

HARMONIC[®] Portfolio – Fact Sheet

HARMONIC[®] Portfolio

Since 1992, when HARMONIC[®] Technology helped launch the laparoscopic revolution, HARMONIC[®] devices have enabled surgeons to perform their best in over 17 million procedures worldwide.¹ HARMONIC[®] technology is changing open, laparoscopic and robotic surgery by delivering precise ultrasonic energy with minimal thermal injury to the patient, while enhancing surgical efficiency through reduced instrument exchanges. HARMONIC[®] technology is supported by more than 1,000 peer-reviewed clinical articles, more than any other Advanced Energy device.²

Breakthrough in Ultrasonic Technology

Our latest addition to the HARMONIC[®] portfolio, The HARMONIC ACE[®]+7 Shears with Advanced Hemostasis (HARMONIC ACE[®]+7), is the first purely ultrasonic device with a 7 mm vessel sealing indication. HARMONIC ACE[®]+7 combines the precision and multi-functionality expected of HARMONIC[®] with reliable large vessel sealing; a benefit combination that does not exist in any other product.

This breakthrough enhances surgeon choice, as surgeons no longer need to trade off precision and multi-functionality for sealing strength. This unique combination of benefits may also reduce the need for additional devices, such as endoscopic linear cutter reloads, clips or other energy devices required for hemostasis, thus potentially improving the cost per procedure and efficiency.



HARMONIC ACE[®]+7 Shears – Technology Benefits

The HARMONIC ACE[®]+7 is setting a new standard in ultrasonic energy by delivering stronger vessel sealing strength with the Advanced Hemostasis mode. Benchtop testing shows:

- Greater 5 to 7 mm vessel-sealing reliability than LigaSure devices³
- 140% higher median burst pressure vs LigaSure 5 mm Blunt Tip, when sealing 5 to 7 mm vessels in the Advanced Hemostasis mode⁴
- 112% higher median burst pressure vs LigaSure Advance™, when sealing 5 to 7 mm vessels in the Advanced Hemostasis mode⁵

Adaptive Tissue Technology – a platform enabling clinical innovation

Introduced with the HARMONIC ACE[®]+ Shears, Adaptive Tissue Technology actively monitors the instrument during use, enabling the system to sense and respond intelligently to changes in patient tissue conditions. The HARMONIC ACE[®]+7 Shears feature the 2nd generation of Adaptive Tissue Technology, delivering secure and reliable large vessel sealing in addition to the intelligent feedback, enhanced thermal management, and precision of HARMONIC ACE[®]+

- This technology is proprietary and exclusive to the next generation HARMONIC[®] devices
- Delivers greater precision through more intelligent energy delivery

- Provides choice and flexibility to meet a diverse set of clinical needs
- Enables innovation and a future pipeline with even greater functionality and benefits

Adaptive Tissue Technology creates limitless potential and redefines the boundaries of Advanced Energy.

HARMONIC® Technology Advantages

- Jaw and blade are uniquely designed for unmatched precision
- Adaptive Tissue Technology intelligently delivers energy with minimal lateral thermal spread
- Performs multiple jobs including dissection, sealing, transection, andotomy creation, across myriad specialties and procedures
- Precisely-directed mechanical energy: a blade vibrating at 55,500 Hz creates cellular friction, causing amino acids in protein to unwind and hydrogen bonds to break down. The amino acids morph into a new protein shape, forming a sticky coagulum that seals vessels up to and including 5 mm as well as lymphatics (up to 7 mm for HARMONIC ACE®+7).
- Minimal thermal spread: precise cutting with minimal thermal damage allows for safer dissection near vital structures, compared with electrosurgery or lasers⁶
 - Because no current is passed to or through the patient, HARMONIC® instruments do not cause current-induced neuromuscular stimulation
 - Less lateral thermal spread and tissue sticking when compared with electrosurgery⁶
- Efficient: one device to dissect, seal, cut, grasp, spot coagulate and create otomies, increasing procedural efficiency
- Comfort: improves surgeon comfort and ease of use through ergonomic design

Surgical Procedures

Devices in the HARMONIC® portfolio may be preferred for open and laparoscopic procedures that involve sculpting, dissection, sealing, transection, and/or mobilization of tissue. Our portfolio is used across a range of specialties including:

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| • General surgery | • Vascular surgery |
| • Gynecology | • Urology |
| • Colorectal surgery | • Thoracic surgery |
| • Bariatric surgery | • Plastic surgery |
| • ENT surgery | |

HARMONIC® Devices

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| • HARMONIC ACE®+7 Shears with Advanced Hemostasis | • HARMONIC FOCUS® +Curved Shears |
| • HARMONIC ACE®+ Shears | • HARMONIC FOCUS® Long Curved Shears |
| • HARMONIC ACE® Curved Shears | • HARMONIC SYNERGY® Blades |
| | • HARMONIC WAVE® Open Shears |

For more information, please visit: <http://www.ethicon.com/healthcare-professionals/products/energy-devices#!harmonic-portfolio>.

¹ Internal sales data as of June 10, 2013.

² As per a literature search conducted in MEDLINE® and Embase™ between 01/01/1990 and 10/01/2012 that identified publications which specifically discussed a given product within an article. Data on file.

³ In benchtop test on 5-7mm porcine carotids that compared burst pressure failures under 240 mmHg, HARMONIC ACE®+7 (2/152 failures) versus LigaSure™ 5mm Blunt Tip and LigaSure™ Advance (15/154 failures) (P = 0.001) Data on file (PRC064872).

⁴ In benchtop test using 5-7mm porcine carotids that compared median burst pressure for HARMONIC ACE®+7 (1419 mmHg) and LigaSure™ 5mm Blunt Tip (591 mmHg) (p< 0.001). Data on file (PRC064872).

⁵ In benchtop test using 5-7mm porcine carotids that compared median burst pressure for HARMONIC ACE®+7 (1419 mmHg) and LigaSure™ Advance (670 mmHg) (p< 0.001). Data on file (PRC064872).

⁶ Product codes SNGCB, SNGHK, SNGHK2 and FCS9