the potential for bleeding and its associated complications,” said Guido Jutten, chief of surgery, Department of General Abdominal and Oncological Surgery at AZ Klina. “Using the G2 Articulating Tissue Sealer during colorectal and gastrointestinal procedures, I can transect soft tissue at a perpendicular angle in almost any situation that might arise, get a good seal in a short amount of time, minimize instrument exchanges, and reduce the overall procedure time.”

Additionally, because it is a multifunctional device, the ENSEAL® G2 Articulating Tissue Sealer, which cuts, dissects, and seals, eliminates multiple steps and the need for additional instruments. “I try to use the instrument as both a dissector and a vessel sealer so that I don’t have to do many instrument exchanges, which makes the process more efficient,” Dr. Kalady said.

**Minimizing Incisions**

With optimal access during surgery, the ENSEAL® G2 Articulating Tissue Sealer can reduce the need for additional ports. “Some of the greatest challenges in bowel surgery involve mobilizing the colon, in particular the hepatic and splenic flexures,” Dr. Kalady explained. “Because many instruments are unable to reach the targeted space or reach it without using extreme torque or angles, additional ports may be required to get the right angle to access that area. This new device actually allows me to articulate the instrument so that I can essentially work around a curve without having to adjust my position.”

In gynecologic procedures, such as hysterectomies, the ENSEAL® G2 Articulating Tissue Sealer can have a significant affect in consolidating the number of incisions. “Hysterectomies performed using robotic laparoscopic technologies require five incisions,” Dr. Frye said. “Traditional laparoscopic hysterectomies use three, one at the belly button, and one in each lower quadrant. The ENSEAL® G2 Articulating Tissue Sealer allows me to articulate the device up to 110 degrees. I can change the angle and bend the device and it still works properly. The end result is that instead of using several incisions throughout the abdomen, the procedure can be performed through one, hidden right in the belly button. The curve lets me reach around as though I were coming in from the side, thereby simplifying the procedure greatly. Needless to say, the patient is greatly pleased with the cosmetic outcome.”

The use of fewer ports also may help reduce costs. “Ports are expensive. The fewer ports used, the greater the cost savings,” Dr. Gillespie explained.

**Improving Patient Recovery and Containing Costs**

The integration of the ENSEAL® G2 Articulating Tissue Sealer adheres to the principles of minimally invasive surgery with safer procedures and faster recovery as well as containing costs. With more control over the procedure, surgeons can optimize outcomes with precision and accuracy while minimizing the number of incisions as well as the risk for complications. Dr. Frye was the first surgeon in the United States to perform a single-incision hysterectomy and bilateral salpingo-oophorectomy using the ENSEAL® G2 articulating device. His patient underwent the procedure and was discharged within 24 hours without any complications. “The device is amazing,” Dr. Frye said. “The way I can articulate it with just movements of my thumb, I think, is revolutionary. This is a game changer.”

Using the perpendicular approach with the ENSEAL® G2 Articulating Tissue Sealer may help contain health care costs associated with bleeding and other complications. “One of the most expensive aspects of surgery is managing complications. If a patient suffers internal bleeding, that patient will require transfusions, which can be dangerous as well as costly,” Dr. Jutten said. “A perpendicular approach to vessel sealing minimizes the chances of entrapping any extraneous tissue, which in turn reduces the potential for bowel damage,” he noted. “The end result is that the potential for bacterial infection is reduced, avoiding a serious complication.”

**Operating Ergonomically**

In laparoscopic surgery, the lack of direct visualization and maneuvering of tissue using ports can be taxing on surgeons performing challenging procedures with limited access.3 “Surgeons are extremely vulnerable to back strain while performing surgical procedures,” Dr. Gillespie said. With the ENSEAL® G2 Articulating Tissue Sealer, surgeons are equipped with an ergonomically flexible
device that articulates to optimize access and control during the procedure. “The way the handle fits the hand is impressive,” Dr. Frye noted. “Also, there are two rotating toggles on the device, one of which allows me to rotate the jaw 360 degrees; the other lets me articulate it 110 degrees. Combined, they let me access [areas] in the abdomen that are much harder to get to with other devices.”

The articulation itself makes the device easier to operate and it doesn’t require changing angles outside the body. “With the ENSEAL® G2 Articulating Tissue Sealer, I don’t have to change angles from the outside of the body or the way that I’m holding the instrument because with the articulation I can change the instrument on the inside to hit the right turns and corners,” said Dr. Kalady. “It allows me to approach my target from a different angle, which results in a little less torque on the port, a little less torque on the instrument, and makes the procedure more comfortable for me.”

Additionally, Dr. Gillespie feels that this device can help to avoid awkward or uncomfortable positions in order to achieve an optimal approach. “This device helps maintain a better ergonomic position. The result is less back strain and anything that reduces back strain is of benefit,” he said.

**Shortening the Learning Curve**

The idea of adopting a new device particularly for laparoscopic procedures can be daunting given the limited visualization and access to the anatomy. With the ENSEAL® G2 Articulating Tissue Sealer, surgeons are able to apply previous training on the ENSEAL® system; however, the articulating design might require some time for the surgeon to adjust to the device’s ability to rotate within the body while using fewer incisions. “The learning curve is not at all steep,” said Dr. Frye. “I just required a few cases in order to get used to the device.” Dr. Kalady has been using the device for the past few months. “As far as the learning curve goes, the general principles of using the ENSEAL® instruments apply. In terms of vessel sealing, the difference is that it takes a little bit of time to get used to the articulation wheel and learn how to turn it so that the instrument moves the way it’s intended to move. So, there is a slight learning curve to using the instrument for the articulating feature,” he noted.

**Conclusion**

For surgeons performing difficult laparoscopic procedures, the ability to have direct access with optimal visualization is critical. As seen with earlier ENSEAL® devices, the ENSEAL® G2 Articulating Tissue Sealer continues to feature essential elements of its signature technology—strong seal with minimal thermal spread—but provides further modifications, giving surgeons even more control when cutting, dissecting, and sealing tissue (Figure 3). “Articulation is an add-on to an already high-quality product with important safety features. It simply adds further to its potential for greater use,” Dr. Kalady said. These new developments will further enhance the vessel sealing experience for surgeons, providing an effective instrument with low risk for bleeding and postoperative complications.

**References**

10. Data on File. ENSEAL® devices tested in a benchtop study on 5-7mm porcine carotid arteries.