

The ETHICON HARMONIC™ FOCUS™ device is the most used advanced Energy device in Head & Neck procedures^{1*}



✓ HARMONIC™ FOCUS™ has been **evaluated in more peer reviewed clinical articles** than LigaSure™ Small Jaw.^{2‡}

✓ HARMONIC™ technology, a leader in advanced energy with more than 22 million procedures worldwide.^{3#}

Speed	Hemostasis	Critical structures	Cost savings
Reduce operative time by 31% ^{4‡}	Reduce intra-operative blood loss by 45ml ^{4‡}	In a preclinical model, the use of HARMONIC™ FOCUS™ Shears at 2mm from the sciatic nerve was not statistically different from cold scissors in affecting nerve function. ^{5†}	HARMONIC™ devices can reduce total operative costs by 10% in thyroidectomy when compared to conventional techniques. ^{6§}
31% (p<0.001)	45 ml (p<0.001)	No difference	10% (p=0.007)
vs. conventional methods in thyroidectomy procedures			

¹As per US internal market share data vs. LigaSure™ Small Jaw or LigaSure™ Exact ²As per literature searches for advanced energy devices in Embase/Medline, PubMed, and Google Scholar through May 2021 ³Internal global sales data as of June 2016 ⁴Based on a meta-analysis of HARMONIC™ FOCUS™ (HF) versus clamp, cut and tie, where HF reduced intra-operative blood loss (p<0.001) ⁵In a preclinical rat model that compared cold scissors, HARMONIC™ ACE+, HARMONIC™ FOCUS and monopolar electrosurgery (MES). Incision with cold scissors, HARMONIC™ ACE+ and HARMONIC FOCUS at 2mm from the sciatic nerve were not different via compound action potential (1621, 1519, 1803 mV-ms), conduction velocity (61.8, 62.3, 60.3 mm/ms), depolarization time (229.5, 211.6, 248.1 micro sec), repolarization time (2687, 2435, 2650 micro sec), vForce (20.2, 17.0, 19.1 g), dForce (24.0, 21.4, 27.7 g) and beta-APP (12.6, 18.1, 18.6 % incidence), respectively (p-value for all >0.05). At 2mm from the sciatic nerve, MES resulted in significantly slower conduction velocity (58.5 mm/ms), longer depolarization time (2831 micro sec), longer repolarization time (4150 micro sec) and higher incidence of beta-APP infiltration (31.8 % incidence) than cold scissors (p-value for all <0.05). (Note: p-values are comparison to cold scissors) ⁶From a 2016 systematic review and meta-analysis focusing on the following European countries: Italy, Sweden, Poland, Spain, France. Total operative costs are inclusive of OR time, OR personnel, pre-operative exams, anesthesia time, drugs, length of stay, intra-operative resources, admission/discharge fees, and Harmonic scalpel device costs

References: **1.** Ethicon, 01092020, U.S. Market & Share Insights Report FY2020, Sept 2020, Data on File (201785-220121) **2.** Ethicon, 09052021, Energy Devices Volume of Publications May 2021 - Literature Search Results, May 2021, Data on File (115409-210622) **3.** Ethicon, 01062016, HARMONIC™ and ENSEAL™ Historical Units June 2016, Data on File (118891-190718) **4.** Cheng, A systematic review and meta-analysis of Harmonic Focus in thyroidectomy compared to conventional techniques; Thyroid Research; 2015; 8:15 (115424-210505) **5.** Ethicon, PSp003539, Monitoring Acute and Subacute Effects of Harmonic Shear Devices on Conduction Velocity and Morphology of Sciatic Nerve, Sept 2013, Data on file (120136-190806) **6.** Cheng, Hospital costs associated with thyroidectomy performed with a Harmonic device compared to conventional techniques: a systematic review and meta-analysis. J Med Econ; 2016; 19:8; 750 (118892-210901)

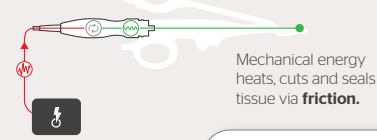
HARMONIC™ FOCUS™+ Shears vs. LigaSure™ Small Jaw and Exact

The delivery of energy is key

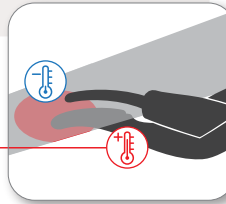
HARMONIC™ FOCUS™+ Shears causes 57% less nerve inflammation compared to LigaSure™ Small Jaw in a preclinical rat model.^{1*}

How HARMONIC™ technology works

Hand piece converts electrical energy to **mechanical energy**.

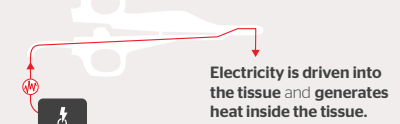


The heat starts in the blade and extends into the tissue, making the **blade hotter** than the tissue.

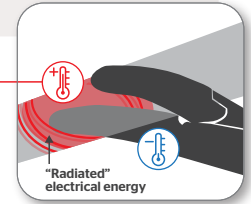


How ABP technology works

Electrical energy passes from active electrode to a return electrode.



The heat generated in the tissue extends to the device, making the **tissue hotter** than the device.



Designed for head and neck surgery

HARMONIC™ FOCUS™+ Shears were designed with a thin profile designed to offer maximum visibility in tight spaces²

HARMONIC™ FOCUS™+ Shears vs. LigaSure™ Exact

■ HARMONIC™ FOCUS™+ ■ LigaSure™ Exact

Active blade width



The distal end/tip of the active blade of the HARMONIC™ FOCUS+ is **37% thinner** than LigaSure™ Exact.^{3†}

Clamp arm width



HARMONIC™ FOCUS+ has a **10% thinner** distal clamp arm compared to LigaSure™ Exact.^{3††}

Jaw height



22% thinner/shorter overall jaw height at the distal end vs LigaSure™ Exact.^{3‡}

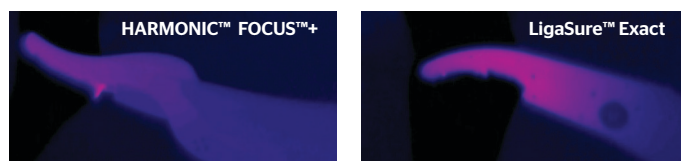
Jaw aperture



98% wider jaw aperture than LigaSure™ Exact.^{3‡‡}

The power of Adaptive Tissue Technology's thermal management

Adaptive Tissue Technology enables lower temperature at the blade^{4§}



Comparison of the 20th consecutive transection on porcine jejunum.



The clamp arm of the HARMONIC™ FOCUS™+ Shears with Adaptive Tissue Technology is **no hotter** than the LigaSure™ Small Jaw™ during transection.^{5#}

For more information, contact your local Ethicon sales professional or go to www.jnjmedicaldevices.com

*As exhibited in a preclinical rat model when activating 2mm away from the sciatic nerve. Inflammatory cell presence measured via H&E staining - 9.2% (HAR9F) vs. 21.4% (S.J.), p=0.005 (PSP003838)
 †Metrology study comparing the width of the distal end of the active blade for Harmonic™ FOCUS+ vs LigaSure™ Exact (1.3716mm vs 2.193mm) ††Metrology study comparing the width of the clamp arm at the distal end for Harmonic™ FOCUS+ and LigaSure™ Exact (1.9812mm vs 2.193mm) ‡Metrology study comparing distal jaw height of Harmonic™ FOCUS+ vs LigaSure™ Exact (2.8194mm vs 3.615mm)
 ‡‡Metrology study comparing the jaw aperture of Harmonic™ FOCUS+ vs LigaSure™ Exact (23.368mm vs 11.830mm) §vs. HARMONIC™ ACE™ without Adaptive Tissue Technology #As exhibited in a bench top transection study on porcine jejunum using an IR camera (p=0.415)

References: 1. Ethicon, PSP003838A, Wayne State Electrophysiological Study Statistical Analysis Results, March 2014, Data on file (118893190718) 2. Ethicon, PRC035138A, Focus FCS17 Customer Validation, June 2009, Data on File (119303190724) 3. Ethicon, PRC087304B, HAR9F Dimensional Comparison, Dec 2018, Data on File (118895190718, 118896190718, 118897190718, 118898190718) 4. Ethicon, PRC053965, HAR36/23 DV- ROIN 6175- Blade Heat, Feb 2012, Data on File (125296191010) 5. Ethicon, PRC065892A, Nighthawk Claims Jaw and Clamp Arm Temperature, March 2014, Data on File (123479190916)

Please refer always to the Instructions for Use / Package Insert that come with the device for the most current and complete instructions.

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