

## THUNDERBEAT PLATAFORMA DE TRATAMIENTO DE TEJIDOS

Guía de consulta para profesionales sanitarios.





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## INFORMACIÓN DEL PRODUCTO: PLATAFORMA THUNDERBEAT

**Única tecnología bipolar y ultrasónica totalmente integrada del mundo.**

# ENERGÍA BIPOLAR Y ULTRASÓNICA INTEGRADA EN UN INSTRUMENTO MULTIFUNCIONAL

## Tecnología integrada revolucionaria

La plataforma THUNDERBEAT es la ÚNICA plataforma electroquirúrgica en el mundo que integra energía bipolar avanzada y energía ultrasónica que se aplica de forma simultánea con un único instrumento multifuncional. La combinación simultánea de ambas energías ofrece lo mejor de cada una de ellas: el corte rápido de tejidos mediante la energía ultrasónica y la capacidad de sellar vasos de forma segura de la energía bipolar.

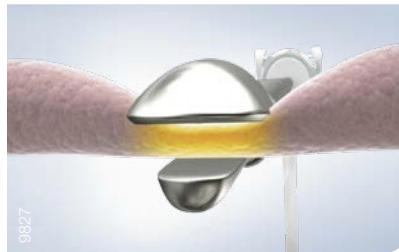
## El factor diferencial de la plataforma THUNDERBEAT

### Solo energía ultrasónica



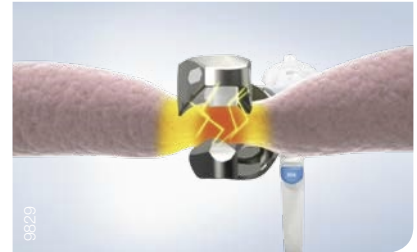
Corte rápido de tejido

### PLATAFORMA THUNDERBEAT



Corte rápido de tejido Y sellado seguro de vasos

### Solo energía bipolar



Sellado seguro de vasos

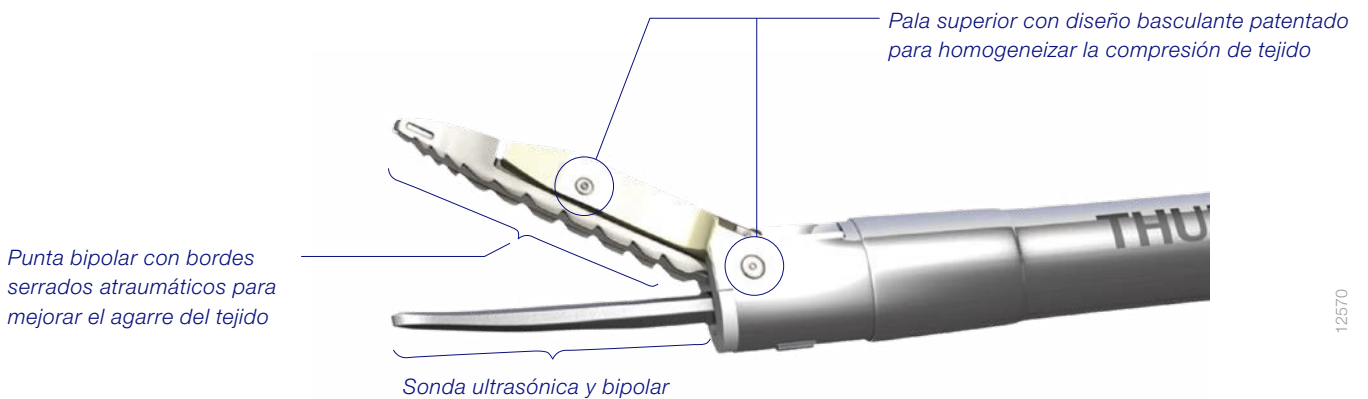
## Ventajas de una versatilidad sin precedentes

- Velocidad de corte más rápida dentro de su categoría.
- Sellado seguro de vasos de 7 mm.
- Disección precisa gracias al diseño de pinza fina.
- Energía bipolar siempre disponible para aplicaciones de hemostasia sin corte.
- Fuerza de agarre máxima en la punta dentro de su categoría.
- Dispersión térmica mínima.
- Reducción de los cambios de instrumentos.
- Menor generación de vapor que mejora la visibilidad.



### Diseño innovador en la punta

Todos los dispositivos THUNDERBEAT presentan una punta distal diseñada con pivote central patentado. Esta exclusiva característica contribuye a distribuir uniformemente la presión de cierre sobre el tejido mientras que mejora la fuerza de agarre. El resultado es una disección fina y roma mejorada y un sellado de los vasos más seguro.



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### Mango con botonera intuitiva y de fácil acceso

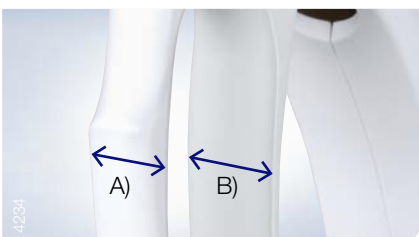
- Botones de pulsación intuitivos y de fácil acceso desde diferentes direcciones, que posibilitan una activación estable independientemente del tamaño o la posición de la mano.
- Los relieves adicionales del botón de sellado (SEAL) permiten un reconocimiento táctil que posibilita un flujo operativo continuo.

#### • Modo de sellado y corte

Energía bipolar y ultrasónica que consigue sellar y coagular los vasos de forma segura con corte simultáneo.

#### • Sellado

Energía bipolar avanzada que permite sellar los vasos y coagular los tejidos de forma segura sin corte simultáneo.



### Accionamiento del mango con un diseño optimizado

- A) Empuñadura frontal más fina que proporciona al cirujano información táctil directa para conseguir una disección roma.
- B) Empuñadura trasera más ancha que aporta estabilidad durante el agarre y el corte del tejido.





# 2

## ESTUDIOS CLÍNICOS PUBLICADOS DE LA PLATAFORMA THUNDERBEAT

# ESTUDIOS CLÍNICOS PUBLICADOS DE LA PLATAFORMA THUNDERBEAT: REVISIÓN

## 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 ( $734 \pm 64$  mm Hg)

than that of the HA ( $453 \pm 50$  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, Pavoov 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-II B) 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.

# 3

## EVALUACIÓN DE LAS PRESTACIONES DE LA PLATAFORMA THUNDERBEAT

# EVALUACIÓN DE LAS PRESTACIONES DE LA PLATAFORMA THUNDERBEAT: LIBRO BLANCO

## 1

### Prestaciones de sellado de vasos de la plataforma THUNDERBEAT en comparación con los sistemas LigaSure V y EnSeal

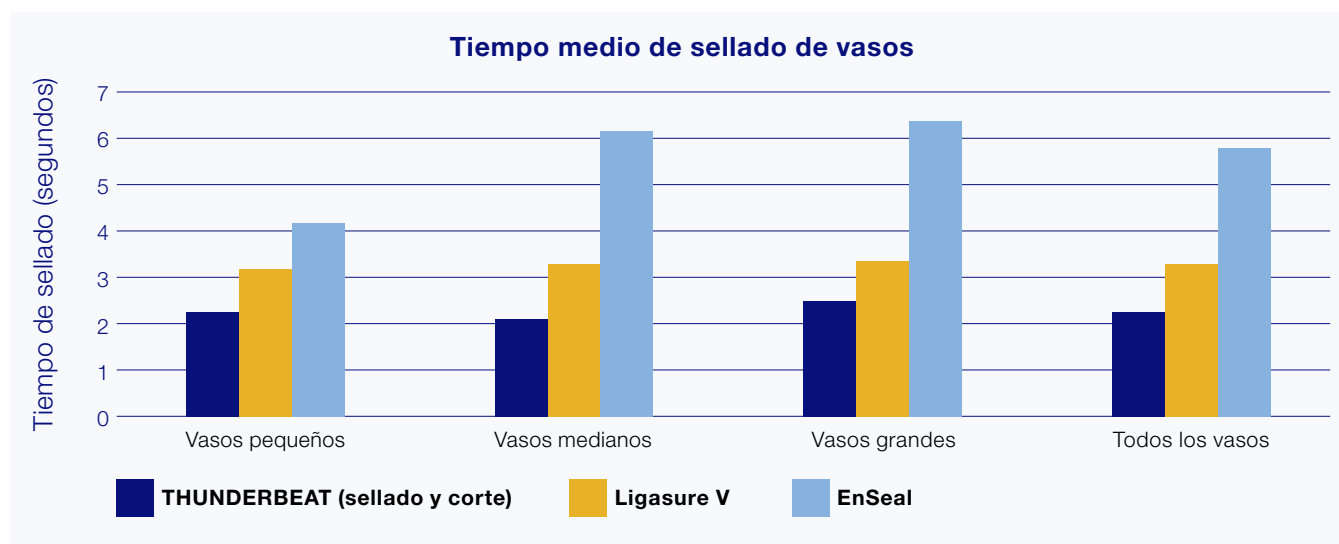
Olympus Medical Systems Corporation, Tokio (noviembre de 2012)

**Objetivo:** el objetivo de este estudio fue evaluar las prestaciones de sellado de vasos (presión de rotura y velocidad de sellado) de la plataforma THUNDERBEAT en comparación con las de otros dispositivos utilizados con tal fin (LigaSure V y EnSeal).

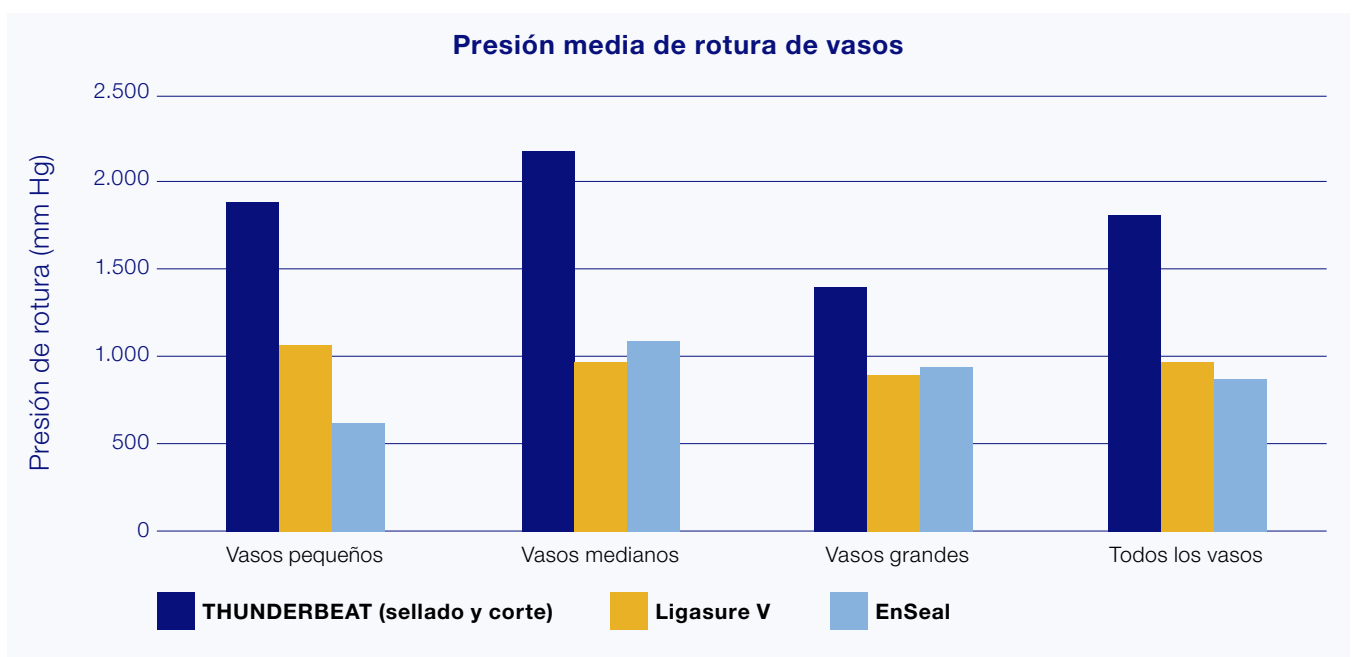
**Métodos:** las pruebas de sellado de vasos se realizaron en arterias carótidas, renales y esplénicas aisladas de un modelo porcino. Se clasificaron como vasos sanguíneos pequeños aquellos cuyo tamaño era igual o inferior a 2,0 mm; como vasos sanguíneos medianos aquellos cuyo tamaño se encontraba entre 2,0 y 4,0 mm; y como vasos sanguíneos grandes aquellos de tamaño entre 4,0 y 7,0 mm. Cada dispositivo selló un mínimo de 30 vasos de cada categoría. Se pinzó el vaso en el punto de sellado con cada dispositivo evaluado. Se registró el tiempo necesario para sellar o sellar y cortar cada vaso. Después de sellar los vasos, se midió y registró la presión de rotura máxima con un manómetro.

#### Resultados:

Velocidad de sellado de vasos					
Instrumentos		Vasos pequeños	Vasos medianos	Vasos grandes	Todos los vasos
<b>THUNDERBEAT (sellado y corte)</b>	Tiempo medio de sellado (segundos)	2,48 ± 0,84	2,18 ± 0,34	2,62 ± 0,92	2,43 ± 0,76
<b>LigaSure V</b>	Tiempo medio de sellado (segundos)	3,15 ± 0,34	3,24 ± 0,33	3,34 ± 0,28	3,24 ± 0,32
<b>Enseal</b>	Tiempo medio de sellado (segundos)	4,25 ± 0,38	6,22 ± 0,34	6,39 ± 0,48	5,62 ± 1,05



Presión de rotura de vasos (mm Hg)					
Instrumentos		Pequeños	Medianos	Grandes	Todos los vasos
<b>THUNDERBEAT (sellado y corte)</b>	Tamaño de la muestra	31	30	35	96
	Presión media de rotura	1.848 ± 567	2.150 ± 730	1.364 ± 733	1.766 ± 751
	Intervalo de presión de rotura	929–3.507	1.052–3.349	282–2.822	282–3.507
<b>LigaSure V</b>	Tamaño de la muestra	30	30	35	95
	Presión media de rotura	1.073 ± 364	945 ± 373	869 ± 366	958 ± 373
	Intervalo de presión de rotura	344–1.944	378–2.202	360–1.902	344–2.202
<b>EnSeal</b>	Tamaño de la muestra	30	31	34	95
	Presión media de rotura	623 ± 276	1.074 ± 469	891 ± 355	866 ± 414
	Intervalo de presión de rotura	213–1.306	290–2.175	327–1.843	213–2.175



**Conclusiones:** la plataforma THUNDERBEAT consiguió una presión de rotura superior a la obtenida con los sistemas LigaSure V y EnSeal para todos los tamaños de vasos evaluados. La plataforma THUNDERBEAT también registró un tiempo de sellado inferior al de los sistemas LigaSure V y EnSeal para todos los tamaños de vasos evaluados. La probabilidad de alcanzar una presión de rotura superior a 360 mm Hg con la plataforma THUNDERBEAT fue del 96,9 % en el modo de sellado y corte, mientras que la probabilidad fue del 94,5 % para el sistema LigaSure V y del 88,9 % para el sistema EnSeal. La plataforma THUNDERBEAT ofrece unas prestaciones equivalentes a las de los sistemas LigaSure V y EnSeal para sellar vasos de un diámetro igual o inferior a 7 mm.

# EVALUACIÓN DE LAS PRESTACIONES DE LA PLATAFORMA THUNDERBEAT: LIBRO BLANCO

## 2

### Velocidad de corte de tejido de las plataformas THUNDERBEAT y SONICBEAT en comparación con los sistemas LigaSure V, Harmonic ACE y EnSeal

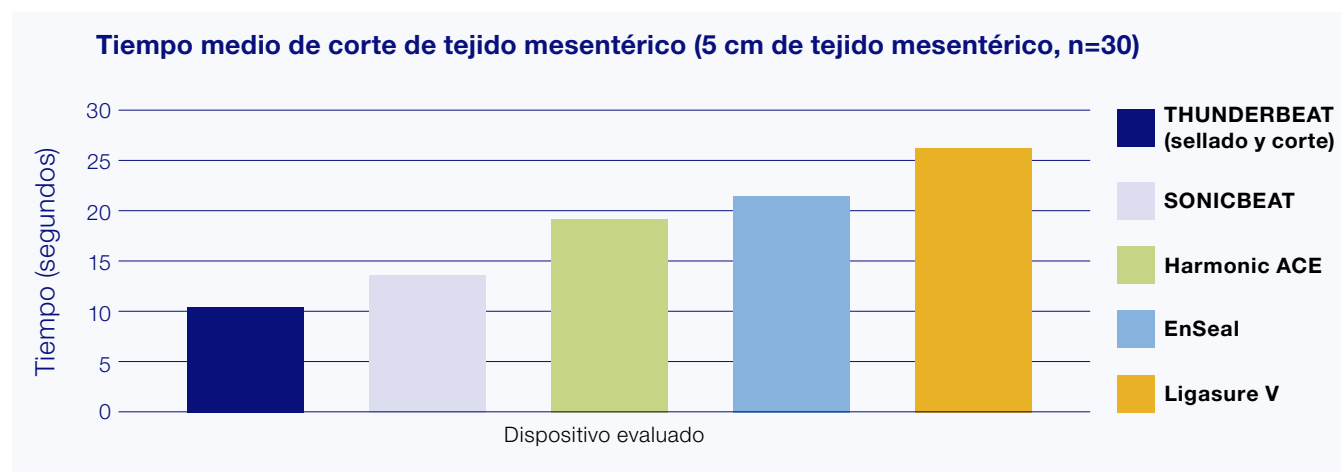
Olympus Medical Systems Corporation, Tokio (noviembre de 2012)

**Objetivo:** el objetivo de este estudio fue comparar la velocidad de corte de tejido de las plataformas THUNDERBEAT y SONICBEAT con la de otros dispositivos utilizados con tal fin en un modelo de tejido porcino establecido.

**Métodos:** la prueba de velocidad de corte se realizó en tejido mesentérico porcino. Para generar datos de evaluación fiables, el tejido se manipuló simulando de la mejor forma posible un entorno "in-vivo". Se aleatorizaron los tejidos y se registró el tiempo de corte de 5 cm del tejido mesentérico. Se utilizó un tamaño de muestra idéntico (n=30) para cada dispositivo.

#### Resultados:

Velocidad de corte de tejido mesentérico medida en segundos		
<b>THUNDERBEAT (modo de sellado y corte)</b>	Tamaño de la muestra	30
	Velocidad media de corte medida en segundos	10,7 ± 4,50
<b>SONICBEAT</b>	Tamaño de la muestra	30
	Velocidad media de corte medida en segundos	13,2 ± 4,18
<b>LigaSure V</b>	Tamaño de la muestra	30
	Velocidad media de corte medida en segundos	26,9 ± 8,00
<b>Harmonic ACE</b>	Tamaño de la muestra	30
	Velocidad media de corte medida en segundos	18,8 ± 3,80
<b>EnSeal</b>	Tamaño de la muestra	30
	Velocidad media de corte medida en segundos	21,6 ± 10,08





**Conclusión:** la plataforma THUNDERBEAT registró una velocidad media de corte de 10,7 segundos (un 68 % más rápido que el dispositivo Harmonic ACE, un 102 % más rápido que el dispositivo EnSeal y un 151 % más rápido que el dispositivo LigaSure V). El corte de tejido mesentérico con la plataforma THUNDERBEAT es considerablemente más rápido ( $p < 0,05$ ) en comparación con los sistemas LigaSure V, Harmonic ACE y EnSeal. La velocidad media de corte obtenida con la plataforma SONICBEAT fue de 13,2 segundos (un 42 % más rápido que con el dispositivo Harmonic ACE, un 64 % más rápido que con el dispositivo EnSeal y un 104 % más rápido que con el dispositivo LigaSure V). El corte de tejido mesentérico con la plataforma SONICBEAT es considerablemente más rápido ( $p < 0,05$ ) en comparación con el sistema LigaSure V.

# EVALUACIÓN DE LAS PRESTACIONES DE LA PLATAFORMA THUNDERBEAT: LIBRO BLANCO

## 3

### Generación de vapor de las plataformas THUNDERBEAT y SONICBEAT en comparación con el sistema Harmonic ACE

Olympus Medical Systems Corporation, Tokio (noviembre de 2012)

**Objetivo:** en las intervenciones quirúrgicas intraabdominales, el uso de un instrumento quirúrgico ultrasónico supone la generación de vapor a causa de la cavitación producida por la vibración ultrasónica de la sonda. El vapor producido llena el abdomen, lo que nubla la vista endoscópica y genera presión sobre el operador. Para reducir la cavitación, OLYMPUS ha desarrollado las plataformas THUNDERBEAT y SONICBEAT con un diseño de pinza patentado. En este informe se analiza la generación de vapor de los dispositivos THUNDERBEAT y SONICBEAT en comparación con uno de los instrumentos quirúrgicos ultrasónicos utilizados con tal fin: el dispositivo Harmonic ACE.

**Métodos:** es de dominio público que, al cortar grasa con un instrumento quirúrgico ultrasónico, dicha grasa produce salpicaduras y genera vapor que queda flotando en el abdomen. Para representar el peor de los casos, se seleccionó tejido graso abdominal como modelo de tejido para este estudio. Para medir cuantitativamente el vapor generado, se utilizó una unidad de evaluación de vapor. En este modelo, la cantidad de vapor generada es directamente proporcional a la atenuación de la luz infrarroja. En cada dispositivo, el tejido evaluado se pinzó con la parte central de la sonda ultrasónica. Cada dispositivo permaneció accionado hasta seccionar por completo el tejido. Se registraron la generación máxima de vapor y la generación de vapor después de 15 segundos. Después de cada prueba, se limpió la superficie interior de la unidad de evaluación de vapor. Se compilaron puntos de datos realizando diez pruebas con cada dispositivo. Se recogieron tres puntos de datos para cada dispositivo durante un total de 30 pruebas por dispositivo.

### Resultados:

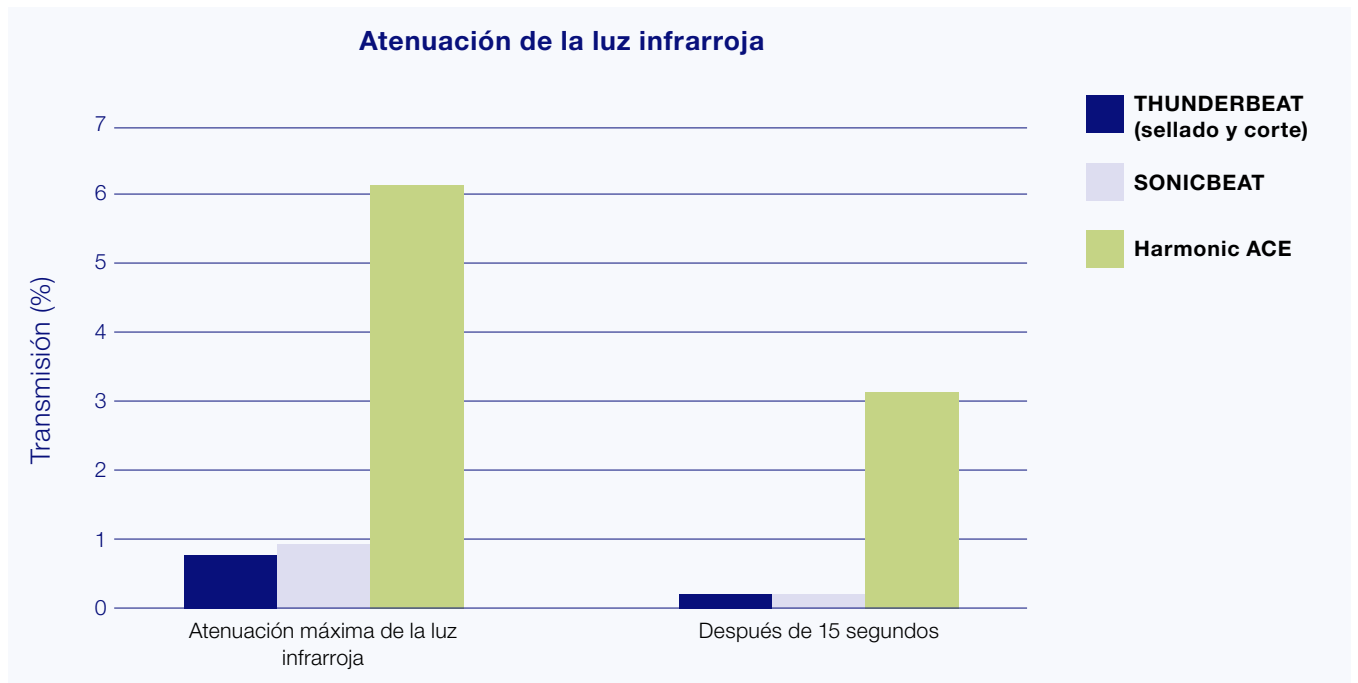
*Evaluación del vapor con una atenuación de luz máxima*

Atenuación de la transmisión de luz infrarroja (%)					
		Prueba 1	Prueba 2	Prueba 3	Media
<b>THUNDERBEAT (sellado y corte)</b>	Tamaño de la muestra	10	10	10	N.A.
	Atenuación media	0,96 ± 0,60	0,77 ± 0,24	0,42 ± 0,26	0,72 ± 0,45
<b>SONICBEAT</b>	Tamaño de la muestra	10	10	10	N.A.
	Atenuación media	0,70 ± 0,30	1,00 ± 0,58	0,90 ± 0,78	0,87 ± 0,61
<b>Harmonic ACE</b>	Tamaño de la muestra	10	10	10	N.A.
	Atenuación media	5,54 ± 1,84	5,89 ± 2,52	7,01 ± 2,67	6,15 ± 2,49

Evaluación del vapor a los 15 segundos de la activación de la salida

Atenuación de la transmisión de luz infrarroja (%)					
		Prueba 1	Prueba 2	Prueba 3	Media
<b>THUNDERBEAT (sellado y corte)</b>	Tamaño de la muestra	10	10	10	N.A.
	Atenuación media	0,33 ± 0,21	0,23 ± 0,18	0,16 ± 0,20	0,24 ± 0,21
<b>SONICBEAT</b>	Tamaño de la muestra	10	10	10	N.A.
	Atenuación media	0,31 ± 0,14	0,23 ± 0,22	0,21 ± 0,15	0,25 ± 0,18
<b>Harmonic ACE</b>	Tamaño de la muestra	10	10	10	N.A.
	Atenuación media	2,69 ± 0,67	3,22 ± 1,44	3,88 ± 1,86	3,26 ± 1,52

Evaluación del vapor



**Conclusión:** La plataforma THUNDERBEAT generó mucho menos vapor que el sistema Harmonic ACE ( $p < 0,001$ ). La plataforma SONICBEAT generó mucho menos vapor que el sistema Harmonic ACE ( $p < 0,001$ ). Las plataformas THUNDERBEAT y SONICBEAT mantienen una visión laparoscópica más clara en la disección en comparación con el sistema Harmonic ACE que, a su vez, produce aproximadamente siete veces más vapor que las plataformas THUNDERBEAT y SONICBEAT.

# EVALUACIÓN DE LAS PRESTACIONES DE LA THUNDERBEAT: LIBRO BLANCO

## 4

### Prestaciones de disección de las plataformas THUNDERBEAT y SONICBEAT en comparación con los sistemas LigaSure V, Harmonic ACE y EnSeal

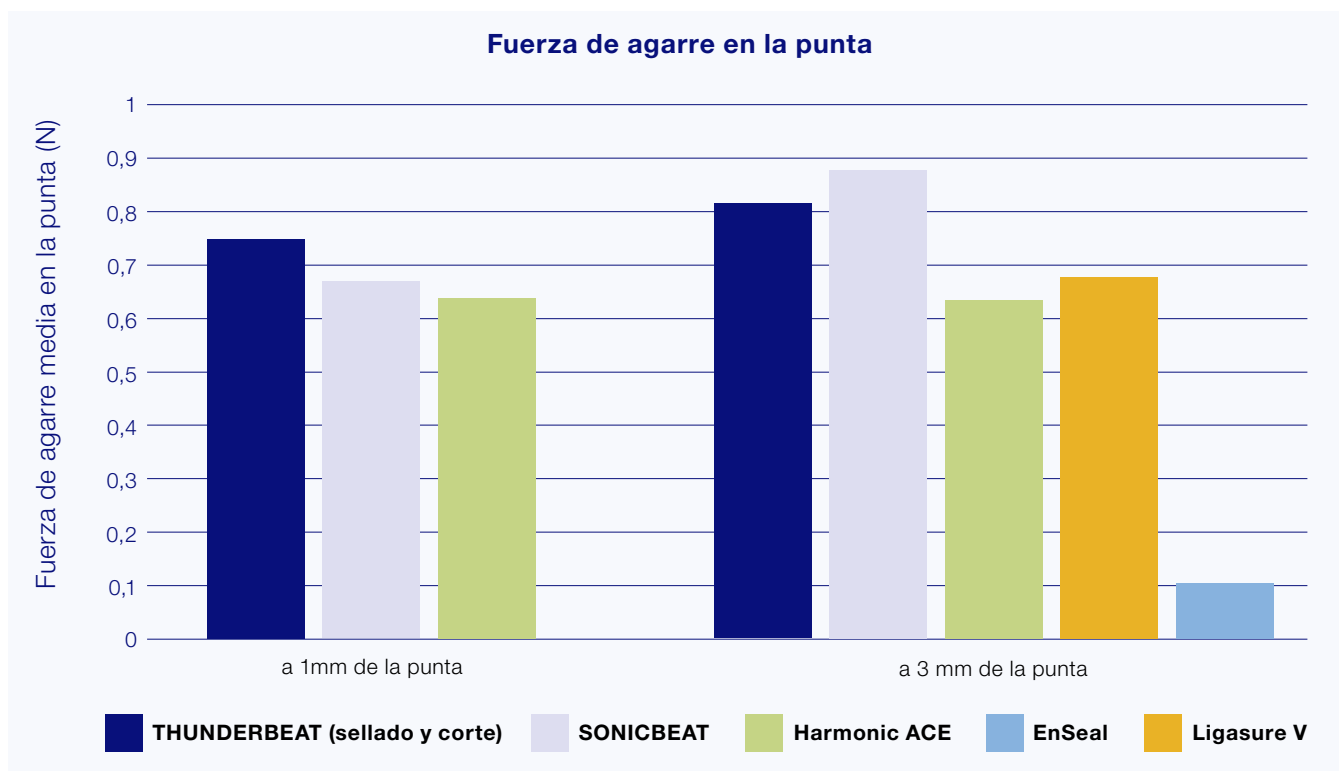
Olympus Medical Systems Corporation, Tokio (noviembre de 2012)

**Objetivo:** la mejora de las prestaciones de disección de los dispositivos de energía quirúrgicos puede contribuir a reducir el uso y los intercambios de instrumentos, conseguir un flujo quirúrgico ininterrumpido y reducir el tiempo de uso total de los quirófanos. El objetivo de este estudio fue comparar las prestaciones de disección de las plataformas THUNDERBEAT y SONICBEAT con las de otros dispositivos utilizados con tal fin (LigaSure V, Harmonic ACE® y EnSeal).

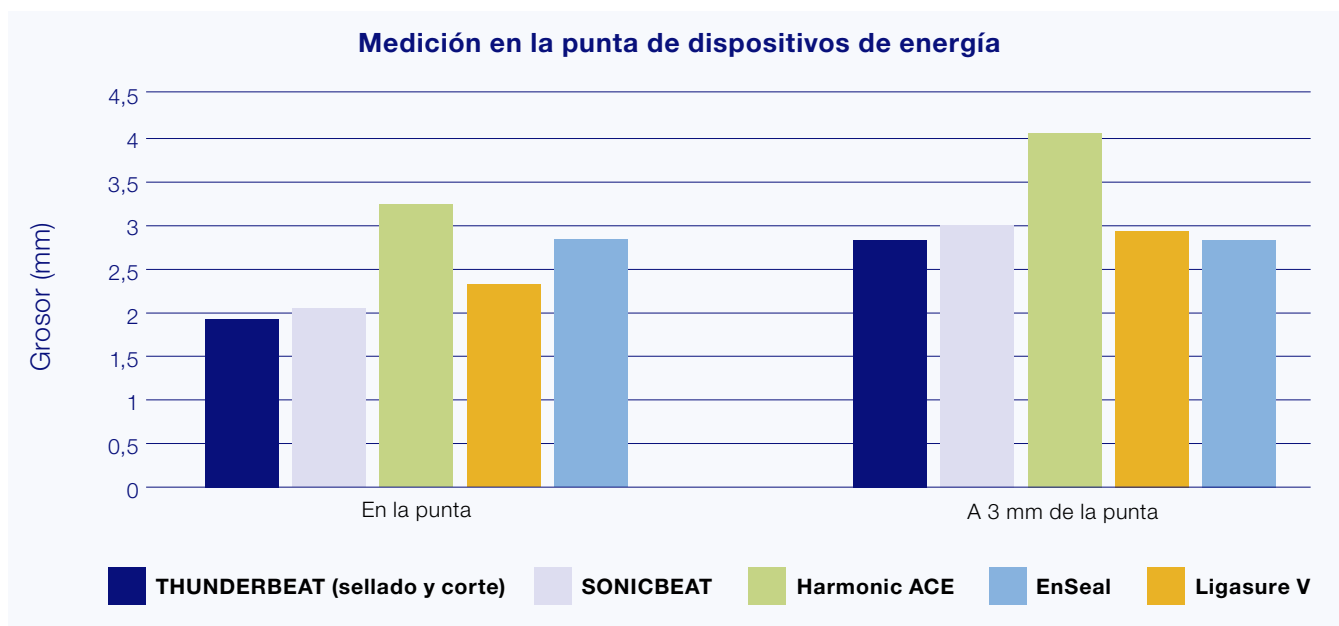
**Métodos:** se evaluaron las prestaciones de disección utilizando diversos factores, como la fuerza de agarre en la punta, el grosor de la punta y la fuerza de disección. La fuerza de agarre se determinó mediante un papel sensible a la presión y se midió a 1 y 3 mm de la punta. El grosor de la punta se evaluó midiendo la pinza de cada dispositivo en la punta y a 3 mm de la punta en sentido proximal. La fuerza de disección se midió aplicando fuerzas conocidas (5, 10 y 15 N) en el mango de cada dispositivo y midiendo la fuerza de apertura en un punto a 3 mm de la punta de la pinza en sentido proximal.

### Resultados:

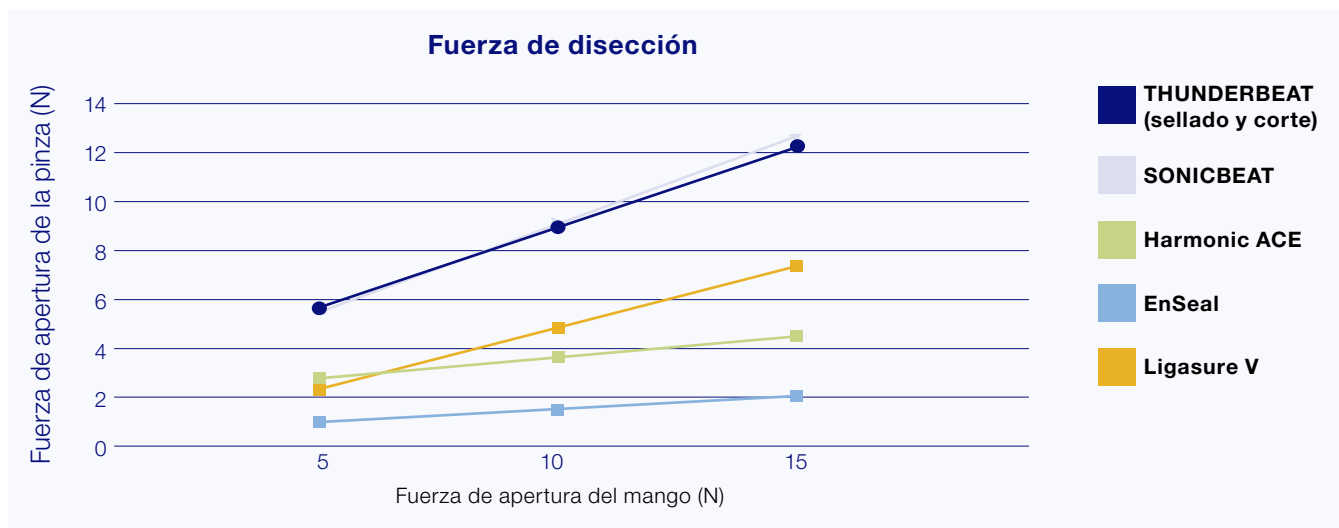
*Fuerza de agarre en la punta*



### Grosor de la punta



### Fuerza de apertura de la pinza (fuerza de disección)



**Conclusión:** las pruebas demostraron que las plataformas THUNDERBEAT y SONICBEAT ofrecen fuerzas de agarre en la punta mayores, dimensiones de la punta más reducidas y una fuerza de apertura de la pinza (disección) mayor que los otros dispositivos. Asimismo, las plataformas THUNDERBEAT y SONICBEAT ofrecen unas prestaciones de disección superiores en comparación con los otros dispositivos utilizados con tal fin (LigaSure V, Harmonic ACE y EnSeal).



# 4

EXPERIENCIA DE LOS USUARIOS  
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**Clinical Perspectives on Using Advanced Vessel-Sealing Technology:  
Experience with the Multifunctional THUNDERBEAT Device**

# EXPERIENCIA CON EL DISPOSITIVO MULTIFUNCIONAL THUNDERBEAT

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### Michael J. Fahey, MD, FACS

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Yuba City, California

### Jeffrey W. Milsom, MD

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Jerome J. DeCosse, MD Distinguished  
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Ann Arbor, Michigan

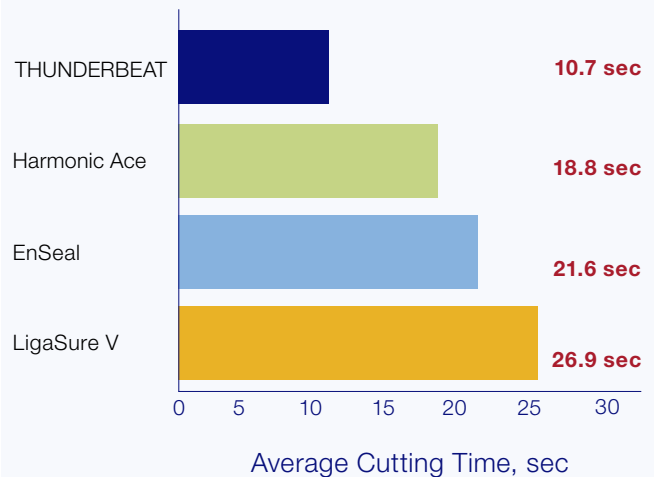
### Douglas Olsen, MD, FACS

Associate Clinical Professor of Surgery  
Vanderbilt University  
Nashville, Tennessee

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.<sup>1</sup> 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.<sup>1</sup> 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).<sup>2,3</sup>



### 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.<sup>4</sup> 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.<sup>4</sup>

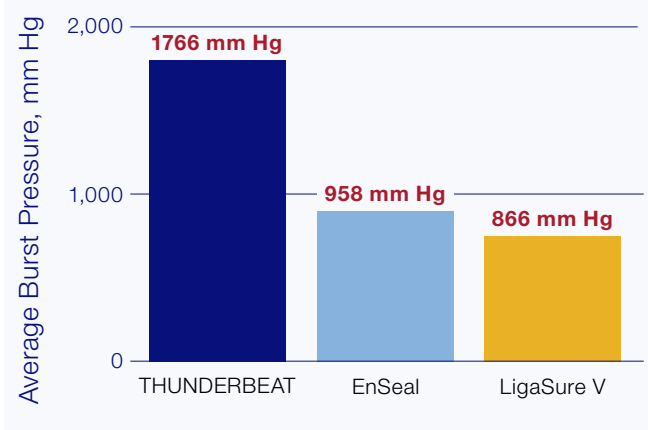
### Considering Energy-Based Devices

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."

## EXPERIENCIA CON EL DISPOSITIVO MULTIFUNCIONAL THUNDERBEAT

“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.<sup>5</sup> These researchers also concluded that THUNDERBEAT has the potential to deliver sealing at a speed exceeding that of a solely ultrasonic device.<sup>5</sup> 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).<sup>6</sup> 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.<sup>7</sup>

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.”

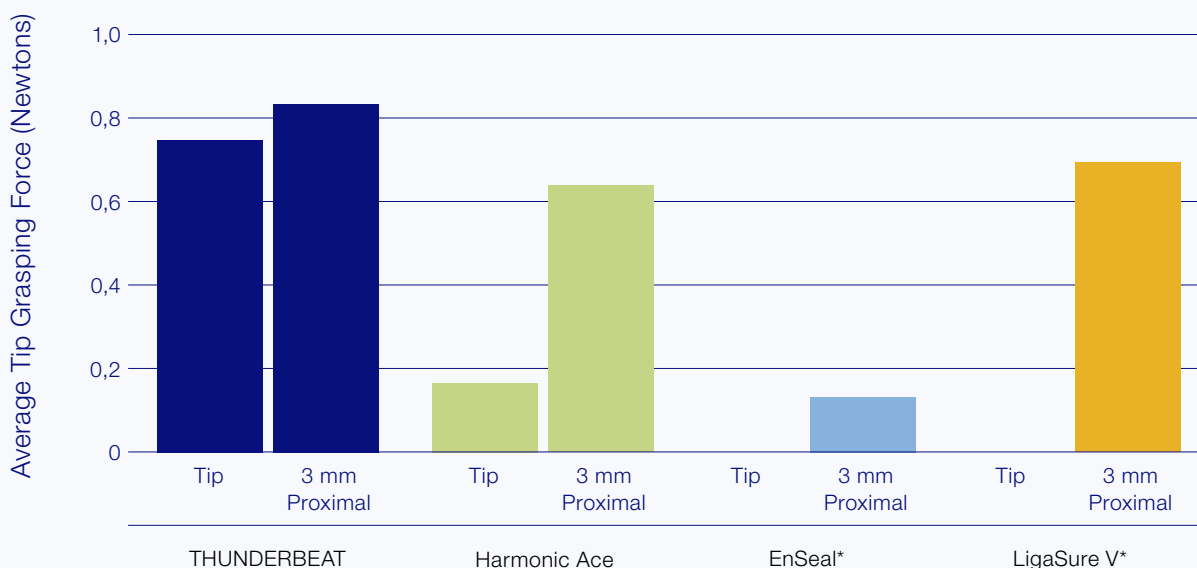
In addition to reducing the need to exchange instruments, Dr. Milsom finds that THUNDERBEAT allows him to cut and seal various tissues quickly and easily. “I think it will allow [a surgeon] to move along more quickly and efficiently, and in tight spaces like

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.<sup>8</sup> 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,<sup>4</sup> making it equivalent in sealing capacity to the leading pure bipolar devices (Figure 2).<sup>7</sup>

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).<sup>5</sup>

“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).<sup>9</sup> 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

## EXPERIENCIA CON EL DISPOSITIVO MULTIFUNCIONAL THUNDERBEAT

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).<sup>9,10</sup>

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.<sup>11,12</sup> 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.<sup>4</sup> 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.”

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*Disclosures: Dr. Fahey reported no relevant financial conflicts of interest. Dr. Milsom reported receiving grant/research funding from Olympus. Dr. Nguyen reported no relevant financial conflicts of interest. Dr. Olsen reported receiving honoraria from Olympus.*

*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.*





# 5

## INFORMACIÓN PARA PEDIDOS

## INFORMACIÓN PARA PEDIDOS

### Pinzas THUNDERBEAT para cirugía abierta

<b>N4505530</b>	THUNDERBEAT Open Extended Jaw, 9 mm, 20cm, Mango con accionamiento frontal
<b>N3810730</b>	THUNDERBEAT Mango axial, 5 mm y 20 cm
<b>N3810830</b>	THUNDERBEAT Mango axial, 5 mm y 10 cm

### Pinzas THUNDERBEAT para cirugía laparoscópica

<b>N4488930</b>	THUNDERBEAT Mango con accionamiento frontal, 5 mm y 45 cm
<b>N4489130</b>	THUNDERBEAT mango con accionamiento frontal, 5 mm y 35 cm
<b>N3810330</b>	THUNDERBEAT mango en pistola, 5 mm y 45 cm
<b>N3810430</b>	THUNDERBEAT Mango en pistola, 5 mm y 35 cm
<b>N3810530</b>	THUNDERBEAT Mango axial, 5 mm y 45 cm
<b>N3810630</b>	THUNDERBEAT Mango axial, 5 mm y 35 cm



12571



Mango con accionamiento frontal

9828



Mango en pistola

9830



Mango axial

9826

La plataforma THUNDERBEAT ofrece tres tipos de mangos y cuatro longitudes de trabajo para satisfacer una amplia variedad de preferencias quirúrgicas de los cirujanos.

### Generadores y accesorios

<b>WB91051W</b>	Generador electroquirúrgico ESG-400*
<b>N3808660</b>	Generador ultrasónico USG-400
<b>N3808760</b>	Transductor para la plataforma THUNDERBEAT
<b>N3809330</b>	Cable de comunicación (corto: 0,25 m)
<b>N3809630</b>	Fijaciones de acoplamiento
<b>WA956215</b>	Enchufe europeo para cable de alimentación (2 unidades)

### Accesorios opcionales

<b>N3635730</b>	Carro de alimentación
<b>N3809230</b>	Pedal para la plataforma THUNDERBEAT
<b>WB50403W</b>	Pedal simple (bipolar)
<b>N3809430</b>	Cable de comunicación (largo: 10 m**)
<b>N3809530</b>	Adaptador para la conexión a un insuflador UHI-2 o UHI-3**
<b>E0427213</b>	Cable de placa paciente (reutilizable)

\* Incluye un pedal doble.

\*\* Necesario para la función de evacuación automática de vapor y humo.



Plataforma de tratamiento de tejidos quirúrgico con carro de alimentación TC-E400

# PLATAFORMA DE TRATAMIENTO DE TEJIDOS THUNDERBEAT

## Instrumento THUNDERBEAT: versatilidad sin igual

El propósito de esta guía es presentar los detalles técnicos (tanto preclínicos como clínicos) y las opiniones de los usuarios sobre la utilidad de la plataforma de tratamiento de tejidos THUNDERBEAT.

Un instrumento de energía laparoscópico verdaderamente avanzado y versátil es aquel que destaca en los parámetros siguientes (fuente: Market Acceptance Study, Olympus Europe, 2011):

- **Velocidad de corte.**
- **Fiabilidad en el sellado de vasos grandes (hasta 7 mm, inclusive).**
- **Capacidad de ofrecer hemostasia secundaria con energía bipolar avanzada.**
- **Capacidad de agarrar, sujetar, manipular y diseccionar tejido.**

La plataforma THUNDERBEAT cumple estos requisitos, ya que sus prestaciones superan las de otros dispositivos del mercado en una variedad de simulaciones.

## Experiencias de los clientes

*Prof. Karl-Hermann Fuchs, Dr., Agaplesion Markus Krankenhaus, Director Médico, Cirujano jefe, Departamento de cirugía general, visceral y torácica*

Estamos llevando a cabo un estudio para evaluar las posibles ventajas de THUNDERBEAT con datos objetivos. A partir de los datos, podemos afirmar que THUNDERBEAT es seguro y rápido, lo que nos da ventaja en el quirófano gracias a una reducción de tiempo de al menos un 15%. El ahorro de tiempo se debe a una coagulación segura y a un corte rápido de cualquier tejido sin tener que cambiar de instrumento, incluso en caso de disección roma y agarres (mayo de 2014).

*Peiman Poornorozy, Dr., Odense University Hospital, Cirujano jefe, Departamento de cirugía gastrointestinal*

THUNDERBEAT se encarga de toda la disección y el sellado de los principales vasos. Ya no es necesario cambiar de instrumento. THUNDERBEAT es muy rápido y seguro, y produce menos vaho en comparación con el Harmonic (mayo de 2014).

*Peter Razek, Dr., Sozialmedizinisches Zentrum Floridsdorf – Hospital y Centro de Medicina Geriátrica, Cirujano sénior, Departamento de cirugía*

THUNDERBEAT es mejor que otros instrumentos. El sellado es muy seguro y la velocidad del instrumento es impresionante (mayo de 2014).

*Andreas Keerl, Dr., Kantonsspital Baden, Médico jefe, Departamento de cirugía*

Prefiero THUNDERBEAT como instrumento estándar en cirugía colorrectal porque las tecnologías combinadas hacen posible una disección precisa y un sellado de vasos seguro y rápido. Utilizo THUNDERBEAT porque es seguro, fácil de usar y rápido (mayo de 2014).

*Andreas Zerz, Dr., Kantonsspital Baselland, Especialista sénior, Departamento de cirugía*

THUNDERBEAT es seguro y rápido, además del instrumento más versátil (mayo de 2014).

*Prof. Yves van Nieuwenhove, Dr., University Hospital Ghent, Director de hospital, Departamento de cirugía gastrointestinal*

THUNDERBEAT: rápido y seco. THUNDERBEAT: hace posible llevar a cabo una colectomía total sin una sola gota de sangre (mayo de 2014).

Los datos técnicos, diseños y accesorios pueden cambiar sin previo aviso y sin responsabilidad alguna por parte del fabricante.

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