ETHICON™ Circular Stapler

# Technical overview


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# 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 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†]

**The spectrum of tissue compression**


***** 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

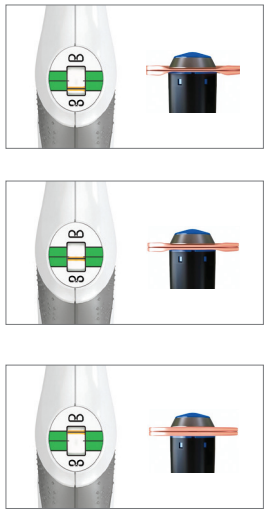
# Fixed vs. controlled tissue compression

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** | ✓ |



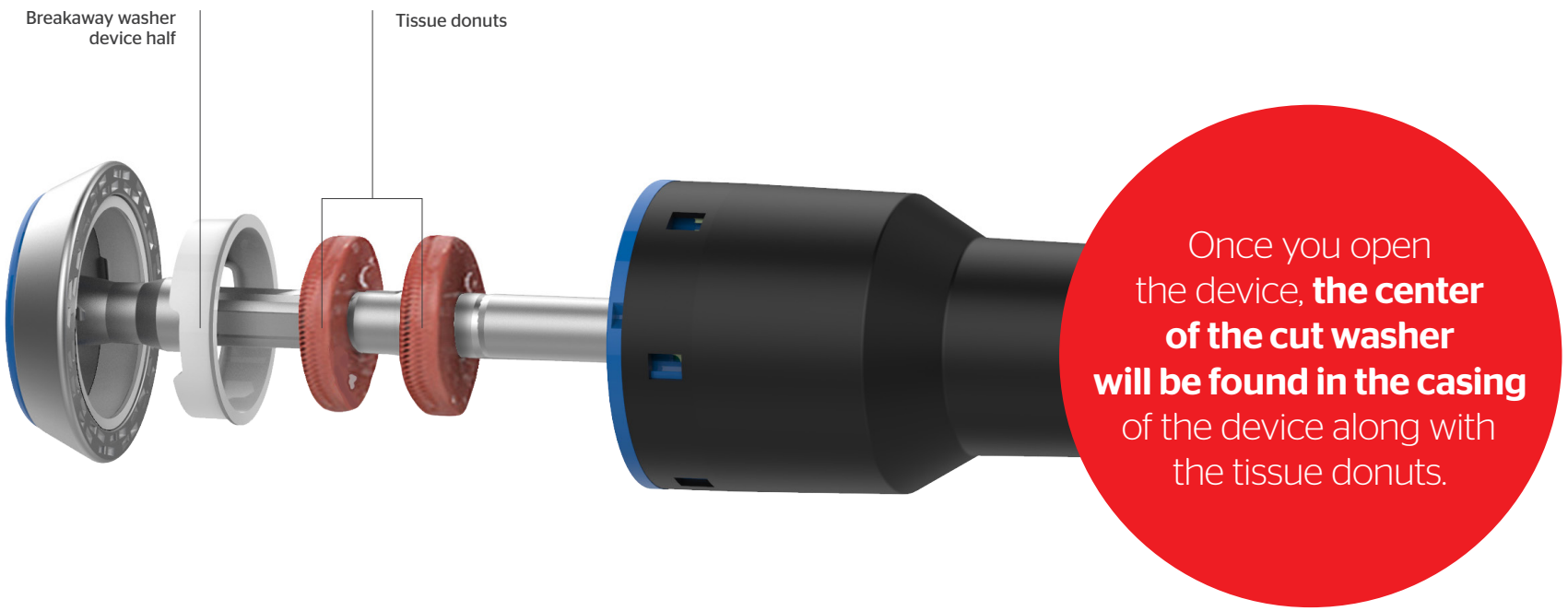
**ETHICON™ Circular Stapler tissue compression selection**

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

***** 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 (CDH29A) exhibited less tissue damage with adjustable compression than with maximal compression [19 out of 232 vs. 32 out of 232]. Per the IFU: Adjust the device slowly until appropriate tissue resistance is felt for a secure anastomosis. Maximum Compression may not be appropriate depending on the tissue condition/thickness. (CDH29A). **†** 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.

# 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.

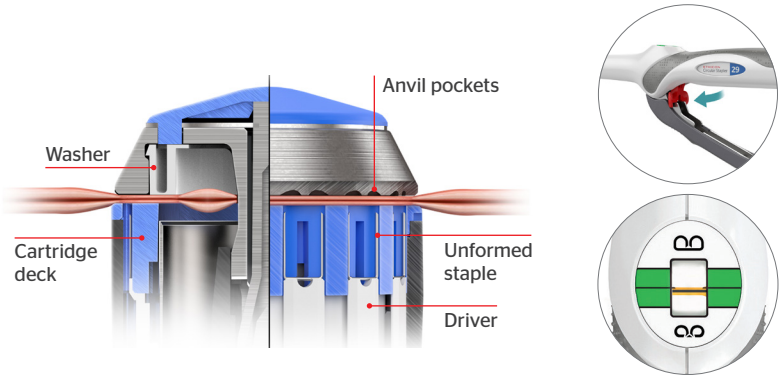


# Feedback throughout the firing sequence

1

## Before firing

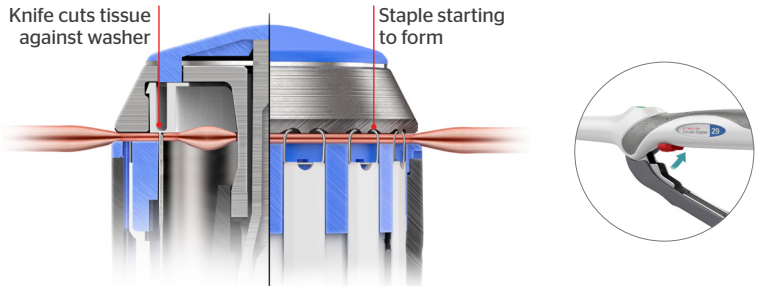
The orange indicator is within the green range of the tissue compression scale, and optimal tissue apposition has been achieved.




2

## Before washer breaks

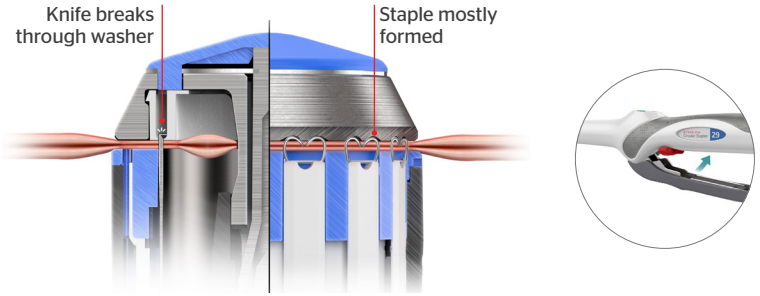
When the firing trigger is squeezed with firm, steady pressure in one continuous stroke, the staple tips go through the tissue and start forming against the anvil.




3

## Washer breaks, staples start to form

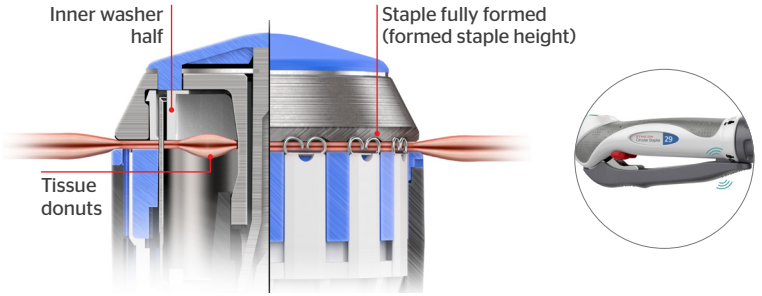
The knife hits the washer, designed to completely cut through all of the tissue as the staples continue forming.




4

## Staples completely formed, trigger touching device body

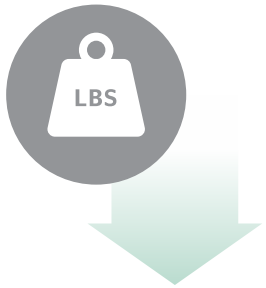
Once the knife breaks through the washer and the handle touches the body of the device, staples are formed to the finished staple height. This creates the new open lumen and strong anastomosis.



# 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*lbf for CDH25B (n=32) to 111.28 in*lbf for CDH25A (n=32), p<0.05.

# Updated Staple Materials and Staple Height[11]

## Updated staple height range[11]

### Reduced staple height

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

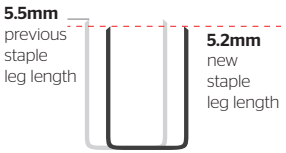
### Change in open staple leg length

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

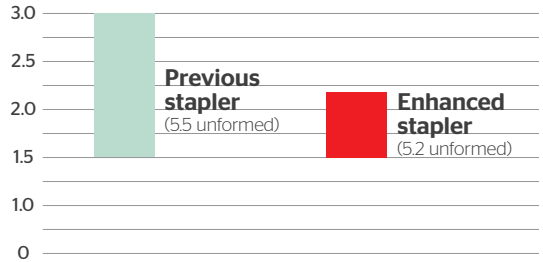
### Change in metal alloy

- 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

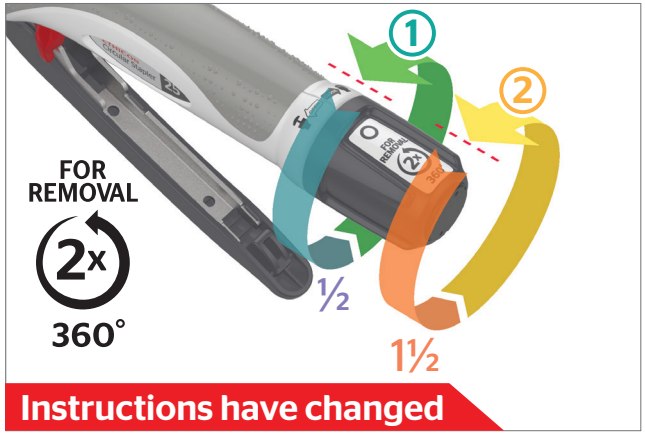



### Formed staple height



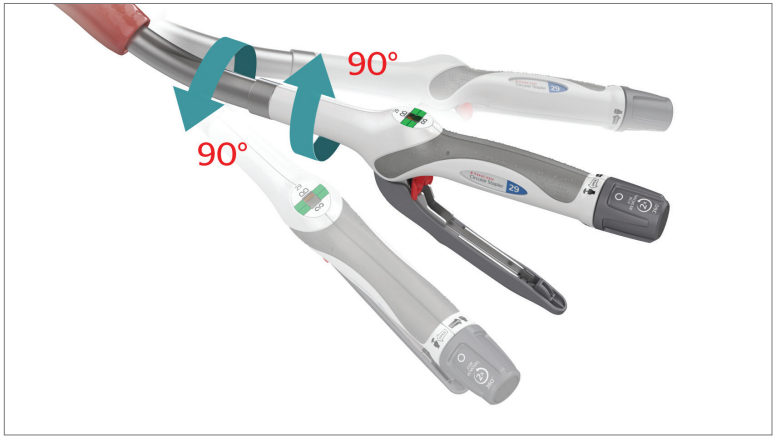
# How to release the device from the anastomosis and remove from patient[12]

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.

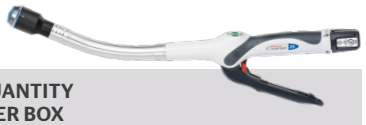
   **CAUTION:** If you rotate the device and it does not freely release from the anastomosis or if the device does not withdraw easily, turn the Adjusting Knob counterclockwise one additional complete revolution (360°), then attempt removal again by rotating the device 90° in both directions taking care 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 tract[8]

**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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