

THUNDERBEAT TISSUE MANAGEMENT SYSTEM

A Reference Guide for Health Care Professionals.





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THUNDERBEAT PRODUCT INFORMATION
The World's Only Fully Integrated Bipolar and Ultrasonic Technology.

INTEGRATED BIPOLAR AND ULTRASONIC ENERGY FROM A MULTIFUNCTIONAL INSTRUMENT

Groundbreaking Integrated Technology

THUNDERBEAT is the world's ONLY integration of both advanced bipolar energy and ultrasonic energy delivered simultaneously from a single, multifunctional instrument. This integration delivers the widely recognized benefits of each type of energy: the ability to rapidly cut tissue with ultrasonic energy and the ability to create reliable vessel seals with bipolar energy.

The THUNDERBEAT Difference

Ultrasonic Energy Only



Rapid tissue cutting

+

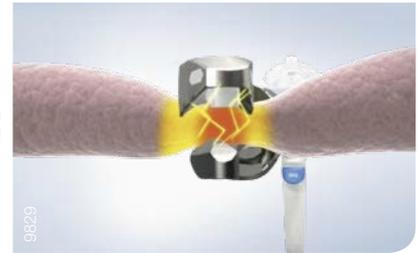
Bipolar Energy Only



Reliable vessel sealing

=

THUNDERBEAT



Rapid tissue cutting **AND** reliable vessel sealing

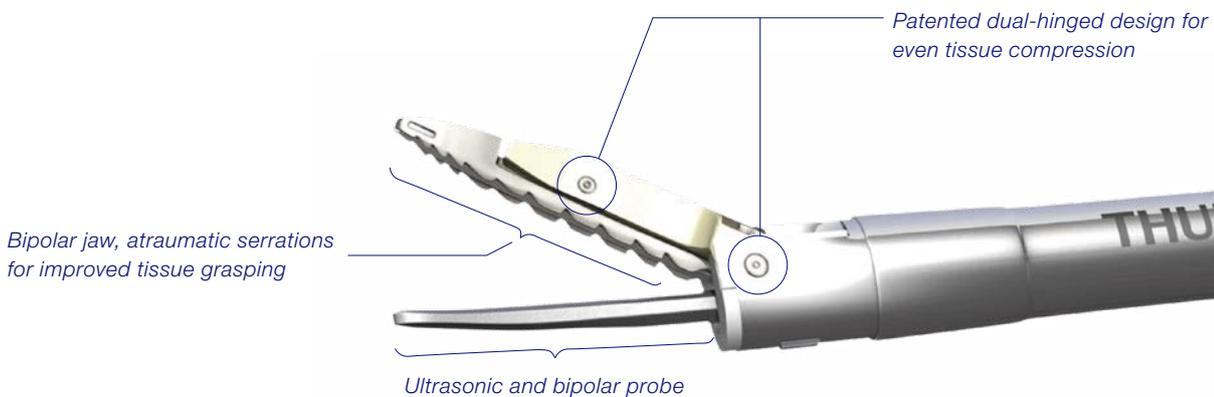
The Benefits of Unprecedented Versatility

- Fastest-in-class cutting speed
- Reliable 7 mm vessel sealing
- Precise dissection with fine jaw design
- Bipolar energy always available for hemostasis without cutting
- Highest-in-class tip grasping force
- Minimal thermal spread
- Fewer instrument exchanges
- Reduced mist generation for improved visibility



Revolutionary Jaw Design

All THUNDERBEAT devices feature a patented center-pivot jaw design. This unique feature allows for even distribution of closing pressures onto the tissue while at the same time improving grasping forces. The result is improved fine and blunt dissection and a more reliable vessel seal.



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Intuitive, Easily Accessible Hand Switches

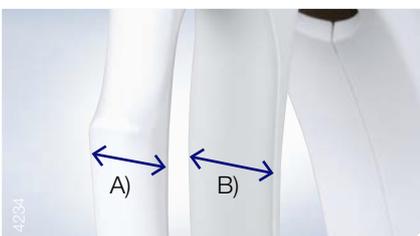
- Intuitive hand switches that are easily accessible from various directions allow for stable activation, regardless of hand size or position
- Additional protrusions on SEAL button provide tactile recognition for a seamless operational flow

• Seal & Cut Mode

Bipolar energy and ultrasonic energy for reliable vessel sealing and coagulation with simultaneous cutting

• Seal

Advanced bipolar energy for reliable vessel sealing and tissue coagulation without simultaneous cutting



Optimized Actuating Handle Design

- A) Thinner front grip of the actuating handle provides surgeon with direct tactile feedback for blunt dissection
- B) Wider rear grip of the actuating handle provides stability when grasping and cutting tissue

2

THUNDERBEAT PEER-REVIEWED PUBLICATIONS

THUNDERBEAT PEER-REVIEWED PUBLICATIONS: ABSTRACTS

1

Safety and efficacy of new integrated bipolar and ultrasonic scissors compared to conventional laparoscopic 5-mm sealing and cutting instruments

Seehofer D, Mogl M, Boas-Knoop S, Unger J, Schirmeier A, Chopra S, Eurich D.

Surg Endosc. 2012 Sep; 26(9): 2541-9

Background: Hemostasis is a central issue in laparoscopic surgery. Ultrasonic scissors and bipolar clamps are commonly used, with known advantages with each technique.

Methods: The prototype of new surgical scissors, delivering ultrasonically generated frictional heat energy and bipolar heat energy simultaneously THUNDERBEAT (TB), was compared to ultrasonic scissors Harmonic ACE (HA) and an advanced bipolar device LigaSure (LS) using a pig model. As safety parameters, temperature profiles after single activation and after a defined cut were determined. As efficacy parameters, seal failures and the maximum burst pressure (BP) were measured after in vivo sealing of vessels of various types and diameters (categories 2–4 and 5–7 mm). Moreover, the vertical width of the tissue seal was measured on serial histological slices of selected arteries. The cutting speed was measured during division of isolated arteries and during dissection of a defined length of compound tissue (10 cm of mesentery). Burst-pressure measurement and histological analysis were performed by investigators blinded to the used sealing device.

Results: Using the TB, the burst pressure in larger arteries was significantly higher (734 ± 64 mm Hg)

than that of the HA (453 ± 50 mm Hg). No differences in the rate of seal failures were observed. The cutting speed of the TB was significantly higher than that of all other devices. Safety evaluation revealed temperatures below 100 °C in the bipolar device. The maximum temperature of the HA and the TB was significantly higher. No relevant differences were observed between the HA and the TB.

Conclusions: The ultrasonic and bipolar technique of the TB has the potential to surpass the dissection speed of ultrasonic devices with the sealing efficacy of bipolar clamps. However, heat production that is comparable to conventional ultrasonic scissors should be minded for clinical use.

2

Postoperative efficacy and safety of vessel sealing: an experimental study on carotid arteries of the pig

Berdah SV, Hoff C, Poornorozy PH, Razek P, Van Nieuwenhove Y.

Surg Endosc. 2012 Aug; 26(8): 2388-93

Background: The aim of this preclinical study was to analyze the burst pressure of large in vivo sealed vessels, not just immediately, but also in the first 7 postoperative days.

Methods: In 26 anesthetized pigs, the right carotid artery was sealed and cut using a novel device that integrates bipolar and ultrasonic energy. The animals were then awakened. They underwent a second surgical procedure after different follow-up periods

ranging from 1 to 7 days: the left common carotid artery was sealed and cut in the same way as the contralateral artery. Perioperative and postoperative clinical events, evolution of burst pressure over time, and comparison between immediate and delayed burst pressure were analyzed.

Results: All sealings were successful. There were no perioperative or postoperative complications. Median immediate (day 0) burst pressure was 949 mm Hg (IQR 781–1181). Burst pressure decreased postoperatively but was never below 500 mm Hg in any pig.

Conclusion: Postoperative variations are observed in the burst pressure of in vivo sealed arteries. Immediate burst pressure alone should not be used for validating vascular sealing devices.

3

Evaluation of the Safety, Efficacy, and Versatility of a New Surgical Energy Device (THUNDERBEAT) in Comparison with Harmonic ACE, LigaSure V, and EnSeal Devices in a Porcine Model

Milsom J, Trencheva K, Monette S, Pavor R, Shukla P, Ma J, Sonoda T.

J Laparoendosc Adv Surg Tech A. 2012 May; 22(4): 378-86

Background: THUNDERBEAT (TB) (Olympus, Japan) simultaneously delivers ultrasonically generated frictional heat energy and electrically generated bipolar energy. The aim of this study was to evaluate the versatility, bursting pressure, thermal spread, and dissection time of the TB compared with

commercially available devices: Harmonic ACE (HA) (Ethicon Endo-Surgery, USA), LigaSure V (LIG) (Covidien, USA), and EnSeal (Ethicon).

Methods: An acute study was done with 10 female Yorkshire pigs (weighing 30–35 kg). Samples 2 cm long of small (2–3 mm)-, medium (4–5 mm)-, and large (6–7 mm)-diameter vessels were created. One end of the sample was sent for histological evaluation, and the other was used for burst pressure testing in a blinded fashion. Versatility was defined as the performance of the surgical instrument based on the following five variables, using a score from 1 to 5 (1 = worst, 5 = best), adjusted by coefficient of variable importance with weighted distribution: hemostasis, 0.275; histologic sealing, 0.275; cutting, 0.2; dissection, 0.15; and tissue manipulation, 0.1. There were 80 trials per vessel group and 60 trials per instrument group, giving a total of 240 samples.

Results: Versatility score was higher ($P < .01$) and dissection time was shorter ($P < .01$) using TB compared with the other three devices. Bursting pressure was similar among TB and the other three instruments. Thermal spread at surgery was similar between TB and HA ($P = .4167$), TB and EnSeal ($P = .6817$), and TB and LIG ($P = .8254$). Difference in thermal spread was noted between EnSeal and HA ($P = .0087$) and HA and LIG ($P = .0167$).

Conclusion: TB has a higher versatility compared with the other instruments tested with faster dissection speed, similar bursting pressure, and acceptable thermal spread. This new energy device is an appealing, safe alternative for cutting, coagulation, and tissue dissection during surgery and should decrease time and increase versatility during surgical procedures.

4

A randomized study comparing the use of Thunderbeat technology vs. standard electrosurgery during laparoscopic radical hysterectomy and pelvic lymphadenectomy for gynecological cancer

A. Fagotti, G. Vizzielli, F. Fanfani, V. Gallotta, C. Rossitto, B. Costantini, S. Gueli-Alletti, N. Avenia, R. Iodice, G. Scambia

J Minim Invasive Gynecol. 2014 May-Jun;21(3):447-53

Study objective: To compare the use of Thunderbeat (TB) with standard electrosurgery (SES), during laparoscopic radical hysterectomy and pelvic lymphadenectomy for gynecological tumors, with respect to operative time

Design: Evidence obtained from a properly designed, randomized, controlled trial.

Design: classification: Canadian Task Force classification I

Setting: Gynecologic Oncology Unit of the Catholic University of the Sacred Heart in Rome

Patients: Fifty patients with early stage cervical cancer (FIGO stages IA2-IB1-IIA<2cm), locally

advanced cervical cancer (FIGO stages IB2-IIA>2cm-IIB) submitted to neo-adjuvant treatment (chemotherapy or radio-chemotherapy) showing a complete/partial clinical response and early stage endometrioid endometrial (FIGO stages IB-II) were randomly assigned to undergo TB (arm A) and SES (arm B)

Intervention: Laparoscopic radical hysterectomies with bilateral pelvic lymphadenectomy, with an easily reproducible technique were performed.

Measurements and main results: Fifty patients were available for the analysis, with 25 women randomly assigned to TB (arm A) and 25 to SES (arm B). The median operative time was 85 min vs. 115 min for TB and SES, respectively ($p=0.001$). At multivariate analysis, endometrial cancer ($p=0.0001$) and TB ($p=0.001$) were independently associated with less operating time. No differences in terms of peri-operative outcomes and post-operative complications were observed in both arms. Patients undergoing TB reported less post-operative pain, both at rest and after Valsalva' maneuver ($p=0.005$ and $p=0.008$, respectively), with less additional analgesics beside standard therapy than in arm B ($p=0.02$)

Conclusion: TB is associated with shorter operative time and less post-operative pain than standard technique (SES) in patients with uterine cancer.

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THUNDERBEAT PERFORMANCE EVALUATION

THUNDERBEAT PERFORMANCE EVALUATION: WHITE PAPER

1

Vessel Sealing Performance of THUNDERBEAT Compared to LigaSure V and EnSeal

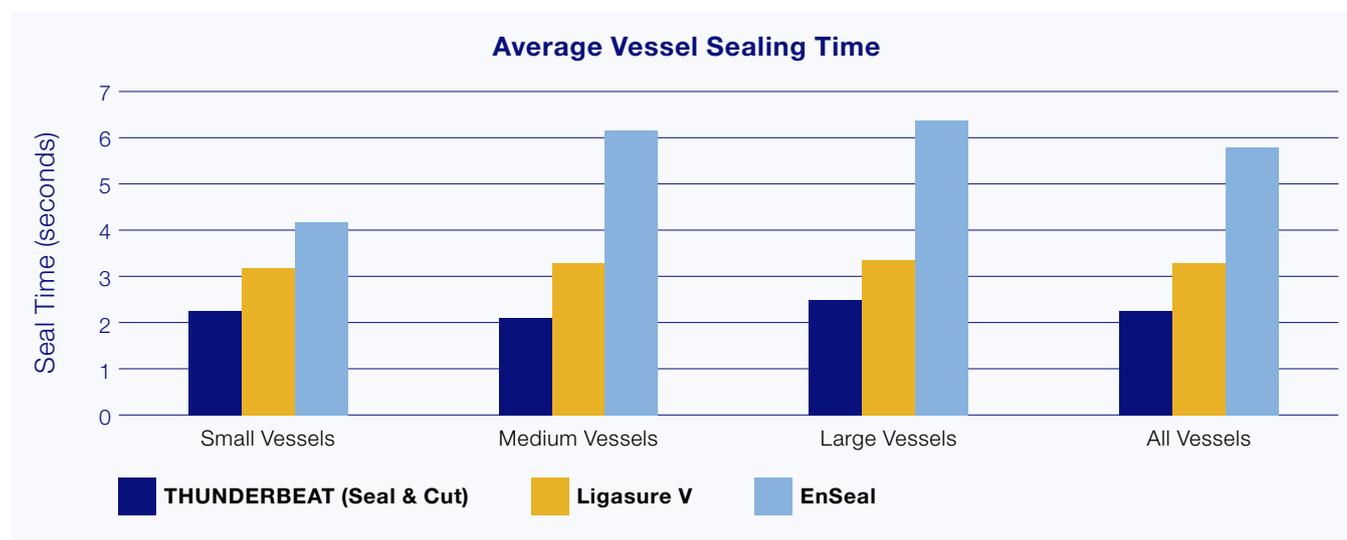
Olympus Medical Systems Cooperation Tokyo 2012, November

Objective: The objective of this study was to evaluate vessel sealing performance (burst pressure and sealing speed) of THUNDERBEAT compared to predicate devices (LigaSure V and EnSeal).

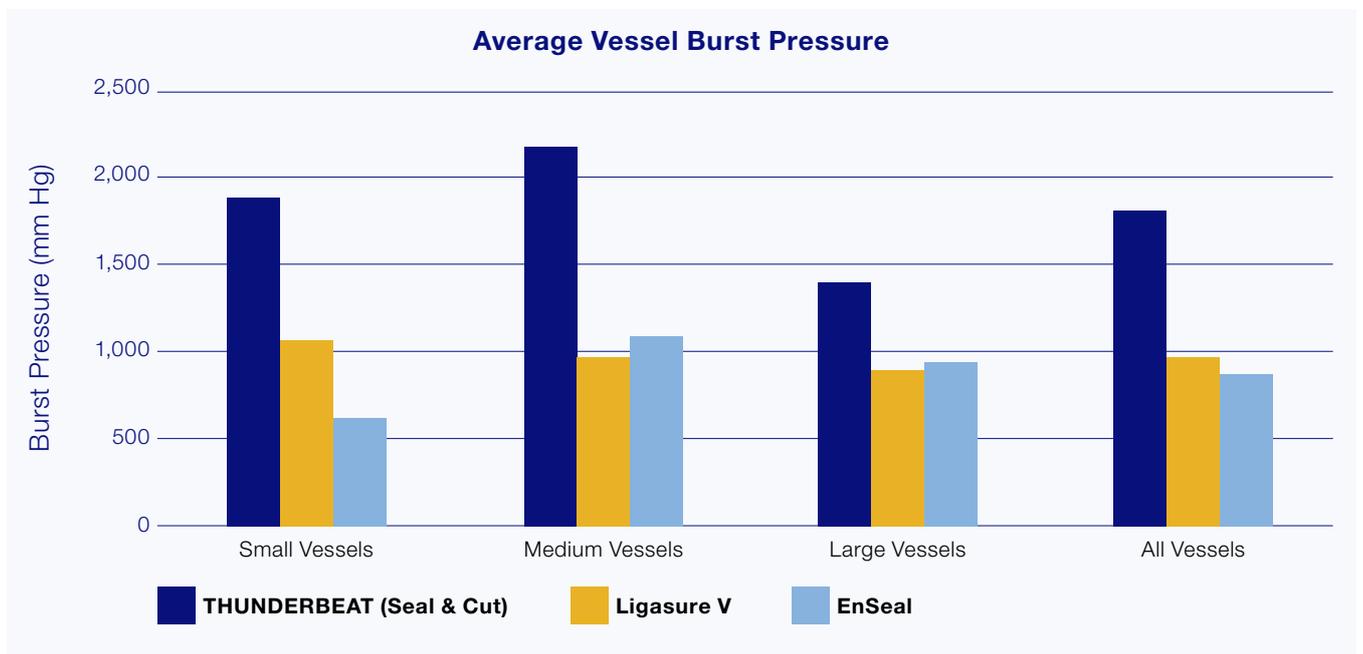
Methods: Vessel sealing tests were performed on carotid arteries, renal arteries, and splenic arteries isolated from a porcine model. Small blood vessels were classified as any blood vessel that was less than or equal to 2.0 mm in size, medium blood vessels were classified as any blood vessel between 2.0 and 4.0 mm in size, and large blood vessels were classified as any blood vessel between 4.0 and 7.0 mm in size. Each device sealed a minimum of 30 vessels in each size category. Each vessel was grasped at the sealing point with each device under test. The time required to seal or seal and cut each vessel was recorded. After vessel sealing, the maximum burst pressure was measured using a pressure gauge, and then recorded.

Results:

Vessel Sealing Speed					
Instruments		Small Vessels	Medium Vessels	Large Vessels	All Vessels
THUNDERBEAT (Seal & Cut)	Mean seal time (seconds)	2.48 ± 0.84	2.18 ± 0.34	2.62 ± 0.92	2.43 ± 0.76
LigaSure V	Mean seal time (seconds)	3.15 ± 0.34	3.24 ± 0.33	3.34 ± 0.28	3.24 ± 0.32
Enseal	Mean seal time (seconds)	4.25 ± 0.38	6.22 ± 0.34	6.39 ± 0.48	5.62 ± 1.05



Vessel Burst Pressure (mm Hg)					
Instruments		Small	Medium	Large	All Vessels
THUNDERBEAT (Seal & Cut)	Sample size	31	30	35	96
	Mean burst pressure	1,848 ± 567	2,150 ± 730	1364 ± 733	1,766 ± 751
	Burst pressure range	929–3,507	1,052–3,349	282–2,822	282–3,507
LigaSure V	Sample size	30	30	35	95
	Mean burst pressure	1,073 ± 364	945 ± 373	869 ± 366	958 ± 373
	Burst pressure range	344–1,944	378–2,202	360–1,902	344–2,202
EnSeal	Sample size	30	31	34	95
	Mean burst pressure	623 ± 276	1,074 ± 469	891 ± 355	866 ± 414
	Burst pressure range	213–1,306	290–2,175	327–1,843	213–2,175



Conclusions: THUNDERBEAT produced a higher mean burst pressure than LigaSure V or EnSeal on all vessel sizes tested. THUNDERBEAT also had a faster mean sealing time than LigaSure V or EnSeal on all vessel sizes tested. The probability of THUNDERBEAT achieving a burst pressure greater than 360 mm Hg was 96.9% in Seal & Cut mode. The LigaSure V has a 94.5% probability of achieving a burst pressure greater than 360 mm Hg. The EnSeal has an 88.9% probability of achieving greater than 360 mm Hg burst pressure. THUNDERBEAT has an equivalent sealing performance to LigaSure V and EnSeal for sealing vessels up to and including 7 mm in diameter.

THUNDERBEAT PERFORMANCE EVALUATION: WHITE PAPER

2

Tissue Cutting Speed of THUNDERBEAT and SONICBEAT versus LigaSure V, Harmonic ACE and EnSeal

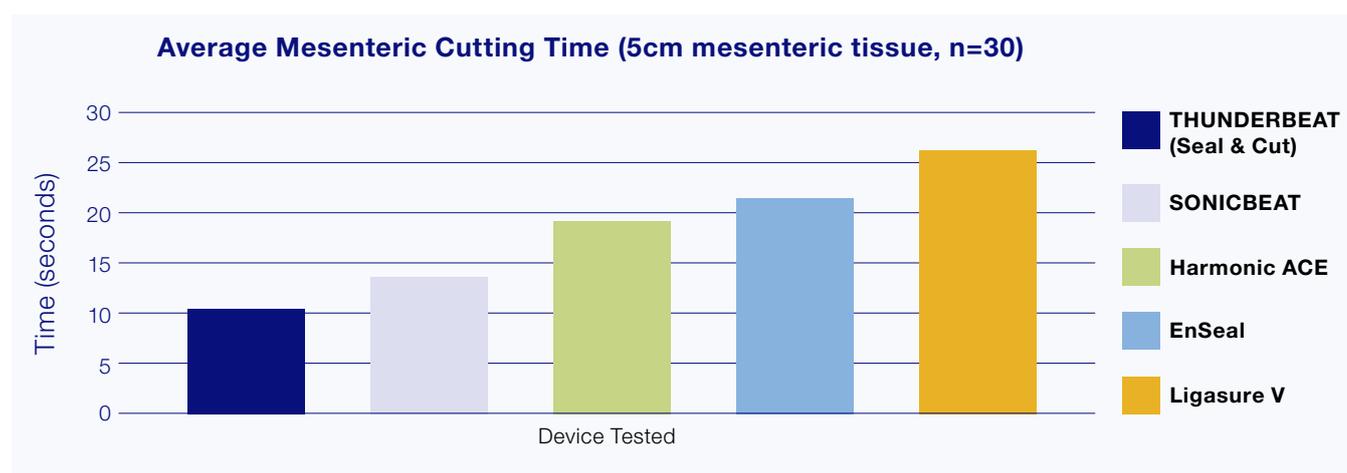
Olympus Medical Systems Cooperation Tokyo 2012, November

Objective: The objective of this study was to compare tissue cutting speed of THUNDERBEAT and SONICBEAT against predicate devices in an established porcine tissue model.

Methods: The cutting speed test was performed on porcine mesenterium. To produce reliable test data, the tissue was handled in a way to best simulate an in-vivo environment. The tissues were randomized, and the time to cut through 5 cm of the mesenteric tissue was recorded. A sample size of 30 was used for each device.

Results:

Mesenteric Cutting Speed Measured in Seconds		
THUNDERBEAT (Seal & Cut Mode)	Sample size	30
	Average cutting speed measured in seconds	10.7 ± 4.50
SONICBEAT	Sample size	30
	Average cutting speed measured in seconds	13.2 ± 4.18
LigaSure V	Sample size	30
	Average cutting speed measured in seconds	26.9 ± 8.00
Harmonic ACE	Sample size	30
	Average cutting speed measured in seconds	18.8 ± 3.80
EnSeal	Sample size	30
	Average cutting speed measured in seconds	21.6 ± 10.08



Conclusion: THUNDERBEAT had an average cutting speed of 10.7 seconds (68% faster than Harmonic ACE, 102% faster than EnSeal, and 151% faster than LigaSure V). THUNDERBEAT is significantly ($p < 0.05$) faster at cutting mesenteric tissue than LigaSure V, Harmonic ACE, and EnSeal. SONICBEAT had an average cutting speed of 13.2 seconds (42% faster than Harmonic ACE, 64% faster than EnSeal, and 104% faster than LigaSure V). SONICBEAT is significantly faster ($p < 0.05$) at cutting mesenteric tissue than LigaSure V.

THUNDERBEAT PERFORMANCE EVALUATION: WHITE PAPER

3

Mist Production of THUNDERBEAT and SONICBEAT versus Harmonic ACE

Olympus Medical Systems Cooperation Tokyo 2012, November

Objective: In intra-abdominal surgeries, using an ultrasonic surgical instrument leads to production of mist due to cavitation caused by ultrasonic vibration of the probe. The mist produced fills the abdomen, leading to an unclear endoscopic view and operator stress. To reduce cavitation, OLYMPUS developed THUNDERBEAT and SONICBEAT with a proprietary jaw design. This report investigated the THUNDERBEAT and the SONICBEAT devices with respect to mist production compared to a predicate ultrasonic surgical instrument, Harmonic ACE.

Methods: It is a general notion that cutting fat with an ultrasonic surgical instrument causes the fat to spatter, leading to wafting mist in the abdomen. To represent a worst-case scenario for mist production, lard was selected as the tissue model for this study. In order to measure the mist product quantitatively, a mist evaluation unit was used. In this model, the amount of mist produced is directly proportional to the amount of infrared light attenuation. The tissue under test was grasped at the middle of the ultrasonic probe for each device. Each device was activated until the tissue was completely severed. The maximum mist production, and mist production after 15 seconds were recorded. Following each test, the inner surface of the mist evaluation unit was cleaned. Data points were compiled by testing each device ten times. Three data points were gathered for each device for a total of 30 tests per device.

Results:

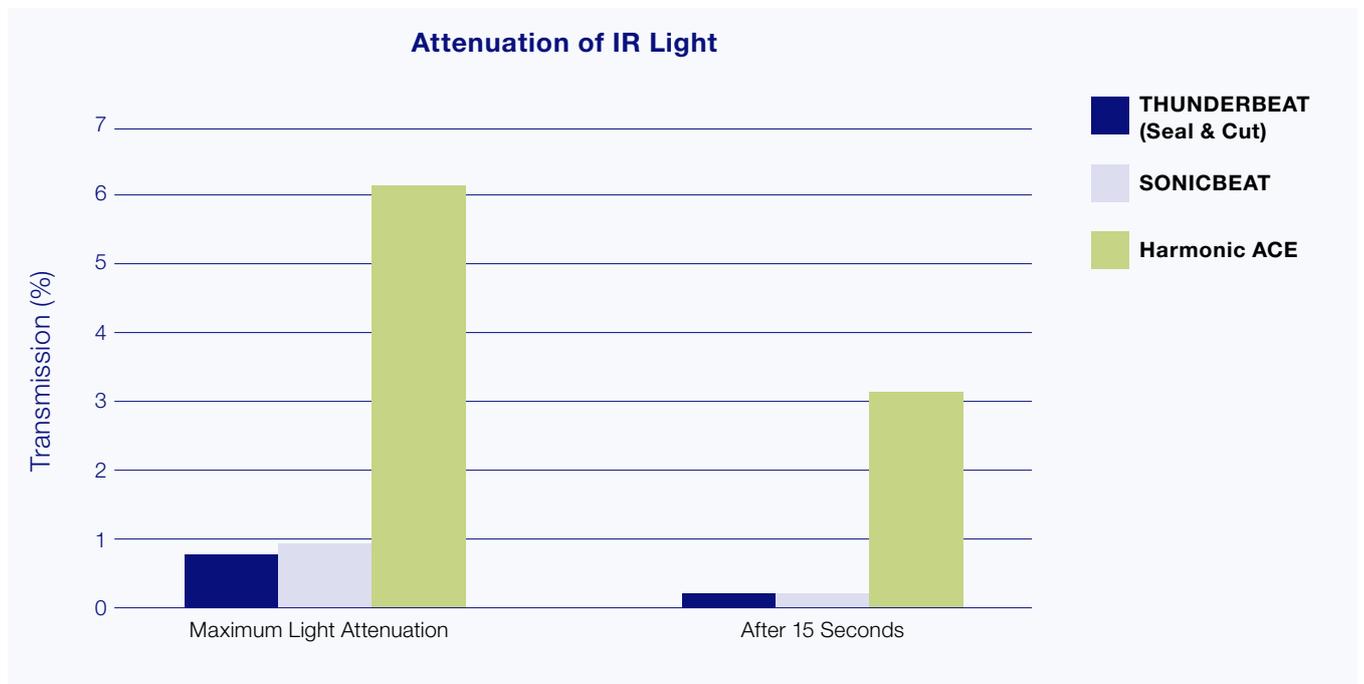
Mist Evaluation at Maximum Light Attenuation

Attenuation of IR Light Transmission (%)					
		Trial 1	Trial 2	Trial 3	Average
THUNDERBEAT (Seal & Cut)	Sample size	10	10	10	n/a
	Average attenuation	0.96 ± 0.60	0.77 ± 0.24	0.42 ± 0.26	0.72 ± 0.45
SONICBEAT	Sample size	10	10	10	n/a
	Average attenuation	0.70 ± 0.30	1.00 ± 0.58	0.90 ± 0.78	0.87 ± 0.61
Harmonic ACE	Sample size	10	10	10	n/a
	Average attenuation	5.54 ± 1.84	5.89 ± 2.52	7.01 ± 2.67	6.15 ± 2.49

Mist Evaluation 15 Seconds after Output Activation

Attenuation of IR Light Transmission (%)					
		Trial 1	Trial 2	Trial 3	Average
THUNDERBEAT (Seal & Cut)	Sample size	10	10	10	n/a
	Average attenuation	0.33 ± 0.21	0.23 ± 0.18	0.16 ± 0.20	0.24 ± 0.21
SONICBEAT	Sample size	10	10	10	n/a
	Average attenuation	0.31 ± 0.14	0.23 ± 0.22	0.21 ± 0.15	0.25 ± 0.18
Harmonic ACE	Sample size	10	10	10	n/a
	Average attenuation	2.69 ± 0.67	3.22 ± 1.44	3.88 ± 1.86	3.26 ± 1.52

Mist Evaluation



Conclusion: THUNDERBEAT generated significantly less mist than Harmonic ACE ($p < 0.001$). SONICBEAT generated significantly less mist than Harmonic ACE ($p < 0.001$). THUNDERBEAT and SONICBEAT maintain a clearer laparoscopic view at dissection compared to Harmonic ACE. Harmonic ACE produces approximately seven times more mist than THUNDERBEAT and SONICBEAT.

THUNDERBEAT PERFORMANCE EVALUATION: WHITE PAPER

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Dissection Performance of THUNDERBEAT and SONICBEAT versus LigaSure V, Harmonic ACE, and EnSeal

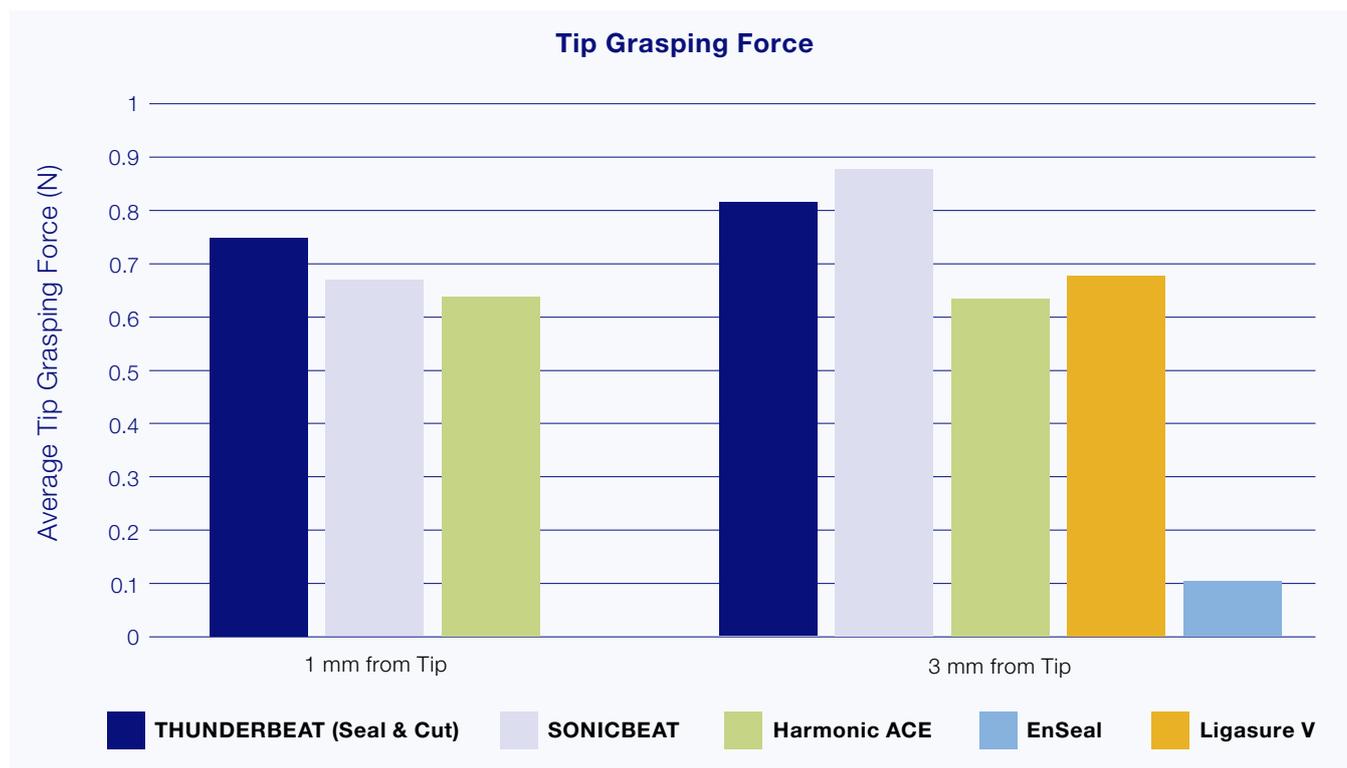
Olympus Medical Systems Cooperation Tokyo 2012, November

Objective: Improved dissection performance from surgical energy devices can contribute to less instrument usage, fewer instrument exchanges, uninterrupted surgical flow, and total OR time savings. The objective of this study was to compare the dissection performance of THUNDERBEAT and SONICBEAT against predicate devices (LigaSure V, Harmonic ACE®, and EnSeal).

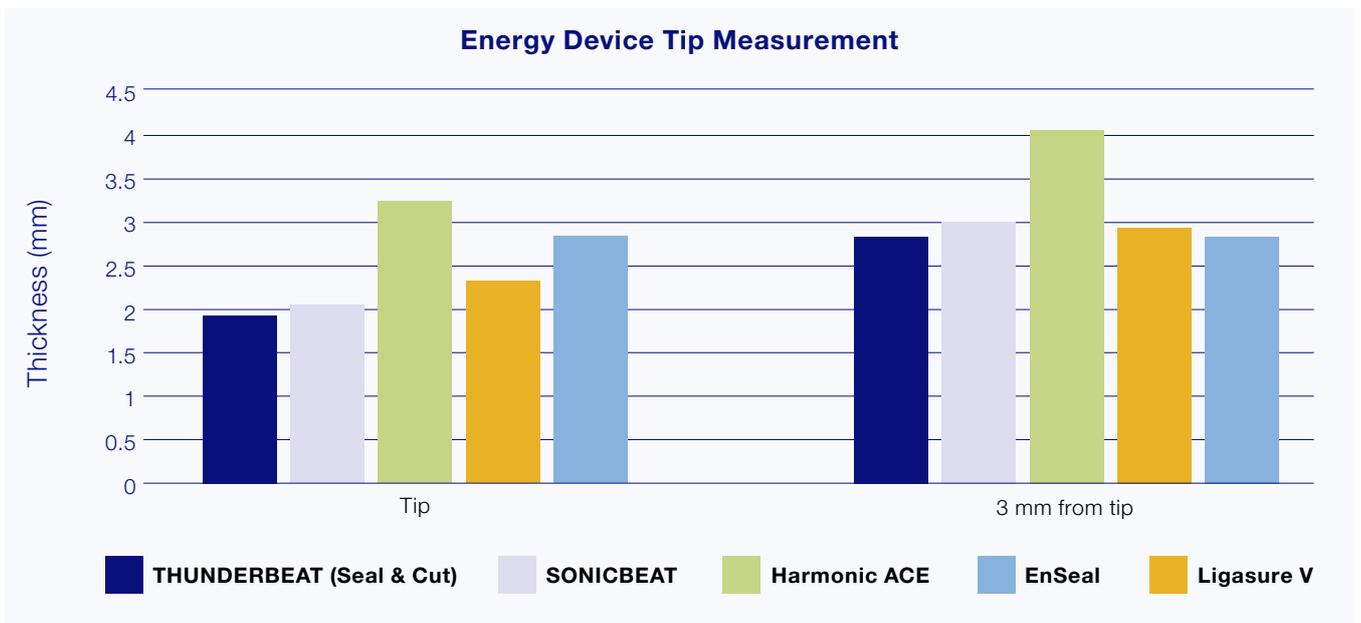
Methods: Dissection performance was evaluated using a variety of factors including tip grasping force, tip thickness, and dissecting force. Grasping force was determined using pressure-sensitive paper and was measured 1 mm and 3 mm from the tip. Tip thickness was evaluated by measuring the jaw of each device at the tip and 3 mm proximal to the tip. Dissecting force was measured by applying known forces (5N, 10N, and 15N) to the handle of each device and measuring the opening force at a point 3 mm proximal from the tip of the jaw.

Results:

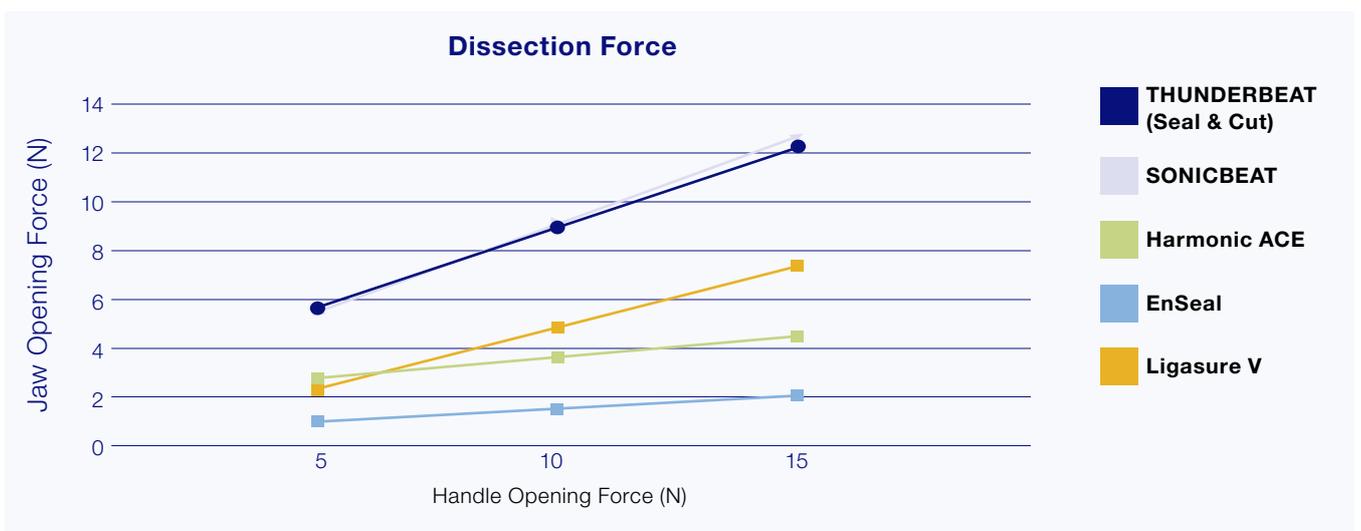
Tip Grasping Force



Tip Thickness



Jaw Opening Force (Dissection Force)



Conclusion: The Testing showed that THUNDERBEAT and SONICBEAT have higher tip grasping forces, slimmer tip dimensions, and higher jaw opening (dissection) force than predicate devices. THUNDERBEAT and SONICBEAT have superior dissection performance compared to predicate devices (LigaSure v, Harmonic ACE, and EnSeal).

USER EXPERIENCE
PUBLISHED IN SPECIAL REPORT -
GENERAL SURGERY NEWS ISSUE:
AUGUST 2013 | VOLUME: 40
**Clinical Perspectives on Using Advanced Vessel-Sealing Technology:
Experience with the Multifunctional THUNDERBEAT Device**

EXPERIENCE WITH THE MULTIFUNCTIONAL THUNDERBEAT DEVICE

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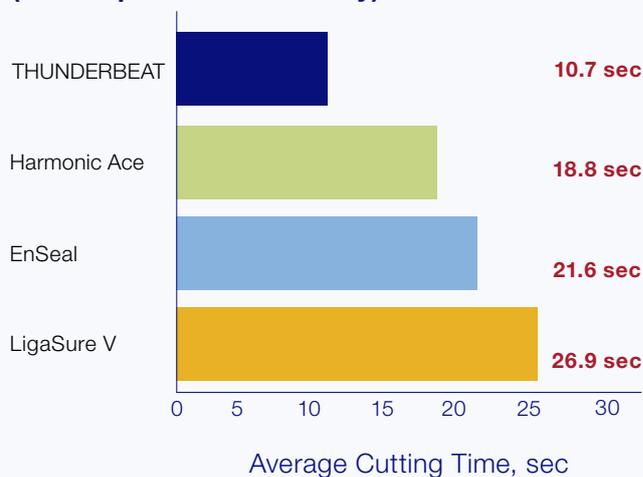
Douglas Olsen, MD, FACS

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Since the introduction of energy-based devices into the surgeon's armamentarium, manufacturers have sought to improve device function and versatility in order to provide surgeons with tools that are effective at both cutting and coagulating tissue.¹ As new models are introduced, manufacturers have added features to advance the use and efficacy of energy-based devices, and not only in their cutting ability. Sealing vessels and providing effective hemostasis, which can be difficult to achieve with methods that solely rely on compression (eg, sutures, clips, and staples), also have improved with each new generation of devices. Although these devices have been developed over time to hone their ability to seal vessels and dissect tissue – as well as provide ease of use and multifunctionality – no device has been able to offer complete efficacy without some risk.

Bipolar devices offer advantages over monopolar instruments in terms of safety and precision as they pass current only between electrodes placed closely together and better control the dispersed current.¹ However, bipolar devices that cut in addition to cauterizing usually rely on the addition of a mechanical blade activated independent of cauterizing. Ultrasonic

Figure 1: Tissue cutting speed (50 mm porcine mesentery)



Harmonic Ace and EnSeal are trademarks of Ethicon Endo-Surgery, Inc. LigaSure V is a trademark of a Covidien company. From reference 6.

energy, which emerged in the 1980s as an alternative to mono- and bipolar devices, relies on friction, rather than radiofrequency energy, to effectively desiccate tissue. Although the risk for electricity to spread through the patient's body is avoided, ultrasonic devices have been known to reach maximum temperatures of approximately 200 °C or even higher at the jaws (eg, after activation for 10 seconds).^{2,3}

The THUNDERBEAT Platform: Fully Integrated Bipolar and Ultrasonic Technology

Energy-based vessel-sealing devices have provided surgeons with increasingly sophisticated options, but only the Olympus THUNDERBEAT combines both bipolar and ultrasonic technology in a single multifunctional instrument. Surgeons have found THUNDERBEAT capable of sealing vessels up to and including 7 mm in diameter while also providing fastest-in-class cutting speed.⁴ THUNDERBEAT's fine jaw design provides precise dissection and forceful grasping, while its always available bipolar energy ensures hemostasis without the need to cut. The 5-mm diameter device can serve surgeons performing open or laparoscopic cases in a variety of disciplines, including general, urologic, gynecologic, bariatric, thoracic, and reconstructive surgery.⁴

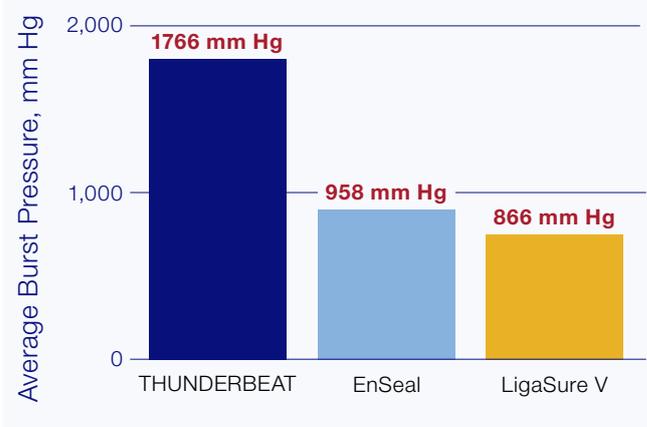
Considering Energy-Based Devices

Kevin Tri Nguyen, MD, PhD, assistant professor of surgery in the Division of Hepatopancreatobiliary Surgery and Advanced Gastrointestinal Surgery at the University of Michigan Health Systems in Ann Arbor, experienced both the benefits and drawbacks of competing devices before he began using THUNDERBEAT. "The Harmonic ACE is fast, but I was not comfortable with its ability to adequately seal vessels," he said. "The LigaSure provided me comfort that it was sealing vessels appropriately, but it was too slow. After I'd seal, I would have to press the cut button multiple times, and even then it didn't cut completely. So when I was introduced to THUNDERBEAT, I liked that it combined the sealing capability of the LigaSure and the quick-cutting ability of the Harmonic ACE all in one."

Dr. Nguyen performs approximately 200 major procedures per year and uses THUNDERBEAT exclusively in all his cases that require an energy-

based device. "I've now replaced the LigaSure with THUNDERBEAT for all my procedures. I use it for all my pancreas and liver cases, to mobilize the stomach and the colon or divide the pancreas or liver – all my procedures. It's helped move the cases along, and since I started using it I've been really happy with it." The surgical armamentarium of Jeffrey W. Milsom, MD, chief of colon and rectal surgery and professor of surgery at NewYork-Presbyterian Hospital/Weill Cornell Medical College in New York City, has included various energy-based devices over the past 25 years.

Figure 2: Vessel (<2 to 7 mm) sealing average burst pressure



*LigaSure V is a trademark of a Covidien company.
ENSEAL is a trademark of Ethicon Endo-Surgery, Inc.
Adapted from reference 7.*

"Monopolar energy, especially in minimally invasive surgery, carries the risk for arcing and for injury by the electrical current straight from the tip. It provides no compression, can result in a build-up of carbon material, and there are a lot of charring issues. It's less precise than other forms of energy and doesn't work on all types of tissues equally," he said. "Bipolar energy requires more specialized equipment and many physicians are not familiar with how to use it. But I think bipolar devices have fewer limitations than monopolar, in general."

EXPERIENCE WITH THE MULTIFUNCTIONAL THUNDERBEAT DEVICE

“Ultrasonic energy has the limitation of becoming hot, and it puts off a lot of vapor and mist, which clouds the operative field sometimes. Also, with traditional ultrasonic devices, you are not able to close off major blood vessels compared with bipolar,” Dr. Milsom said. “The THUNDERBEAT represents the latest development of energy use in surgery and it will allow surgeons to be much more efficient in their procedures.”

THUNDERBEAT Technology and the Benefits of Versatility

Cutting Speed

The area in which THUNDERBEAT offers perhaps its greatest advantage over competing devices is in terms of speed, without sacrificing any vessel-sealing security. Douglas Olsen, MD, FACS, associate clinical professor of surgery at Vanderbilt University in Nashville, Tennessee, has used THUNDERBEAT for bariatric procedures—mostly sleeve gastrectomy, Roux-en-Y gastric bypass, and duodenal switch—and said that he was instrumental in bringing THUNDERBEAT to his institution. “When I first began performing bariatric surgery, I used Harmonic technology and then I used a variety of bipolar devices before finally settling on LigaSure, which I’ve used over the past couple of years,” he said, “But when Olympus began working on THUNDERBEAT, I was very interested.”

Comparing the THUNDERBEAT with its competitors, Dr. Olsen added, “where the THUNDERBEAT wins is as the fastest in class in cutting speed. It beats the rest of them hands down.” Even when the speed of a Harmonic device is optimal, that device sacrifices another element crucial to surgery: “Most surgeons use the fast mode on the Harmonic. They can get through tissues pretty quickly, but the device’s seal ability falls off tremendously,” he said.

In a study by Seehofer et al, THUNDERBEAT surpassed the Harmonic ACE and LigaSure V in terms of cutting and sealing speed.⁵ These researchers also concluded that THUNDERBEAT has the potential to deliver sealing at a speed exceeding that of a solely ultrasonic device.⁵ On 5-cm porcine mesentery, THUNDERBEAT has been shown to be 76% faster than the Harmonic ACE, 102% faster than ENSEAL, and 151% faster than the LigaSure V, which was a significant improvement in speed over all 3 devices (Figure 1).⁶ Additionally, a study conducted by Milsom et al reported that THUNDERBEAT has a higher versatility compared with other energy instruments with faster dissection speed and acceptable thermal spread.⁷

When using THUNDERBEAT during major colorectal procedures, Dr. Milsom said the device speeds up procedures via its multifunctionality, ability to independently seal and divide vessels, and its capacity to be used as a dissector and grasper. “It’s versatile. You can use one instrument for all the tissue dissection you need to do within the abdomen,” he said. “First of all, it lets you use fewer instruments. You can use it for virtually all applications. It gives you the ability to do some very fine dissection compared with other instruments. You can use the grasping function to pick up tissue, which you can’t really do with other instruments. As with all ultrasonic devices, you do have to be careful – it can get hot so you may have to modify things to make sure you don’t touch any neighboring tissues within the first few seconds after using it.”

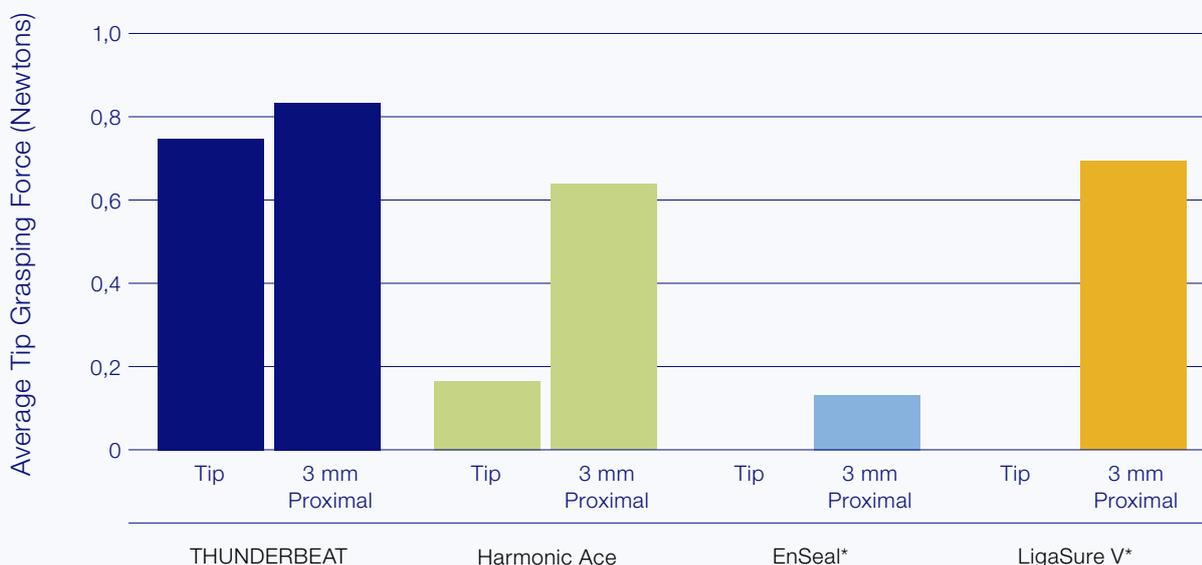
In addition to reducing the need to exchange instruments, Dr. Milsom finds that THUNDERBEAT allows him to cut and seal various tissues quickly and easily. “I think it will allow [a surgeon] to move along more quickly and efficiently, and in tight spaces like

the pelvis, it will allow you to dissect with a lot of precision,” he said. This greater potential for speed benefits everyone, Dr. Milsom noted. “For a 2-hour procedure, this may save you 10 or 15 minutes, which is really quite significant. The patient has shorter anesthesia and the health care team gets through the procedure more quickly.” Overall, longer surgical times often are associated with increased rate of complications, whereas shorter operating times are associated with better patient outcomes.⁸ Michael J. Fahey, MD, a general, vascular, thoracic, and trauma surgeon in Yuba City, California, performs a wide variety of noncardiac chest, general surgical, and hernia procedures every year. He has worked with every generation of ultrasonic and bipolar device in both open and laparoscopic procedures. “Probably the biggest limitation with the LigaSure™ [device] is that it’s a little slow to work, a little unpredictable in maintaining a seal on a 7-mm vessel, and there’s a fair amount of charring and instrument jaw cleaning that goes on in some cases. Sometimes, the blade is

either not as reproducibly sharp as it should be or it dulls quickly,” he said. “The precision of the Harmonic® [device] is nice, and it can be used in areas where a stapling device has left staples, which you can’t do with the LigaSure™. But its secondary use as a grasper is not very good; things slip through its jaws more easily than they do with the LigaSure™.”

Thus, the drawbacks of using those instruments can lengthen the duration of a procedure. “If you have to go back and control bleeding that should have been controlled the first time from the device you’re using, whether it’s an energy device or a stapler, that’s a big increase in time,” Dr. Fahey explained. “Also, if you’re using a bipolar or ultrasonic device, you have to wait for the tissue to be functionally desiccated. These are 5-mm devices; if you need to divide 10 inches or 20 cm of tissue, there’s a true wait time for each opening and closing of the jaws. If you can turn to a device in which each division is faster and more hemostatic, you’ll have a smoother case, rather than constantly

Figure 4: Distal Grasping Force



1. Sample Size: = 9

* Due to jaw design, the LigaSure V and EnSeal were unable to exert any grasping force at the tip of the device

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having to backtrack to control bleeding or waiting (for an instrument to perform) before moving forward to your next step.”

THUNDERBEAT seems to have resolved these time-consuming problems, Dr. Fahey explained. “Overall, it’s faster and more accurate. As you move through the case, it saves you time without the risk for increased bleeding. Usually I was pushing the other technologies to move a little faster, or having to wait on them,” he said. “Also, the jaws of THUNDERBEAT have fairly good grasping capability, the clarity of the division of tissue is good, and the jaws require minimal cleaning.”

Reliable Vessel Sealing

The same integration of ultrasonic and bipolar energy that makes THUNDERBEAT fast also enhances its reliability in sealing vessels up to and including 7 mm in diameter,⁴ making it equivalent in sealing capacity to the leading pure bipolar devices (Figure 2).⁷

In the comparison of THUNDERBEAT to Harmonic ACE and LigaSure V by Seehofer et al, researchers found that all 3 instruments were capable of safely dividing vessels up to 4 mm in size, but the burst pressure of larger vessels, 5 to 7 mm, was significantly higher (734±64 mm Hg) in those sealed with THUNDERBEAT than in those sealed with the Harmonic ACE (453±50 mm Hg).⁵

“Speed and the dependability of the seal are important factors,” Dr. Olsen said. “From a surgeon’s standpoint, THUNDERBEAT’s speed is certainly nice. When I’m doing something like a sleeve gastrectomy, taking down the greater curvature of the stomach and I have multiple vascular pedicles to divide, I want to be able to move through that quickly and know with confidence that I have the vessels sealed.” In bariatric

surgery, Dr. Olsen often encounters mixed tissues, such as pedicle or adipose tissue, all with vessels throughout. He found both Harmonic and LigaSure devices good at sealing some, but not all, types of tissues. “Harmonic is very good at sealing larger vessels, but is not good at sealing the little capillaries in the adipose tissue; same with the LigaSure,” he said. “I feel THUNDERBEAT gets better hemostasis through those tissues completely.”

In Seal mode, THUNDERBEAT uses only advanced bipolar energy for vessel sealing and tissue coagulation, a feature that other ultrasonic devices cannot provide. Dr. Fahey noted that hemostasis provided by THUNDERBEAT was superior to the sealing capabilities of competing devices. “We always test (new) devices on the open mesentery of colon in the open portions of cases before we start trusting them in closed, laparoscopic procedures, and the ability of the THUNDERBEAT to divide sigmoid colon or rectal lateral stocks was much more efficacious in terms of hemostasis than the 2 competitors,” he said. “The larger vessels seemed to be controlled.

THUNDERBEAT still runs into the same limitations all devices have in people with atherosclerotic arteries, where they don’t work best. But because it features an ultrasonic side, you can use it around staples, whereas with LigaSure, you would have to change modalities to monopolar devices or clips.”

Dr. Fahey advises that surgeons spend some time becoming familiar with the instrument. “You have to play with it, be appropriately instructed, and take some time with your first few cases so that you appreciate the range of settings that are available on THUNDERBEAT,” Dr. Fahey said.

Also, his colleagues in gynecologic surgery who perform laparoscopic hysterectomy – a procedure

Figure 5: NEW Handle

Front Actuated handle designed to help minimize hand fatigue through improved ergonomics



historically associated with postoperative bleeding – have migrated to THUNDERBEAT as their device of choice for uterine vessel division. “Clearly the other service lines have decided that between competing technologies, this is the one that gives them the best hemostasis,” Dr. Fahey said.

Dr. Nguyen added that THUNDERBEAT saves him time in procedures. “There are certain parts of procedures that just move a lot faster. For example, mobilizing the greater curve of the stomach,” he said. Also, having confidence that THUNDERBEAT provides a reliable seal contributes to operative time savings. “There are a lot of major blood vessels that I dissect around and divide in my surgeries, and I feel comfortable sealing and dividing with THUNDERBEAT,” Dr. Nguyen said. In the past, when he wasn’t confident about the seal a device provided, he would, “either clip or tie, which is more time-consuming.”

Precise Dissection and Optimized Grasping

In addition to providing superior speed and equivalent

hemostasis compared with its leading competitors, THUNDERBEAT offers several other features that make it a truly multifunctional instrument: a fine-tip design, strong jaw-opening force, wide jaw-opening aperture, high grasping force at the tip, and stability of the jaw. All of these features are designed to ease the surgeon’s ability to access and separate tissue planes (Figure 3).

Employing an advanced “wiper jaw” mechanism, THUNDERBEAT provides a high grasping force throughout the length of the jaw, which creates the potential for the device to be used as an alternative to generic graspers (Figure 4).⁹ THUNDERBEAT’s dissecting and grasping capabilities together may result in a reduction of instruments used in the operating room, which in turn may lead to shorter procedure duration. When he was using LigaSure, Dr. Olsen found the bulky jaw design to be a subpar dissector, which he said often is the case with pure

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bipolar devices. “That meant that you’d often need to use a second instrument to develop a tissue plane so that you could bring your (bipolar) device in across that tissue, close it, divide and seal,” he said. “So that would slow down surgery because you would have to stop and bring in a dissecting instrument to develop that tissue plane.

“Harmonic and THUNDERBEAT, on the other hand, have the ability to be excellent dissectors; the active blade on THUNDERBEAT, which is the same as the active blade on the Harmonic, is a long, thin rod, so you can use it to tease into tissues, develop the tissue plane, then close the instrument and fire it,” Dr. Olsen added. Now that he uses THUNDERBEAT in his procedures predominantly, Dr. Olsen said that he rarely needs to employ other dissectors, and in most cases does not need a curved dissector, which has streamlined his operating efficiency. Dr. Milsom also finds that using THUNDERBEAT allows him to cut down on the number of additional instruments he might use. “It gives you the ability to do some very fine dissection compared with other instruments, and you can use the grasping function to pick up tissue— with other instruments you can’t really do that,” he said.

Dr. Fahey has found the integration of fine dissection and reliable grasping to contribute to THUNDERBEAT’s ability to save surgical time and reduce instrument use. “Olympus has listened, I think, to surgical discussions that you don’t need just fine dissection, but you also need to be able to grasp tissue and hold it. Otherwise, you’re having to add other ports or other instruments— so the combination of fine dissection and grasping has been a nice integration,” Dr. Fahey said.

In the past, during complex paraesophageal or redo antireflux procedures, Dr. Fahey found that he would need to use 2 energy-based technologies to complete the surgery. “We’d use a Harmonic (device) for

dissection and a LigaSure (device) for vessel control. Or, we’d plan to staple everything else to save on energy source in terms of cost,” he said. “But now in those cases we tend to use only THUNDERBEAT. This is probably why it is more reproducible to say it takes only 20 minutes or less to take down the splenic flexure of the colon, because we don’t run into a vessel or omental bleeding that is not controlled by the device.”

The THUNDERBEAT Platform

By integrating ultrasonic and bipolar energy into one multifunctional device, THUNDERBEAT gives surgeons the option of selecting the technology option most appropriate to their specific procedural needs.

THUNDERBEAT also is compatible with the Olympus Integrated OR System, is hand- and/or foot-switch compatible, and features 3 handle designs (inline, pistol, and the new front-actuated grip (Figure 5) and 4 working lengths (10, 20, 35, and 45 cm).^{9,10}

Furthermore, the THUNDERBEAT Platform also is the only surgical tissue management system that delivers every common form of energy used in surgery today (ie, monopolar, bipolar, ultrasonic, and advanced bipolar) as well as the revolutionary combination of advanced bipolar and ultrasonic energies. “For institutions that are looking for a cost-efficient way to add an entire energy platform, it makes a lot of sense,” Dr. Olsen said.

For those who prefer to use an ultrasonic energy – only device, Olympus offers SONICBEAT. Like THUNDERBEAT, SONICBEAT cuts tissue faster and provides a stronger grasping force than the Harmonic ACE; it also produces 85% less smoke and mist.^{11,12} Per Dr. Olsen, “If they’re comfortable just with the ultrasonic [devices], they can use the SONICBEAT, and for more advanced procedures when they want to add bipolar energy, they can plug in THUNDERBEAT.”

Conclusion: THUNDERBEAT is the first device available that combines the speed of ultrasonic energy with the reliability of bipolar energy into a single instrument. It allows surgeons to cleanly divide tissue and effectively seal blood vessels up to 7 mm in size.⁴ Also, THUNDERBEAT acts as precise dissecting and powerful grasping tool, allowing surgeons to cut down on instrument exchange. “Certainly, the management of tissue division is in evolution and this product represents the future of the use of energy in safely dividing tissues,” Dr. Milsom said. “Surgeons who want to be a part of futuristic energy management in tissue division have to get their hands on this.”

References

1. Massarweh NN, Cosgriff N, Slakey DP. Electrosurgery: history, principles, and current and future uses. *J Am Coll Surg*. 2006;202(3):520-530.
2. Person B, Vivas DA, Ruiz D, et al. Comparison of four energybased vascular sealing and cutting instruments: a porcine model. *Surg Endosc*. 2008;22(2):534-538.
3. Emam TA, Cuschieri A. How safe is high-power ultrasonic dissection? *Ann Surg*. 2003;237(2):186-191.
4. Olympus America Inc. Olympus Introduces the World's Only Integrated Bipolar and Ultrasonic Energy Platform. www.olympusamerica.com/msg_section/msg_presscenter_headline.asp?pressNo=905. Accessed June 17, 2013.
5. Seehofer D, Mogl M, Boas-Knoop S, et al. Safety and efficacy of new integrated bipolar and ultrasonic scissors compared to conventional laparoscopic 5-mm sealing and cutting instruments. *Surg Endosc*. 2012;26(9):2541-2549.
6. Data on file.
7. Milsom J, Trencheva K, Monette S, et al. Evaluation of the safety, efficacy, and versatility of a new surgical energy device (THUNDERBEAT) in comparison with Harmonic ACE, LigaSure V, and EnSeal devices in a porcine model. *J Laparoendosc Adv Surg Tech A*. 2012;22(4):378-386.
8. Jackson TD, Wannares JJ, Lancaster RT, et al. Does speed matter? The impact of operative time on outcome in laparoscopic surgery. *Surg Endosc*. 2011;25(7):2288-2295.
9. Olympus. Olympus to Launch THUNDERBEAT: The World's Only Vessel Sealing and Tissue Cutting Device Integrated with both Advanced Bipolar and Ultrasonic Energy. www.olympus-global.com/en/news/2012a/nr120321thunderbeat.jsp. Accessed June 17, 2013.
10. Olympus America Inc. THUNDERBEAT Universal Platform. www.olympusamerica.com/msg_section/thunderbeat/platform.asp. Accessed June 17, 2013.
11. Data on file.
12. Surgical Tissue Management System 510(k) submission. www.accessdata.fda.gov/cdrh_docs/pdf11/K111202.pdf. Accessed June 17, 2013.

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Disclaimer: This monograph is designed to be a summary of information. While it is detailed, it is not an exhaustive clinical review. McMahon Publishing, Olympus, and the authors neither affirm nor deny the accuracy of the information contained herein. No liability will be assumed for the use of this monograph, and the absence of typographical errors is not guaranteed. Readers are strongly urged to consult any relevant primary literature.

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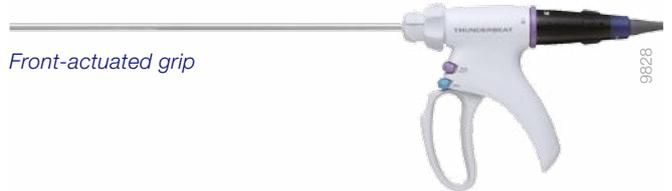
ORDERING INFORMATION

THUNDERBEAT Handpieces for Open Surgery

N4505530	THUNDERBEAT Open Extended Jaw, 9 mm, 20cm, front-actuated grip
N3810730	THUNDERBEAT 5 mm, 20 cm, in-line grip
N3810830	THUNDERBEAT 5 mm, 10 cm, in-line grip

THUNDERBEAT Handpieces for Laparoscopic Surgery

N4488930	THUNDERBEAT 5 mm, 45 cm, front-actuated grip
N4489130	THUNDERBEAT 5 mm, 35 cm, front-actuated grip
N3810330	THUNDERBEAT 5 mm, 45 cm, pistol grip
N3810430	THUNDERBEAT 5 mm, 35 cm, pistol grip
N3810530	THUNDERBEAT 5 mm, 45 cm, in-line grip
N3810630	THUNDERBEAT 5 mm, 35 cm, in-line grip



Front-actuated grip



Pistol grip



In-line grip

THUNDERBEAT features three handle types and four working lengths to meet a variety of surgeons' procedural preferences.

Generators and Accessories

WB91051W	ESG-400* electrosurgical generator
N3808660	USG-400 ultrasonic generator
N3808760	Transducer for THUNDERBEAT
N3809330	Communication cable – short: 0.25 m
N3809630	Docking fixture
WA956215	Power cable Europlug (2x)

Optional

N3635730	Energy cart
N3809230	Foot switch for THUNDERBEAT
WB50403W	Foot switch, single (bipolar) pedal
N3809430	Communication cable – long: 10 m**
N3809530	Adapter for the connection to UHI-2 or UHI-3 insufflator**
E0427213	Neutral electrode cable (reusable)

* Including one double foot switch

** Required for the automatic mist and smoke evacuation function



Surgical tissue management system with energy cart TC-E400

THUNDERBEAT TISSUE MANAGEMENT SYSTEM

The THUNDERBEAT Instrument: Unsurpassed Versatility

The purpose of this booklet is to present the technical details of these tests (both preclinical and clinical) and user feedback on the utility of the THUNDERBEAT Tissue Management System.

A truly versatile laparoscopic advanced energy instrument is one that scores highly on the following parameters: (source: Market Acceptance Study, Olympus Europe, 2011)

- **Cutting speed**
- **Reliability of large vessel sealing (up to and including 7 mm)**
- **The capability of providing secondary hemostasis using advanced bipolar energy**
- **The ability to grasp, hold, manipulate, and dissect tissue**

THUNDERBEAT fulfills these requirements with its performance surpassing that of other devices on the market in a variety of simulations.

Customer Experiences

Prof. Karl-Hermann Fuchs, MD, Agaplesion Markus Krankenhaus, Medical Director, Head Surgeon, Department for General, Visceral, Thoracic Surgery

We have started a study to assess the possible advantage of THUNDERBEAT with objective measurements. From the data, we can state that THUNDERBEAT is safe and fast, which gives us an advantage in the OR with a decrease in time of at least 15%. The time savings is the result of dependable coagulating and quick cutting action through any tissue without having to change instruments – even for blunt dissection and grasping. (May 2014)

Peiman Poornorozy, MD, Odense University Hospital, Head Surgeon, Department for Gastrointestinal Surgery

THUNDERBEAT does all the dissecting and sealing of major vessels. Instrument exchanges are no longer required. THUNDERBEAT is very fast and safe, and there is less mist compared to Harmonic. (May 2014)

Peter Razek, MD, Sozialmedizinisches Zentrum Flordisdorf - Hospital and Center for Geriatric Medicine, Consultant Surgeon, Department for Surgery

THUNDERBEAT is better than the other instruments. The seal is extremely safe, and the speed of the instrument is really impressive. (May 2014)

Andreas Keerl, MD, Kantonsspital Baden, Leading Physician, Department for Surgery

I prefer THUNDERBEAT as my standard device in colorectal surgery because the combined technologies allow for precise dissection, and safe and quick vessel sealing. I use THUNDERBEAT as it is safe, easy to use, and fast. (May 2014)

Andreas Zerz, MD, Kantonsspital Baselland, Senior Consultant, Department for Surgery

THUNDERBEAT is safe, quick, and the most versatile instrument. (May 2014)

Prof. Yves van Nieuwenhove, MD, University Hospital Ghent, Head of Clinic, Department for Gastrointestinal Surgery

THUNDERBEAT: Fast and dry. THUNDERBEAT: Means total colectomy without a single drop of blood. (May 2014)

Specifications, design, and accessories are subject to change without any notice or obligation on the part of the manufacturer.

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