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.[1] Among complications, **anastomotic leaks are a dominant surgical concern due to their high mortality risk.[2]**

Post-operative anastomotic leaks occur in up to 8.6% of colorectal surgeries[3] with mortality reported between 12% and 27%.[4]

Anastomotic leak rates

8.6% of colorectal resections[3]

Up to **4%** of gastrectomies[5]

Up to **11%** of esophagectomies[6]

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Executive overview

Reduced leaks at the staple line without compromising perfusion[7*]

ECHELON CIRCULAR™ Powered Stapler with two innovative stapling technologies

ECHELON CIRCULAR demonstrated a **1.8% anastomotic leak rate** in a multi-site, multi-country clinical study.[1#] 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).[2†]

- 3D Stapling Technology **evenly distributed compression**[8‡]
- Gripping Surface Technology provided **gentler handling** with a 33% reduction in compressive forces on tissue[9¥]
- The combination of 3D Stapling Technology and the Gripping Surface Technology **maintained perfusion and reduced leaks at the staple line**[7*]

Built on a powered firing platform, the ECHELON CIRCULAR Powered Stapler had 37% less movement at the distal tip for **increased stability.**[10§]

Designed for creating the anastomosis throughout the alimentary tract[11]

Examples of applicable procedures

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

Claims compared to Medtronic DST Series™ EEA™ Stapler
Based on benchtop testing

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***** Benchtop testing in porcine tissue ≤30mmHg (26mmHg average pressure experienced during intra-operative leak test), comparing Ethicon CDH29P to Medtronic (Covidien) manual EEA2835 (p<0.001) and preclinical perfusion model, in which perfusion was not significantly different between devices.

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

† 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]

‡ Staple line analysis in benchtop testing (non tissue), comparing Ethicon CDH25P (closed to the lowest end of the tissue compression scale) to Covidien (Medtronic) manual EEA2535 (p<0.05). Even refers to pressure distribution underneath each individual staple. Comprehensive refers to pressure distribution over the entire staple line.

¥ Benchtop testing on porcine colon, comparing Ethicon CDH29P (closed to the lowest end of the tissue compression scale) to Covidien (Medtronic) manual EEA2835, p<0.001.

§ Users firing in a porcine model, comparing Ethicon CDH29P (n=15) to Medtronic Covidien EEA2835 (n=15), p=0.003.

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Economic value

Impact of complications

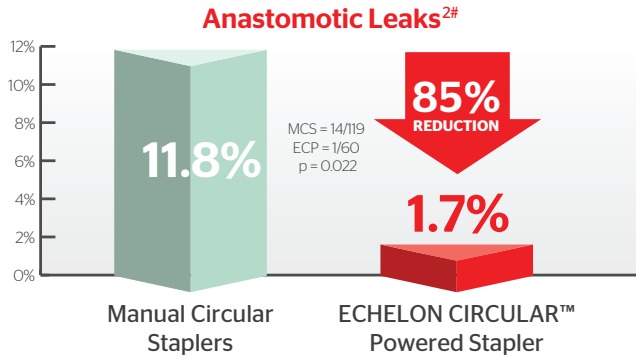
The impact of a post-operative anastomotic leak on healthcare costs and patient lives can be significant:

Up to €35,000 increased average hospital costs[12]

Lengthen hospital stay by up to 26 days[13]

The cause of anastomotic leaks is multi-factorial, including both patient and surgical factors. With two technologies, the ECHELON CIRCULAR Powered Stapler addresses device-to-tissue interaction to reduce leaks at the staple line without compromising perfusion.[7]* This can have **a 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** in a multi-site, multi-country clinical study [1†]
- **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) [2#]

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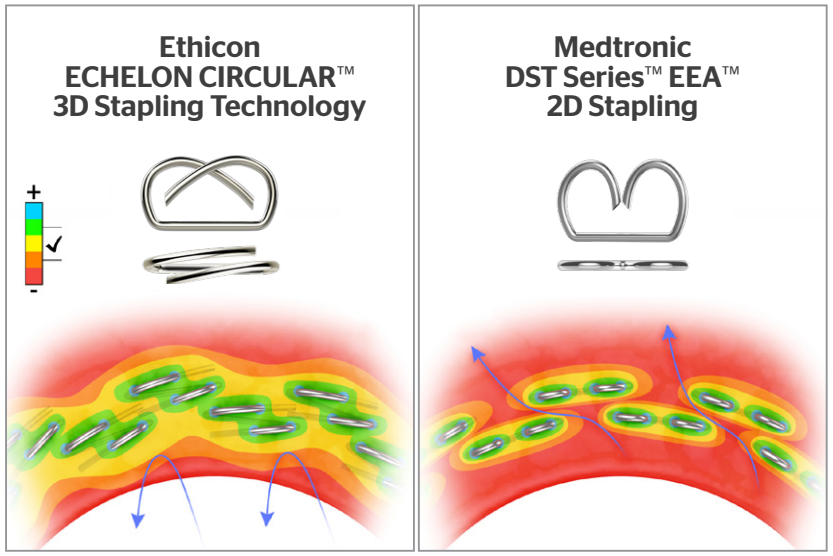
Product performance highlights

3D Stapling Technology

- With offset closure of the staple legs, 3D Stapling Technology **is designed to evenly distribute compression throughout the anastomosis to reduce potential leak paths.**[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
Based on benchtop testing

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* Staple line analysis in benchtop testing (non tissue), comparing Ethicon CDH25P (closed to the lowest end of the tissue compression scale) to Covidien (Medtronic) manual EEA2535 ($p<0.05$). Even refers to pressure distribution underneath each individual staple. Comprehensive refers to pressure distribution over the entire staple line.

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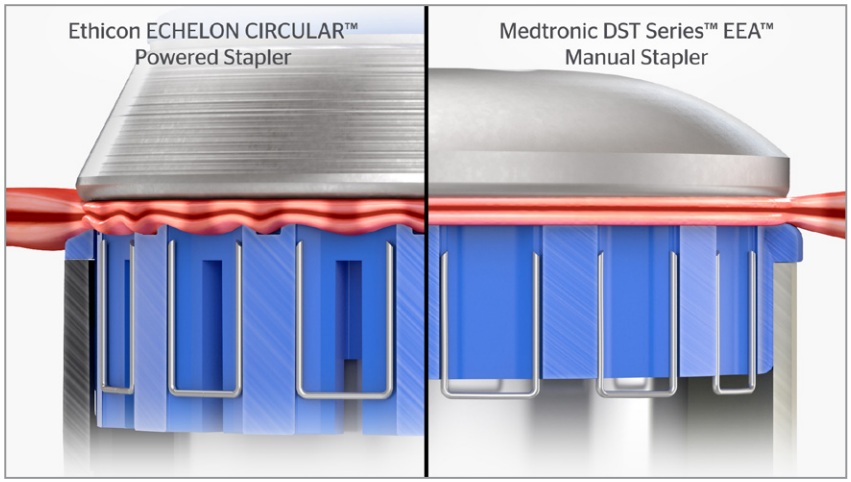
Product performance highlights

Gripping Surface Technology

- Atraumatic Gripping Surface Technology gave **precise compression where it is needed** to prepare the tissue for staple formation.[9]*
- Provided gentler handling with a 33% reduction in compressive forces on tissue.[9]*



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
Based on benchtop testing

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* Benchtop testing on porcine colon, comparing Ethicon CDH29P (closed to the lowest end of the tissue compression scale) to Covidien (Medtronic) manual EEA2835, $p<0.001$.

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Key safety features

Powered firing platform

- 37% less movement at the distal tip for **increased stability.**[10*]
- Is designed with safety features that may help to minimize variation in usage and standardize performance across users.[14]

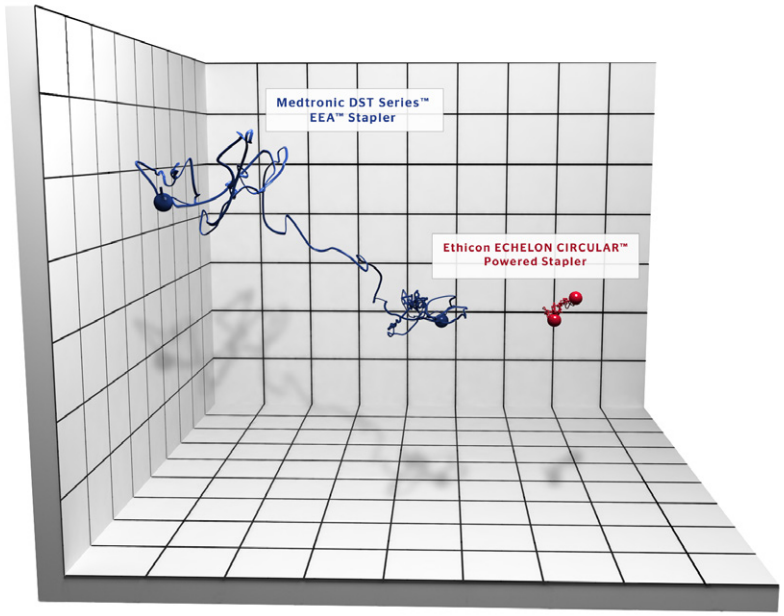

Illustration depicts actual paths of tip movement during testing—each cube represents a space measuring 5mm

Claims compared to Medtronic DST Series™ EEA™ Stapler
Based on benchtop testing

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***** Users firing in a porcine model, comparing Ethicon CDH29P (n=15) to Medtronic Covidien EEA2835 (n=15), p=0.003.

Benchtop testing (2-sample t test), comparing Ethicon CDH29P to Medtronic EEA2835, p=0.001.

ECHELON CIRCULAR™ Powered Stapler

Controlled Tissue Compression

Less overcompression and less tissue damage[16*]

- Ethicon's portfolio of circular staplers with adjustable compression had less unacceptable tissue damage than Medtronic's fixed compression circular staplers[16#]

Simplified inventory management

- Accommodates a range of tissue thicknesses†

Tissue compression scale

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* 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 (EEA28 with green cartridge), and 19 out of 232 collagen tissues exhibited unacceptable tissue damage with adjustable compression (CDH29A), vs. 32 out of 232 with maximal compression (CDH29A), and vs. 29 out of 88 with Medtronic fixed compression (EEA28 with green cartridge). Unacceptable tissue damage was defined as cases where the damage exceeded half of the collagen thickness.

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 (EEA28 with green cartridge). Unacceptable injury was defined as cases where the damage exceeded half of the collagen thickness.

† Adjustable Closed Staple Height of 1.5-2.2mm per Instructions for Use.

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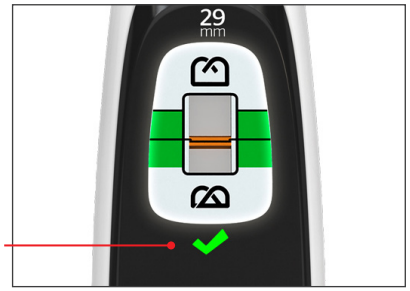
Key highlights – steps for use

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 www.jnjmedicaldevices.com 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.

ECHELON CIRCULAR™ Powered Stapler

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

Note:

Recycling of lithium batteries is obligatory in the European Union. If the battery pack requires decontamination prior to disposal, follow your hospital's protocol or instructions below.*

1. Disconnect battery pack.*

2. The battery pack should be returned to a battery collection point. It must not be disposed of in the hospital waste

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

*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

References:

1. Herzig DO, Ogilvie JW, Chudzinski A, et al. Assessment of a circular powered stapler for creation of anastomosis in left-sided colorectal surgery: A prospective cohort study. Int J Surg. 2020;84:140-146

2. Pla-Martí V, Martín-Arévalo J, Moro-Valdezate D, et al. Impact of the novel powered circular stapler on risk of anastomotic leakage in colorectal anastomosis: a propensity score-matched study. Tech Coloproctol. 2020. https://doi.org/10.1007/s10151-020-02338-y.

3. 2017 European Society of Coloproctology (ESCP) Collaborating Group. The 2017 European Society of Coloproctology (ESCP) international snapshot audit of left colon, sigmoid and rectal resections - Executive Summary. Colorectal Dis. 2018;20 Suppl 6:13-14.

4. Trencheva K, Morrissey KP, Wells M, et al. Identifying important predictors for anastomotic leak after colon and rectal resection: prospective study on 616 patients. Ann Surg. 2013;257:108-113.

5. 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(2):239-245.

6. Kassis ES, Kosinski AS, Ross P Jr, Koppes KE, Donahue JM, Daniel VC. Predictors of anastomotic leak after esophagectomy: an analysis of the society of thoracic surgeons general thoracic database. Ann Thorac Surg. 2013;96(6):1919-1926.

7. Ethicon, PRC077848 Leak Claims Testing, October 2016, Data on File. Ethicon, PSB004557 A comparison of staple line perfusion between 29mm ECHELON CIRCULAR™ Powered Stapler (CDH29P) and 28mm DST Series™ EEA™ Circular Stapler (EEA2835), November 2016, Data on File (114092-201126 EMEA)

8. Ethicon, PRC078258A Even Compression Claims Testing, November 2016, Data on File (115263-200608 EMEA)

9. Ethicon, PRC078621 Echelon Powered Circular Gentler Handling Test Completion Report, January 2017, Data on File (115224-200608 EMEA)

10. Ethicon, PRC078105 Distal Tip Movement Claims Testing, November 2016, Data on File (114093-210125 EMEA)

11. Instructions for use

12. Zoucas E, Lydrup ML. Hospital costs associated with surgical morbidity after elective colorectal procedures: a retrospective observational cohort study in 530 patients. Patient Saf Surg. 2014;8(1):2. Published 2014 Jan 3. doi:10.1186/1754-9493-8-2

13. 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.

14. Ethicon, Summary of Design intent for ECHELON CIRCULAR Powered Stapler to support claims, November 2016, Data on File (115899-190605 EMEA)

15. Ethicon, PRC078173A Reduced Force to Fire Claims Study, November 2016, Data on File (115898-210125 EMEA)

16. Son G, Kwon M, Ahn H, et al. Compression injury of the circular stapler for gastrointestinal end-to-end anastomosis: preliminary in-vitro study. Ann Surg Treat Res. 2020;99:72-81

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

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