HARMONIC® HD 1000i Shears:

The product behind the **“Wow”**

Learn more inside ▸

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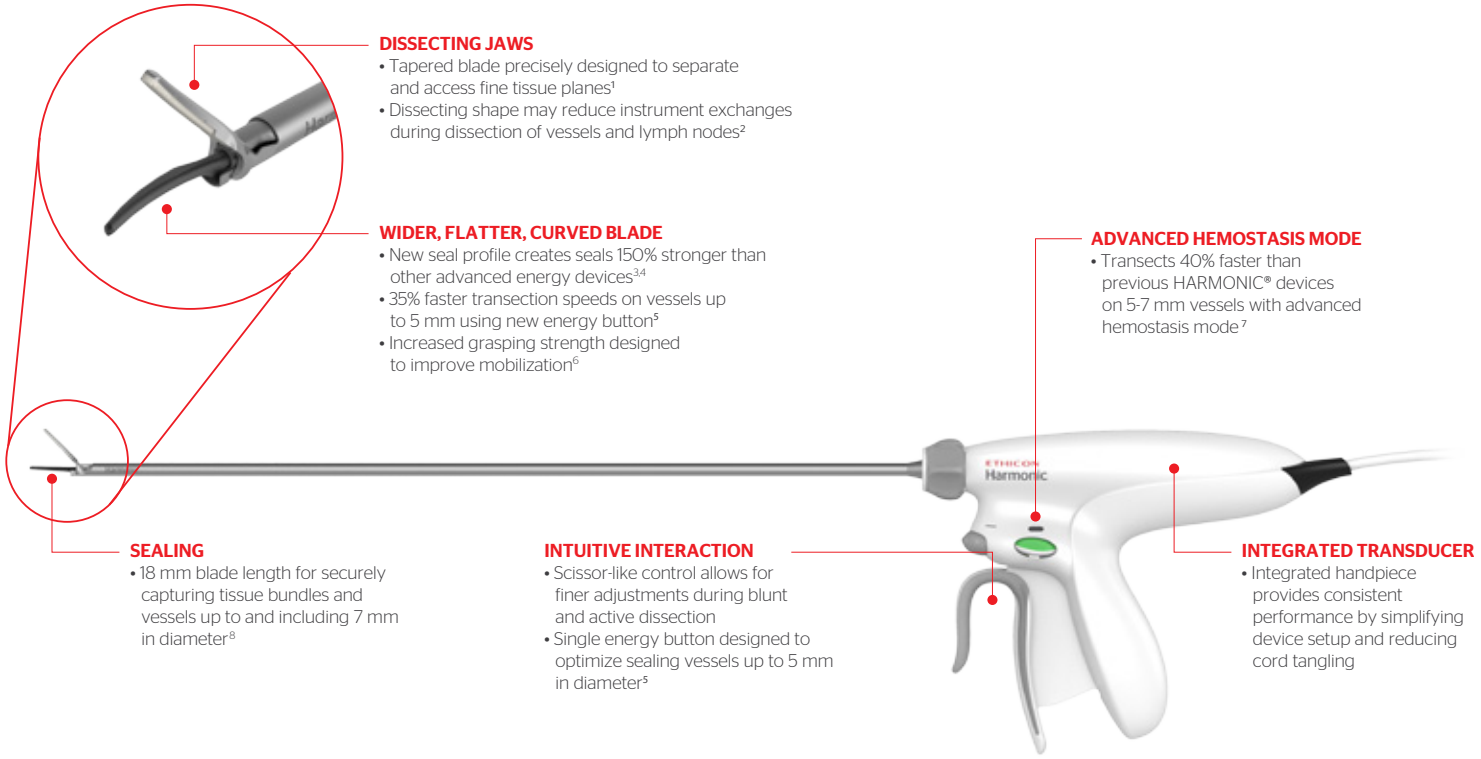
Shaping the future of surgery

Harmonic®

Introducing the new HARMONIC® HD 1000i

Unprecedented clinical performance and usability in a single device

Designed to address unique challenges in complex open and laparoscopic procedures, the HARMONIC® HD 1000i offers a seamless combination of precision and strength for improved dissection, faster transection, and more secure sealing.



[1] In a pre-clinical study, for both iliac dissection and lymph node dissection, the HD 1000i was significantly superior to ACE®+7 in dissecting capability (p<0.001 in all cases). #051950-160425
[2] In a design validation study with surgeons (n=33) operating in simulated procedures in an animate porcine laboratory model (26/33) #053344-160516
[3] In a benchtop study with 5-7 mm porcine carotid arteries that compared median burst pressure, HARMONIC® HD 1000i (1878 mmHg) vs. LigaSure Impact™ (1224 mmHg) (p<0.0001). #049305-160315
[4] In a benchtop study with 5-7mm porcine carotid arteries that compared median burst pressure, HARMONIC® HD 1000i (1878 mmHg) vs. LigaSure™ Maryland (1171 mmHg) (p<0.0001). #049315-160315
[5] In a benchtop study with porcine vessels 3-5 mm in diameter (p=0.0000). #050521-160401
[6] Based on average device tip grasping force (distal 5mm of the jaw). #050295-160329
[7] In a porcine study comparing sealing times of HARMONIC ACE®+7 and HARMONIC® HD 1000i. HARMONIC® HD 1000i Shears transected vessels faster than HARMONIC ACE®+7 (mean vessel transection time of 9.186 vs 15.291). #051753-160420
[8] Device measurements based on a metrology study (median cut length 18.87 mm vs. 14.80 mm for Sonicision™ and 16.90 mm for THUNDERBEAT).
In a pre-clinical study, 100% (54/54) of porcine blood vessels, up to and including 7 mm vessels, remained hemostatic over a 30 day survival period." #050340-160330

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HARMONIC® HD 1000i: A step forward in the evolution of HARMONIC® advanced energy devices

Unmatched precision + **Unparalleled strength** + **Optimal efficiency**

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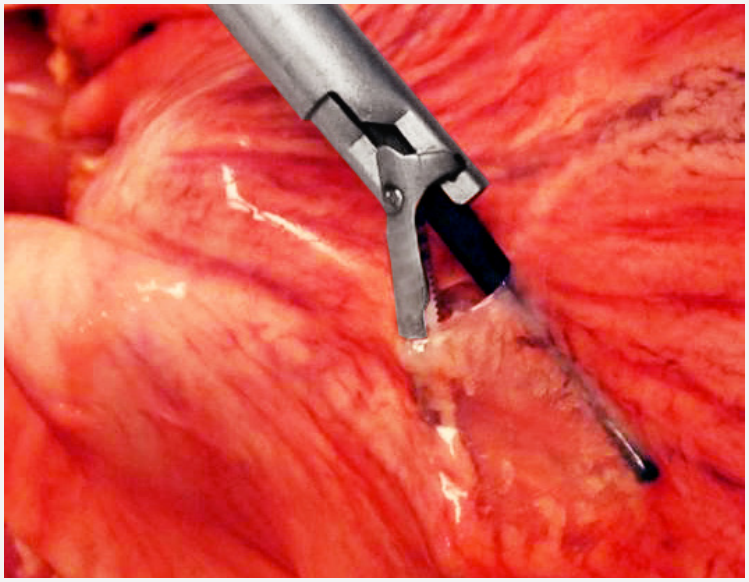
Unique shape mimics a mechanical dissector[1], reducing the need to use a separate dedicated dissecting instrument[2]

More tapered jaw designed to enable more precise access to tissue planes[3]



Curved, tapered blade geometry mirrors a mechanical dissector[3], delivering superior dissection among advanced energy devices

HARMONIC® HD 1000i vs ENDOPATH Maryland Dissector

Jaws Closed: Side | Jaws Closed: Top | Jaws Closed: Front

HARMONIC® HD 1000i | ENDOPATH Maryland Dissector

[1] Design Validation Study with surgeons (n=33) operating in simulated procedures in an animate porcine laboratory model. #051950-160425
[2] In a design validation study with surgeons (n=33) operating in simulated procedures in an animate porcine laboratory model (26/33) #053344-160516
[3] In a pre-clinical study, for both iliac dissection and lymph node dissection, the HD 1000i was significantly superior to the predicate devices in dissecting capability (p<0.001 in all cases). #051950-160425

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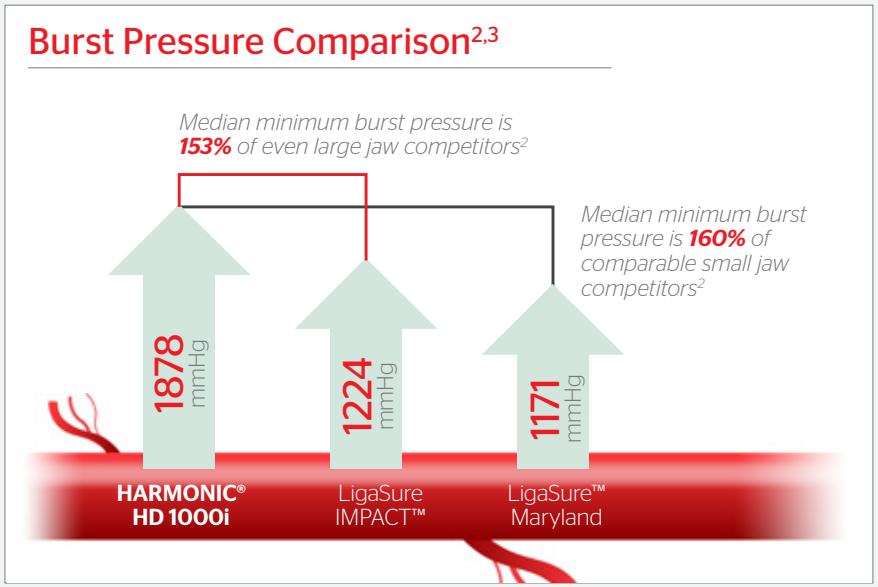
Unmatched precision + **Unparalleled strength** + Optimal efficiency

Unique blade design delivers more secure seals, even in the most challenging conditions

Produces consistent and reliable hemostasis[1] which has been shown in challenging hemostasis conditions.

Exceptional sealing strength as evidenced by burst pressures of 150% relative to both small *and* large jaw devices[2,3]



[1] In a pre-clinical study, 100% (56/56) of porcine blood vessels remained hemostatic over a 30-day survival period. #049339-160315
[2] In a benchtop study with 5-7 mm porcine carotid arteries that compared median burst pressure, HARMONIC® HD 1000i (1878 mmHg) vs. LigaSure Impact™ (1224 mmHg) ($p<0.0001$). #049305-160315.
[3] In a benchtop study with 5-7 mm porcine carotid arteries that compared median burst pressure, HARMONIC® HD 1000i (1878 mmHg) vs. LigaSure™ Maryland (1171 mmHg) ($p<0.0001$). #049315-160315

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HARMONIC® HD 1000i: A step forward in the evolution of HARMONIC® advanced energy devices

Unmatched precision + Unparalleled strength + **Optimal efficiency**

Increased sealing speed, multi-functionality, and simplified steps for use allow for optimal efficiency[1,2,3]

Simple energy activation utilizing a single energy button

- Provides the reliable sealing of the HARMONIC® MIN button with faster cutting than HARMONIC® MAX button for vessels up to 5 mm in diameter[4]

- Longer cut length[5]
- Strong tip grasping is designed to minimize tissue slippage and may aid in tissue manipulation and control[6]

- Indicated for vessels up to and including 7 mm diameter
- 40% faster sealing using the Energy with Advanced Hemostasis button, compared to previous generations of HARMONIC®[1]

New integrated transducer drives performance and efficiency

- Drives clinical performance, and eliminates the need to order, manage, or clean a separate item

[1] In a porcine study comparing sealing times of HARMONIC ACE®+7 and HARMONIC® HD 1000i, HARMONIC® HD 1000i Shears transected vessels faster than HARMONIC ACE®+7 (mean vessel transection time of 9.186 vs 15.291). #051753-160420
[2] In a design validation study with surgeons (n=33) operating in simulated procedures in an animate porcine laboratory model (26/33) #053344-160515
[3] Design Validation Study with surgeons (n=33) operating in simulated procedures in an animate porcine laboratory model (33/33) #053346-160516
[4] Seal reliability at 240 mmHg of 98.2% vs. 98.4% for HARMONIC ACE®+7 MIN button. Speed based on average time to transect 150 mm of porcine jejunum (p=0.0000). #050508-160401
[5] Device measurements based on a metrology study (median cut length of 18.87 mm vs. 14.56 mm). #050283-160329
[6] Based on average device tip grasping force (distal 5 mm of the jaw). #050295-160329

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Ideal for use in a variety of surgically complex procedures

The distinct performance features of the HARMONIC® HD 1000i are particularly well-suited for a number of surgical settings.

Hepato-pancreato-biliary

HARMONIC® technology allows for less intraoperative blood loss and fewer surgical complications in liver surgery.*

GYN Oncology and Lymphadenectomy

HARMONIC® HD 1000i may be used in GYN oncology procedures including hysterectomy and to dissect lymph nodes in procedures such as lymphadenectomy.

Colorectal

The longer, more tapered blade design and dissection capabilities of the HARMONIC® HD 1000i may provide visibility and access in the pelvis in colorectal procedures.

Thoracic

Jaw design, device ergonomics, and modulated energy delivery of Adaptive Tissue Technology enable the HARMONIC® technology to be used in thoracic procedures to dissect lymph nodes, seal lymphatic ducts, and seal vessels with diameters of less than 7 mm.

* vs. Pringle Maneuver in a prospective randomized controlled trial comparing Pringle Maneuver (n=80) vs. liver resection with Harmonic scalpel (n=80). Hanyong S et al. A prospective randomized controlled trial: comparison of two different methods of hepatectomy. EJSO 2015; 41:243-248. 051294-160413

The complete HARMONIC® portfolio

Devices that build on the performance and precision of previous generations

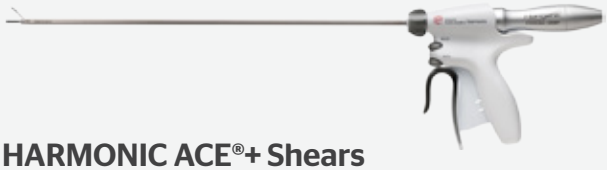
HARMONIC® HD 1000i

- ✓ HD 1000i Platform
- ✓ Advanced Hemostasis
- ✓ Adaptive Tissue Technology

HARMONIC ACE®+7 Shears

- ✓ Advanced Hemostasis
- ✓ Adaptive Tissue Technology

HARMONIC ACE®+ Shears



HARMONIC FOCUS®+ Shears

- ✓ Adaptive Tissue Technology

HD 1000i Platform

Blade designed for unprecedented precision, seal strength, and efficiency—all powered by an integrated transducer

Advanced Hemostasis

Modulated energy provides strong and secure sealing in all vessel sizes up to 7 mm in diameter

Adaptive Tissue Technology

System enables surgical precision by delivering energy intelligently

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Ordering information

All HARMONIC® HD 1000i purchase orders are made to Johnson & Johnson Healthcare Care Systems, Inc. (JJHCS).

PRODUCT CODES	DESCRIPTION	QUANTITY/SALES UNIT
HARHD20, HARHD36	HARMONIC® HD 1000i	6

HARMONIC® HD 1000i is supplied sterile for single-patient use. It is compatible with the existing Ethicon Generator G11 (software version 2016-1 or later versions).

For more information or product support, contact your Ethicon Sales Representative or visit www.ethicon.com.

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

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22851 Norderstedt, Germany

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