Intelligent Ultrasonic Energy
Delivered by HARMONIC® devices with Adaptive Tissue Technology

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Introduction

The use of laparoscopic devices in surgical procedures has led to the development of new devices and techniques for minimally invasive surgical procedures. The continuing evolution of these devices has created a new generation of laparoscopic instruments that has overcome many of the limitations inherent to previous technologies and designs. These devices have reduced the time required for surgical procedures, length of hospital stays, patient recovery times, healthcare costs, and improved outcomes. These advanced technology devices also have applications in open surgery, particularly when working in confined spaces such as the pelvis and upper abdomen where longer and precise instruments confer an access advantage.

Energy-based surgical devices designed to seal and transect blood vessels along with associated soft tissue have been in a continuous state of development since the introduction of the first monopolar electrosurgical device in the 1920s. In addition, the introduction of devices such as those based on earlier generations of ultrasonic technology has continued to improve hemostasis and transection of tissue. Ultrasonic devices have been particularly beneficial in that they have the ability to reduce thermal spread to adjacent tissue [1,a] while reducing the time required for surgical procedures by simultaneously sealing vessels and transecting tissue.

The most recent advancement in the area of ultrasonic technology is the newly developed, next generation ultrasonic energy device – HARMONIC ACE®+7 Shears with Advanced Hemostasis (Ethicon US, LLC., Cincinnati, OH, USA). This device represents a significant advancement over the previous HARMONIC ACE®+ Shears (Ethicon US, LLC., Cincinnati, OH, USA) by combining the precision of the previous HARMONIC® device with large vessel sealing capabilities. An advanced ultrasonic algorithm provides the HARMONIC ACE®+7 Shears with the ability to seal vessels up to and including 7 mm in diameter. The system actively monitors the conditions of the tissue within the jaws of the device and responds intelligently to changes in patient tissue conditions. The system modulates the delivery of energy based on tissue thickness and tissue type to optimize vessel sealing. The result is a more intelligent and sophisticated ultrasonic device that excels at delivering the right amount of energy for the right amount of time to create large vessel seals that are both reliable and secure.

The HARMONIC ACE®+7 Shears will be reviewed in greater detail below after presenting a brief background on currently available energy devices, including both their advantages and disadvantages.

Background

Electrosurgical Devices

Advanced bipolar and ultrasonic energy devices possess numerous advantages over previous monopolar and conventional bipolar devices. Even so, monopolar devices are still widely used due to their diversity of tissue effects, wide availability, and relatively low cost [2]. Monopolar electrosurgery devices are useful for a variety of tissue applications including blunt dissection, coagulation of vessels, and contact coagulation on the surface of tissues. A major drawback of monopolar devices is that they cannot seal vessels ≥2 mm in diameter. In addition, these devices are limited in that they require: a) passing of current between two electrodes set at distant sites so that the patient’s body becomes part of the electrical circuit, b) high power settings (high voltage, low current), and c) proper patient grounding. Importantly, stray current injuries from direct leakage of current can potentially occur to the patient, as well as surgeon, if the insulation becomes damaged resulting in direct leakage of current or capacitive leakage of current from the shaft.

Bipolar energy devices also pass current through the patient’s tissue; however, both the active and return electrodes are integrated into a single instrument and the alternating current is distributed symmetrically through the tissue between the two electrodes. Thus, one of the main benefits of bipolar electrosurgery is that the current does not flow through various, and often unpredictable, pathways in the patient to complete the circuit. Bipolar electrosurgery reduces the risk of return electrode injury and the potential for capacitive coupling injury [2]. In addition, the use of alternating current more evenly distributes thermal energy through the tissue held between the electrodes, and a lower tissue temperature is therefore required to achieve the desired tissue effect.
as less voltage is necessary due to the use of a continuous waveform [2]. It is important to remember that when electrons in a circuit meet resistance (e.g., the patient’s tissue) more voltage will be necessary to push past the resistance and keep the flow of electrons moving in a non-advanced electrosurgery system. However, the higher the voltage, the more tissue injury that will occur. Consequently, the optimal device will provide vessel sealing and tissue effects with a minimal amount of voltage and associated heat generation.

Bipolar electrosurgery devices are particularly useful for hemostasis, coagulation, and coaptation of blood vessels; however, tissue transection is usually accomplished by a separate cutting mechanism integrated into the jaws of the device so hemostasis and cutting is a two-step procedure. Prolonged activation times result in increased temperatures that can cause thermal spread into adjacent tissues, as well as tissue sticking to the device’s jaws.

Advanced bipolar electrosurgery devices use bipolar technology but at lower voltage and higher current compared with conventional bipolar devices, and typically utilize pulsed/bursts of energy. Pulsing of the energy, as opposed to a constant flow, allows tissue cooling during activation of the device and helps to reduce lateral thermal spread. More specifically, the generator has a feedback control to monitor and calculate tissue impedance so that current and voltage are continuously adjusted [2]. The jaws are designed to apply sufficient mechanical compression while grasping the tissue; the combination of mechanical compression and energy can seal vessels up to 7 mm [3]. Vessels are sealed with supra-physiologic burst pressures that are comparative with ligatures or surgical clips. It is important to note that compression of the vessel is an important factor for sealing devices because compression is required to stop the blood flow, thereby eliminating the potential heat sink effect of the moving liquid [2]. It is also important in bringing the opposing vessel walls together close enough to enable the broken hydrogen bonds created by the heat denaturation of the proteins to reform and seal the vessel [2].

The feedback control system will automatically discontinue the flow of energy to the jaws once the sealing cycle has been completed. These advanced bipolar devices are designed to help reduce lateral thermal spread, excessive charring, and sticking of tissue to the jaws, as well as utilizing lower temperatures during sealing vessels, compared with monopolar or conventional bipolar devices [2]. Similar to conventional bipolar devices, advanced bipolar devices also use an integrated cutting mechanism to transect tissue.

**Ultrasonic Surgical Devices**

Ultrasonic surgical instruments are advanced energy devices that use mechanical energy to seal vessels and transect tissues rather than passing current to, or through, the patient. This eliminates the need for a grounding pad and can be used even in patients with metal implants. A high frequency ultrasonic transducer transforms electrical energy from a generator into mechanical energy. The resulting vibrations produce mechanical friction that generates thermal energy thereby resulting in extracellular heating followed subsequently by intracellular heating. As observed for all vessel sealing devices, the independent variables of mechanical compression, temperature, and time determine seal strength and integrity. However, unlike monopolar and bipolar devices, coagulation and transection occur with a single activation of the device. As such, the frequency and geometry of the ultrasonic blade are additional critical determinants of both the seal strength, seal integrity and the device’s ability to cut tissue effectively.

Early ultrasonic devices could seal vessels up to 3 mm in outer diameter [4], so some surgeons would choose to use bipolar devices to seal larger vessels and ultrasonic devices to transect tissue. This required multiple instruments, multiple instrument exchanges, and diminished some of the time advantage gained by the ultrasonic device’s ability to rapidly transect tissue.

Modern ultrasonic surgical devices are multifunctional instruments capable of performing tissue plane dissection, coaptation, coagulation, and transection during laparoscopic or open surgical procedures. The primary advantages of these devices are listed below.

**Advantages of Ultrasonic Devices**

- Generator can vary the mechanical energy delivered to the tissue amount in accordance with the desired effect [5]
- Reduced damage to surrounding tissues [1,a]

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*Intelligent Ultrasonic Energy · Delivered by HARMONIC® devices with Adaptive Tissue Technology*
- Mechanical energy is designed to keep heat in the blade rather than passing current through the patient’s tissues to produce heat as with electrosurgery
- Minimal lateral thermal spread [a]
- Reduced risk of nerve damage [6, b]
- Simultaneous cutting and coagulation
- Reduced visual impairment due to smoke or mist [5, 7]
- Tissue plane dissection occurs at lower temperatures versus electrosurgery

**HARMONIC ACE®+ Shears**

The HARMONIC ACE®+ Shears is an important technological advancement in ultrasonic devices as it incorporated Adaptive Tissue Technology into the device [5]. Adaptive Tissue Technology enables the device to actively monitor the conditions of the tissue within the jaws of the device and respond intelligently to changes in patient tissue conditions. The system regulates energy delivery when the blade temperature begins to rise rapidly to slow the increase in temperature.

- Adaptive Tissue Technology regulates the delivery of energy to improve the thermal management of the device and to reduce the risk of thermal injury.
- The device provides enhanced audible feedback through a secondary tone, which alerts the surgeon that the device is managing the thermal profile
- The HARMONIC ACE®+ has 5 power settings in conjunction with MIN and MAX hand activation buttons with the MAX button set at power setting 5 (highest power output, ie, longitudinal blade movement = 75 microns) [2]. The MAX setting delivers the fastest cutting and is able to seal smaller vessels. The MIN button could be set from 1 to 5 (adjustable down to 38 microns of longitudinal movement at setting 1) and defaults to setting 3, which offers increased hemostasis and vessel sealing up to 5 mm in diameter.
- The HARMONIC ACE®+ Shears with Adaptive Tissue technology provides for enhanced audible feedback, enabling more precise delivery of energy and improved thermal management. It produces 23% less thermal spread than HARMONIC ACE® without Adaptive Tissue Technology [c]. The maximum temperature reached is >30% less than that reached when using ACE without Adaptive Tissue Technology [d].

The Next Generation in Ultrasonic Technology - HARMONIC ACE®+7 Shears with Advanced Hemostasis

HARMONIC ACE®+7 Shears are the latest advancement in the HARMONIC® portfolio of ultrasonic surgical devices (Figure 1). HARMONIC ACE®+7 Shears maintains all the benefits of HARMONIC ACE®+ Shears while incorporating the increased functionality and ability to seal larger vessels. This next generation device is enabled by an advancement in Adaptive Tissue Technology. An advanced ultrasonic algorithm actively monitors the condition of the tissue within the jaws of the device and allows the system to intelligently sense and respond to changes in patient tissue conditions. The system modulates energy delivery based on tissue thickness and tissue type to optimize vessel

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**Figure 1 The HARMONIC ACE®+7 Shears.**
sealing and provide for secure and reliable large vessel sealing. The first generation of HARMONIC® devices with Adaptive Tissue Technology (HARMONIC ACE®+ Shears and HARMONIC FOCUS®+) provided for improved thermal management. The second generation device provides for both improved thermal management and Advanced Hemostasis (HARMONIC ACE®+7 Shears).

**How the System Improves the Thermal Profile**

The HARMONIC® system monitors blade movement and is specifically designed to maintain the resonant frequency of the blade. The system monitors the movement of the blade and provides critical feedback to the generator. For example, the system can detect when there is little to no tissue remaining in the jaws of the device or when the active blade comes into contact with the non-active tissue pad. These types of conditions can cause a rise in blade temperature. Adaptive Tissue Technology regulates energy delivery when the blade temperature begins to rise rapidly and helps to slow the increase in temperature, providing for improved thermal management and reduced thermal spread. There is dynamic feedback between the device and the surgeon, guiding optimal tissue handling by maximizing vessel sealing and transection of tissue while minimizing lateral thermal spread.

The HARMONIC ACE®+7 Shears retain the MAX and MIN buttons with the same default power settings (5 and 3, respectively). The MAX button is typically used for smaller vessels where cutting speed is fastest. The MIN button is typically used in slightly larger vessels and has reduced cutting speed. It is indicated for vessels up to 5 mm in size. The Advanced Hemostasis button is designed for larger vessels and is indicated for vessels up to 7 mm in size. The Advanced Hemostasis mode provides for larger, more secure vessel sealing compared to power levels 3 and 5.

**How the System Delivers Large Vessel Sealing with Ultrasonic Energy**

In addition to the MAX and MIN power settings, the HARMONIC ACE®+7 Shears also incorporates a new Advanced Hemostasis hand control button that when activated will seal vessels up to and including 7 mm (Figure 2). Pressing this button activates the Advanced Hemostasis mode, which enables the system to modulate energy delivery, either up or down based on tissue thickness and tissue type to optimize vessel sealing. The system leverages data stored in the generator to optimize the delivery of energy. The Advanced Hemostasis mode has three distinct phases of vessel sealing, the pre-heating phase, the vessel sealing phase, and the transection phase:

1. In the pre-heating phase, the instrument uses a high power setting to establish the necessary functional temperature required for vessel sealing and begins to breakdown the protein in the vessel walls.
2. In the vessel sealing phase, the system modulates energy delivery, utilizing various power settings. The system optimizes the key requirements for vessel sealing, which are compression, temperature and time, to provide for secure and reliable vessel seals that can withstand bursting pressure that are well above normal physiologic pressures.
3. In the transection phase, the system determines the most effective and efficient way to complete the vessel sealing process without compromising the integrity of the seal. These advancements with HARMONIC ACE®+7 Shears represent a significant breakthrough with ultrasonic energy devices and demonstrate that the previous limitation around sealing larger vessels with ultrasonic energy was not due to the type of energy used by the device, but rather how the energy is delivered to the tissue. Energy delivery has been optimized in the new HARMONIC ACE®+7 Shears via the Adaptive Tissue Technology’s new advanced algorithm thereby enabling the sealing of larger vessels up to 7 mm in diameter.

In addition to the novel features mentioned above, the new HARMONIC ACE®+7 Shears also features a refined
blade design that has a tapered-tip designed for precise dissection and tissue transection, which, in combination with the beveled bottom, flat sides, and curved top of the blade, provide increased multifunctionality (Figure 3). This refined blade also features a proprietary non-stick coating to help prevent tissue from sticking to the jaws of the device.

Another potential advantage of the HARMONIC ACE®+7 Shears is that its blade is narrower versus the wider blade typically found on bipolar devices. A narrower blade has a smaller thermal footprint, and, in the case of the HARMONIC ACE®+7, its thermal footprint is 36% smaller than LigaSure™ Blunt Tip [e]. In comparison, the wider advanced bipolar jaws appear to result in more sealed tissue; however, the extra tissue does not participate in the actual seal itself, and is actually produced as a result of increased thermal spread to the surrounding tissue. One of the goals of an optimal sealing device is to minimize lateral thermal spread such as been demonstrated with HARMONIC ACE®+7 Shears [a].

The intelligent energy delivery and increased multifunctionality of the instrument provides surgeons with maximum flexibility and efficiency during their surgical procedures by reducing the number of surgical devices required to achieve secure and reliable hemostasis.

Preclinical Data

In recent preclinical studies, the performance of the HARMONIC ACE®+7 Shears was compared with advanced electrical surgical devices in sealing vessels ranging from 1 to 7 mm in diameter.

In excised porcine carotid arteries 5 to 7 mm in diameter that were sealed and transected, the vessels sealed and cut by the HARMONIC ACE®+7 Shears in Advanced Hemostasis mode demonstrated significantly higher burst pressures, ie, stronger seals, (Figure 4) than those observed with LigaSure® 5 mm Blunt Tip and LigaSure® Advanced (1419 mmHg versus 591 mmHg and 670 mmHg, respectively; [P<0.001 for both]) [f, g]. Burst pressure in vessels sealed in Advanced Hemostasis mode by HARMONIC ACE®+7 Shears was also significantly greater compared with the THUNDERBEAT® device (1717 mmHg versus 1528 mmHg, respectively; P=0.023; Olympus America Inc., Center Valley, PA, USA) [h].

In order to assess the rate of first-pass vessel sealing, the number of fully sealed versus leaking vessels at the time of transection was measured. In porcine carotid vessels 5 to 7 mm in diameter, HARMONIC ACE®+7 Shears demonstrated significantly greater first-pass vessel sealing at transection versus the LigaSure™ 5 mm Blunt Tip and Advanced™ devices (pooled data; P=0.003; Covidien, Mansfield, MA, USA) (Figure 5) [i]. The total number of leaks per transection were as follows: 2 leaks/152 transections with HARMONIC ACE®+7 Shears (1.3%) versus 13 leaks/154 transections with the LigaSure™ 5 mm Blunt Tip and Advanced™ devices (8.4%; pooled data). Similarly, HARMONIC ACE®+7 Shears

![Figure 3 Refined Blade of the HARMONIC ACE®+7 Shears.](image)
The refined blade design of HARMONIC ACE®+7 Shears has a tapered tip, beveled bottom, flat sides, and curved top along with a proprietary non-stick coating.

![Figure 4 Burst pressure of vessels sealed with HARMONIC ACE®+7 Shears versus LigaSure™ 5 mm Blunt Tip and LigaSure Advance™.](image)
HARMONIC ACE®+7 Shears deliver 140% higher median burst pressure than LigaSure™ 5 mm Blunt Tip and 112% higher than LigaSure Advance™.
delivered significantly greater first-pass vessel sealing than THUNDERBEAT®: 2 leaks/152 transections versus 5 leaks/78 transections, respectively; \(P=0.046\) [j].

Seal reliability was tested in vitro in porcine carotid vessels by comparing the number of seals made with the number of seal failures while the sealed vessels were placed under 240 mmHg pressure (ie, twice the average human systolic blood pressure). The total number of leaks per transection were as follows: 2 leaks/152 transections with HARMONIC ACE®+7 Shears (1.3%), versus 15 leaks/154 transections with the LigaSure™ 5 mm Blunt Tip and Advance™ devices (9.7%; \(P=0.001\) versus LigaSure™; Figure 6) [k]. HARMONIC ACE®+7 Shears delivers greater 5 to 7 mm vessel sealing reliability than the LigaSure™ devices. Similarly, HARMONIC ACE®+7 Shears delivered greater vessel sealing reliability than THUNDERBEAT® wherein HARMONIC ACE®+7 Shears resulted in 2 leaks/152 transections versus 6 leaks/78 transections with THUNDERBEAT® (\(P=0.020\)) [l].

In vivo trials were completed in caprine and porcine models. No vessel failures were observed after a 30 day survival period or after blood pressure challenge in any vessel in any treatment group. In addition, no tissue sticking was observed during sealing and there was no difference in adhesion scores at the end of the survival period.

Minimizing lateral thermal damage is important in surgical procedures in order to prevent damage to vital structures. Caprine carotid vessels 5–7 mm in diameter were sealed with either the HARMONIC ACE®+7 Shears in Advanced Hemostasis mode or LigaSure™ 5 mm Blunt Tip. The vessels subsequently underwent histological assessment. Histological examination showed that lateral thermal damage was significantly smaller (ie, 18%) with HARMONIC ACE®+7 Shears than that observed with LigaSure™ 5 mm Blunt Tip (2.54 mm versus 3.08 mm, respectively; \(P=0.003\) versus LigaSure™; Figure 7) [a]. In addition, the thermal footprint (defined as the total width of thermal damage inclusive of the device tip) is 36% smaller with HARMONIC ACE®+7 Shears compared with LigaSure™ 5 mm Blunt Tip (6.48 mm versus 10.07 mm, respectively; \(P<0.001\) versus LigaSure™; Figure 7) [e].
Lateral thermal damage on vessels 5–7 mm in diameter

<table>
<thead>
<tr>
<th>Device</th>
<th>N</th>
<th>Mean thermal damage, mm</th>
<th>Standard deviation, mm</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HARMONIC ACE®+7 Shears</td>
<td>12</td>
<td>2.54</td>
<td>0.48</td>
<td>0.003</td>
</tr>
<tr>
<td>LigaSure™ 5 mm Blunt Tip</td>
<td>64</td>
<td>3.08</td>
<td>0.67</td>
<td></td>
</tr>
</tbody>
</table>

Thermal footprint for vessels 5–7 mm in diameter

<table>
<thead>
<tr>
<th>Device</th>
<th>N</th>
<th>Mean thermal footprint, mm</th>
<th>Standard deviation, mm</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HARMONIC ACE®+7 Shears</td>
<td>6</td>
<td>6.48</td>
<td>0.81</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LigaSure™ 5 mm Blunt Tip</td>
<td>32</td>
<td>10.07</td>
<td>1.12</td>
<td></td>
</tr>
</tbody>
</table>

Figure 7 The HARMONIC ACE®+7 Shears blade has a smaller thermal footprint and decreases the amount of lateral thermal damage compared with the LigaSure™ 5 mm Blunt Tip device. A, HARMONIC ACE®+7 Shears; B, LigaSure™ 5 mm Blunt Tip.
Surgical Cases

Case 1: Utility of the HARMONIC ACE®+7 Shears in Gynecological Surgical Procedures

Robert K. Zurawin, MD, FACOG is a board-certified, practicing gynecologist who is an Associate Professor in the Division of Gynecology at the Baylor College of Medicine, and is Chief of Minimally Invasive Gynecologic Surgery. In addition to being honored by Best Doctors in America since 2005, Dr. Zurawin has the distinction of being one of the first GYN surgeons to use the new HARMONIC ACE®+7 Shears during a scheduled patient surgery, ie, laparoscopic total hysterectomy. The patient is a 53 year old, menopausal female complaining of chronic pelvic pain as well as lower back pain, rectal pain, constipation during menses, and her uterus was extremely tender to manipulation. An MRI showed the presence of adenomyosis and the patient had previous myomectomies. Endometrial biopsy and a previous colonoscopy were both negative. Histology of the endometrial biopsy was benign. In addition, the patient had 3 cesarean sections from previous child births and a tubal ligation. Patient opted to have a hysterectomy and the decision was made to perform a total hysterectomy including removal of the ovaries.

During surgery it was discovered that patient had a dense wall of adhesions from the omentum to anterior abdominal wall. Dr. Zurawin initially used the HARMONIC ACE®+7 Shears to take down all the adhesions to provide access to the pelvis. He commented that the device worked perfectly for the lysis of the adhesions at the MAX setting. A standard TLH was performed with removal of the ovaries later in the procedure after removal of the uterus. Dr. Zurawin noted that from the previous cesarean sections the bladder had been densely scarred to the anterior portion of the lower uterine segment, which came down easily after careful dissection with the HARMONIC ACE®+7 Shears. A key advantage of the HARMONIC ACE®+7 Shears is its ability to facilitate the creation and identification of surgical planes.

He commented that the key benefit of the HARMONIC ACE®+7 Shears at this stage was to seal each large uterine vessel (approximately 5 mm in diameter) with a single use of the device’s new Advanced Hemostasis mode (exemplified in Figures 8A and 8B). Dr. Zurawin said if he had used the previous HARMONIC ACE®+ model, he would have normally used the MIN setting at power level 2 and applied it in a couple of locations along the vessel, then flipping the blade 180° he would have used the blade on both sides of the pedicles, and subsequently cut in-between the seals. However, the HARMONIC ACE®+7 Shears enabled him to seal and cut each of the ascending uterine vessels, along with its associated vein (approximately 4 mm in diameter), with a single application of the device. He remarked that the vessels were sealed and cut perfectly with no bleeding observed.

He utilized the new Advanced Hemostasis mode on all the pedicles, including the round ligament, uteroovarian ligament, and fallopian tube. Dr. Zurawin observed that the Advanced Hemostasis mode took a couple of seconds longer than it would have on the MIN setting (set at power level 2); however, it consistently resulted in secure and reliable hemostasis. He was able to use the MAX setting on the device for the colpotomy ring as he would have normally done with the previous version of the device. More specifically, Dr. Zurawin said he likes to lateralize the uterine vessel part of the pedicles in order to obtain a clear
and routinely used it for many different applications during surgery; however, to do so required an intimate knowledge of how the device worked, and not every surgeon was familiar enough with the device to take full advantage of its multiple functions. Although the device was also highly regarded by other surgeons, he commented that the biggest pushback he encountered when training surgeons around the world to use the HARMONIC ACE®+ device was that they did not feel confident with its hemostasis capabilities in gynecology. However, he feels the new device has revolutionized ultrasonic technology, particularly when it comes to hemostasis, sealing, and the device’s ability to detect tissue changes and automatically lower the temperature to continue sealing or cutting the target tissue while helping to minimize the risks of thermal injury.

When queried about any specific advice in using the device, he mentioned that surgeons need to be conscious of the tension on the tissue and avoid excessive traction to maximize the sealing effect. “You need to let the device do its work and not get impatient in order to avoid premature transection, as the tissue will separate when it’s ready.” This is especially true for the Advanced Hemostasis mode as transection times will vary. Surgeon needs to fight the impulse to move the device prematurely when the tissue is not yet ready for separation. He emphasized that the total time it takes for the HARMONIC ACE®+7 Shears to seal and cut is still significantly less than that required for an advanced bipolar devices wherein the surgeon would first seal on either side and then cut in-between the seals.

Dr. Zurawin stated that he was very comfortable with the previous generation HARMONIC ACE®+ device

![Image of colpotomy ring](image_url)

**Figure 8 Laparoscopic supracervical hysterectomy.** Use of the HARMONIC ACE®+7 Shears to seal and transect the left uterine artery (A) and right uterine artery (B) during a laparoscopic supracervical hysterectomy. Image courtesy of © Ethicon US, LLC., 2014. All rights reserved.
Surgical Cases

Case 2: Utility of HARMONIC ACE®+7 Shears in Colorectal Surgical Procedures

T. Bartley Pickron, MD, FACS is a certified colorectal staff surgeon/Assistant Program Director of the Minimally Invasive Colon and Rectal Surgery Fellowship at University of Texas Medical School at Houston, who recently used the HARMONIC ACE®+7 Shears for the laparoscopic removal of a tumor from a 53 year old, healthy female who was found to have a tumor in the rectosigmoid colon on screening colonoscopy. Further workup was unremarkable and she was brought to the operating room for a laparoscopic low anterior resection.

Dr. Pickron commented that he typically uses the HARMONIC ACE®+ for this type of procedure as he feels “it provides excellent fine dissection and hemostasis on smaller vessels.” For this procedure, Dr. Pickron utilizes a lateral to medial dissection to mobilize the rectosigmoid colon. Once the colon has been mobilized laterally down to the base of the mesentery and the ureter identified, he then isolates and divides the vascular pedicle with a powered ECHELON stapler using a grey load. He then proceeds to mobilize the upper rectum. He usually uses a HARMONIC ACE®+ to divide the mesorectum at his planned distal transection site (typically with minimal bleeding observed), and then uses the device to divide the mesentery of the proximal colon. The colon is then extra-corporealized, the proximal colon divided, and the anastomosis completed.

Dr. Pickron commented that in the case of this 53 year old patient, he followed his normal procedure up until vascular pedicle transection. At this point, rather than opening an additional endocutter reload, he was able to divide the vascular pedicle with no blood loss by utilizing the HARMONIC ACE®+7 Shears (Figure 9). Once the pedicle division was complete, he then continued dissecting using the same HARMONIC ACE®+7 Shears instrument without having to perform another instrument exchange. In addition, he also used the Advanced Hemostasis mode while dividing the proximal mesentery just to see how it would perform and he reported that it worked very well. He commented “The Advanced Hemostasis mode delivered impressive hemostasis.”

Dr. Pickron noted the new device maintained the precision and multifunctionality that he is accustomed to, and helped to reduce the need for multiple instruments. He further commented that the traditional criticism of the HARMONIC® device has been that it is inferior to advanced bipolar devices for large vessel sealing, especially when sealing vessel larger than 5 mm. After using the new HARMONIC ACE®+7 Shears, he feels that criticism is simply

Figure 9 Low anterior resection by Dr. T. Bartley Pickron. Use of the HARMONIC ACE®+7 Shears on the inferior mesenteric artery (IMA) pedicle to transect the vessels using Advanced Hemostasis. Image courtesy of © Ethicon US, LLC., 2014. All rights reserved.
no longer true and commented “Its multifunctionality gives then best of both worlds; precise dissection and large vessel sealing with hemostasis.”

Dr. Pickron was especially pleased with the versatility of the device because it helps to avoid instrument exchange, “For surgeons who typically use a stapler to divide large vascular pedicles, this device will get the job done. That means saving time by not having to remove the HARMONIC®, insert and use a stapler, remove the stapler, and then reinsert the HARMONIC® in order to continue dissection. Not only is avoiding instrument exchange a time saver in the operating room, but it can have the additional benefit of lowering the cost of the surgical procedure as well.”

Dr. Pickron felt that no special technique was required to use the new device and he simply used it in the same way he used the HARMONIC ACE®+. He did recommend that the surgeon should remember to take tension off of the vessel at the time of transection in order to achieve an optimal seal.
Surgical Cases

Case 3: Utility of HARMONIC ACE®+7 Shears in Bariatric Surgical Procedures

Robin P. Blackstone, MD, FACS
Medical Director
Scottsdale Healthcare
Bariatric Center
Scottsdale, AZ

Robin P. Blackstone, MD, FACS, is the Medical Director of the Scottsdale Healthcare Bariatric Center in Scottsdale, Arizona; a multidisciplinary medical and surgical weight loss clinic and has performed over 5000 complex bariatric procedures in a community hospital setting. She is the Past President of the American Society for Metabolic and Bariatric Surgery and is a Clinical Associate Professor of Surgery at the University of Arizona School of Medicine, Phoenix where she teaches second year medical students the pathophysiology of obesity, and medical and surgical therapies during a weeklong intensive course called Obesity Week. She is a leading expert in the surgical treatment of obesity and obesity-related disease.

Dr. Blackstone recently had the opportunity to use for the first time the new HARMONIC ACE®+7 Shears in a laparoscopic gastric bypass (LGBP) and three sleeve cases in a single day. The first patient was a 43 year old male undergoing a LGBP, whose parents had LGPs by Dr. Blackstone almost 10 years earlier. During the LGBP, Dr. Blackstone stated that, “We are able to couple the ECHELON FLEX™ Powered ENDOPATH® Stapler, HARMONIC ACE®+7 Shears, and ENDOPATH XCEL® Trocars with OPTIVIEW® Technology that enter the abdominal wall without cutting the muscle…These advances are critical to feeling that our team can offer patients a much safer surgery” than what the surgical technology offered 10 years ago.

The second patient was a 38 year old woman with a BMI of 54 kg/m² and a hiatal hernia. “Dissecting tissue in the chest, required when you are bringing the gastro esophageal junction back into the abdomen, is very intense and tricky…The new HARMONIC ACE®+7 Shears is a superb instrument for dissecting the hiatus and the stomach and soft tissue that has herniated up into the mediastinum because the thinner blade gives you better vision and, most importantly, the design of the blade coupled with the addition of the Adaptive Tissue Technology means you have less chance of injuring surrounding tissue, critical in avoiding unintended injury.”

The final patient had a BMI of 70 kg/m². “It is at these extremes of weight that we encounter our most difficult circumstances. We call this ‘extreme surgery’ and we need our most reliable tools for these cases.” Dr. Blackstone commented that the HARMONIC ACE®+7 Shears is “an ideal device for dividing mesentery and its use during the procedures resulted in no bleeding of divided tissue during the dissection of the lesser curve or the short gastric vessels in the sleeve [Figure 10]. Short gastric vessels, depending on the status of the liver, can often be very large, and we add clips to the vessels on the splenic side of the division of the vessels. This increases surgery time. Using the HARMONIC ACE®+7 Shears in the Advanced Hemostasis mode means we can divide vessels up to 7 mm safely, without adding additional cost in time and additional materials cost, to the procedure.”

Dr. Blackstone felt that the key component of the new device is its ability to sense and respond to changes in patient tissue conditions. She felt that it is more intuitive than the previous HARMONIC® device; the advanced ultrasonic algorithm enables the device to make decisions based on tissue thickness and tissue type similar to those that surgeons would make if they were operating in
an open abdomen by hand. Additional flexibility and feedback to the surgeon, both visually and through sound (ie, audible alert tones produced by the device), are key ways in which the instrument extends the surgeon’s operating skill.

Dr. Blackstone believes that surgeons who have been using the current HARMONIC® will adapt easily to the new device. Ethicon is committed to helping surgeons adapt by having representatives who are very well versed in the instrument on hand to help with the integration. Depending on the shaft length, the new device may be budget neutral, therefore, in some cases, exchanging the new HARMONIC ACE®+7 Shears for the previous version will be greatly facilitated with the buying committees at the hospital. By working closely with the company representative the surgeon will be able to maximize their early use of the device by developing a thorough understanding of its capabilities. She further commented that coupled with the suite of products now available to minimize adverse events during and after surgery, including the ECHELON powered endocutter and bladeless trocars, and other devices, the modern laparoscopic surgeon can be more secure in performing complex procedures in high-risk patients.

Dr. Blackstone summarized her experience with the HARMONIC ACE®+7 Shears by saying that “it will become one of the standard classic instruments used in nearly every laparoscopic case. The ergonomics coupled with the flexibility to get real time feedback from the tissue, allows the surgeon to have confidence in dividing vessels, in particular, those vessels that are significantly larger in diameter.”

Figure 10 Laparoscopic sleeve gastrectomy by Dr. Robin P. Blackstone. Sealing and transection of short gastric arteries using the HARMONIC ACE®+7 Shears during a laparoscopic sleeve gastrectomy. Image courtesy of © Ethicon US, LLC., 2014. All rights reserved.
Conclusions

Energy-based surgical devices are routinely used today in numerous open and minimally invasive surgical procedures. The most common classes of devices designed to seal and transect blood vessels, and the associated soft tissues during surgical procedures, are the electrosurgical devices using electrical energy to accomplish these effects (ie, monopolar, bipolar, and advanced bipolar devices) and ultrasonic devices that use mechanical energy to perform these functions. The continued development of ultrasonic technology has led to improvements in both hemostasis and transection of tissue by these devices. Ultrasonic devices have been particularly beneficial in that they have the ability to reduce thermal spread to adjacent tissue [a] while reducing the time required for surgical procedures by simultaneously sealing vessels and transecting tissue.

The next generation of ultrasonic device technology is embodied in the new HARMONIC ACE®+7 Shears. HARMONIC ACE®+7 Shears is the latest advancement in the HARMONIC® line of ultrasonic surgical devices and maintains all the previous benefits of HARMONIC ACE®+ while incorporating the increased functionality and ability to seal larger vessels. The HARMONIC ACE®+7 Shears is powered by Adaptive Tissue Technology and provides for both improved thermal management and larger vessel sealing capabilities. HARMONIC ACE®+7 Shears makes possible dynamic feedback between the device and the surgeon that helps guide optimal tissue handling by maximizing vessel sealing and transection of tissue while minimizing lateral thermal spread. These advancements represent a significant breakthrough in ultrasonic energy devices that has resulted in the ability to optimally seal vessels as large as 7 mm in diameter.
Footnotes

a In a preclinical study on 5–7 mm goat carotids (n=76) that compared the mean thermal damage via histology of HARMONIC ACE®+7 Shears in Advanced Hemostasis mode vs LigaSure™ Blunt Tip (LF1537) (2.54 [±0.48] mm vs. 3.08 [±0.67] mm, respectively, P=0.003). Data on file, Ethicon Endo-Surgery (PSP003910, PSP003620, PCS0000215).

b In a preclinical rat model that compared cold scissors, HARMONIC ACE®, HARMONIC FOCUS® and monopolar electrosurgery (MES). Incision with cold scissors, HARMONIC ACE®+ and HARMONIC FOCUS® at 2 mm from the sciatic nerve were not different via compound action potential (1621, 1519, 1803 mV-ms), conduction velocity (61.8, 62.3, 60.3 mm/ms), depolarization time (229.5, 211.6, 248.1 micro secs), repolarization time (2687, 2435, 2650 micro secs), vForce (20.2, 17.0, 19.1 g), dForce (24.0, 21.4, 27.7 g) and beta-APP (12.6, 18.1, 18.6 % incidence), respectively (P-value for all >0.05). At 2 mm from the sciatic nerve, MES resulted in significantly slower conduction velocity (58.5 mm/ms), longer depolarization time (283.1 micro secs), longer repolarization time (4150 micro secs) and higher incidence of beta-APP infiltration (31.8 % incidence) than cold scissors (P-value for all <0.05). (Note: P-values are comparison to cold scissors) (PSP003539).

c As exhibited in porcine histology (2.2 mm vs. 1.7 mm, P<0.001).

d In a bench top study measuring on Power Level 5, HARMONIC ACE®+7 Shears (HAR36 and HAR23) exhibited 30.1% and 34.2% lower mean (P<0.001) and median (P<0.001) blade heat, respectively.

e In a preclinical study on 5–7 mm goat carotids (n=38) that compared the mean thermal footprint via histology of HARMONIC ACE®+7 Shears in Advanced Hemostasis mode vs LigaSure™ Blunt Tip (LF1537) (6.48 [±0.81] mm vs. 10.07 [±1.12] mm, respectively, P<0.001). Thermal footprint = left thermal damage + jaw width + right thermal damage. Data on file, Ethicon Endo-Surgery (PSP003909, PSP003620, PCS0000215).

f In benchtop test using 5–7 mm porcine carotids that compared median burst pressure for HARMONIC ACE®+7 Shears (1419.5 mmHg) and LigaSure™ 5mm Blunt Tip (591.0 mmHg) (P< 0.001). Data on file (PRC064872B).

g In benchtop test using 5–7 mm porcine carotids that compared median burst pressure for HARMONIC ACE®+7 Shears (1419.5 mmHg) and LigaSure™ Advance (670.5 mmHg) (P< 0.001). Data on file (PRC064872B).

h In benchtop test using 5–7 mm porcine carotids that compared median burst pressure for HARMONIC ACE®+7 Shears (1716.5 mmHg) and Thunderbeat™ (1528.3 mmHg) (P=0.0226). Data on file (PRC064872B).

i In benchtop test on 5–7 mm porcine carotids that compared seal leaks at transection, HARMONIC ACE®+7 in Advanced Hemostasis mode (2/152 failures) versus LigaSure™ 5 mm Blunt Tip and LigaSure™ Advance (13/154 failures) (P=0.003) Data on file (PRC064872B).

j In benchtop test on 5–7 mm porcine carotids comparing seal leaks at transection, HARMONIC ACE®+7 in Advanced Hemostasis mode (2/152 failures) versus Thunderbeat™ (5/78 failures) (P=0.046). Data on file (PRC064872B).

k In benchtop test on 5–7 mm porcine carotids that compared burst pressure failures under 240 mmHg, HARMONIC ACE®+7 Shears in Advanced Hemostasis Mode (2/152 failures) versus LigaSure™ 5mm Blunt Tip and LigaSure™ Advance (total failures for both Blunt Tip and Advance: 15/154 failures) (P=0.001). Data on file (PRC064872B).

l In benchtop test on 5–7 mm porcine carotids that compared burst pressure failures under 240 mmHg, HARMONIC ACE®+7 Shears in Advanced Hemostasis Mode (2/152 failures) versus Thunderbeat™ (6/78 failures) (P=0.020). Data on file (PRC064872B).
References

## Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td><strong>Amp (ampere)</strong></td>
<td>A unit of current. A measure of the amount of electric charge passing a point in an electric circuit per unit time.</td>
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<tr>
<td><strong>Cavitation</strong></td>
<td>The tip of an ultrasonic device increases the temperature within a tissue resulting in the vaporization of water and expansion of the tissue and the production of an exhaustive transient pressure change (local drop in atmospheric pressure) in the tissue enabling the water to vaporize at a lower temperature (between 50°C and 100°C). The water expands between the tissue planes to dissect the tissue planes without cutting.</td>
</tr>
<tr>
<td><strong>Coagulation</strong></td>
<td>Increasing the temperature of a tissue (&gt;63°C) causes protein denaturation that results in a process that changes blood from a liquid to a gel to form a solid clot and can result in hemostasis.</td>
</tr>
<tr>
<td><strong>Coaptation</strong></td>
<td>The adherence and/or sealing together of tissues. If temperature of the tissue is increased (≤63°C), fragmentation of proteins causes the collagen molecules to collapse, forming a sticky coaptate. The concomitant application of pressure seals the vessel walls together.</td>
</tr>
<tr>
<td><strong>Current</strong></td>
<td>The time rate of flow of electric charge or the flow of charge through a circuit, eg, from one electrode to another.</td>
</tr>
<tr>
<td><strong>Hemostasis</strong></td>
<td>Cessation of bleeding by a damaged blood vessel due to coagulation.</td>
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<tr>
<td><strong>Impedance</strong></td>
<td>A measure of the opposition that a circuit presents to a current when a voltage is applied.</td>
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<tr>
<td><strong>Resistance</strong></td>
<td>The opposition offered by an electrical conductor to the flow of a current through itself, resulting in a conversion of electrical energy into heat and radiation.</td>
</tr>
<tr>
<td><strong>Volt</strong></td>
<td>Unit of electric potential.</td>
</tr>
<tr>
<td><strong>Voltage</strong></td>
<td>The force required to push electrons past a resistance and around the circuit. More specifically, it is the difference in electrostatic potential between two points in space or the potential difference between live conductors and neutral conductors in a system when in operation.</td>
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</table>
Additional images of HARMONIC ACE®+7 Shears

Figure A1 Use of HARMONIC ACE®+7 Shears to seal and transect the ileocolic artery during a hand-assisted right hemicolecctionomy. Image courtesy of © Ethicon US, LLC., 2014. All rights reserved.

Figure A2 Use of HARMONIC ACE®+7 Shears to transect tissue during removal of ovary in a laparoscopic oophorectomy. Image courtesy of © Ethicon US, LLC., 2014. All rights reserved.