Echelon Circular™

BACKED BY A
BODY OF EVIDENCE

Value Analysis Summary:

ECHELON CIRCULAR™ Powered Stapler

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Clinical challenges

Needed: An optimized stapling solution that reduces leaks without compromising perfusion

Tissue tension, poor blood supply and variable tissue thickness can compromise the anastomosis and lead to significant complications. Among complications, **anastomotic leaks are a dominant surgical concern due to their high mortality risk.**

Post-operative anastomotic leaks occur in up to 12% of colorectal surgeries with mortality reported between 12% and 27%.[1]

Anastomotic leak rates

Up to **12%** of colorectal resections[1]

Up to **4%** of gastrectomies[2]

Up to **11%** of esophagectomies[3]

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[1] Koianka T, Kevin M, Martin W, et al. Identifying Important Predictors for Anastomotic Leak After Colon and Rectal Resection. Annals of Surgery. 2013; 257: 108.

[2] Oh SJ, Choi WB, Song J. et al. Complications requiring reoperation after gastrectomy for gastric cancer: 17 years experience in a single institute. J Gastrointest Surg. 2009; 13:239.

[3] Kassis E, Kosinski A, Ross P, et al. Predictors of anastomotic leak after esophagectomy: an analysis of the society of thoracic surgeons general thoracic database. Ann Thorac Surg. 2013; 96:1919.

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Executive overview

Optimized perfusion.[4] Reduced leaks at the staple line.[4]

ECHELON CIRCULAR™ Powered Stapler with two innovative stapling technologies

ECHELON CIRCULAR demonstrated a **1.8% anastomotic leak rate**[5] in a multi-site, multi-country clinical study. In a separate clinical study, it demonstrated a **1.7% anastomotic leak rate**, which was an 85% reduction compared to manual circular staplers (1.7% v. 11.8%, p=0.02).[6]

- 3D Stapling Technology **evenly distributed compression**[8]
- Gripping Surface Technology provided **gentler handling** with a 33% reduction in compressive forces on tissue[6]
- The combination of 3D Stapling Technology and the Gripping Surface Technology **optimized perfusion and reduced leaks at the staple line**[4]

Built on a powered firing platform, the ECHELON CIRCULAR Powered Stapler had 37% less movement at the distal tip for **increased stability.**[9]

Examples of applicable procedures

Designed specifically for creating the anastomosis in colorectal, gastric and thoracic procedures.

Colon resection **Gastrectomy** **Esophagectomy**

Claims compared to Medtronic DST Series™ EEA™ Stapler

4 Benchtop testing in porcine tissue ≤30mmHg (26mmHg average pressure experienced during intra-operative leak test), comparing Ethicon CDH29P to Medtronic EEA2835 (p<0.001) and pre-clinical perfusion model, in which perfusion was not significantly different between devices (p>0.005). **5** A Prospective, Multi Center Evaluation of the ECHELON CIRCULAR Powered Stapler in Left-Sided Colorectal Anastomoses, N=168. **6** Impact of the Novel Powered Circular Stapler on Risk of Anastomotic Leakage in Colorectal Anastomosis. A Propensity Score-Matched Study. [ECHELON CIRCULAR 1.7% (1/60) vs. manual circular 11.8% (14/119), p=0.022]. **7** Staple line analysis in benchtop testing, comparing Ethicon CDH25P to Medtronic EEA2535. **8** Benchtop testing on porcine colon, comparing Ethicon CDH29P to Medtronic EEA2835, p<0.001. **9** Users firing in a porcine model, comparing Ethicon CDH29P to Medtronic EEA2835, p=0.003.

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Economic value

Impact of complications

The impact of a post-operative anastomotic leak on healthcare costs and patient lives can be significant:

x3

2-3 times higher healthcare costs[10]

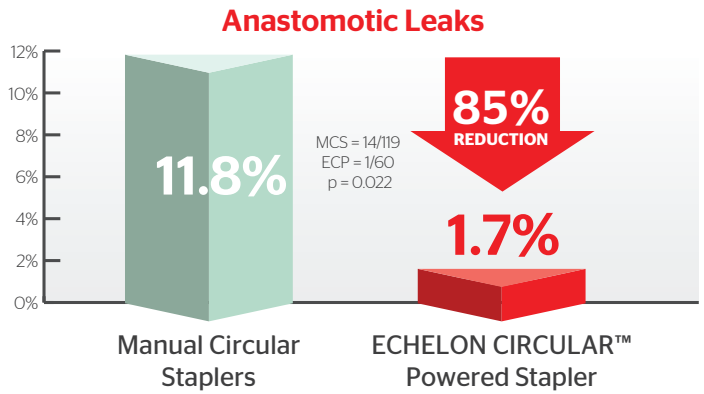
x2

2 times longer length of stay[10]

Patients who had post-operative anastomotic leaks incurred an **additional hospital cost of $24,129.**[11]

The cause of anastomotic leaks is multi-factorial, including both patient and surgical factors. With two proprietary technologies, the ECHELON CIRCULAR Powered Stapler addresses device-to-tissue interaction and device-to-user interaction to reduce leaks at the staple line without compromising perfusion.[4] This can have **a significant positive impact on healthcare costs.**

Performance in clinical studies



While leaks are multifactorial, this stapler demonstrated the following in two clinical studies:

- **1.8% anastomotic leak rate**[5] in a multi-site, multi-country clinical study
- **1.7% anastomotic leak rate** in a single institution clinical study, which represented an **85% reduction compared to manual circular staplers** (1.7% v. 11.8%, p=0.02)[6]

Claims compared to Medtronic DST Series™ EEA™ Stapler

[4] Benchtop testing in porcine tissue ≤30mmHg (26mmHg average pressure experienced during intra-operative leak test), comparing Ethicon CDH29P to Medtronic EEA2835 ($p<0.001$) and pre-clinical perfusion model, in which perfusion was not significantly different between devices ($p>0.005$).

[5] A Prospective, Multi Center Evaluation of the ECHELON CIRCULAR Powered Stapler in Left-Sided Colorectal Anastomoses, N=168.

[6] Impact of the Novel Powered Circular Stapler on Risk of Anastomotic Leakage in Colorectal Anastomosis. A Propensity Score-Matched Study. [ECHELON CIRCULAR 1.7% (1/60) vs. manual circular 11.8% (14/119), p=0.022].

[10] Schiff A, Brady BL, Ghosh SK, et al. Estimated Rate of Post-Operative Anastomotic Leak Following Colorectal Resection Surgery: A Systematic Review. Journal of Surgery and Surgical Research. 2016;2(1): 060-067.

[11] Hammond J, Lim S, Wan Y, et al. The Burden of Gastrointestinal Anastomotic Leaks: an Evaluation of Clinical and Economic Outcomes. J Gastrointest Surg. 2014; 18:1176-1185.

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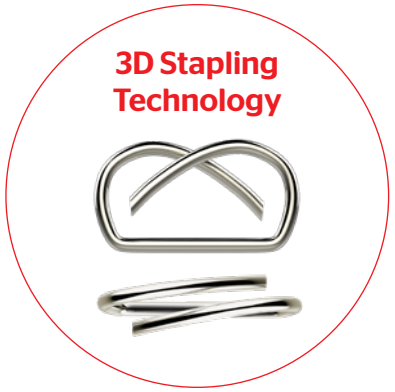
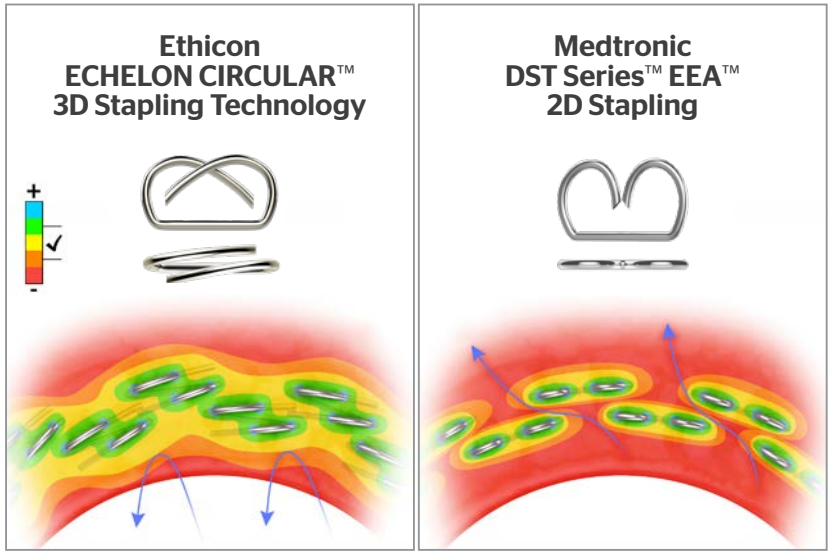
Product performance highlights

3D Stapling Technology

- Designed with offset closure of the staple legs, 3D Stapling Technology **evenly distributed compression throughout the anastomosis.**[7]
- **Reduced potential leak paths.**[7]





Conceptual comparison demonstrating potential effects of tissue compression during firing. Results can vary based on tissue characteristics, device design, techniques and other factors.

Claims compared to Medtronic DST Series™ EEA™ Stapler

[7] Staple line analysis in benchtop testing, comparing Ethicon CDH25P to Medtronic EEA2535.

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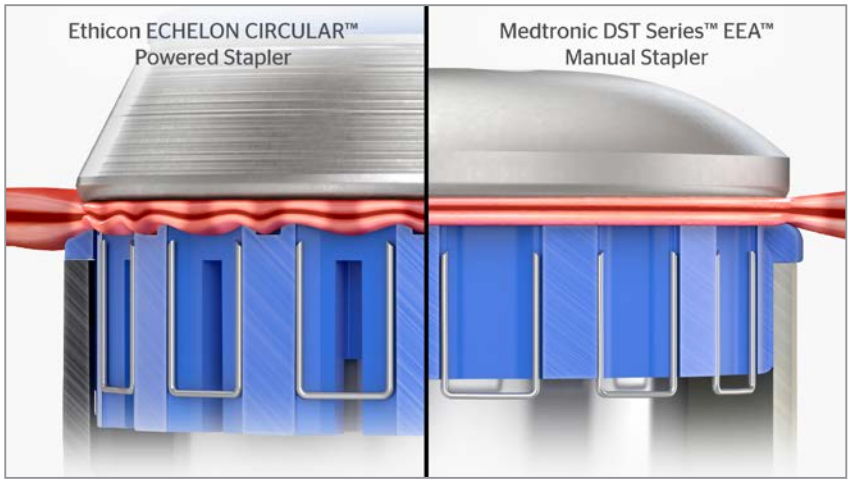
Product performance highlights

Gripping Surface Technology

- Atraumatic Gripping Surface Technology gave **precise compression only where it is needed**[8] to prepare the tissue for staple formation.
- Provided gentler handling with a 33% reduction in compressive forces on tissue.[8]



Conceptual comparison demonstrating potential effects of tissue compression during firing. Results can vary based on tissue characteristics, device design, techniques and other factors.

Claims compared to Medtronic DST Series™ EEA™ Stapler

[8] Benchtop testing on porcine colon, comparing Ethicon CDH29P to Medtronic EEA2835, p<0.001.

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Key safety features

Powered firing platform

- 37% less movement at the distal tip for **increased stability.**[9]
- Is designed to help minimize variation in usage and standardize performance across users.

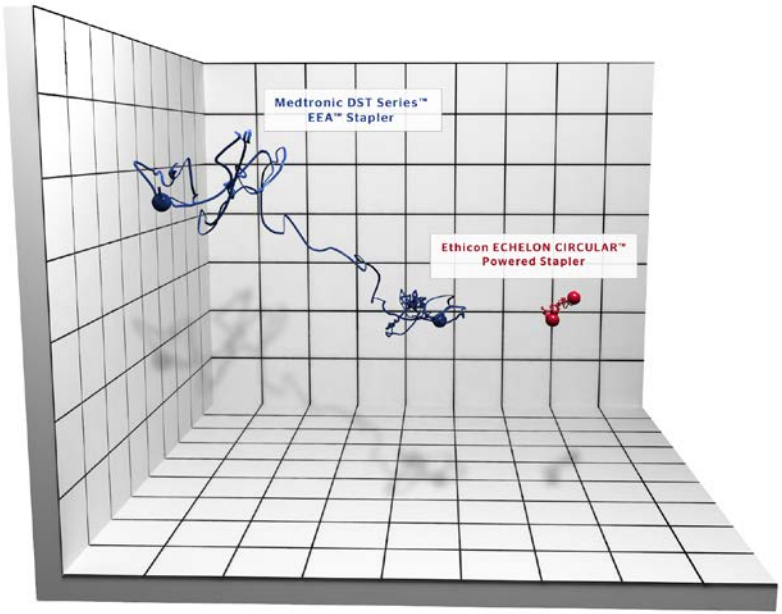

Illustration depicts actual paths of tip movement during testing—each cube represents a space measuring 5mm

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Claims compared to Medtronic DST Series™ EEA™ Stapler

[7] Users firing in a porcine model, comparing Ethicon CDH29P to Medtronic EEA2835, p=0.003.

[12] Benchtop testing, comparing Ethicon CDH29P to Medtronic EEA2835, p=0.001.

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Controlled Tissue Compression

Designed for less overcompression and less tissue damage[16]

- Ethicon's portfolio of circular staplers with adjustable compression had less tissue damage than Medtronic's fixed compression circular staplers[17]

Simplified inventory management

- Accommodates a range of tissue thicknesses,[13] potentially minimizing SKUs

Tissue compression scale

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[13] Adjustable Closed Staple Height of 1.5-2.2mm per Instructions for Use.

[16] In-vitro collagen tissue model with Ethicon Circular Staplers, 56 out of 136 collagen tissues exhibited overcompression with adjustable compression (CDH29A), vs. 48 out of 48 Medtronic circular staplers with fixed compression (EEA28MT), and 19 out of 232 collagen tissues exhibited unacceptable tissue damage with adjustable compression, vs. 29 out of 88 with Medtronic fixed compression (EEA28MT)

[17] In-vitro collagen tissue model with Ethicon Circular Staplers, 19 out of 232 collagen tissues exhibited unacceptable tissue damage with adjustable compression (CDH29A), vs. 29 out of 88 with Medtronic fixed compression (EEA28MT).

ECHELON CIRCULAR™ Powered Stapler

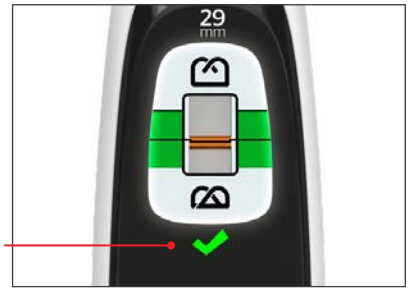
Key highlights – steps for use

Note: These steps are different from other Ethicon circular staplers.

Please see below for key highlights in the steps for use of this device. It is highly recommended that all potential users access the broad resources available to them on ethicon.com/EchelonCircular prior to use:

- Steps for use video
- Optimal Device Performance Guide
- Contact your local Ethicon representative for a full in-service

1. To fire the device, move the Red Safety back toward the handle. Activate the firing sequence by completely depressing the Firing Trigger.



2. An illuminated green check mark indicates that the firing sequence is complete.

** If the device fails to stop after 7-10 seconds, remove the battery and use caution when removing the device.

3. To release the device from the anastomosis, turn the adjusting knob counterclockwise for two complete revolutions.

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For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

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Disposable Battery Pack

Responsible power

The ECHELON CIRCULAR™ Powered Stapler battery pack provides:

- **Reliability:** Disposable batteries ensure full power for the case
- **Environmental responsibility:** Battery pack does not contain heavy metals and is considered nonhazardous waste at time of final disposal
- **Cost control and convenience:** No capital purchase or hassles with extra setup, disposal, recharging equipment, or hospital sterilization processes

Simple disposal

It is safe to discard the battery pack in your hospital's normal medical waste stream.[14] If your local regulations require lithium batteries to be recycled, the battery pack must first be decontaminated according to the instructions below.[15]

1. Disconnect battery pack.[15]

2. Discard pack in normal medical waste stream.[14]

IMPORTANT

Do NOT incinerate/autoclave battery pack in the hospital.

- Per the manufacturer, the batteries are not to be exposed to temperatures above 100° Celsius
- The batteries are not reusable and do not need to be sterilized
- Do not use Ethylene Oxide (EtO) process for battery pack

[14] Once the drain has been activated by insertion of the battery into the device, disposal is compliant with the US EPA and state regulations as of December 2010.

[15] In the event that the battery pack needs to be decontaminated before disposal, follow this process between Steps 1 and 2:
- Use a soft bristle brush to clean the battery pack surface with a neutral pH detergent or neutral pH enzymatic detergent (eg, Simple Green D Pro 3®; 10% bleach; 70% isopropyl alcohol), prepared according to the manufacturer's instructions
- Thoroughly scrub areas that contain crevices
- Thoroughly wipe off detergent with lukewarm tap water (DO NOT SUBMERGE IN WATER OR DETERGENTS)
- Visually inspect to ensure the debris is removed; repeat cleaning if necessary to obtain a visually clean battery pack

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System components and codes

The ECHELON CIRCULAR Powered Stapler is available in four sizes to allow proper matching of device to diameter of the lumen.

ECHELON CIRCULAR™ Powered Stapler

CODE	DIAMETER	QUANTITY PER SALES UNIT
CDH23P	23mm	3
CDH25P	25mm	3
CDH29P	29mm	3
CDH31P	31mm	3

ECHELON CIRCULAR™ Powered Stapler

Ordering information

For more information on our product please call customer service in:

Australia on 02 9815 4260 or 1800 252194

New Zealand on 0800 803 988

For complete product details, see Instructions for Use.

Australia: Johnson & Johnson Medical Pty Ltd, 1-5 Khartoum Road, North Ryde, NSW 2113
New Zealand: Johnson & Johnson (New Zealand) Ltd, 507 Mt Wellington Highway, Mt Wellington, Auckland 1060

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FDA clearance letter

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K163523