

ETHICON™ Circular Stapler

Technical overview



Introducing the enhanced ETHICON™ Circular Stapler

The Ethicon Circular Stapler with controlled tissue compression caused significantly less unacceptable tissue damage than Medtronic fixed compression circular staplers^{1*} It is designed to deliver the desired compression necessary for a strong anastomosis and effective perfusion.^{2,3#}



* 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.
In a porcine model maximum intraluminal pressure of an anastomosis correlated most strongly with the compression of the tissue involved in the anastomosis.

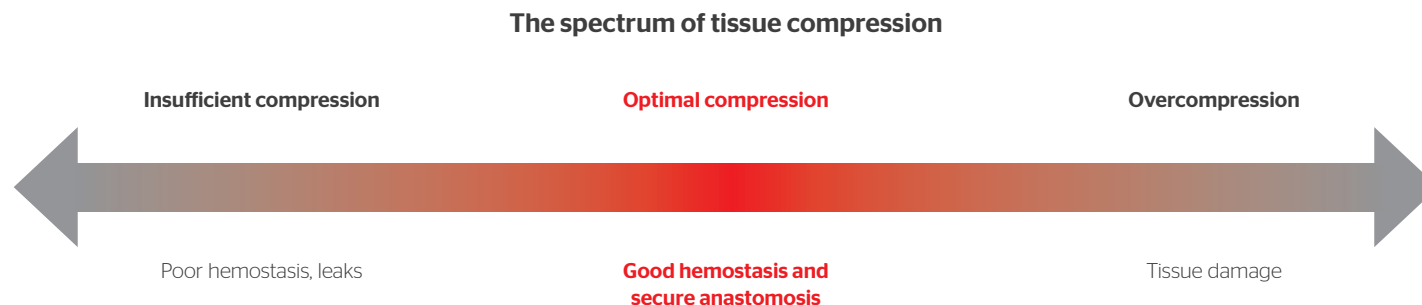
Surgeon-controlled tissue compression

The ETHICON™ Circular Stapler combines the benefits of Controlled Tissue Compression and Adjustable Height Staple Technology so you can address the individual tissue conditions of each patient. This allows you to control the amount of compression applied depending on tissue conditions.

Tissue compression prior to stapling is required with all surgical stapling devices to reliably deliver a staple line with proper staple formation. The optimal amount of compression is variable and is affected by multiple factors such as the type, condition and thickness of targeted tissue.⁴ **To help address tissue variability, the ETHICON™ Circular Stapler delivers tissue compression differently from fixed-height circular staplers.**

Achieving optimal compression

Circular staplers with fixed compression may result in more overcompression^{1*} and unacceptable tissue damage.^{1*} ETHICON™ Circular Stapler allows you to adjust the staple height during surgery based on the needs of the tissue. This may help you apply enough pressure to achieve a desired hemostasis and strong anastomosis while maintaining control of the applied pressure to avoid potential injury to the tissue. In fact, adjustable compression staplers resulted in 75% less unacceptable tissue damage compared to fixed compression staplers.^{1#} Precompressing with Ethicon's circular staplers have been shown to reduce anastomotic leak rates.^{5†}



* 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 injury 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.

† In retrospective clinical study with Ethicon Circular Staplers (CDH21A, CDH25A, CDH29A, CDH33A), 11 out of 126 patients with precompression had AL (8.7% leak rate) vs. 8 out of 28 patients (28.6%) in non-precompression group; P=0.008

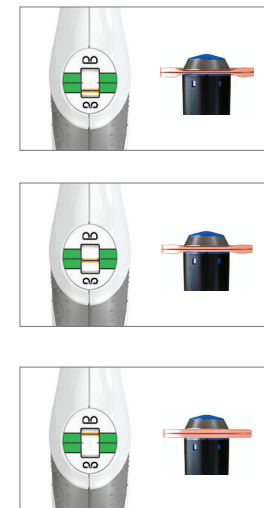
Fixed vs. controlled tissue compression

Circular staplers with fixed-height staples require you to compress tissue to a predetermined gap regardless of tissue characteristics. Circular staplers with fixed compression may result in more overcompression and unacceptable tissue damage.^{1*} **The ETHICON™ Circular Stapler, with Controlled Tissue Compression, allows you to control the amount of compression applied to tissue depending on the clinical situation to accommodate a wide range of compressed tissue thickness.**⁶

This allows you to control the compression based on tissue thickness to achieve a desirable staple height. Appropriate compression and staple height may be associated with a stronger staple line and strong anastomosis with decreased risk of stenosis, leaks and hemorrhage.^{3,7,8} Ethicon's circular staplers with adjustable compression had significantly less tissue damage than when maximum compression was used,^{1#} and adjustable compression staplers resulted in significantly fewer instances of unacceptable tissue damage compared to fixed compression staplers.^{1†}

Many other circular staplers only close to a fixed height. This forces surgeons to compress tissue to a predetermined gap regardless of tissue characteristics.

Fixed-height staplers		ETHICON™ Circular Stapler
✘	Adapts to tissue thickness (no need to choose staple height in advance)	✔
✘	Widest range of staple heights	✔
✘	Surgeon can sense tissue and apply appropriate compression	✔
✘	Allows for precompression	✔



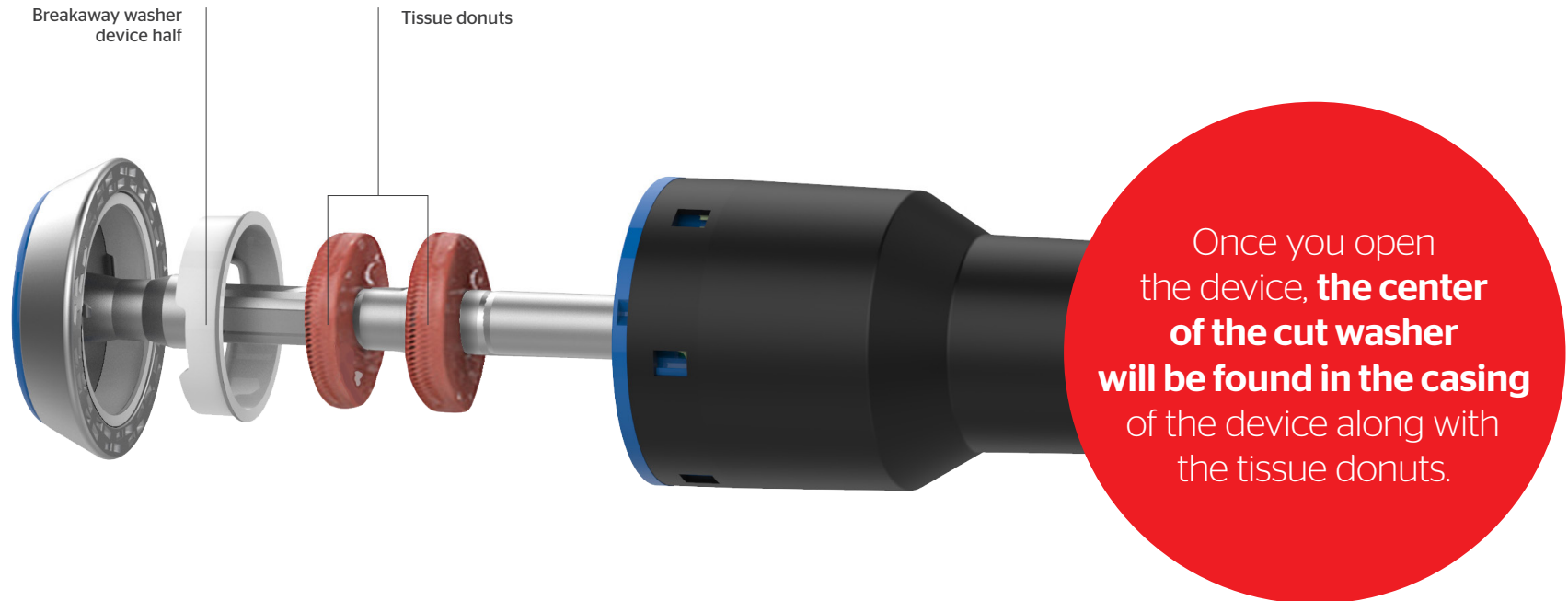
ETHICON™ Circular Stapler tissue compression selection

The tissue compression scale allows you to choose appropriate compression based on tissue resistance.

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Tactile and audible feedback

The ETHICON™ Circular Stapler with its breakaway washer gives the user audible and tactile feedback of complete firing to help confirm a formed anastomosis.⁹ You will experience distinct audible and tactile feedback when the washer is broken. Once the knife breaks through the washer and the handle touches the body of the device, staples are formed to the finished staple height. This creates the new open lumen and desired anastomosis.

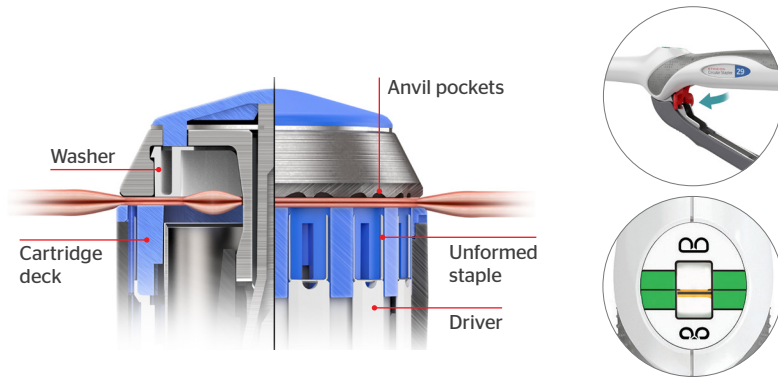


Feedback throughout the firing sequence

1

Before firing

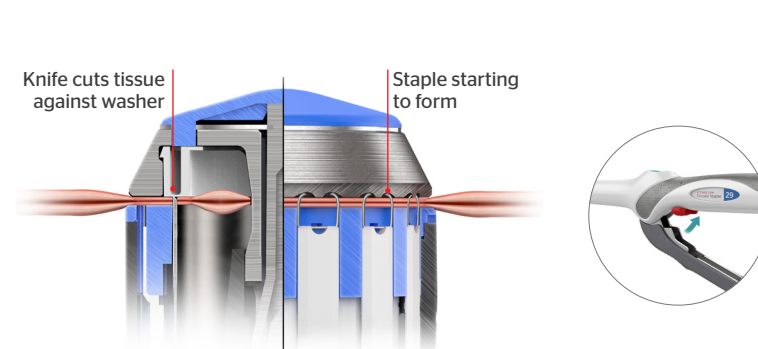
The orange indicator is within the green range of the tissue compression scale, and optimal tissue apposition has been achieved.



2

Before washer breaks

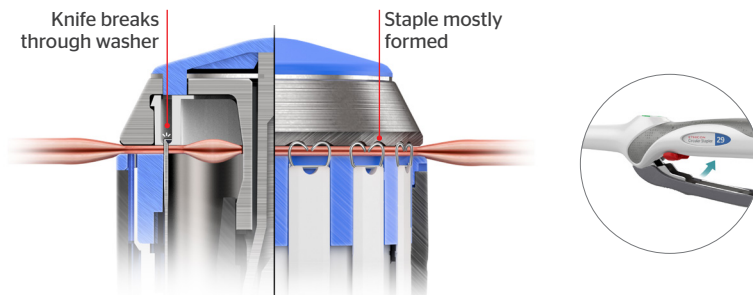
When the firing trigger is squeezed with firm, steady pressure in one continuous stroke, the staple tips go through the tissue and start forming against the anvil.



3

Washer breaks, staples start to form

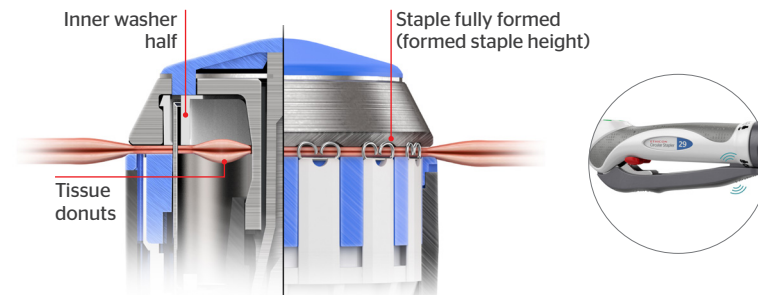
The knife hits the washer, designed to completely cut through all of the tissue as the staples continue forming.



4

Staples completely formed, trigger touching device body

Once the knife breaks through the washer and the handle touches the body of the device, staples are formed to the finished staple height. This creates the new open lumen and strong anastomosis.



Reduced force to break through the cutting washer^{10*}

The enhanced ETHICON™ Circular Stapler contains a thinner washer and improved knife angle for each device size to reduce the force to break through the washer without compromising the distinct audible and tactile feedback.¹¹

These design changes result in:



Up to **35% reduced force** to break through the cutting washer^{10*}



* Benchtop testing of force to fire of Ethicon 25mm devices, comparing means of 70.92 in*lb for CDH25B (n=32) to 111.28 in*lb for CDH25A (n=32), p<0.05.

Updated Staple Materials and Staple Height¹¹



Updated staple height range¹¹

Reduced staple height

- Closed staple height has been reduced from 1.5mm - 3.0mm to 1.5mm - 2.2mm

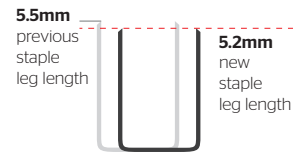
Change in open staple leg length

- Open staple leg length has been reduced from 5.5 - 5.2mm to enable tighter formed staples.

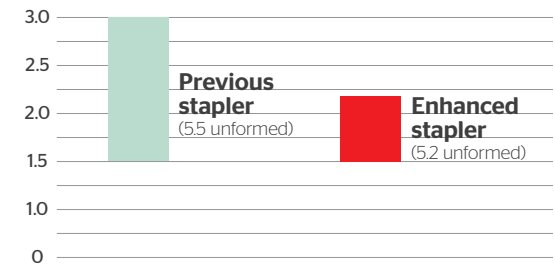
Change in metal alloy

- Change in metal alloy from titanium alloy (Ti-6Al-4V) to titanium alloy (Ti-3Al-2.5V) enables staple formation with lower force.

Unformed staple height



Formed staple height



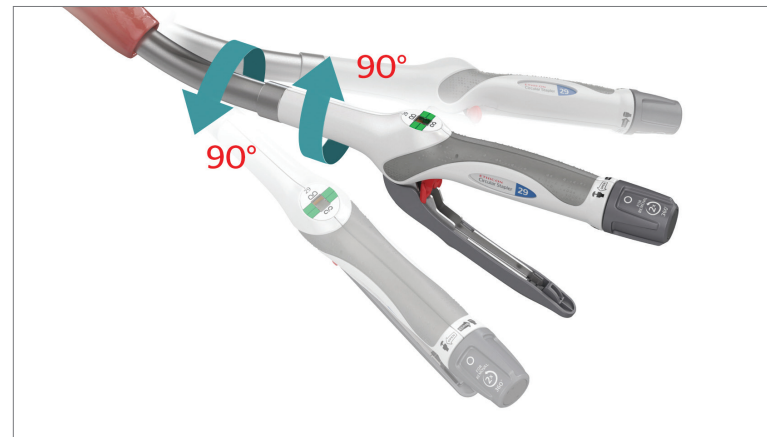
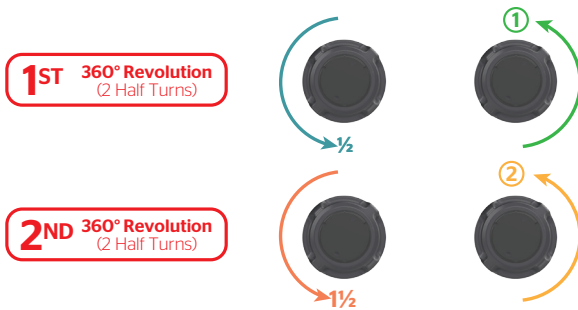
How to release the device from the anastomosis and remove from patient¹²

The ETHICON™ Circular Stapler features the same opening function as the ECHELON CIRCULAR™ Powered Stapler.



Releasing the anastomosis:

1. Open device by turning Adjusting Knob counterclockwise for 2 complete 360° revolutions (2 X 360°) or 4 half turns (4 x 180°)



Removing from patient:

1. Rotate device 90° in both directions taking care to minimize movement of the distal tip to release tissue.

CAUTION: If you rotate the device and it does not freely release from the anastomosis or if the device does not withdraw easily, turn the Adjusting Knob counterclockwise one additional complete revolution (360°), then attempt removal again by rotating the device 90° in both directions taking care to minimize movement of the distal tip.

2. Gently pull out device while simultaneously rotating

ETHICON™ Circular Stapler, XL Sealed



CODE	DIAMETER	# OF STAPLES	OPEN STAPLE LEG LENGTH	CLOSED STAPLE HEIGHT	SHAFT LENGTH	QUANTITY PER BOX
ECS21B	21mm	16	5.2mm	1.5 - 2.2mm	XL	3
ECS25B	25mm	20	5.2mm	1.5 - 2.2mm	XL	3
ECS29B	29mm	24	5.2mm	1.5 - 2.2mm	XL	3
ECS33B	33mm	28	5.2mm	1.5 - 2.2mm	XL	3

ETHICON™ Circular Stapler



CODE	DIAMETER	# OF STAPLES	OPEN STAPLE LEG LENGTH	CLOSED STAPLE HEIGHT	SHAFT LENGTH	QUANTITY PER BOX
CDH21B	21mm	16	5.2mm	1.5 - 2.2mm	Standard	3
CDH25B	25mm	20	5.2mm	1.5 - 2.2mm	Standard	3
CDH29B	29mm	24	5.2mm	1.5 - 2.2mm	Standard	3
CDH33B	33mm	28	5.2mm	1.5 - 2.2mm	Standard	3

Designed for creating the anastomosis throughout the alimentary tract⁸

Examples of applicable procedures



Colon resection



Gastrectomy
Gastric bypass



Esophagectomy

1. 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.
2. Ethicon, SCN052882B Summary of Design Intent for Ethicon Circular Stapler to support market claims, Jan 2021, Data on file (107243-210118 EMEA)
3. Meyer S, Rothermel WS Jr, Shaffer L. The effect of tissue compression on circular stapler line failure. *Surg Endosc.* 2011; 25(9):3043-9
4. Chekan E, Whelan RL. Surgical stapling device-tissue interactions: what surgeons need to know to improve patient outcomes. *Med Devices (Auckl).* 2014;7:305-318.
5. Kawada K, Hasegawa S, Hida K, et al. Risk factors for anastomotic leakage after laparoscopic low anterior resection with DST anastomosis. *Surg Endosc.* 2014;28:2988-2995.
6. Ethicon, SCN052882B.2 Design Intent for Circular Stapler with Manual Actuation, Jan 2021, Data on file (109636-210505 EMEA)
7. Sakran N, Assalia A, Sternberg A, et al. Smaller staple height for circular stapled gastrojejunostomy in laparoscopic gastric bypass: early results in 1,074 morbidly obese patients. *Obes Surg.* 2011;21:238-243.
8. Hanna K, Seder C, Chengelis D, McCullough P, Krause K. Shorter circular staple is height associated with lower anastomotic stricture rate in laparoscopic gastric bypass. *Surg Obes Relat Dis.* 2012;8:181-184.
9. Ethicon, SCN052882A Summary of design intent for Ethicon Circular Stapler product lines with manual actuation, to support marketing claims, Aug 2017, Data on file (107246-210503 EMEA)
10. Ethicon, PRC085922C Reno vs. Kodiak Force to Fire Comparison, April 2020, Data on file Ethicon, SCN051609 Attachment 1 Reno Surgeon Research Executive Summary, May 2017, Data on file (109888-200713 EMEA)
11. Ethicon, DOC022562F Project Reno Concept Selection Summary, Jan 2020, Data on file
12. Instructions for use

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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