



Sonicision™ System Product Manual





[Energy whenever
and wherever
you want it]



The **SONICISION™** System
The industry's first cordless
ultrasonic dissection system now
offers the widest portfolio and
ease of standardization



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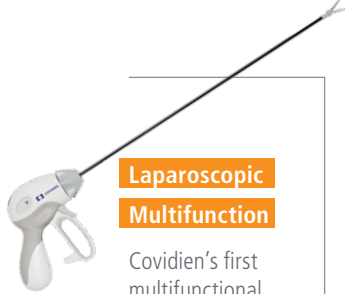
Why Ultrasonic?

Covidien has long been a pioneer in creating medical devices that use various forms of energy. Covidien Energy offers the largest energy-based, and now the most versatile cordless ultrasonic portfolio in the industry.



Monopolar

Hundreds of products you use every day 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.

**MORE ENERGY
MORE PLACES**



Valleylab™ Devices

ForceTriad™ Energy Platform ▶



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



Ultrasonic Energy

With the Sonication™ device, Covidien has an expanded portfolio and is a single solution provider for energy devices.

The energy portfolio available allows complete standardization to reduce costs.

Product Overview

The **Sonicision™** cordless ultrasonic dissection device is an unparalleled advancement in ultrasonic energy. The device delivers comparable clinical effectiveness associated with leading ultrasonic technologies and unique benefits from **the industry's first cordless design**.

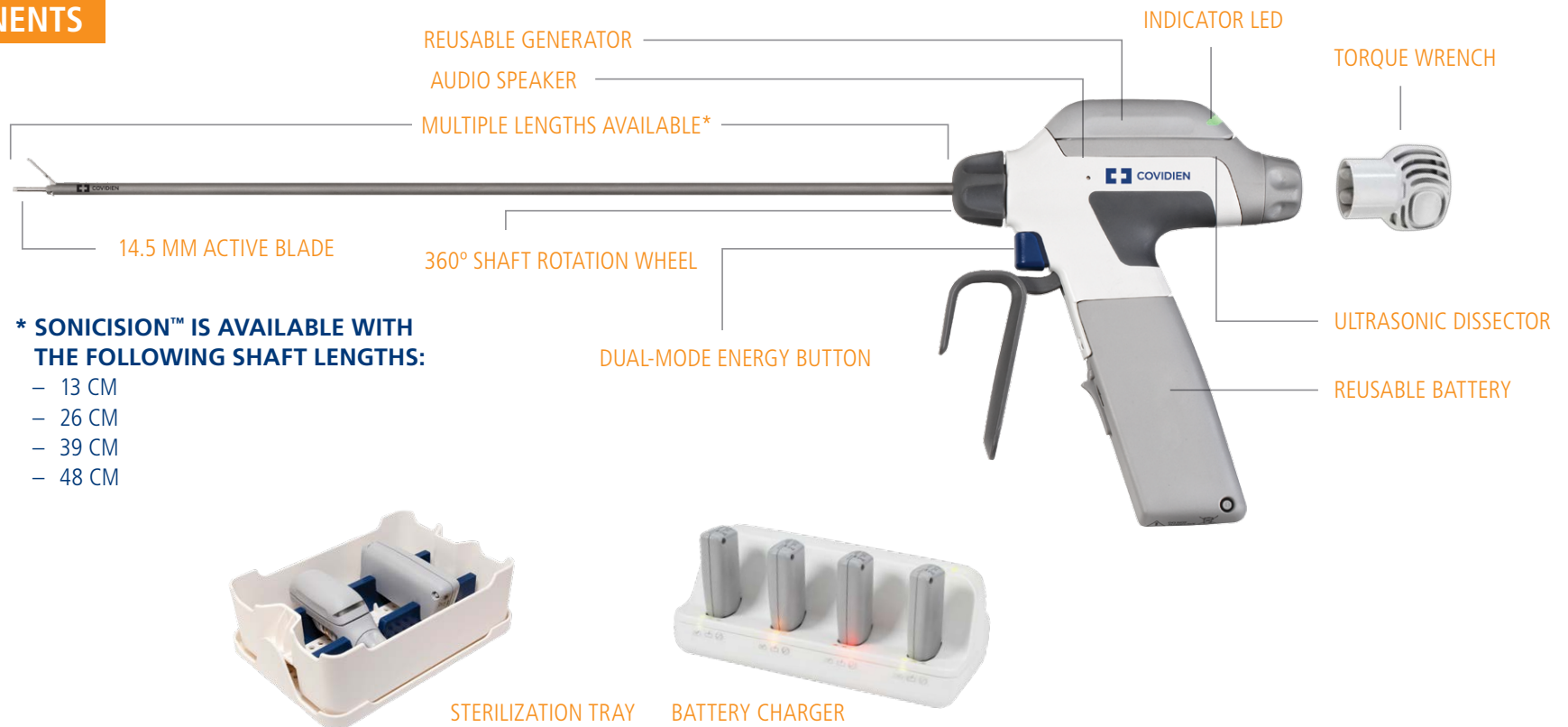
The Sonicision™ device allows **improved freedom of movement** in the operating room through the innovation of cordless technology. The streamlined design features a **quick and simple set up** that increases O.R. efficiency.

The Sonicision™ device reliably seals vessels up to 5 mm, provides faster dissection speed² and up to 5x less plume than the Harmonic ACE™*³, and is comparable to the Harmonic ACE™* and Harmonic ACE+™* in thermal spread⁸, burst pressure¹¹, sealing time⁹ and temperature.^{2,4,10}

The Sonicision™ device also utilizes a unique **dual-mode energy activation control** for seamless transition between two power modes within a single button. This intuitive design allows a surgeon's eyes to remain in the surgical field rather than on the instrument **for improved procedural focus**.

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

COMPONENTS



Product Overview

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)

26 CM LENGTH



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

39 CM LENGTH



Ordering Code: SCD396
Order Quantity: 6 ultrasonic dissectors 39 cm (1 torque wrench included with each dissector)

SCD391
(select countries only)
1 ultrasonic dissector 39 cm
(1 torque wrench included)

48 CM LENGTH



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

Product Overview

AVAILABLE LENGTHS

REUSABLE BATTERY

Ordering Code: SCG
Order Quantity: 1 battery pack

- Reusable for up to 100 uses
- Sterilizable via low temperature hydrogen peroxide
- Advanced lithium polymer battery chemistry



BATTERY CHARGER

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

- Four charging bays
- Supports charging of 4 batteries simultaneously



REUSABLE GENERATOR

Ordering Code: SCG
Order Quantity: 1 generator

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



STERILIZATION TRAY

Ordering Code: SCST (U.S. customers only)
SCST1 (outside U.S. customers only)
Order Quantity: 1 sterilization tray

- Holds one generator and one battery



Award-Winning Device

MDEA GOLD

The Medical Design Excellence Awards (MDEA) competition is the MedTech Industry's Premier Award — given to the most significant advances in medical product design and engineering of a groundbreaking product in the surgical equipment.



RED DOT

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.



reddot award 2014
winner

ESP AWARD

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



BOULDER IQ

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.



2013 WINNER



Thermal spread, vessel burst pressure, hemostasis, seal time and blade temperature are comparable to the Harmonic ACE™* and Harmonic ACE+™*2, 4, 8-11

Clinical Performance

Performance of the Sonicision™ Cordless Ultrasonic Dissection Device compared to the Harmonic ACE™* and Harmonic ACE+™*.

OVERVIEW

- The Sonicision™ device mean thermal spread, mean 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 provides faster dissection speed than the Harmonic ACE™*2
- The Sonicision™ device produces up to 5x less plume than the Harmonic ACE™*3
- The Sonicision™ device provides faster active blade cool down time to 60°C than the Harmonic ACE™*1
- 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 surgery. The latest innovation from Covidien into this arena is the completion of the Sonicision™ cordless ultrasonic portfolio. Now with four available shaft lengths, inclusive of the the longest and 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 the 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+™*.

The following table summarizes the pre-clinical comparative testing between the Sonicision™ device and the Harmonic ACE™*:

SUMMARY

Differences between the Sonicision™ cordless ultrasonic dissection device and the Harmonic ACE™* were found to be non-significant in regard to mean vessel burst pressure, mean thermal spread, mean peak active blade temperature and mean seal time. The Sonicision™ device was **statistically faster in mean dissection speed and mean active blade cool down time to 60 degrees C in these tests.**^{1,2,4}

	Mean Vessel Burst Pressure (mmHg ± SD) ²	Mean Dissection Speed (sec ± SD) ²	Mean Peak Active Blade Temperature (°C ± SD) ⁴	Mean Active Blade Cool Down Time to 60°C (sec ± SD) ¹	Mean Thermal Spread (mm ± SD) ²	Mean Seal Time (sec ± SD) ²
Sonicision™	578 ± 284	24.8 ± 4.9	249.7 ± 24.3	41.2 ± 1.3	1.06 ± 0.05	5.2 ± 1.7
ACE™*	605 ± 288	33.8 ± 5.4	239.3 ± 28.4	50.4 ± 7.5	1.08 ± 0.5	4.9 ± 1.5
P-Value	0.48	<0.001	0.173	0.006	0.82	0.20
Statistical Relevance	NS	Statistically Significant	NS	Statistically Significant	NS	NS

Sonicision™ provides faster dissection² and has a faster active blade cool down time⁴ than the Harmonic Ace™*.

	Average Coagulation Obstruction	Average Cutting Obstruction
	Maximum Obstruction (%) ³	Maximum Obstruction (%) ³
Sonicision™	4.80 ± 0.86	8.76 ± 1.49
ACE™*	26.63 ± 3.70	12.65 ± 0.97
P-Value	<0.001	0.026
Statistical Relevance	Statistically Significant	NS

Sonicision™ produces up to 5x less plume than the Harmonic Ace™*³



The following table summarizes benchtop testing between the Sonicision™ device and the Harmonic ACE+™*:

	Mean Vessel Burst Pressure (mmHg ± SD) ¹¹	Mean Dissection Speed (sec ± SD) ¹⁰	Mean Peak Active Blade Temperature (°C ± SD) ¹⁰	Mean Active Blade Cool Down Time to 60°C (sec ± SD) ¹⁰	Mean Thermal Spread (mm ± SD) ⁸	Mean Seal Time (sec ± SD) ⁹
Sonicision™	868.4 ± 419.9	43.4 ± 7.0	263.1 ± 18.8	37.6 ± 4.4	1.44 ± 0.5	8.40 ± 3.60
ACE+™*	1030.1 ± 405.1	44.6 ± 4.3	266.3 ± 20.2	37.4 ± 5.8	1.25 ± 0.2	8.12 ± 3.74
P-Value	P = 0.18	P = 0.777	P = 0.771	P = 0.704	P = 0.100	P = 0.62
Statistical Relevance	NS	NS	NS	NS	NS	NS

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





Procedural Applications

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

- Pneumonectomy
- Pulmonary Lymph Node Dissection

Urology

- Prostatotomy

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

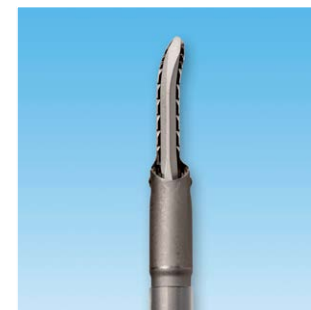
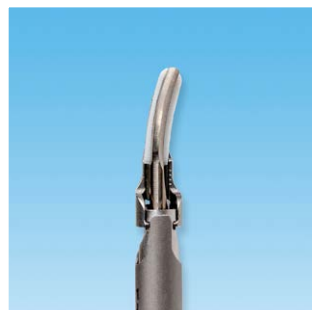
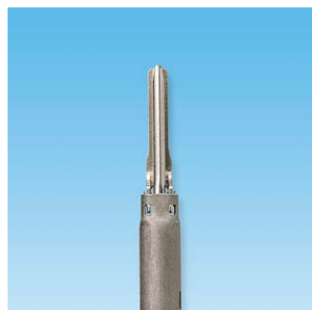
Complete Product Portfolio

The right energy solution for procedural need and surgeon preference — from a single manufacturer

Dissection	Multi-Function		Vessel Sealing
• Smaller vessels	• Primarily dissection with some vessel sealing	• Primarily vessel sealing with some dissection	• Up to 7 mm vessels
Electrosurgery	Ultrasonic	RF and ES	RF
Force TriVerse™	Sonicision™	LigaSure Advance™ II	LigaSure™ 5 mm
• Sterile field power control • Access to Valleylab™ mode	• Freedom (cordless) • Standardization • Faster set up and dissection²	• Multi-functionality • Bariatric length (44 cm) • Valleylab™ mode dissection	• Proven LS performance • Independent cutting and sealing • Cooler temperature profile

Competitive Comparison

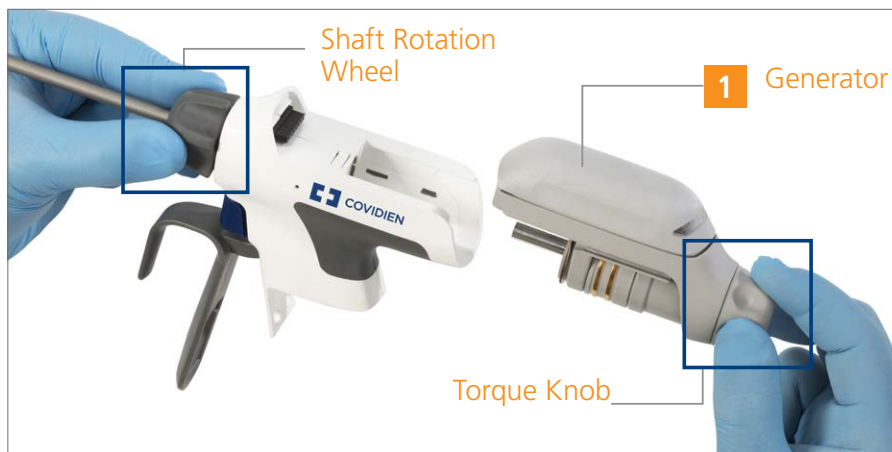
ULTRASONIC DISSECTOR COMPARISON



Measure:	Sonicision™	J&J Harmonic™ ACE	J&J Harmonic ACE+™*	Olympus Thunderbeat™*
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 Length ¹²	14.5 mm	11.1 mm	10.7 mm	16.5 mm
Total Weight of Device Assembled ¹³ (with cords and transducer)	394.25 grams	337.47 grams	341.86 grams	386.86 grams

Assembly and Disassembly

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.

Assembly and Disassembly

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.

Assembly and Disassembly

REPLACING BATTERY



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



RED INDICATOR LIGHT
Device is non-functional

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.

Assembly and Disassembly

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

CLEANING

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.

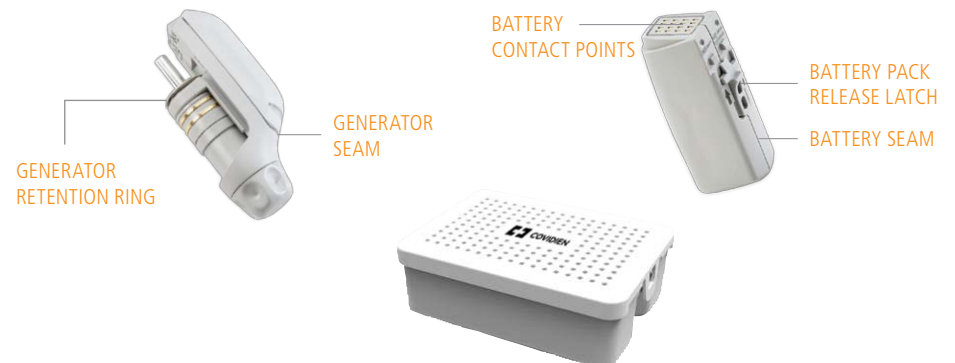
CAUTION: DO NOT wash components in automatic instrument washer or ultrasonic washer.

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.



Cleaning and Sterilization

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:

Sterilizer	Sterile Barrier		
	Polypropylene Wrap	Tyvek Pouch (Single)	Tyvek Pouch (Double)
STERRAD™ 100S	✓		
STERRAD™ NX™*	✓	✓	
STERRAD™ 100NX™*	✓	✓	✓
STERIS V-PRO™ 1	✓	✓	✓
STERIS V-PRO™ 1 PLUS	✓	✓	✓
STERIS V-PRO™ maX	✓	✓	✓

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.

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.
 - **Single Tyvek Pouch** – Place the sterilization tray in a single compatible Tyvek pouch, and seal according to the manufacturer's instructions.
 - **Double Tyvek Pouch** – Place the sterilization tray within two compatible Tyvek pouches, and seal according to the manufacturer's instructions. The Tyvek side of the inside pouch must be aligned with the Tyvek side of the outside pouch.
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:

Model	Cycle
STERRAD™ 100S	Standard, Short or Long*
STERRAD™ NX™*	Standard
STERRAD™ 100NX™*	Standard
STERIS AMSCO™ V-PRO™ 1	Lumen
STERIS AMSCO™ V-PRO™ 1 Plus	Lumen
STERIS AMSCO™ V-PRO™ maX	Lumen

*Short and Long cycles are not available on 100S models sold in the United States

Cleaning and Sterilization

STORAGE

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.



CENTRAL PROCESSING

Used battery and generator exit O.R.

Cleaning and Decontamination

Manual Cleaning

Battery, Generator and Sterilization Tray
soak five to ten minutes in pH-neutral enzymtic, scrub with a stiff, nylon bristle brush



Stage Generator until battery charge is complete

Charge Battery

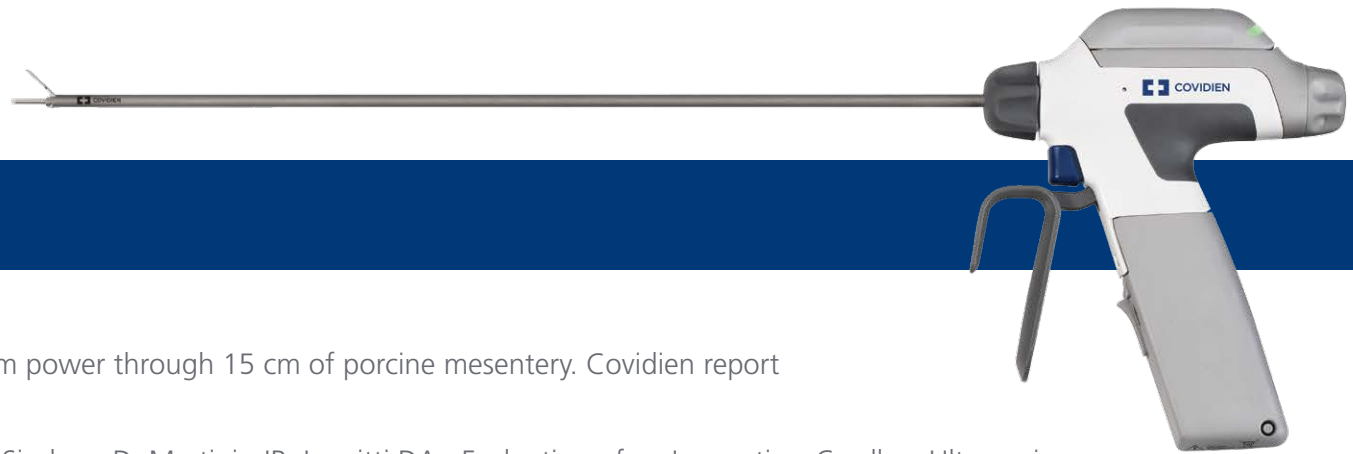


Place components in sterilization tray and wrap

Sterilize using low temperature sterilization (i.e. STERRAD™)

Store components. Recharge and sterilize batteries after one month of storage

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.



References

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11. Based on internal testing using minimum mode on isolated vessels. Covidien report December 12, 2013 R0047124 Rev A.
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The Sonicision™ System

The Science of Performance, The Ease of a Full Portfolio

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