30 Years of HARMONIC®

Helping Patients Heal Today, Innovating Tech for Tomorrow

30주년 역사의 기준은 글로벌 시장 런칭 기준입니다.

ETHICON

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

A legacy of meaningful innovation

HARMONIC® technology has a longstanding history of advancing surgery and improving outcomes—with innovation that's created many firsts in the ultrasonic energy market. We've helped advance surgery by accelerating the adoption of minimally invasive procedures and focusing device development on minimizing the impact on tissue[1] to help reduce complications, improve outcomes and quicken recovery.[2]

A history of firsts from HARMONIC® technology...

HARMONIC® LCS Shears

10mm shafted shears and clamp arm

Added clamp arm to control compression, improve hemostasis and cutting.

HARMONIC® LCS 5mm

Shaft diameter reduced to 5mm

5mm shaft that advanced the use of ultrasonic energy in minimally invasive surgery

HARMONIC® LCSC-5mm

Blade curvature and ergonomic improvements clamp arm

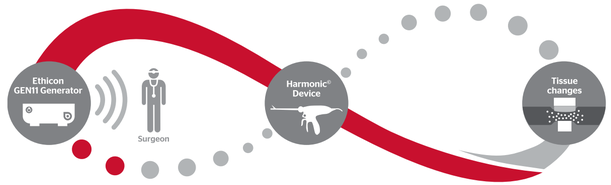
Designed curved ultrasonic blade for improved visualization and dissection capability.

HARMONIC ACE® Shears

Improved ergonomics, performance and 5mm vessel indication

Ultrasonic device with a 5mm indication

with input from surgeons...



HARMONIC FOCUS® Shears
First scissor-design shears for open procedures

- Pioneer in scissor-design shears for open procedures

Generator GEN11
Combined modality generator

- Combined ENSEAL® and HARMONIC® generators into one unit

HARMONIC ACE®+ Shears
Heat management and improved blade design

- Ultrasonic device with thermal management system to deliver more precise energy

Adaptive Tissue Technology
Intelligent feedback, thermal management and superior precision[1]

- A foundational platform for future design and development

[1] vs. HARMONIC ACE® without Adaptive Tissue Technology. (044005-200826)

every step of the way.

HARMONIC ACE®+7 Shears

Advanced Hemostasis Mode provides 7mm vessel indication

- Ultrasonic device with up to 7mm vessel indication

HARMONIC FOCUS®+ Shears

Improved precision with finer tip and Adaptive Tissue Technology to minimize lateral thermal spread[1]

- Received EARTHWARDS® recognition for reducing surgical waste

[1] As exhibited in a preclinical model (n=16), mean lateral thermal spread of 1.68mm. (012142-200109)

HARMONIC® HD 1000i Shears

Unique blade design and integrated transducer

- Ultrasonic device with integrated transducer, redesigned blade for enhanced precision, faster transection speed and more powerful hemostasis[2]

[2] Based on benchtop metrology and porcine comparative studies vs. legacy HARMONIC® (084839-210630)

HARMONIC® 1100 Shears

Better tissue protection

- Active thermal management system that controls blade heat for lower maximum blade temperature.[3]

[3] Compared to previous generations of HARMONIC devices. (140049-210108)

A trusted partner in the OR

Collaborating with surgeons is an integral part of the **HARMONIC®** innovation journey. We partner with you to help deliver **the precision you need to help patients heal faster.** Ethicon Energy creates tools:

- For the most challenging cases
- That enable precise tissue mobilization
- Allowing strong vessel sealing in a wide range of tissues
- That gives you the ability to grasp, precisely dissect, seal and transect, with minimal lateral thermal spread

The undisputed ultrasonic leader[1]

30 +MILLION
procedures worldwide[1]

1,000 More peer-reviewed clinical articles
than any other advanced energy manufacturer[2]

[1] Global sales data and market share & insights for HARMONIC® as of 09/30/20. (062951-201105).
[2] As per literature searches for advanced energy devices in Embase/Medline, PubMed, and Google Scholar through May 2021.(110924-210609)

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Designed for less impact on tissue. And greater impact on healing.

HARMONIC® devices minimize tissue damage so that inflammatory response is suppressed, which results in accelerated healing.

Less inflammation
The **HARMONIC®** curved blade produces less acute inflammation processes, which has been linked to increased perceptions of pain, as compared to monopolar electrosurgery.

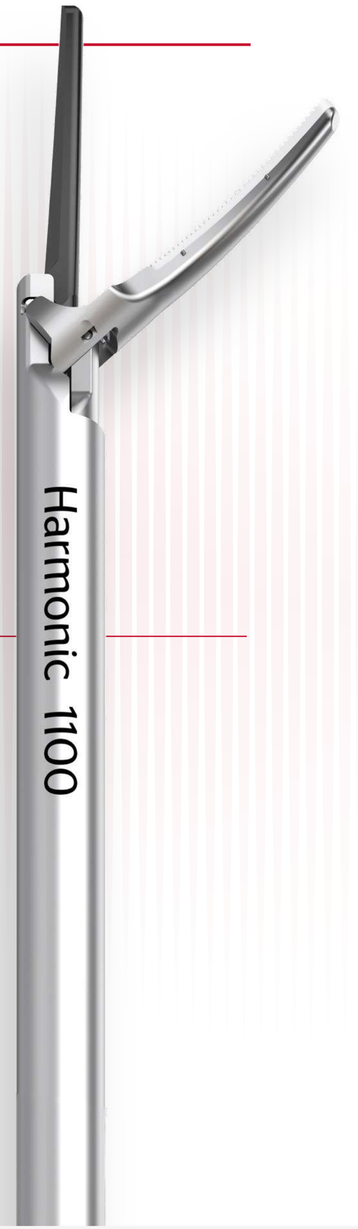
Less post op-pain
Use of a **HARMONIC®** device may reduce postoperative pain score when compared to conventional hemostasis

Less drainage
Reduced serous drainage and drain days

Less adhesions
The use of **HARMONIC®** technology resulted in significantly less postoperative adhesion formation

The latest innovation:
Experience better tissue protection[1] with

HARMONIC® 1100 Shears



Improved algorithm that actively controls blade heat — for lower maximum blade temperature[2]

Transection speeds 35% faster — for shorter heat exposure on tissue than **HARMONIC ACE®+7** Shears with Advanced Hemostasis[3]

Curved, tapered tip — for more precise dissection than **HARMONIC ACE®+7** Shears[4]

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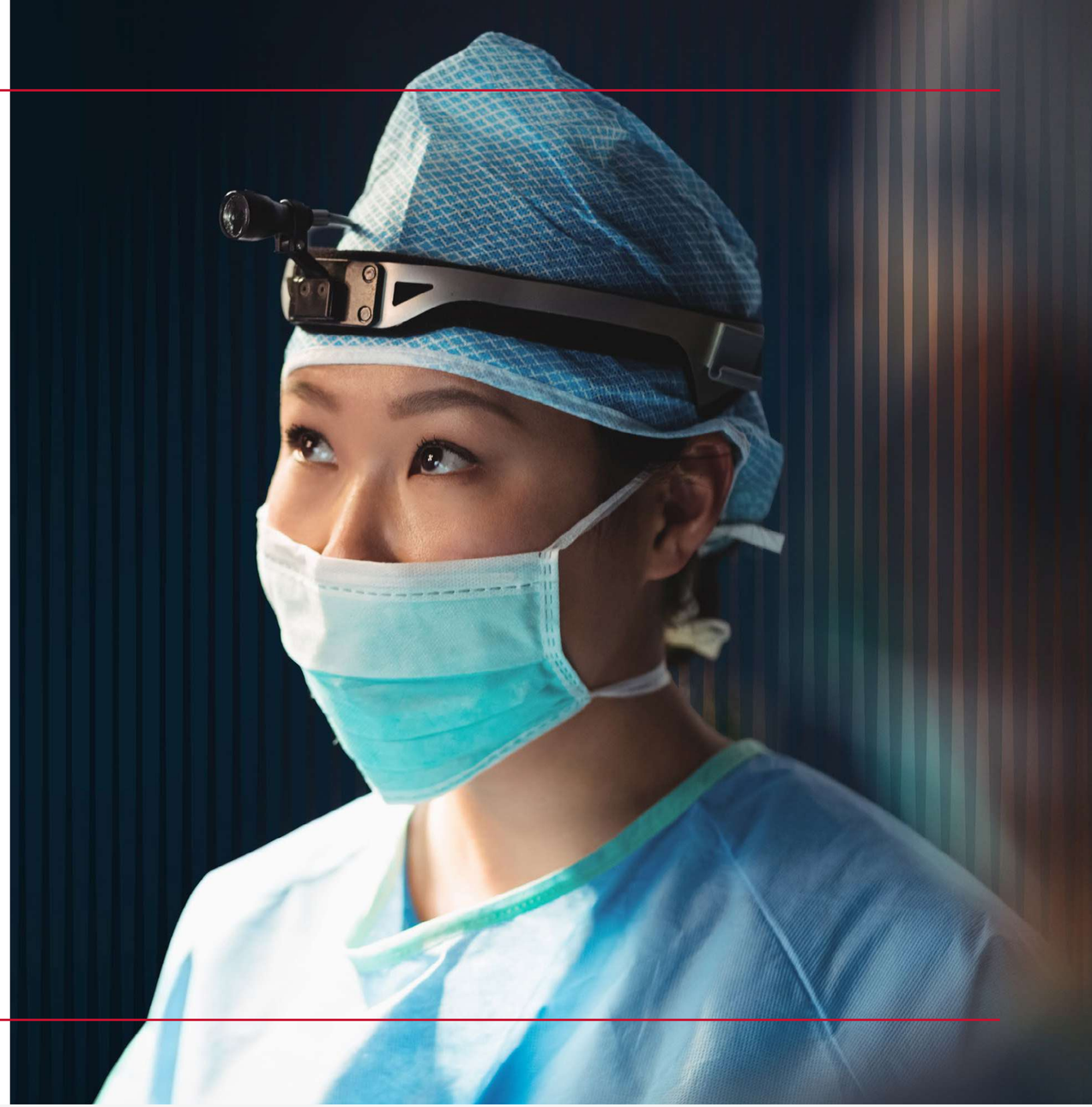

1 Based on benchtop study that showed HARMONIC® 1100 Shears had 35% faster transection speed and significantly lower maximum blade temperature post transection than HARMONIC ACE+7 Shears for shorter heat exposure. (140047-200512) **2** Compared to previous generations of HARMONIC devices. (140049-200512) **3** Based on benchtop study with porcine vessels 3-5 mm in diameter. (138458-200427) **4** Based on preclinical evaluation. (138469-200427)

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1992

HARMONIC® LCS Shears

10mm shafted shears and clamp arm

Clamp
arm to ultrasonic blades

1998

HARMONIC® LCS 5mm

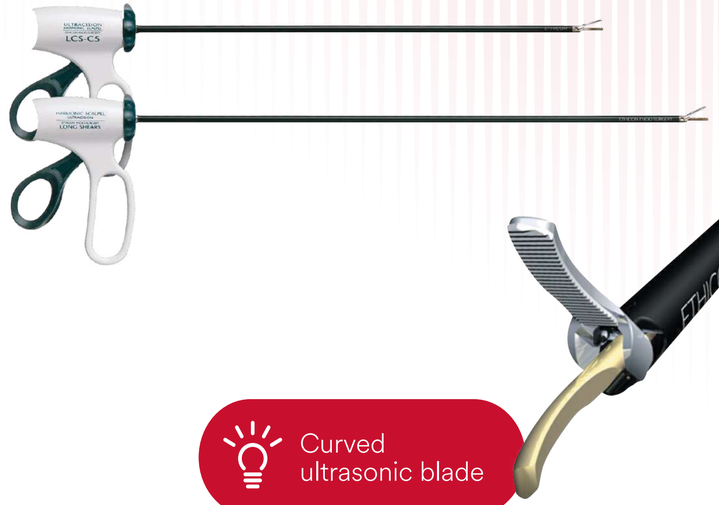
Shaft diameter reduced to 5mm

Provide a more minimally invasive
laparoscopic ultrasonic energy approach

2000

HARMONIC® LCSC-5mm

Blade curvature and ergonomic improvments



Curved
ultrasonic blade

This product is discontinued in Korea

HARMONIC ACE® Shears

Improved ergonomics, performance and 5mm vessel indication

Summary:
- Ergonomic improvements
- Blade and pad improvements
- Vessel indication: 5mm

Impact:
- First ultrasonic device with the ability to seal 5mm vessels
- Improvements to blade and pad for improved performance
- Improved ergonomics was the impetus for a better product:
  - Improved pistol grip design for more comfort
  - Integrated buttons for hand activation of device
  - One finger rotation knob for easier device movement

Procedure focus:
- Gynecologic procedures, including:
  - Total Laparoscopic Hysterectomy
  - Laparoscopic Supracervical Hysterectomy
- Colorectal procedures, including:
  - Right/Left Hemicolectomy
  - Sigmoid Colectomy
  - Laparoscopic Anterior Resection (LAR)

Ultrasonic device with a 5mm indication

HARMONIC FOCUS® Shears

First scissor-design shears for open procedures

Summary:

- Overall ergonomics and design developed specifically for open procedures
- Vessel indication: 5mm

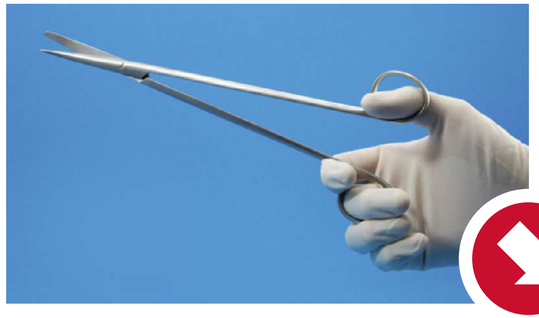
Impact:

- **First ultrasonic** shears specifically designed for open procedures
- **Scissor-like design** for more natural open surgical feel
- Ergonomically designed to allow surgeon m**obility and access** in open procedures
- Fine curved tip for **precise dissection, sealing and visualization**

Procedure focus:

- Positioned for Breast, Head and Neck/ENT with a primary focus on Thyroidectomy procedures

The ETHICON HARMONIC ® FOCUS brand is supported by many peer reviewed publications.[1]



HARMONIC FOCUS® Curved Shears has been used in more than **1,000,000 procedures worldwide**

Pioneer in scissor-design shears for open procedures

[1] As per literature searches for advanced energy devices in Embase/Medline, PubMed, and Google Scholar through May 2021. (110926-210609)

Generator GEN11

Combined modality generator

Summary:

- Combined ENSEAL® and HARMONIC® generators into one unit
- Software modified
- Touchscreen operation
- High-resolution display

Impact:

- **Software actively monitoring device performance**
- **HARMONIC® and ENSEAL® in one generator**
  - Both ultrasonic and advanced bipolar capabilities **reduce capital footprint** and **enable flexibility** to fit surgical needs
  - Universal connector and automatic device recognition to **optimize energy delivery**
  - **Touchscreen** provides fast and easy setup, operation and onscreen diagnostics
- **Gateway to future solutions**
  - Upgradable to support future Energy devices
  - Supports all current devices

Intelligent energy delivery to advance patient outcomes

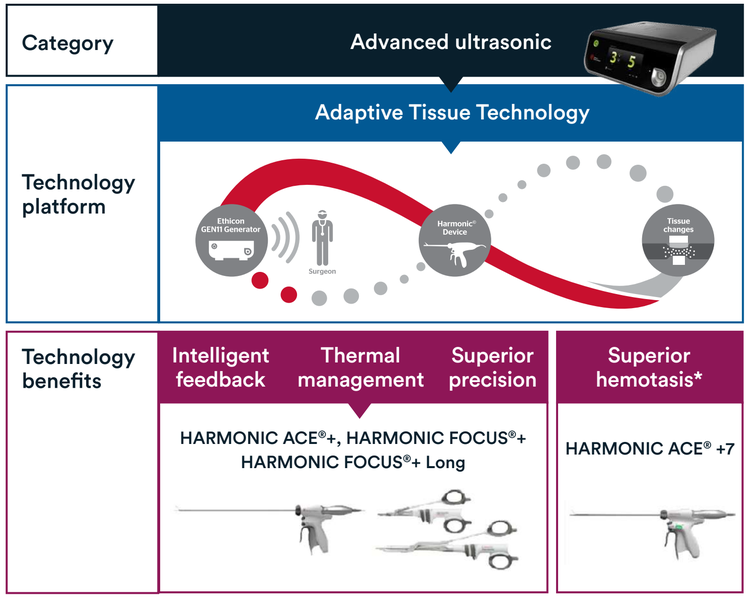
Adaptive Tissue Technology powered by the Ethicon GEN11 Generator, uses an advanced algorithm for intelligent and efficient energy delivery.

Summary:

- Continuously senses changes in tissue and device conditions and responds with the optimal amount of energy to deliver greater precision[1] and efficiency[2].
- A foundational platform for future design and development.

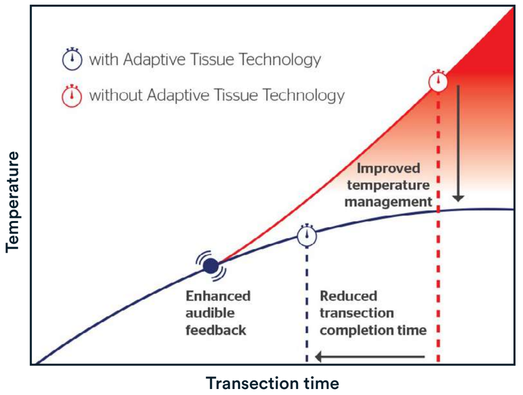
Impact:

- Adaptive Tissue Technology:
  - enables greater surgical precision and performance[3]
  - actively manages and improves the thermal profile of the device[4]
  - achieved minimal lateral spread[5]
  - enabled strong and secure vessel sealing[6]



*Compare to HARMONIC ACE®

Improved temperature management and efficiency with Adaptive Tissue Technology



[1] As compared to HARMONIC® devices without Adaptive Tissue Technology (041693-151008).
[2] Based on a bench-top analysis of cycles-to-failure following induced damage to blade v. ACE-E; Median cuts to failure: Sterilmed 17.5, Ascent 8.5, HAR36 1987, HAR23 2110. (p<0.001). And based on a bench-top comparison of time to cool to 50°C, HAR36 versus ACE36E without Adaptive Tissue Technology. Mean time 93s HAR36 vs. 123s Sterilmed reprocessed ACE36 (p<0.05); mean time 94s HAR36 vs. 124s Ascent reprocessed ACE36 (p<0.05) (080390-170914).
[3] As compared to HARMONIC® devices without Adaptive Tissue Technology (041693-151008).
[4] (037740-180601)
[5] In a preclinical study on ≤5mm porcine carotids in MIN mode. Thermal damage determined via histology (95% CI). (035146-150602)
[6] In bench-top studies with 5-7mm porcine carotids that compared median burst pressure, HARMONIC ACE®+7 exhibited higher burst pressures. (031943-150325)

HARMONIC ACE®+ Shears

Heat management and improved blade design

Summary:

- Incorporated Adaptive Tissue Technology
- Improved blade design
- Vessel indication: 5mm

Impact:

- First ultrasonic device to employ active heat management with Adaptive Tissue Technology to improve device performance.
- **23% less thermal** spread versus HARMONIC ACE® without Adaptive Tissue Technology[1]
- **21% faster transection time** versus HARMONIC ACE without Adaptive Tissue[2]

Procedure focus:

- Gynecologic procedures, including:
  - Total Laparoscopic Hysterectomy
  - Laparoscopic Supracervical Hysterectomy
- Colorectal procedures, including:
  - Right/Left Hemicolectomy
  - Sigmoid Colectomy
  - Laparoscopic Supracervical Hysterectomy
- Bariatric procedures including:
  - Sleeve gastrectomy, Gastric Bypass

Ultrasonic device to employ active heat management to improve device performance

[1] As exhibited in porcine histology (2.2mm vs. 1.7mm, p<0.001). (070587-170406)
[2] As measured in porcine labs (5.7s vs. 4.5s, p<0.001). (070019-170328)

HARMONIC FOCUS®+ Shears

Improved precision and heat management

Summary:

- Added Adaptive Tissue Technology
- Improved blade design
- Vessel indication: 5mm

Impact:

- Improved precision with finer tip and Adaptive Tissue Technology to minimize lateral thermal spread[1]
- Improved transection speed with 49% faster transections at the tip[2]
- First medical device to receive EARTHWARDS® recognition for reducing surgical waste

Procedure focus:

- Positioned for Breast, Head and Neck/ENT with a primary focus on Thyroidectomy procedures

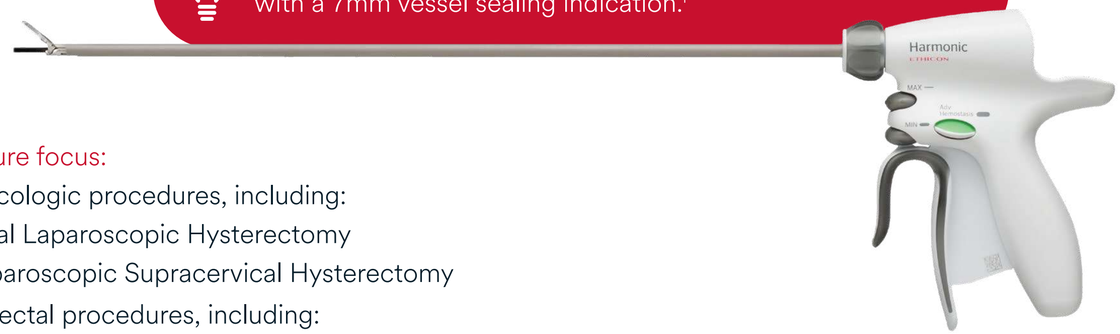
The HARMONIC FOCUS® family of curved shears was shown to have superior clinical outcomes versus conventional methods in Thyroidectomy procedures[3]

[1] As exhibited in a preclinical model (n=16), mean lateral thermal spread of 1.68mm. (012142-200109)
[2] Versus HARMONIC FOCUS® Shears without Adaptive Tissue Technology, as exhibited in a bench-top study performed with devices on porcine tissue (median transection time of 2.22 sec vs. 4.41 sec for tip cuts on thin tissue, p=0.045). (008813-200109)
[3] *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. (044266-151204)

HARMONIC ACE®+7 Shears

Advanced Hemostasis Mode provides 7mm vessel indication

HARMONIC ACE®+7 Shears was the ultrasonic device with a 7mm vessel sealing indication.[1]



Summary:

- Added Advanced Hemostasis Mode
- Vessel indication: 7mm

Impact:

- **Improve hemostasis:** delivered significantly higher burst pressure than competitive devices[2,3]
- **Minimal thermal damage:** Enables precise dissection with mean lateral thermal damage of less than 2mm[4]
- **Better heat management:** May reduce the risk of unintended thermal tissue damage[5,6]

Procedure focus:

- Gynecologic procedures, including:
  - Total Laparoscopic Hysterectomy
  - Laparoscopic Supracervical Hysterectomy
- Colorectal procedures, including:
  - Right/Left Hemicolectomy
  - Sigmoid Colectomy
  - Laparoscopic Supracervical Hysterectomy
- Bariatric procedures including:
  - Sleeve Gastrectomy, Gastric Bypass
- Thoracic procedures including:
  - Wedge Resection, Segmentectomy, and Lobectomy
- HPB procedures including
  - Hepatectomy, Pancreatectomy, Splenectomy

[1] (011066-170816)
[2] In a bench-top study with 3-5mm porcine carotids that compared median burst pressure, HARMONIC ACE®+7(031939-150325).
[3] Benchtop analysis on 5-7mm porcine carotids that measured median burst pressure of HARMONIC ACE®+7 (079438-180309).
[4] In a preclinical study on ≤5mm porcine carotids in MIN mode. Thermal damage determined via histology (95% CI) (035146-150602).
[5] In a bench-top study on porcine jejunum (032853-150818).
[6] In a bench-top study on porcine jejunum (031930-190206).

HARMONIC® HD 1000i Shears

Unique blade design for the more precise dissection

Summary:

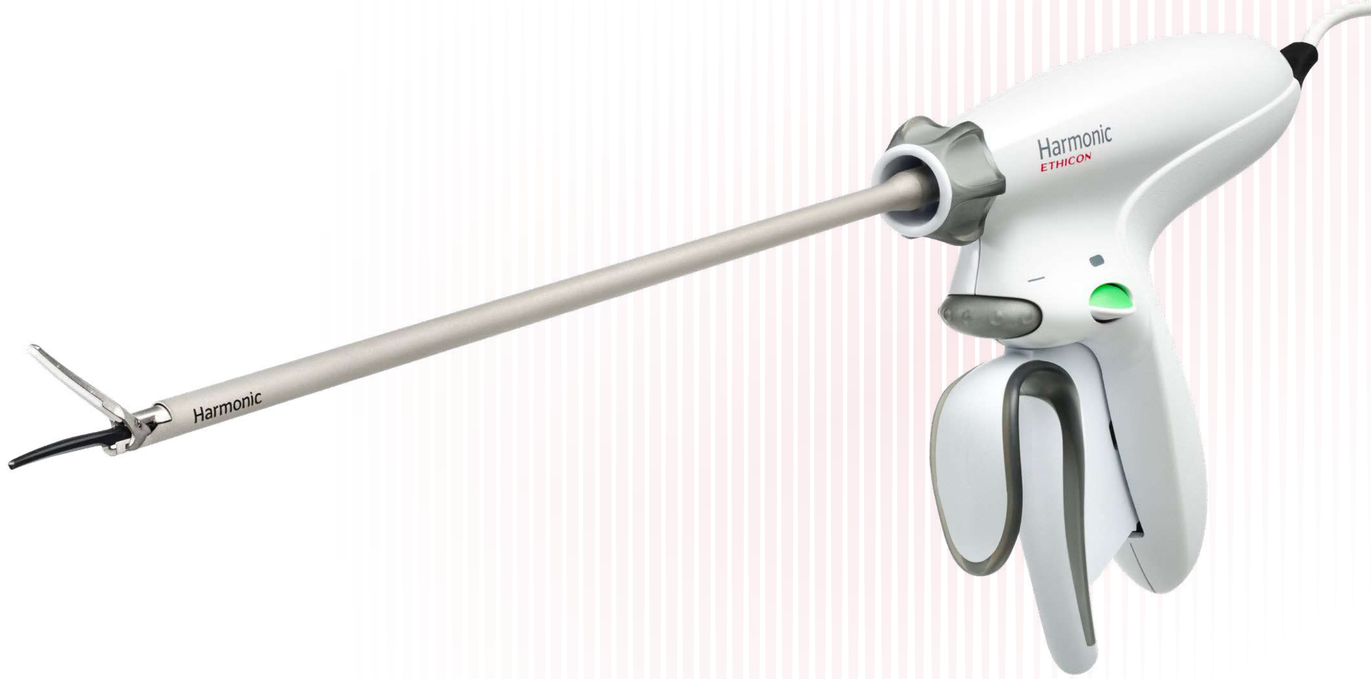
- Curved, tapered tip blade design mimics a mechanical dissector
- Integrated transducer for simplified set up
- Single Energy button design

Impact:

- More tapered jaw designed to enable more precise access to tissue planes[1]
- The Energy button is designed to provide the reliable sealing of the MIN button on HARMONIC ACE®+7 with the cutting speed of the MAX button[2]
- Increased sealing speed, multi-functionality, and simplified steps for use allow for optimal efficiency[3]

Procedure focus:

- For complex and challenging cases in GYN oncology, thoracic, and HPB



[1] Device measurements based on a metrology study compared to HARMONIC® ACE+7. (057588-190711)
[2] Seal reliability at 240 mm Hg of 98.2% vs. 98.4% for HARMONIC ACE®+7 MIN button. Speed based on average time to transect 150mm of porcine jejuum. (050508-190523)
[3] Based on a benchtop study compared to HARMONIC® ACE+7. (057619-190711)

HARMONIC® 1100 Shears

Next-generation Adaptive Tissue Technology Algorithm

Summary:

- Most advanced thermal management algorithm[1]

Impact:

- Up to 35% faster transection speed[2]
- Lower maximum blade temperature[3]
- Precise dissection enables more access to tissue planes[4]

Procedure focus:

- For complex and challenging cases in GYN oncology, thoracic, and HPB

[1] (146617-200715)
[2] Based on bench top study with porcine vessels 3-5 mm in diameter. (138458-200427)
[3] Based on benchtop study that showed Harmonic 1100 had significantly lower maximum blade temperature than Harmonic ACE+7 Shears after 15 tip bite transections. (140050-200512)
[4] Device measurements based on a metrology study compared to HARMONIC® ACE+7. (057588-200427)