Harmonic<sup>™</sup>

# Value Analysis Summary

Harmonic 1100

## HARMONIC<sup>™</sup> 1100 Shears

**Ethicon Energy Solutions. Healing first.** 

**ETHICON** PART OF THE Johnson Johnson FAMILY OF COMPANIES Shaping the future of surgery At Ethicon we understand that surgeons, nurses, and administrators are aiming to deliver...

## POSITIVE SURGICAL OUTCOMES

while...

## IMPROVING EFFICENCY, OR SAFETY, AND REDUCING COSTS.



Surgical burdens increase complications which can **increase cost by up to five times**<sup>1\*</sup>

Our focus for Ethicon Energy Solutions is on addressing surgical burdens including:

- ✓ Bleeding
- Length and cost of operative time
- ✓ Safety for patients and OR team

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PART OF THE Johnson - Johnson FAMILY OF COMPANIES Shaping the future of surgery \* In a study evaluating 1,200 consecutive patients undergoing major surgery, patients without complications had mean in-hospital costs per case of \$27,946 while patients with grade IV complications had mean in-hospital costs per case of \$159,345. Based in a US setting.
 1. Vonlanthen R, et al. The impact of complications on costs of major surgical procedures: a cost analysis of 1200 patients. Ann Surg., 2011;254(6)



## ETHICON ENERGY SOLUTIONS

# Healing comes first for health care providers

That's why Ethicon Energy is dedicated to delivering energy solutions for surgeons to help patients heal faster and protect the OR team from risks.

## Less invasive energy



Ethicon Energy may help reduce surgical burdens through optimized energy delivery which may cause less tissue damage.<sup>25-31±</sup>

Right energy product for the right job



The most comprehensive portfolio of Intelligent Energy Solutions.<sup>\*</sup> Surgeon's have the right tools for the right energy job in a particular procedure.

## Enhance OR safety and efficiency



**Work** with OR staff to provide the training and education they need for optimal product use and help improve OR safety and efficiency.

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±Based on preclinical studies of Adaptive Tissue Technology

\*Upon review of 2017 product catalogs and websites (Advanced Energy, Core Energy, Surgical Smoke Evacuation) for the respective manufacturers: Medtronic, Olympus, Intuitive Surgical, Conmed (121066-191128)

# HARMONIC<sup>™</sup> 1100 Shears

## Executive overview

Designed for open and laparoscopic procedures, the HARMONIC<sup>™</sup> 1100 Shears provides:

#### Fast Transection<sup>1-5\*</sup>

- Had transection speeds statistically faster than
   HARMONIC<sup>™</sup> ACE+7 for shorter tissue exposure<sup>1-3,6,7¥</sup>
- Cuts 29.6% longer than HARMONIC<sup>™</sup> ACE<sup>™</sup>+7<sup>3,8≠</sup>

#### **Precise Dissection**<sup>1-5\*</sup>

- With a unique blade design, HARMONIC<sup>™</sup> 1100 shears delivered secure seals<sup>10-12^</sup>
- Curved, tapered tip has enabled more precise dissection than HARMONIC<sup>™</sup> ACE+7<sup>3,5,9≤±</sup>

#### Improved Temperature Control<sup>4</sup>

- Improved Adaptive Tissue Technology that actively controls blade heat for lower maximum blade temperature  $^{4\delta}$ 



\*Compared to HARMONIC<sup>™</sup> ACE+7 Shears as demonstrated in engineering and pre-clinical studies ¥Based on bench top study with porcine vessels 3-5 mm in diameter ≠Device measurements based on a metrology study (median cut length of 18.87mm vs. 14.56mm) ≤Based on a Pre Clinical evaluation ±Compared to HARMONIC<sup>™</sup> ACE+7 ABased on a benchtop study with 5-7mm porcine carotid arteries. (Burst pressure:1878 mmHg) δCompared to previous generations of HARMONIC<sup>™</sup> devices

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### HARMONIC<sup>™</sup> 1100 Shears

# **Executive overview**

The HARMONIC<sup>™</sup> 1100 Shears is designed to deliver fast transection speeds, low maximum blade temperature & precise dissection capabilities.<sup>1-5\*</sup> This latest HARMONIC<sup>™</sup> replaces HARMONIC<sup>™</sup> HD 1000i Shears.

#### Has an improved **CURVED, TAPERED TIP** Adaptive Tissue · Has enabled more precise dissection than Technology algorithm HARMONIC<sup>™</sup> ACE<sup>™</sup>+7 Shears with Advanced · Has an integrated transducer that actively controls Hemostasis<sup>3.5.9\*</sup> that provides consistent blade heat to lower the . The improved dissection capability of the fine jaw performance and simplified maximum blade design may allow for precise dissection similar to device set $up^{17\pi}$ temperature of the that of a mechanical dissector<sup>3,13,14¥</sup> device<sup>4≤</sup> ETHICON Harmonic 1100 With a UNIQUE BLADE DESIGN SINGLE ENERGY BUTTON HARMONIC<sup>™</sup> 1100 shears delivered HARMONIC<sup>™</sup> 1100 Shears Energy **ADVANCED** secure seals<sup>3.10.11≤</sup> button offers reliable seals on **HEMOSTASIS MODE** vessels 3-5 mm in diameter and · Had transection speeds statistically faster · Is indicated for vessels up to than HARMONIC<sup>™</sup> ACE+7<sup>1-3,6,7±</sup> faster than the MIN button on the and including 7mm diameter HARMONIC<sup>™</sup> ACE<sup>™</sup>+7<sup>.2,3,7,11,16µ</sup> Longest ultrasonic blade on the market to using the Energy with capture large vessels and tissue bundles Advanced Hemostasis prior to transection<sup>3,8,15^</sup> button<sup>17</sup>

\*Compared to HARMONIC<sup>TM</sup> ACE+7 Shears as demonstrated in engineering and pre-clinical studies ¥In a pre-clinical study, for both iliac dissection and lymph node dissection, the device showed improvements compared to HARMONIC ACE T+7 Shears in dissecting capability (p<0.001 in all cases) ≤Based on a benchtop study with 5-7mm porcine carotid arteries. (Burst pressure:1878 mmHg) ±Based on bench top study with porcine vessels 3-5 mm in diameter ^Device measurements based on a metrology study (median cut length 18.87mm vs. 14.80mm for Sonicision<sup>TM</sup> and 16.90mm for Thunderbeat) µIn a benchtop study, versus HARMONIC<sup>TM</sup> ACE<sup>TM</sup>+7, with porcine vessels 3-5 mm in diameter (p<0.001) and median transection time was 4.095 seconds ≤Compared to previous generations of HARMONIC<sup>TM</sup> devices  $\pi$ Compared to HARMONIC ACE+7

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# HARMONIC<sup>™</sup> 1100 Shears Product overview



\*Compared to HARMONIC<sup>TM</sup> ACE+7 Shears as demonstrated in engineering and pre-clinical studies ¥Based on benchtop testing, tip-bite includes the distal 5mm of the device tested on porcine jejunum and mesentery (p<0.001) ≠Seal reliability at 240 mm Hg of 98.2% vs. 98.4% for HARMONIC<sup>TM</sup> ACE<sup>TM</sup>+7 MIN button. Speed based on average time to transect 150mm of porcine jejunum (p>0.001) ≤Based on bench top study with porcine vessels 3-5 mm in diameter

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# HARMONIC<sup>™</sup> 1100 Shears Product overview

Fast transection<sup>1-5\*</sup>

+

Improved Temperature Control<sup>1-5\*</sup>

Precise dissection<sup>1-5\*</sup>

## Smart Energy Delivery4¥

 Maintains blade temperature when prolonged activation is required<sup>4</sup>

 Had improved tissue pad life compared to HARMONIC<sup>™</sup> HD 1000i Shears<sup>21,22≠</sup> HARMONIC<sup>™</sup> 1100 Shears had lower maximum blade temperature than HARMONIC<sup>™</sup> ACE<sup>™</sup>+7 Shears<sup>4≤</sup> and HARMONIC<sup>™</sup> HD 1000i Shears<sup>4^</sup>



\*Compared to HARMONIC<sup>TM</sup> ACE+7 Shears as demonstrated in engineering and pre-clinical studies ¥Compared to previous generations of HARMONIC<sup>TM</sup> devices ≠Based on testing at Power Level 5 ≤Based on benchtop study that showed Harmonic 1100 had significantly lower maximum blade temperature than HARMONIC<sup>TM</sup> ACE+7 Shears after 15 tip bite transections. ABased on benchtop study that showed HARMONIC<sup>TM</sup> 1100 had significantly lower maximum blade temperature than HARMONIC<sup>TM</sup> ACE+7 Shears after 15 tip bite transections. Based on benchtop study that showed HARMONIC<sup>TM</sup> 1100 had significantly lower maximum blade temperature than HARMONIC<sup>TM</sup> ACE+7 Shears after 15 tip bite transections.

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## HARMONIC<sup>™</sup> 1100 Shears Product overview

Fast transection<sup>1-5\*</sup>

+

Improved temperature control<sup>1-5\*</sup>

#### Precise dissection<sup>1-5\*</sup>

Curved, tapered tip has enabled more precise dissection than HARMONIC<sup>™</sup> ACE+7<sup>3,5,9¥</sup>



The unique shape mimics a mechanical dissector and may reduce the need to use a separate dedicated dissecting instrument according to 79% of surgeons surveyed<sup>5,14,23≠</sup>

\*Compared to HARMONIC<sup>TM</sup> ACE+7 Shears as demonstrated in engineering and pre-clinical studies ¥Based on a Pre-Clinical evaluation ≠Based on a pre-clinical study of both iliac dissection and lymph node dissection, and a Design Validation Study with surgeons in an animate porcine laboratory model where 79% (26 out of 31) of surgeons indicated that they believed Harmonic<sup>TM</sup> HD1000i would reduce instrument exchanges

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### The complete HARMONIC<sup>™</sup> portfolio

# Devices that build on the performance and precision of previous generations



	HARMONIC™ ACE+7	HARMONIC™ 1100
Strong sealing <sup>17</sup>	•	•
Fast transection <sup>1-5*</sup>		•
Improved temperature control <sup>1-5*</sup>		٠

#### Based on HARMONIC<sup>™</sup> HD 1000i Platform

HARMONIC<sup>™</sup> 1100 Shears has a next generation Adaptive Tissue Technology algorithm that actively controls blade heat to lower the maximum blade temperature of the device<sup>4^</sup>

#### Strong vessel sealing

For vessels up to and including 7mm diameter using the Energy with Advanced Hemostasis button<sup>3,4,10≥≤</sup>

#### Adaptive Tissue Technology

Power modulation reduces delivery of unnecessary energy, enabling more precise energy application<sup>24±</sup>

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\*Compared to HARMONIC<sup>TM</sup> ACE+7 Shears as demonstrated in engineering and pre-clinical study with surgeons in #Based on a pre-clinical study of both iliac dissection and lymph node dissection, and a Design Validation Study with surgeons in an animate porcine laboratory model where 79% (26 out of 31) of surgeons indicated that they believed Harmonic<sup>™</sup> HD1000i would reduce instrument exchanges ^Compared to previous generations of HARMONIC<sup>™</sup> devices ≥Based on a benchtop study with 5-7mm porcine carotid arteries, achieved burst pressure of 1878 mmHg ≤ Based on a benchtop study with 5-7mm porcine carotid arteries, achieved burst pressure of 1697 mmHg ± Based on preclinical studies, HARMONIC<sup>™</sup> ACE<sup>™</sup> with Adaptive Tissue Technology (Power Drop and Tones) demonstrated decreased activation times and thermal damage vs. HARMONIC™ ACE™ without Adaptive Tissue Technology

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## HARMONIC<sup>™</sup> 1100 Shears Ordering information

### **Customer Support**

Please contact your local Ethicon Sales Representative or visit www.jnjmedicaldevices.com

**Ordering information** 

PRODUCT CODES	DESCRIPTION	QUANTITY/SALES UNIT
HAR1120	HARMONIC™ 1100 Shears, 20 cm length	6
HAR1136	HARMONIC™ 1100 Shears, 36 cm length	6

HARMONIC<sup>™</sup> 1100 Shears is supplied sterile for single-patient use. It is designed for use exclusively with the Generator G11 (GEN11) software version 2018-1 or later.

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#### HARMONIC<sup>™</sup> 1100 Shears

1. Ethicon, PRC74432B, Buccaneer Energy Button Vessel Claims, April 2016, Data on File (176074-210823, 173359-210705)

2. Ethicon, PRC094080B, Scarlet DV- Vessel Transection Speed (and Burst Pressure), March 2020, Data on File (176074-210823, 173359-210705, 133325-210521, 117220-210514)

3. Ethicon, SCN075090A, Scarlet Witch Physical Equivalence memo, April 2020, Data on File (176074-210823, 173359-210705, 133333-210511, 173360-210409, 118723-210720, 118720-210514, 133325-210521, 118457-210629, 117220-210514, 177627-210521)

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4. Ethicon, PRC095370C, Project Scarlet: Blade Temperature, May 2020, Data on File (176074-210823, 176071-210705, 173361-210409, 173358-210409, 177627-210521)

5. Ethicon, PSP004888A, HARMONIC<sup>TM</sup> HD 1000i Open Shears (HARHD20) and HARMONIC<sup>TM</sup> HD, 1000i Laparoscopic Shears (HARHD36): Design Verification Acute Study in the Pig, March 2016, Data on File (176074-210823, 173360-210409, 118653-190715)

6. Ethicon, PRC092654A, Buccaneer Harmonic Burst Pressure Investigation, Nov 2019, Data on File (173359-210705, 117220-210514)

7. Ethicon, PRC051292A, Vic - transection time evaluation with surgeons, June 2011, Data on File (173359-210705, 133325-210521, 118457-210629)

8. Ethicon, PRC074607A, Buccaneer Metrology Claims, March 2016, Data on File (133333-210511, 176839-210514)

9. Welling AL et al, Superior dissecting capability of a new ultrasonic device improves efficiency and reduces adhesion formation, Glob Surg. 2017;3(1):1-5 (173360-210409)

10. Ethicon, PRC074054A, Buccaneer Thermal Spread And Burst Claims, Feb 2016, Data on File (118720-210705, 177627-210521)

11. Ethicon, PSB004423A, Project Buccaneer HARMONIC® HD 1000i Laparoscopic Shears (HARHD36): Design Verification Chronic (30 day) Survival Study in the Pig, march 2016, Data on File (118720-210705, 133325-210521)

12. Ethicon, SCN075090A, Scarlet Witch Physical Equivalence, April 2020, Data on File (118720-210705)

13. Ethicon, PSB004399A, Project Buccaneer HARMONIC<sup>M</sup> HD1000i Open Shears (HARHD20) and HARMONIC<sup>M</sup> HD1000i Laparoscopic Shears (HARHD36): Design Verification Acute Study in the Pig, March 2016, Data on File (118723-210720)

14. Ethicon, 03082016, Harmonic 1000i Competitive Overlays, Aug 2016, Data on File (118723-210720, 118653-190715

15. Ethicon, PSP004867A, Project Buccaneer HARMONIC® HD 1000i Laparoscopic Shears (HARHD36): Design Verification Chronic (30 day) Survival Study in the Pig, March 2016, Data on File (176839-210514)

16. Ethicon, PRC092654A, Buccaneer Harmonic Burst Pressure Investigation, Nov 2019, Data on File (133325-210521)

17. As Per Instructions For Use (177628-210521, 139256-210507)

18. Ethicon, PRC074127B, Buccaneer DV Transection Speed – Marching And Tip Bite, March 2016, Data on File (118457-210629, 117220-210514)

19. Ethicon, PRC094084B, Project Scarlet – Marching Transection Speed (Full & Tip), March 2020, Data on File (118457-210629, 117220-210514)

20. Ethicon, PRC074432A, Buccaneer Energy Button Vessel Claims, April 2016, Data on File

21. Ethicon, PRC093983B, Scarlet 510k and Design Verification - Pad Life, March 2020, Data on File (176081-210705)

22. Ethicon, DR000290S, Quality Record, June 2018, Data on File (176081-210705)

23. Ethicon, DOC021988A, Design Validation Marketing Questions, May 2016, Data on File (118653-190715)

24. Ethicon, PSP005693A, Memorandum: HAR & ACE Size and Adaptive Tissue Technology Comparison Intra-operative and Histopathology, June 2017, Data on File (126027-191022)

25. Ethicon, 16022012, HAR & ACE Size and Adaptive Tissue technology Comparison Intra-operative and Histopathology memo, Feb 2012, Data on File (179359-210609)

26. Ethicon, PCS0000215, Harmonic \* HARH36 and HARH23 Shears: Acute 5-7mm Vessel Study in the Goat – Performance and Lateral Thermal Damage, March 2015, Data on File (179359-210609)

27. Ethicon, PSP003620A, Project Q/MAC – HARH36: Verification Acute Study in the Goat, April 2014, Data on File (179359-210609)

28. Ethicon, PSP0003910A, Q/MAC vs LigaSure Thermal Damage Statistical Analysis, April 2014, Data on File (179359-210609)

29. Ethicon, PSP004469A, Lateral Thermal Damage of HARMONIC ACE® Shears HARH36 vs LigaSure<sup>™</sup> 5mm Blunt Tip LF1637, and THUNDERBEAT 5mm TB-0535FC, May 2015, Data on File (179359-210609)

30. Ethicon, PSP004502B, Thermal Footprint Statistical Analysis, June 2015, Data on File (179359-210609)

31. Ethicon, 500645881, ENSEAL<sup>™</sup> X1 Adaptive Tissue Technology, Feb 2021, Data on File (179359-210609)

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