Harmonic®

Proven clinical and economic outcomes
from the industry leader in head and neck

- HARMONIC FOCUS® technology has been **evaluated in more peer-reviewed clinical articles** than LigaSure™ Small Jaw and LigaSure™ Exact combined[2]
- Over **22M** HARMONIC® **procedures performed worldwide**.[3]

Enables precise energy delivery, efficiency and superior clinical outcomes[1]

Speed	Hemostasis	Critical structures	Cost savings
Reduced total operative time by 31%[4]	Reduced intraoperative blood loss by 45ml[4]	Same nerve function following use at 2mm from sciatic nerve[5]	Reduced total operative costs by 10%[6]
31% (p<0.001)	**45ml** (p<0.001)	**No difference**	**10%** (p=0.007)

vs. conventional methods in thyroidectomy procedures

1 Based on a meta-analysis of HARMONIC FOCUS® (HF) versus clamp, cut and tie, where HF reduced OR time, intra-operative blood loss, length of stay and drainage volume (all p≤0.01). Cheng et al., A systematic review and meta-analysis of Harmonic Focus in thyroidectomy compared to conventional techniques. Thyroid Research (2015) 8:15 **2** As per a literature search conducted by Ethicon in Scopus between 01/01/2008 and 05/11/2016 **3** Internal global sales data as of June 2016 **4** Based on a meta-analysis of HARMONIC FOCUS® (HF) versus clamp, cut and tie, where HF reduced operative time (p<0.001) and intra-operative blood loss (p<0.001). Cheng et al., A systematic review and meta-analysis of Harmonic Focus in thyroidectomy compared to conventional techniques. Thyroid Research (2015) 8:15. **5** In 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 secs), repolarization time (2687, 2435, 2650 micro secs), 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 (283.1 micro secs), longer repolarization time (4150 micro secs) 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) **6** Cheng H et al., Hospital costs associated with thyroidectomy performed with a Harmonic device compared to conventional techniques: a systematic review and meta-analysis. J Med Econ. 2016 Apr 5:1-9. [Epub ahead of print]

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Shaping the future of surgery

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

The delivery of energy is key

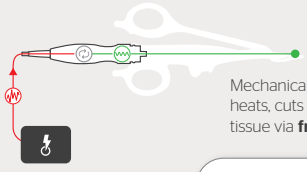
The effects of "radiated" electrical energy when activated 2mm from a nerve

Compared to Ligasure™ Small Jaw, in a preclinical rat model HARMONIC FOCUS®+ Shears exhibited:

- **57% less nerve inflammation**[1]
- **50% less nerve damage**[2]

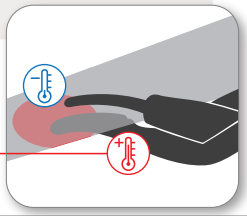
How HARMONIC® technology works

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



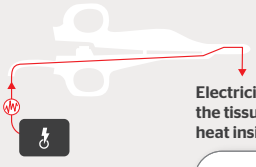
Mechanical energy heats, cuts and seals tissue via **friction.**

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



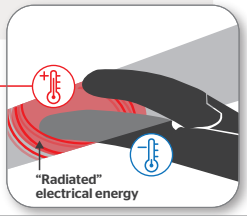
How ABP technology works

Electrical energy passes from active electrode to a return electrode.



Electricity is driven into the tissue and **generates heat inside the tissue.**

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 small profile to provide **precise dissection** and **delivery of energy in tight spaces**

HARMONIC FOCUS®+ Shears vs. LigaSure™ Exact

HARMONIC FOCUS®+ | LigaSure™ Exact

Active blade width

37% narrower[3] active blade at the distal tip

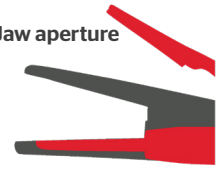
Clamp arm width

10% thinner[4] clamp arm at the distal tip

Jaw height

22% smaller[5] jaw height at the distal tip

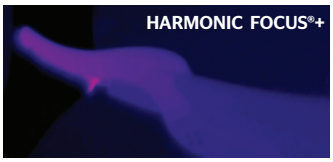
Jaw aperture



98% greater[6] jaw aperture

The power of Adaptive Tissue Technology's thermal management

Adaptive Tissue Technology enables more precise energy delivery and **improved temperature management**[7]



Comparison of the 20th consecutive transection on porcine jejunum.

No significant difference in clamp arm temperature between HARMONIC FOCUS®+ and LigaSure™ Exact.[8]

For more information, contact your local Ethicon Surgical Product Specialist.

1 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% (SJ), p=0.005 **2** As exhibited in a preclinical rat model when activating 2mm away from the sciatic nerve. Mean nerve damage assessed as axonal transport impairment: 12.2% (HAR9F) vs. 24.3% (SJ), p<0.001 **3** Metrology study comparing the width of the distal end of the active blade for HARMONIC FOCUS®+ vs LigaSure™ Exact (1.37mm vs 2.19mm). **4** Metrology study comparing the width of the clamp arm at the distal end for HARMONIC FOCUS®+ and LigaSure™ Exact (1.98mm vs 2.19mm). **5** Metrology study comparing distal jaw height of HARMONIC FOCUS®+ vs LigaSure™ Exact (2.82mm vs 3.62mm). **6** Metrology study comparing the jaw aperture of HARMONIC FOCUS®+ vs LigaSure™ Exact (23.4mm vs 11.8mm). **7** vs. HARMONIC ACE® without Adaptive Tissue Technology **8** Benchtop thermal testing comparing HARMONIC FOCUS®+ and LigaSure™ Exact. No statistically significant difference existed (95% confidence interval for difference in median clamp arm temperature: -5.0 to 1.0 C°).

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For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

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