



October 28, 2013

## **Ethicon Receives 510(K) Clearance For New Harmonic Ace®+ 7 Shears With Advanced Hemostasis**

**Breakthrough technology in ultrasonic energy designed to improve surgeon confidence in vessel sealing, while maintaining the HARMONIC® promise of precision and multi-functionality.**

**Cincinnati, OH** - October 28, 2013 - Redefining the boundaries of ultrasonic energy in surgery, Ethicon Endo-Surgery, Inc. (Ethicon) today announces that HARMONIC ACE®+ 7 Shears with Advanced Hemostasis (HARMONIC ACE® +7) has received 510(k) clearance from the U.S. FDA. The HARMONIC ACE®+ 7 is the first ultrasonic surgical device indicated to seal vessels up to and including 7mm, while also delivering on the HARMONIC® promise of precision and multi-functionality.

The HARMONIC ACE®+ 7 represents the latest evolution in the HARMONIC® legacy of innovation. The device leverages the proprietary Adaptive Tissue Technology, which enables the system to actively sense and adapt to changing tissue conditions and intelligently deliver energy resulting in improved performance with superior precision.

"I use HARMONIC® because it offers me the ability to perform precise dissection that you simply don't get with an advanced bipolar energy device. However, the advanced bipolar energy devices have always been able to seal larger vessels," said Bartley Pickron, MD, Colon and Rectal Surgeon, Colorectal Surgical Associates, Houston, Texas. "The addition of the 7mm vessel sealing capability to the HARMONIC ACE®+ 7 makes it an optimal tool for laparoscopic colon surgery. Previously, I would have to use a HARMONIC ACE® for tissue dissection and then another device, such as stapler, clips, or endoloops, for control of the larger vascular pedicle. The development of the HARMONIC ACE®+7 has the potential for improved operative efficiency by eliminating instrument exchanges during a procedure. Furthermore, the avoidance of using multiple instruments should result in a cost savings for the overall procedure."

HARMONIC ACE®+ 7 is designed for use in numerous procedures and specialties including General, Colorectal, Bariatric, Gynecology, Thoracic and Urology, enhancing surgeons' ability to handle multiple jobs with superior precision. The new HARMONIC ACE®+ 7 is best suited for cases which require dissection, mobilization and large vessel sealing.

"We continue to set the standard for performance in both ultrasonic and advanced bipolar energy." says Tom O'Brien, Ethicon Vice President, Energy Global Strategic Marketing. "The recent introduction of our ENSEAL® G2 Articulating (advanced bipolar) tissue sealer and now the 510(k) clearance of the new HARMONIC ACE®+ 7 both demonstrate our commitment to developing meaningful innovations that can help improve outcomes in critical procedures, while giving surgeons the best choices to meet the needs of their unique patients and procedures."

### **About Our Energy Business**

Ethicon is a leader in advanced energy solutions and offers the broadest portfolio of ultrasonic energy devices using HARMONIC® technology and advanced bipolar energy devices using ENSEAL® technology. [Click here](#) to learn more.

HARMONIC® ultrasonic devices combine precision and multifunctionality: Uniquely designed for precise dissection, sealing and transection, one device enables surgeons to perform multiple jobs without instrument exchanges. HARMONIC® technology is the proven leader in advanced energy with more than 16 million procedures worldwide<sup>1</sup>. Devices in the HARMONIC® portfolio are used for open and laparoscopic procedures that require precision. The portfolio can be used across a range of surgical specialties: General, Colorectal, Bariatric, Vascular, Gynecology, ENT, Urology, Thoracic, and Plastic and Reconstructive. [Click here](#) to learn more.

ENSEAL® Tissue Sealers consistently cut and seal vessels up to and including 7mm through high uniform compression. Devices in the ENSEAL® portfolio are intended for use during both open and laparoscopic surgical procedures where division of vessels, lymphatics and tissue bundles is performed. These surgical specialties include: General, Colorectal, Bariatric, Gynecology, Thoracic, Plastic and Reconstructive, Urology, and ENT. [Click here](#) to learn more.

### **About Our Company**

Ethicon represents the products and services of Ethicon, Inc. and Ethicon Endo-Surgery, Inc., two companies with long histories of medical innovation, which provide globally a broad range of surgical technologies and products (including energy devices, sutures, staplers, clip applicators, trocars and meshes) used to treat colorectal and thoracic conditions, women's health conditions, hernias, cancer and obesity. Ethicon, Inc. and Ethicon Endo-Surgery, Inc. are part of the Johnson & Johnson Family of Companies. [www.ethicon.com](http://www.ethicon.com)

**Contact:**

Bridgett Golden

513-375-9524

[bgolden@its.jnj.com](mailto:bgolden@its.jnj.com)

Ann Leibson

513-479-1210

[aleibso@its.jnj.com](mailto:aleibso@its.jnj.com)

---

<sup>1</sup> Internal sales data as of June 10, 2013.

Dr. Bartley Pickron, MD is a paid consultant for Ethicon.