Sonicision™ device
The industry’s first cordless ultrasonic dissection device.
Are you ready to cut the cord?
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Dear Colleagues,

It is our pleasure to introduce you to one of Surgical Solutions’ most exciting products: Sonicision™, the healthcare industry’s first cordless ultrasonic dissection device.

Surgeons told us that cords on surgical devices get in their way, potentially taking their focus off their patients. We listened to their feedback and put extensive research and development effort into finding a solution: the result is the Sonicision™ device.

The Sonicision™ device is a hand-held, pistol-grip style ultrasonic device used for soft-tissue dissection and vessel occlusion. The revolutionary cordless design of the Sonicision™ device eliminates frustration resulting from tangled cords and the difficulty of managing cords in a sterile environment, giving surgeons more freedom of movement in the operating room. The cordless design also enables more natural movement for the surgeon and the surgical support team. A surgeon no longer needs to worry about dealing with shaft rotation in both directions to prevent a tangled cord mess; they can now consistently rotate the instrument shaft in the direction most comfortable for them. In addition, the intuitive dual-mode energy activation control enables minimum and maximum power modes with one button, allowing for easy transition between energy modes, further enabling focus on the patient.

The reusable hand-held generator working in cohort with the reusable battery produces ultrasonic energy that delivers a variety of tissue effects. The ability to take the sophistication of a generator and shrink it down to easily fit in the palm of your hand is a real innovation that frees the surgeon from the need to connect the device to a bulky generator outside of the surgical field.

The Sonicision™ device is the latest addition to our comprehensive portfolio of technology-driven solutions for today’s O.R. It broadens the Covidien portfolio of energy solutions, allowing your customers to obtain all of their energy solutions from Covidien, resulting in cost saving opportunities through standardization.

This Launch Book contains the key information you will need to successfully introduce this innovative new product to your customers. This is a complex system that will take us to new procedural call points, so please take the time to review this information and do not hesitate to contact us if you have questions that this book does not answer.

We are all very excited to bring innovation and choice to the ultrasonic space with the introduction of the Sonicision™ device. It is truly Covidien innovation at its best, and I believe your customers will wholeheartedly welcome it. The Sonicision™ device will be key to ensuring we remain the number one energy provider in the industry!

On behalf of the entire Sonicision™ device team, good luck selling and we look forward to hearing your success stories!

Sincerely,

John Chindlund  
Director, Global Marketing

Kelly Schneiderman  
Global Product Manager
Covidien Surgical Solutions has long been a pioneer in creating medical devices that utilize various forms of energy. Covidien Energy offers the largest energy-based, and now the most versatile cordless ultrasonic portfolio in the industry.

### Why Ultrasonic?

- **Monopolar**
  - Hundreds of every-day products with over 40 years of innovation

- **Laparoscopic Multifunction**
  - Covidien’s first multifunctional instrument for vessel sealing and monopolar dissection in minimally invasive surgery

- **Open Vessel Sealing**
  - Instruments for hemostasis in open surgery

- **Efficient and Versatile**
  - Multifunctional device offering one-step sealing, a Maryland dissector, grasper and cold scissors.

- **ValleyLab™ Device**
  - ForceTriad™ Energy Platform

- **LigaSure™ Technology**
  - ValleyLab™ Device
  - In creating the Sonicision™ device, Covidien has expanded its portfolio and become a single solution provider for energy devices.
  - The energy portfolio available allows for complete standardization to reduce costs.

- **Bipolar**
  - Energy and instruments for specialty procedures in gynecology, urology and neurosurgery

- **Laparoscopic Vessel Sealing**
  - Energy and instruments for hemostasis in minimally invasive surgery

- **Open Small Jaw Vessel Sealing**
  - Instrument for hemostasis and fine dissection in open surgery
With the introduction of Sonicision™, Covidien has an expanded portfolio and is now a single solution provider for energy devices.
The Sonicision™ cordless ultrasonic dissection device is a breakthrough in ultrasonic energy, combining comparable clinical effectiveness associated with leading ultrasonic technologies and unique benefits from the industry's first cordless design.

The Sonicision™ device allows improved freedom of movement in the operating room through the innovation of cordless technology. The streamlined design features a quick and simple set up that may increase O.R. efficiency. The Sonicision™ device also utilizes a dual-mode energy activation control for seamless transition between two power modes with a single button. This intuitive design allows a surgeon's eyes to remain on the surgical area rather than on the instrument for sustained procedural focus.

The Sonicision™ system is composed of single use and reusable components for efficiency and utilization in surgical specialties that include: general (including upper gastrointestinal), bariatric, colorectal, pediatrics, gynecological and urological procedures.

The Sonicision™ device reliably seals vessels up to 5 mm, provides faster dissection speed\(^2\) and up to 5x less plume than the Harmonic ACE\(^*\)\(^3\), and is comparable to the Harmonic ACE\(^*\) and Harmonic ACE+\(^*\) in thermal spread\(^8\), burst pressure\(^11\), sealing time\(^9\) and temperature.\(^2,4,10\)

**COMPONENTS**

- Reusable Generator
- Audio Speaker
- Multiple lengths available* 
- 360° Shaft Rotation Wheel 
- Dual-Mode Energy Button 
- Indicator LED 
- Torque Wrench 
- Ultrasonic Dissector 
- Reusable Battery 
- Sterilization Tray 
- Battery Charger

* Sonicision™ available with the following shaft lengths: 13 cm, 26 cm, 39 cm, 48 cm
AVAILABLE LENGTHS

ULTRASONIC DISSECTOR
• Single patient use
• 5 mm diameter
• 14.5 mm active blade
• Dual-mode energy button (minimum and maximum)

13 CM LENGTH

Ordering Code: SCD13
Order Quantity: 6 ultrasonic dissectors 13 cm (1 torque wrench included with each dissector)

39 CM LENGTH

Ordering Code: SCD36
Order Quantity: 6 ultrasonic dissectors 39 cm (1 torque wrench included with each dissector)

Ordering Code: SCD391
Order Quantity: 1 ultrasonic dissector 39 cm (1 torque wrench included)

(Select countries only)

26 CM LENGTH

Ordering Code: SCD26
Order Quantity: 6 ultrasonic dissectors 26 cm (1 torque wrench included with each dissector)

48 CM LENGTH

Ordering Code: SCD48
Order Quantity: 6 ultrasonic dissectors 48 cm (1 torque wrench included with each dissector)
PRODUCT OVERVIEW

**REUSABLE BATTERY**
- Reusable up to 100 uses
- Sterilizable via low temperature hydrogen peroxide gas plasma
- Advanced lithium polymer battery chemistry

**Ordering Code:** SCG  
**Order Quantity:** 1 battery pack

**REUSABLE GENERATOR**
- Reusable up to 100 uses
- Sterilizable via low temperature hydrogen peroxide
- Integrated LED provides device feedback

**Ordering Code:** SCG  
**Order Quantity:** 1 generator

**BATTERY CHARGER**
- Four charging bays
- Supports charging of 4 batteries simultaneously

**Ordering Code:** CBC  
**Order Quantity:** 1 battery charger (batteries not included)

**STERILIZATION TRAY**
- Holds one generator and one battery

**Ordering Code:** SCST1  
**Order Quantity:** 1 sterilization tray
The Medical Design Excellence Awards (MDEA) competition is the MedTech industry's most prestigious award — given to the most significant advances in medical product design and engineering of groundbreaking surgical equipment.

An international design and business competition awarded by the Design Zentrum Nordrhein, Westfalen in Essen, Germany. An internationally recognized quality label and award for excellent design selected by expert juries in the areas of product design, communication design and design concepts.

At the 2013 Excellence in Surgical Products Awards, the Sonicision™ System won the Best in Show category (2nd place), based on products that have contributed to surgical performance, efficiency and safety.

The Innovation Quotient, or IQ, program honors the most innovative new products and services in Colorado. The Sonicision™ System won both the Innovation of the Year Award from the audience and the Business Products and Services category from a panel of judges.
Performance of the Sonicision™ Cordless Ultrasonic Dissection Device compared to the Harmonic ACE™* and Harmonic ACE+™*

Overview
• The Sonicision™ device mean thermal spread, vessel burst pressure, hemostasis, mean seal time and mean peak active blade temperature are comparable to the Harmonic ACE™* and Harmonic ACE+™*2,4,8‑11
• The Sonicision™ device delivers faster dissection speed than the Harmonic ACE™*2
• The Sonicision™ device produces up to 5x less plume than Harmonic ACE™*3
• The Sonicision™ device reliably seals vessels up to 5 mm in diameter2

Background
Energy‑based hemostatic devices have evolved over the past century to become an essential tool in the surgical field. The latest innovation from Covidien to enter the arena is the completion of the Sonicision™ cordless ultrasonic portfolio. Now with four available shaft lengths, inclusive of both the longest and the shortest pistol grip ultrasonic device on the market with optimized ergonomic design. In turn this portfolio utilizes advanced ultrasonic technology to provide rapid dissection and hemostasis without the need for a stand‑alone generator or cord, therefore increasing ease of operation and freedom of movement. A variety of tests have been performed to date by Covidien to evaluate the performance of the Sonicision™ device compared to the Harmonic ACE™* and Harmonic ACE+™*. 

Thermal spread, vessel burst pressure, hemostasis, seal time and blade temperature are comparable to the Harmonic ACE™* and Harmonic ACE+™*2, 4, 8‑11
The following table summarizes the pre-clinical comparative testing between the Sonicision™ device and the Harmonic ACE™:

<table>
<thead>
<tr>
<th></th>
<th>Mean Vessel Burst Pressure (mmHg ± SD)</th>
<th>Mean Dissection Speed (sec ± SD)</th>
<th>Mean Peak Active Blade Temperature (°C ± SD)</th>
<th>Mean Active Blade Cool Down Time to 60 °C (sec ± SD)</th>
<th>Mean Thermal Spread (mm ± SD)</th>
<th>Mean Seal Time (sec ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sonicision™ device</td>
<td>578 ± 284</td>
<td>24.8 ± 4.9</td>
<td>249.7 ± 24.3</td>
<td>41.2 ± 1.3</td>
<td>1.06 ± 0.05</td>
<td>5.2 ± 1.7</td>
</tr>
<tr>
<td>ACE™*</td>
<td>605 ± 288</td>
<td>33.8 ± 5.4</td>
<td>239.3 ± 28.4</td>
<td>50.4 ± 7.5</td>
<td>1.08 ± 0.5</td>
<td>4.9 ± 1.5</td>
</tr>
<tr>
<td>P-Value</td>
<td>0.48</td>
<td>&lt;0.001</td>
<td>0.173</td>
<td>0.006</td>
<td>0.82</td>
<td>0.20</td>
</tr>
<tr>
<td>Statistical Relevance</td>
<td>NS</td>
<td>Statistically Significant</td>
<td>NS</td>
<td>Statistically Significant</td>
<td>NS</td>
<td>NS</td>
</tr>
</tbody>
</table>

The Sonicision™ provides faster dissection and has a faster active blade cool down time than the Harmonic ACE™.

<table>
<thead>
<tr>
<th></th>
<th>Average Coagulation Obstruction</th>
<th>Average Cutting Obstruction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Maximum Obstruction (%)</td>
<td>Maximum Obstruction (%)</td>
</tr>
<tr>
<td>Sonicision™ device</td>
<td>4.80 ± 0.86</td>
<td>8.76 ± 1.49</td>
</tr>
<tr>
<td>ACE™*</td>
<td>26.63 ± 3.70</td>
<td>12.65 ± 0.97</td>
</tr>
<tr>
<td>P-Value</td>
<td>&lt;0.001</td>
<td>0.026</td>
</tr>
<tr>
<td>Statistical Relevance</td>
<td>Statistically Significant</td>
<td>NS</td>
</tr>
</tbody>
</table>

Sonicision™ produces up to 5x less plume than the Harmonic ACE™.

Results
The table above summarizes the pre-clinical comparative testing between the Sonicision™ device and the Harmonic ACE™ device:
The following table summarizes benchtop testing between the Sonicision™ device and the Harmonic ACE™+:

<table>
<thead>
<tr>
<th></th>
<th>Mean Vessel Burst Pressure (mmHg ± SD)</th>
<th>Mean Dissection Speed (sec ± SD)</th>
<th>Mean Peak Active Blade Temperature (°C ± SD)</th>
<th>Mean Active Blade Cool Down Time to 60 °C (sec ± SD)</th>
<th>Mean Thermal Spread (mm ± SD)</th>
<th>Mean Seal Time (sec ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sonicision™</td>
<td>868.4 ± 419.9</td>
<td>43.4 ± 7.0</td>
<td>263.1 ± 18.8</td>
<td>37.6 ± 4.4</td>
<td>1.44 ± 0.5</td>
<td>8.40 ± 3.60</td>
</tr>
<tr>
<td>ACE+™*</td>
<td>1030.1 ± 405.1</td>
<td>44.6 ± 4.3</td>
<td>266.3 ± 20.2</td>
<td>37.4 ± 5.8</td>
<td>1.25 ± 0.2</td>
<td>8.12 ± 3.74</td>
</tr>
<tr>
<td>P-Value</td>
<td>P = 0.18</td>
<td>P = 0.777</td>
<td>P = 0.771</td>
<td>P = 0.704</td>
<td>P = 0.100</td>
<td>P = 0.62</td>
</tr>
<tr>
<td>Statistical Relevance</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
</tbody>
</table>

The Harmonic Ace+™* showed no statistical improvements compared to the Sonicision™ ultrasonic dissector.

Summary
The differences between the Sonicision™ cordless ultrasonic dissection device and the Harmonic ACE™+ were found to be non-significant in regards to mean vessel burst pressure, mean thermal spread, mean peak active blade temperature and mean seal time. The Sonicision™ device was statistically faster in terms of mean dissection speed and mean active blade cool down time to 60 °C in these tests.¹²⁴
PROCEDURAL APPLICATIONS

LAPAROSCOPIC PROCEDURES

Bariatric
- Gastric Band
- Roux-en-Y
- Sleeve Gastrectomy

Colorectal
- Colectomy

General
- Adrenalectomy
- Appendectomy
- Cholecystectomy
- Nissen Fundoplication
- Splenectomy

Gynecology
- Hysterectomy
- Lysis Pelvic Adhesions
- Salpingo-Oophorectomy
- Supracervical Hysterectomy

Thoracic
- Lobectomy
- Minimally Invasive Esophagectomy

Urology
- Cystectomy
- Nephrectomy

OPEN PROCEDURES

Colorectal
- Abdominoperineal Resection
- Low Anterior Resection

General
- Axillary Node Dissection
- Liver Resection
- Mastectomy
- Ventral Hernia

Gynecology
- Myomectomy
- Total Abdominal Hysterectomy

Pediatrics
- Appendectomy
- Colectomy
- Splenectomy

Thoracic
- Pneumonecotomy
- Pulmonary Lymph Node Dissection

Urology
- Prostatetomy
PURCHASING

Standardization / Cost Savings
• Current capital cost advantages mean ultrasonic can be used in more operating rooms
• One vendor that can address energy needs may allow for savings through standardization
• Built-in upgrades means generators don’t become technologically outdated
• Simplified set up improves O.R. efficiency
• Self-contained system eliminates trip hazards from cords

Clinical Performance
• Burst pressure, thermal spread, hemostasis and temperature are comparable to Harmonic ACE™
• Faster dissection than the Harmonic ACE™

Cordless Design
• Improves mobility and natural movement
• Makes it easier to pass between operators
• Reduces cord entanglement

Simplified Set up
• Allows for autonomous, quick set up, all within the sterile field
• Can improve efficiency by reducing set-up time

Elimination of cords
• Reduces potential cord contamination concerns
• Cord reduction in the O.R. enhances mobility
• Self-contained system eliminates trip hazards from cords

Self-contained System
• Improves the use of the O.R. space
• Portable system enhances use in the O.R.
• System provides essential feedback within the operative field
• Dual-mode energy button allows surgeon to transition between power modes without adjusting the generator

Clinical Performance
• Burst pressure, thermal spread, hemostasis and temperature are comparable to Harmonic ACE™
• Faster dissection than the Harmonic ACE™

SURGEONS

Clinical Performance
• Burst pressure, thermal spread, hemostasis and temperature are comparable to Harmonic ACE™
• Faster dissection than the Harmonic ACE™

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Clinical Performance
• Burst pressure, thermal spread, hemostasis and temperature are comparable to Harmonic ACE™
• Faster dissection than the Harmonic ACE™

NURSES

Clinical Performance
• Burst pressure, thermal spread, hemostasis and temperature are comparable to Harmonic ACE™
• Faster dissection than the Harmonic ACE™

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Clinical Performance
• Burst pressure, thermal spread, hemostasis and temperature are comparable to Harmonic ACE™
• Faster dissection than the Harmonic ACE™

KEY MESSAGES
After hundreds of customer interactions and development exercises, we observed a consistent and central theme to the Sonicision™ device: Freedom. Each piece of our 5-point value proposition speaks to the features and advantages of this revolutionary system.

**Freedom from tethered designs that limit range of motion.**

**Freedom from non-upgradable larger capital investments.**

**Freedom to focus on the patient, not the device.**

**Freedom from time consuming set up.**

**Freedom to experience faster dissection and less visual obstruction.**

\(^1\) ^{6}
The right energy solution for procedural need and surgeon preference — from a single manufacturer

<table>
<thead>
<tr>
<th>Dissection</th>
<th>Multi-Function</th>
<th>Vessel Sealing</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Smaller vessels</td>
<td>• Primarily dissection with some vessel sealing</td>
<td>• Up to 7 mm vessels</td>
</tr>
<tr>
<td><strong>Electrosurgery</strong></td>
<td><strong>Ultrasonic</strong></td>
<td></td>
</tr>
<tr>
<td><em>Force TriVerse™</em></td>
<td><em>Sonicision™</em></td>
<td></td>
</tr>
<tr>
<td>• Sterile field power control</td>
<td>• Freedom (cordless)</td>
<td>• Proven LigaSure™ performance</td>
</tr>
<tr>
<td>• Access to Valleylab™ mode</td>
<td>• Standardization</td>
<td>• Independent cutting and sealing</td>
</tr>
<tr>
<td></td>
<td>• Faster set up and dissection²</td>
<td>• Cooler temperature profile</td>
</tr>
<tr>
<td><strong>Advanced bipolar and electrosurgery</strong></td>
<td><em>LigaSure Advance™ II</em></td>
<td></td>
</tr>
<tr>
<td><strong>LigaSure™ 5 mm</strong></td>
<td>• Multi-functionality</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Bariatric length (44 cm)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Valleylab™ mode dissection</td>
<td></td>
</tr>
</tbody>
</table>
**COMPETITIVE COMPARISON**

**ULTRASONIC DISSECTOR COMPARISON**

**Sonicision™ device**

- 39 cm Shaft Length
- Combined transducer and generator for cordless design
- Statistically significant faster dissection\(^1,2\)
- Straight jaw for less plume\(^3\)
- Intuitive dual-mode energy button

**J & J Harmonic™ ACE45E**

- Two product codes for 36 cm and 45 cm
- Curved jaw creates plume obstruction\(^3\)
- Two buttons
- Corded design with transducer

<table>
<thead>
<tr>
<th>Measure</th>
<th>Sonicision™</th>
<th>J &amp; J Harmonic™ ACE36E</th>
<th>Olympus SonoSurg™</th>
<th>AutoSonix™ Standard Ultra Shears</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shaft Length</td>
<td>39 cm</td>
<td>36 cm (45 cm is longest)</td>
<td>34 cm</td>
<td>30 cm (38 cm is longest)</td>
</tr>
<tr>
<td>Method of Activation</td>
<td>Hand 1 button, 2 stage</td>
<td>Hand 2 buttons</td>
<td>Footswitch (hand adapter available)</td>
<td>Footswitch (hand switch can tape on)</td>
</tr>
<tr>
<td>Frequency</td>
<td>55.5 khz</td>
<td>55.5 khz</td>
<td>23.5 and 47 khz</td>
<td>55.5 – 60 khz</td>
</tr>
</tbody>
</table>
## COMPETITIVE COMPARISON

<table>
<thead>
<tr>
<th>Measure:</th>
<th>Sonicision™</th>
<th>J &amp; J Harmonic™* ACE</th>
<th>J &amp; J Harmonic ACE+™*</th>
<th>Olympus Thunderbeat™*</th>
</tr>
</thead>
</table>
| Shaft Length | - 13 cm  
- 26 cm  
- 39 cm  
- 48 cm | - 14 cm  
- 23 cm  
- 36 cm  
- 45 cm | - 23 cm  
- 36 cm | - 10 cm  
- 20 cm  
- 35 cm  
- 45 cm |
| Method of Activation | Hand  
1 button, 2 stage | Hand  
2 buttons | Hand  
2 buttons | Hand  
2 buttons |
| Frequency | 55.5 khz | 55.5 khz | 55.5 khz | 47.7 khz |
| Jaw Length¹² | 14.5 mm | 11.1 mm | 10.7 mm | 16.5 mm |
| Total Weight of Device Assembled¹³ (with cords and transducer) | 394.25 grams | 337.47 grams | 341.86 grams | 386.86 grams |
CUSTOMER VALUE

SURGEONS

Clinical Performance
• Burst pressure, thermal spread, hemostasis and temperature are comparable to Harmonic ACE™ and Harmonic ACE+™ 2,4,8-11
• Faster dissection² and mean active blade cool down time than the Harmonic ACE™¹

Cordless Design
• Improves mobility and natural movement
• Makes it easier to pass between operators
• Reduces cord entanglement

Complete Portfolio
• Complete cordless ultrasonic portfolio for optimized ergonomic design
• Longest advanced energy device on the market
• Longest and shortest pistol grip ultrasonic device on the market

Dual-Mode Energy Button
• Allows for efficient transition between low and high power modes without eyes leaving the surgical area
• Improved procedural focus

NURSES

Simplified Set Up
• Allows for autonomous, quick set up, all within the sterile field
• Can improve efficiency by decreasing set-up time

Elimination of Cords
• Cord reduction in the O.R. enhances mobility
• Self-contained system eliminates trip hazards from cords
• Reduction of cords improves OR safety.⁶
• The Sonicision™ device contributes to a safer O.R. and patient experience.⁷

Self-Contained System
• Improves the use of O.R. space
• Portable system expands use in the O.R.
• System provides essential feedback within the operative field
• Dual-mode energy button allows surgeon to transition between power modes without adjusting the generator

PURCHASING

Standardization / Cost Savings
• Current capital cost advantages mean ultrasonic can be used in more operating rooms
• The broadest and most complete energy portfolio available allowing for full system standardization.
• Built-in upgrades mean generators don’t become technologically outdated
• Optimized lengths help minimize SKUs and reduce inventory costs
• Self-contained system eliminates trip hazards from cords
• Reduced overhead costs with no maintenance schedule⁵
• The Sonicision™ device contributes to a safer O.R. and patient experience.⁷
**STEP 1 – ATTACH AND TORQUE GENERATOR**

1. Slide the generator into the opening of the ultrasonic dissector and hand tighten clockwise while holding the shaft rotation wheel.

2. Place torque wrench over the generator torque knob.

3. Rotate clockwise while holding rotation wheel in place until two clicks are felt or heard.

Remove torque wrench and keep in sterile field.

**STEP 2 – ATTACH BATTERY**

1. Orient battery pack as shown.

2. Swing the battery forward and snap into place.

When properly assembled, a series of tones sound and the LED on the generator illuminates green.

**STEP 3 – TEST**

1. With jaws open, activate the dual-mode energy button in minimum (half squeeze) and maximum (full squeeze) power modes.

Device is ready for use if minimum and maximum power pulsating tones are heard.
1. Remove battery by pushing up on the battery pack release latch.
2. Swing the battery toward the rear of the ultrasonic dissector to disconnect.
3. Attach new battery as shown in Step 2 above.
   *When the device is fully assembled repeat STEP 3 – TEST.*

### INTRAOPERATIVE TROUBLESHOOTING

1. Clean jaw and blade (wipe with wet gauze and/or immerse in saline and activate energy with jaws open).
2. Disconnect and reconnect battery.
3. Replace battery.
4. Replace ultrasonic dissector.

### GENERATOR INDICATOR LIGHTS

- **GREEN**
  - System is ready (minimum or maximum power).

- **RED**
  - Device is non-functional (see intraoperative troubleshooting section or IFU).

- **FLASHING YELLOW**
  - Battery charge is less than 20% capacity (approximately 10-20 activations remaining upon initial notice).

- **FLASHING PURPLE**
  - Generator has reached end of life (replace generator).
CLEANING AND STERILIZATION

1. Preparation for Cleaning
   • Visually inspect the generator, battery, and sterilization tray for damage. Replace if damaged.
   • Prepare a solution of pH neutral, pH neutral enzymatic or alkaline detergent in accordance with the manufacturer’s instructions.

2. Soaking
   • Soak the generator, battery and sterilization tray in the detergent mix for 5 to 10 minutes

3. Manual Cleaning
   • Manually clean the battery, generator and sterilization tray using a stiff, nylon-bristle brush and the detergent solution.
   • Thoroughly clean the generator retention ring, generator seam, battery seam, battery pack release latch, and battery contact points. Do not use abrasive cleaning agents or metal cleaning tools, such as stainless steel brushes.
   • Thoroughly rinse components with clean water.

4. Drying
   • Dry generator, battery, and sterilization tray with a clean, lint-free cloth. With cool, clean oil-free air, blow dry all components until completely dry.

5. Disinfecting (optional)
   • If facility processes require disinfection prior to sterilization, wipe the surfaces of the generator, battery and sterilization tray with an isopropyl-alcohol (up to 100%) surface disinfectant.

CAUTION:
Do not wash components in ultrasonic washer.
CHARGING BATTERY

Charging a Battery

1. Verify the battery and charger are clean.

2. Insert battery into a charger bay until battery is fully seated. Note the color of the illuminated battery status LED:

- Green
  Battery is fully charged and can be sterilized for use.

- Yellow
  Battery is charging. Do not remove the battery until the charge cycle is complete and the status light turns green.

- Red
  Battery has reached its maximum usage or is otherwise nonfunctional. Do not use. Recycle or properly dispose of the battery.

- Red
  The charger bay is unusable. Insert a known functional battery into the bay. If the condition persists, use another bay to charge the battery. Contact Covidien to order a replacement charger.

3. When fully charged, remove battery from charger and sterilize.

CAUTION:
The batteries must be sterilized AFTER charging. Do not sterilize batteries before charging.
STERILIZING

Sterilizing

1. Ensure generator, battery and sterilization tray are clean and dry before sterilization.
2. Place the generator and battery in the tray.
3. Cover sterilization tray base with lid and latch.
4. Utilize one of the following sterilization configurations:

<table>
<thead>
<tr>
<th>Sterilizer</th>
<th>Sterile Barrier</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Poly- propylene Wrap</td>
</tr>
<tr>
<td>STERRAD™* 100S</td>
<td>✓</td>
</tr>
<tr>
<td>STERRAD™* NX™*</td>
<td>✓</td>
</tr>
<tr>
<td>STERRAD™* 100NX™*</td>
<td>✓</td>
</tr>
<tr>
<td>STERIS V-PRO™* 1</td>
<td>✓</td>
</tr>
<tr>
<td>STERIS V-PRO™* 1 PLUS</td>
<td>✓</td>
</tr>
<tr>
<td>STERIS V-PRO™* maX</td>
<td>✓</td>
</tr>
</tbody>
</table>

5. Follow these steps according to the sterile barrier selected:

• **Polypropylene Wrap** – Wrap the sterilization tray in a compatible polypropylene sterilization wrap according to the manufacturer’s instructions.

6. Sterilize the generator and battery within the enclosed sterilization tray using the following STERRAD™* or STERIS V-PRO™* models/cycles in accordance with manufacturer’s instructions:

<table>
<thead>
<tr>
<th>Model</th>
<th>Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>STERRAD™* 100S</td>
<td>Standard, Short or Long</td>
</tr>
<tr>
<td>STERRAD™* NX™*</td>
<td>Standard</td>
</tr>
<tr>
<td>STERRAD™* 100NX™*</td>
<td>Standard</td>
</tr>
<tr>
<td>STERIS AMSCO™* V-PRO™* 1</td>
<td>Lumen</td>
</tr>
<tr>
<td>STERIS AMSCO™* V-PRO™* 1 Plus</td>
<td>Lumen</td>
</tr>
<tr>
<td>STERIS AMSCO™* V-PRO™* maX</td>
<td>Lumen</td>
</tr>
</tbody>
</table>

Storing System

• Store system components at 64°F to 77°F (or 18°C to 25°C). Elevated temperatures can result in reduced battery-service life.

• Recharge and re-sterilize battery packs after one month of continuous storage to ensure adequate charge when needed.

**CAUTION:**
Do not steam Autoclave, flash or use EtO to sterilize any part of the device or accessories.
Use low-temperature hydrogen peroxide sterilization only.
CAUTION: Do not steam Autoclave, flash, or use EtO to sterilize any part of the device or accessories. Use low-temperature hydrogen peroxide gas plasma sterilization (i.e. STERRAD) only.
This section is designed to provide training for answering customer questions or objections to the Sonicision™ system. This content is designed to provide a basic framework open to appropriate regional customization and relevancy at the discretion of the region.

**CENTRAL PROCESSING**

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>How long does it take to recharge a battery?</td>
<td>About two hours depending on the battery depletion level.</td>
</tr>
<tr>
<td>How long does it take to clean, sterilize and charge a Sonicision™ system?</td>
<td>The average time frame is about four hours.</td>
</tr>
</tbody>
</table>

**JAW DESIGN**

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Why is your blade straight? I prefer a curve.</td>
<td>Other surgeons have mentioned that to us as well. The straight design was selected for its performance and reduced visual obstruction. After trying the device surgeons have found the blade geometry not to be an issue.</td>
</tr>
<tr>
<td>Were you forced into a straight design because of patent issues?</td>
<td>The straight design was selected for its performance and reduced visual obstruction. Surgeons have also noted its performance in creating enterotomies. I can address any questions that you might have on performance issues and would be happy to connect you with a member of our legal team regarding patents.</td>
</tr>
</tbody>
</table>

**Coaching point:**
Never discuss patents or speculate in this area with surgeons.
BATTERY LIFE

How long does a battery last during a case?

Response:
Our research shows that a single battery will be sufficient for most surgical procedures. It will deliver full power for the life of the charge. A yellow flashing light will indicate approximately 20% remaining capacity during a case.

How do I know when the battery and generator have reached 100 uses?

Response:
Both components have internal counters and display different lights when they have reached maximum use life — 100 uses. A red indicator on the battery charger and purple indicator on the generator indicate end of useful life for the components. The battery and generator were designed to provide optimal performance throughout their lifespan.

Coaching point:
It is always a good idea to have an extra battery and generator readily available.

PERFORMANCE

You state that the Sonicision™ device has faster dissection speed. How do you define faster?

Response:
Ultrasonic performance is predicated on tissue type, blade displacement, pressure, and time. When we tested the devices on similar tissues and power levels, the Sonicision™ device was faster through tissue than the Harmonic ACE™*. If you would like, I have a copy of the study for your review. Would that interest you?

What will I have to compromise by switching from the box on the floor to your small cordless generator?

Response:
Absolutely nothing. Advances in design and technologies enable the Sonicision™ device to deliver dissection and hemostasis in vessels up to 5 mm in diameter. The dual-mode energy activation button enables easy transitioning between minimum and maximum power settings... and it all comes in a cordless unit.

Coaching point:
The Sonicision™ device delivers the same performance in the key areas (thermal spread, vessel burst pressure, temperature) as the Harmonic ACE™* with the additional advantage of being cordless.*
ENVIROMENTAL

**Your device is less environmentally friendly because of the Battery and Generator.**

**Response:**
Covidien has gone to great lengths to make the system environmentally friendly. While, like the competition, the transducer will have to be disposed of at the end of its useful life — Covidien has set up a free battery recycling program for Sonicision™ device users within the U.S. and Canada (www.call-2-recycle.com).

**Coaching point:**
The Sonicision™ device battery recycling program reduces the environmental burden of spent medical devices.

EVIDENCE

*The Harmonic Scalpel™* has hundreds of studies that establish its capabilities in vessels up to 5 mm in diameter. You have only one study. Why should I trust your technology?

**Response:**
There are hundreds of studies that prove the effectiveness of ultrasonic dissection technology. In our efforts to prove the capabilities of this device and achieve FDA and European Clearance, we put Sonicision™ device through thorough testing to establish substantial equivalence in performance to the Harmonic ACE™. While the device is new and we are starting with a single study, we are confident that there will be additional studies as the technology proliferates. What types of studies are you most interested in seeing going forward?

**Coaching point:**
Many ground-breaking surgical technologies start with a single clinical study.
## ERGONOMICS

**Your device requires that I start in low power mode before advancing to maximum.**

*Response:* You will find that a light squeeze of the dual-mode energy button activates the device in the Minimum power setting and a complete squeeze brings you directly to the Maximum power. This design allows you to keep your finger in the same relative position while easily transitioning between the two power modes. Please give it a try doctor, I think you will find it easy to work with.

**Your device is heavier than the Harmonic ACE™?**

*Response:* Depending on how you account for the weight of the cord, the Sonicision™ device may weigh one or two ounces more (28 to 57 g). Further, surgeons told us that the pull from the cords of traditional instruments makes them feel heavier and restricts their movement in ways the Sonicision™ device does not.

**Coaching point:** Freedom of movement gained from the elimination of device tethering impacts the surgeons’ movement during a procedure.

## PORTFOLIO

**Why are you only offering one size?**

*Response:* We chose to focus our best efforts on a single version to start. The 39 cm length was designed to hit the “sweet spot” for standard laparoscopic and bariatric applications. What other shaft length variations would you like to see in the future?

**You are an Electrosurgery company. Why are you getting into Ultrasonics?**

*Response:* Covidien and Valleylab™ have a long legacy in Ultrasonics. Valleylab™ led the ultrasonic aspirator market with CUSA™ device and Autosonix™ device was the first 5 mm laparoscopic dissector. Ultrasonic and Vessel Sealing technologies both play important roles in your surgical instrumentation and Covidien is committed to providing a complete portfolio for all your energy needs.

**Are you saying that Ultrasonic is better than Valleylab™ Mode?**

*Response:* Both advanced bipolar energy and ultrasonics have their place in the surgical introduction of the Sonicision™ device. Covidien has an expanded portfolio and is now a single solution.
Olympus Sonosurg™* 34 cm

Olympus Thunderbeat™* 45 cm

Autosonix UltraShears™ 38 cm

Sonicision™ 39 cm

J & J Harmonic™ ACE45E 45 cm
FREQUENTLY ASKED QUESTIONS

GENERAL

**What is the weight of the assembled Sonicision™ device?**

The Sonicision™ cordless ultrasonic dissection device is approximately 14 oz. or 396.89 grams when fully assembled. This is approximately 2 oz. or 56.69 grams more than an assembled Harmonic ACE™ (includes transducer cable and plug).

**What is the frequency of operation of the Sonicision™ device?**

The Sonicision™ cordless ultrasonic dissection device operates at 55,500 Hz. This is the same as the Harmonic ACE™.

**How do I know when the battery and generator have reached 100 uses?**

Both components have internal counters and display different lights when they have reached maximum use life — 100 uses. A red indicator on the battery charger and a purple indicator on the generator indicate the end of useful life for the components. The battery and generator were designed to provide optimal performance throughout their lifespan.

**How do you define dissection relative to your claim that you are faster than the Harmonic ACE™?**

Internal testing conducted on the Sonicision™ cordless ultrasonic dissection device and the Harmonic ACE™ was conducted to transect 15 cm segments of small bowel mesentery on maximum power. The Sonicision™ transection time was 27% time faster than the Harmonic ACE™.

**What actions should be taken to remedy a red device indicator light upon assembly?**

- Remove and re-attach battery pack
- Re-torque generator
- Replace battery pack
- Replace generator
- Replace cordless ultrasonic dissector
What action should be taken to remedy a red device indicator light during use?

- Clean jaw and blade
- Remove and re-attach battery pack
- Replace battery pack
- Replace cordless ultrasonic dissector

What size vessels can be coagulated with Sonicision™ device?

The Sonicision™ cordless ultrasonic dissection device can be used to coagulate isolated vessels up to 5 mm in diameter.

Can the Sonicision™ device system be left in a car?

It is not recommended to leave the Sonicision™ system in your car other than when transporting it to hospitals. Temperatures outside the range of 10 °C – 30 °C can result in reduced battery service life and may also impact the amount of time it takes to charge a battery.

When is a cordless LigaSure™ device coming?

Cordless technology is undeniably a huge leap in our technology portfolio. We will actively monitor the market response to the Sonicision™ device and explore opportunities to apply cordless technology to Covidien products where it makes sense.

Do you plan to introduce a shorter shaft product in the future?

We are actively monitoring market response to the Sonicision™ device to determine how to best expand our ultrasonics portfolio. Please share your feedback on the needs of ultrasonic products with your global and regional marketing teams.
Why does the device “time out” during activation of energy?

The device will “time out” (stop delivery of energy to tissue) after approximately 20 seconds of continuous activation. This safety feature provides protection against prolonged unintentional activations. When a “time out” occurs during intended use the operator should simply release and re-engage the dual-mode energy activation button.

Is there a good way to estimate how many batteries and generators a hospital should purchase?

The first method is to simply replace the total number of competitive transducers in the hospital with the same number of Sonicision™ batteries and generators. For example, if the hospital has 100 Harmonic™* transducers they should replace them with 100 “sets” of Sonicision™ batteries and generators, with an additional calculation for spare batteries. The second method calculates a suggested initial order using variables such as the number of procedures on a given day, safety factor margin, delay for reprocessing. This tool is available to RSM and product marketers.

What are the benefits of the Sonicision™ device compared with other ultrasonic dissectors?

The Sonicision™ device delivers improved performance with the convenience and sophistication of an entirely cordless design. Sonicision™ ultrasonic technology provides faster dissection* through tissue and reduced visual obstruction from plume.2,3 the Sonicision™ device also utilizes an advanced ultrasonic generator that is small enough to fit in the palm of your hand — no software upgrades required.

What procedures can be performed using the Sonicision™ device?

The Sonicision™ device is used in a variety of procedures across multiple specialties such as: general (including upper gastrointestinal), bariatric, colorectal, gynecological and urological procedures.

What size vessels can be coagulated with the Sonicision™ device?

The Sonicision™ system can be used to coagulate isolated vessels up to 5 mm in diameter.

*compared to HARMONIC™* ACE
**Why is the Sonicision™ battery unique?**

The Sonicision™ battery is unique because it can be fully submersed in water, cleaned and re-sterilized for use. This design enhancement makes the battery small and easy to handle compared to other battery devices found in the operating room, such as orthopedic batteries.

**How long does a battery last during a case?**

Battery life depends on many factors including: idle time, how long it’s been on the shelf, the use profile (number and length of minimum vs maximum activations), and tissue type. One fully charged Sonicision™ battery should be sufficient for the majority of procedures when ultrasonic energy is typically used. It is always wise to have a second battery on hand for all cases.

**What sizes are available?**

The Sonicision™ ultrasonic dissection device currently has four available lengths: 13 cm, 26 cm 39 cm and 48 cm.
**BATTERY**

*How long does a battery last intra-operatively?*

The actual capacity for energy activations depends on many factors including; idle duration, shelf life and use profile, however our research indicates that one fully-charged Sonicision™ battery should satisfy the majority of procedures when ultrasonic energy is typically used. It is always wise to have a second battery available for all cases.

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*How long can a battery last once connected to the dissector?*

The Sonicision™ dissector draws minimal power from the battery when connected but not activated. The battery’s life is primarily determined by the number of activations.

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*How many times can the battery and generator be re-used?*

Both the battery and generator are limited to 100 procedures and low-temperature sterilization cycles. An internal counter in the battery monitors use and provides a red LED light on the battery charger when the battery has exceeded its 100 use life. The internal counter on the generator monitors use for that component and provides a flashing purple LED when the generator has exceeded its 100 use lifespan.

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*How long does it take to recharge a battery?*

A depleted battery typically takes approximately two hours to fully recharge.

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*Approximately how many activations remain once the yellow LED indicator light is displayed?*

The yellow LED indicator signals a battery has less than 20% remaining capacity. It is recommended to replace the battery as soon as possible.
Does the power output from the battery degrade as the charge state declines during a procedure?

No—this is one of the primary advantages of Sonicision™ battery chemistry and design. The output of a Sonicision™ battery will not diminish as the battery charge life decreases, meaning power output for the last activation is the same as the output for the first activation. The Sonicision™ battery works in a manner similar to a cell phone battery, it is either powered on and delivering full functionality or it is powered off.

What is the typical time that should be anticipated for the battery and generator components to be processed through the central sterile department (i.e. from the end of a procedure until the components can be reused in a procedure again)?

Based on the processes outlined in our user guide and feedback from central processing managers, we anticipate the cleaning, charging and sterilization steps will take several hours to complete. In hospitals with on-site central sterile capabilities products may be available for reuse as soon as these steps are completed. For hospitals that contract their central sterile services offsite this may lead to a turn-around time of up to several days. You are encouraged to confirm the specifics of this process with each Sonicision™ target hospital.

What would cause the battery’s safety valve to release pressure? Is the battery rendered useless at this point?

• A scenario that would possibly cause the safety valve to release pressure is placing the battery in the autoclave.
• If the safety valve has been released the battery is no longer usable.

Can I recharge the batteries using a DC power converter in my car?

No. Because the performance of DC Power converters may vary, the Covidien battery charger should only be powered using standard AC power to avoid damage to the charger.

How long can a battery sit on a shelf before needing a recharge?

To maintain optimal performance the battery pack should be used as soon as possible after completing charge. However, the battery should be submitted for recharging and sterilization after 30 days of continuous time on the shelf without use.
How long after a battery is initially purchased and received should it receive its first charge?

Battery packs are shipped from Covidien to the customer with a low charge and in a “deep sleep” state. To avoid damage and ensure the battery pack remains functional, the battery pack should be charged upon initial receipt by the customer.

What happens if the battery and generator are autoclaved?

The materials used to house the battery and generator are not designed to withstand the high temperatures experienced in an autoclave system. Exposing the battery and generator to autoclave temperatures will cause the external material to deform, damage the battery cells, and render the components unusable.

If the battery is colder than 10 °C how long will it take to charge?

Batteries that are colder than 10 °C will charge at roughly 10% of the normal charge rate until that battery temperature exceeds 10 °C at which time it will return to the normal charging rate.
The Sonicision™ System
The Science of Performance, The Ease of a Full Portfolio
You won’t believe where we’re taking you next.

2. On maximum power through 15 cm of porcine mesentery.

IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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