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EEA™ Circular Stapler with Tri-Staple™ Technology

Date

Presenter

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Introduction

Key Improvements

Tri-Staple™ Technology

- 3 rows of varied height staples
- Sloped cartridge face

Available in:

Standard (22cm)
Shaft Length

Extra Thick
(Black)

Medium/Thick
(Purple)

XL (35cm)
Shaft Length

†21 mm staplers are not cleared for sale in the US market.

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Design and performance

Design Improvements

- Sloped cartridge face[2]
- Third row of varied height staples while maintaining the same inner and outer lumen diameters as circular staplers with DST Series™ technology[2]
- 62 percent more staples compared to two-row staplers[7,†]
- New anvil and tilt spring design
- The EEA™ circular stapler with Tri-Staple™ technology provides louder audible feedback during unclamping compared to Ethicon™* circular staplers and EEA™ circular staplers with DST Series™ technology.[8,‡,ΩΩ]
- The EEA™ circular stapler with Tri-Staple™ technology provides 60 percent lower firing force compared to Ethicon™* circular staplers.[8,§,ΩΩ]

Performance Improvements

- Generates less stress on tissue during compression and clamping vs. two-row staplers[5,Ω,ΩΩ]
- 20% greater security at the staple line vs. Echelon Circular™* Powered Stapler[9,††,ΩΩ]
- 140% greater perfusion into the staple line than Echelon Circular™* Powered Stapler[6,‡‡]
- Consistent staple performance over a broad range of tissue thickness vs. two-row[2,3,4,§§]

†Compared to Ethicon™*, Touchstone™*, Chex™*, Panther™*, and Medtronic two-row staplers

‡Based on measurement of sound intensity when firing TRIEEA28XT, TRIEEA33XT, EEA28, and EEA33 in foam (n = 15; p < 0.001). Ethicon™* CDH circular staplers do not provide audible feedback during unclamping. Based on comparison of TRIEEA28MT (n = 15) and CDH29A (n = 14) when firing into foam. P < 0.001.

§Based on comparison of TRIEEA28MT (n = 15) and CDH29A (n = 14) when firing into foam. P < 0.001.

ΩFinite element analysis (FEA) was used to determine the strain profiles of three circular staplers during clamp-up. The EEA™ circular stapler with Tri-Staple™ technology demonstrated a graduated compression profile upon clamping. Compared to Ethicon™* CDH circular staplers and EEA™ circular staplers with DST Series™ technology.

††Based on tensile strength testing comparing TRIEEA31XT and CDH31P (n =10, P = 0.002).

‡‡Preclinical results may not correlate with clinical performance in humans. Compared to the Ethicon™* Echelon Circular™* Powered Stapler. Based on staple-line vascularity analysis using MicroCT in an in vivo canine model (CDH31P: n = 13; TRIEEA31XT: n = 15. P = 0.007).

§§Compared to EEA™ circular staplers with DST Series™ technology.

ΩΩBench test results may not necessarily be indicative of clinical performance.

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Smooth transition between trocar and anvil

EEA™ Circular Stapler with
DST Series™ Technology

EEA™ Circular Stapler with
Tri-Staple™ Technology

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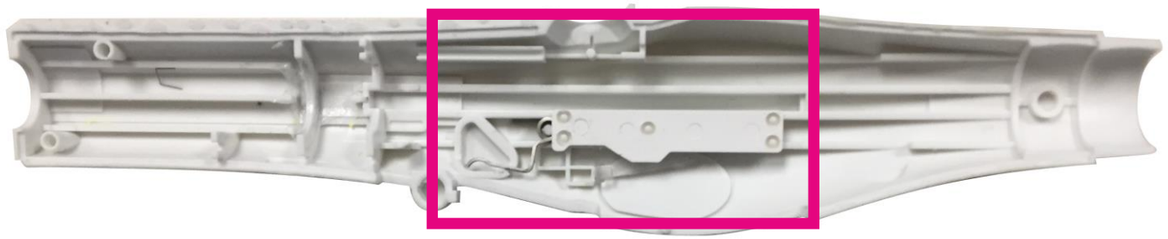
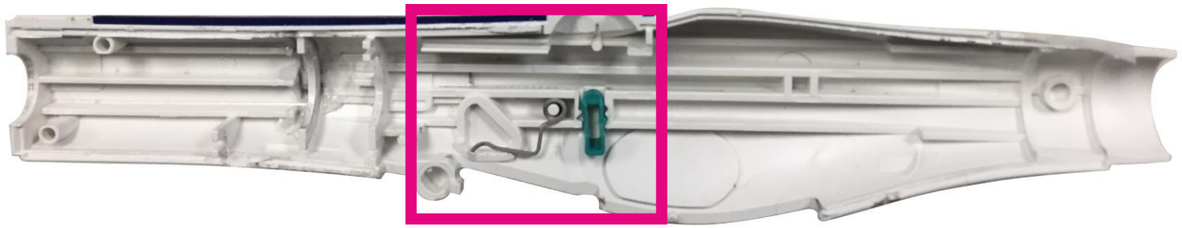
The EEA™ Circular Stapler with Tri-Staple™ technology provides louder audible feedback[8, †] during unclamping compared to Ethicon™* CDH circular staplers and EEA™ circular staplers with DST Series™ technology



EEA™ Circular Stapler with Tri-Staple™ Technology



EEA™ Circular Stapler with DST Series™ Technology

†Based on measurement of sound intensity when firing TRIEEA28XT, TRIEEA33XT, EEA28, and EEA33 in foam (n = 15; $p < 0.001$). Ethicon™* CDH circular staplers do not provide audible feedback during unclamping. Bench test results may not necessarily be indicative of clinical performance

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Message Platform & Claims

Message Platform

BRAND IDEA

CONFIDENCE IN THE CIRCULAR STAPLE LINE

Strategic Statement of Value

The EEA™ circular stapler with Tri-Staple™ technology is the only circular stapler that offers the benefits of Tri-Staple™ technology[11], and 20% greater security at the staple line vs. Echelon Circular™* Powered Stapler.[9,†] With louder audible feedback compared to two-row circular staplers[8,‡] surgeons can feel confident in their circular staple line.

Core Messages	Staple Line Security	EEA™ circular stapler with Tri-Staple™ technology provides 20% greater security at the staple line vs. Echelon Circular™* Powered Stapler.[9,†]
	Tri-Staple™ Technology	EEA™ circular stapler with Tri-Staple™ technology offers all the benefits expected of our proven technology, less stress on tissue during compression and clamping[5,§,‡‡] provides 140% greater perfusion into the staple line[6,Ω] and consistent staple performance over a broad range of tissue thicknesses as compared to two-row circular staplers.[2,3,4,††,‡‡]
Supporting Message	Louder Audible Feedback	The EEA™ circular stapler with Tri-Staple™ technology provides louder audible feedback during unclamping compared to Ethicon™* CDH circular staplers and EEA™ circular staplers with DST Series™ technology.[8,‡]

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‡Based on measurement of sound intensity when firing TRIEEA28XT, TRIEEA33XT, EEA28, and EEA33 in foam (n = 15; p < 0.001). Ethicon™* CDH circular staplers do not provide audible feedback during unclamping.

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ΩPreclinical results may not correlate with clinical performance in humans. Compared to the Ethicon Echelon Circular™* Powered Stapler. Based on staple-line vascularity analysis using MicroCT in an in vivo canine model (CDH31P: n = 13; TRIEEA31XT: n = 15. P = 0.007).

††Compared to EEA™ circular staplers with DST Series™ technology.

‡‡Bench test results may not necessarily be indicative of clinical performance.

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CLINICAL CONFIDENCE. BECAUSE IT'S PROVEN TECHNOLOGY.

The advantages of the EEA™ circular stapler with Tri-Staple™ technology, compared to two-row circular staplers.

GREATER PERFUSION
Into the staple line[6,†]

LESS STRESS
during compression and clamping[5,‡,Ω]

CONSISTENT STAPLE PERFORMANCE
In variable tissue thicknesses[2,3,4,§,Ω]

†Preclinical results may not correlate with clinical performance in humans. Compared to the Ethicon Echelon Circular™* Powered Stapler. Based on staple-line vascularity analysis using MicroCT in an in vivo canine model (CDH31P: n = 13; TRIEEA31XT: n = 15. P = 0.007).

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§Compared to EEA™ circular staplers with DST Series™ technology.

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Next Generation Circular Portfolio

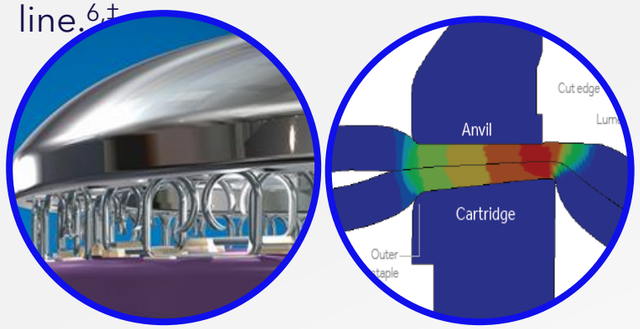
Innovation Path

COMPRESSION | PERFUSION | HEALING

TRI-STAPLE™ TECHNOLOGY

Sloped Cartridge Face

Tri-Staple™ circular reload design has unique proprietary features that facilitate blood flow into the staple line.[6,†]



Variable-Staple Height

The idea is to support adequate perfusion in the stapled tissue, thus allowing for adequate delivery of oxygen.[18]

GREATER PERFUSION

Allowed into the staple line[6,†]

LESS STRESS

On tissue during compression/clamping[5,‡,Ω]

CONSISTENT PERFORMANCE

Over a broad range of tissue thicknesses[2-4,§]

†Preclinical results may not correlate with clinical performance in humans. Compared to the Ethicon Echelon Circular™* Powered Stapler. Based on staple-line vascularity analysis using MicroCT in an in vivo canine model (CDH31P: n = 13; TRIEEA31XT: n = 15. P = 0.007).

‡Finite element analysis (FEA) was used to determine the strain profiles of three circular staplers during clamp-up. The EEA™ circular stapler with Tri-Staple™ technology demonstrated a graduated compression profile upon clamping. Compared to Ethicon™* CDH circular staplers and EEA™ circular staplers with DST Series™ technology.

§Compared to EEA™ circular staplers with DST Series™ technology.

ΩBench test results may not necessarily be indicative of clinical performance.

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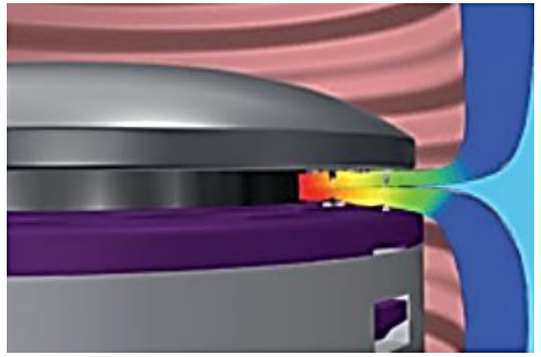
EEA™ Tri-Staple™ Technology 80% Fewer Leaks[20,†]

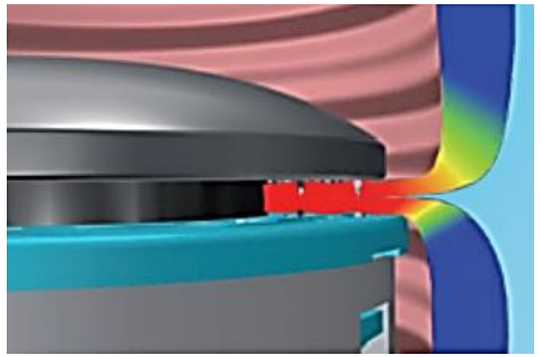
EEA™ Tri-Staple™ Technology provides:

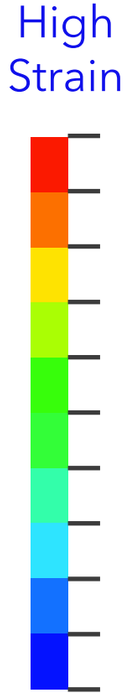
- 3 rows of varied height staples vs. 2 rows
- 63 percent more staples with the same lumen diameter[19,‡]
- The EEA™ circular stapler with Tri-Staple™ technology provides louder audible feedback during unclamping compared to Ethicon™* CDH circular staplers and EEA™ circular staplers with DST Series™ technology.[8,§]
- The EEA™ circular stapler with Tri-Staple™ technology provides 60 percent lower firing force compared to Ethicon™* circular staplers.[8,Ω]
- The EEA™ circular stapler with Tri-Staple™ technology generates less stress on tissue during compression and clamping.[5, ††,Ω,ΩΩ]

SLOPED CARTRIDGE FACE



FLAT CARTRIDGE FACE





LESS STRESS
On tissue during compression and clamping [5,††,ΩΩ]

GREATER PERFUSION
Allowed into the staple line[6, ‡‡]

CONSISTENT PERFORMANCE
Over a broad range of tissue thicknesses[2-4,§§,ΩΩ]

†Preclinical results may not correlate with clinical performance in humans. Based on leak testing in an in vivo canine model comparing TRIEEA25XT to Ethicon™* CDH25P (n = 9; P = 0.023), where 50 mm Hg represented a maximum expected colonic pressure.

‡Compared to EEA™ circular staplers with DST Series™ technology. Preclinical results may not correlate with clinical performance in humans. 10 out of 11 Surgeons surveyed agreed.

§Based on measurement of sound intensity when firing TRIEEA28XT, TRIEEA33XT, EEA28, and EEA33 in foam (n = 15; p < 0.001). Ethicon™* CDH circular staplers do not provide audible feedback during unclamping.

ΩBased on comparison of TRIEEA28MT (n = 15) and CDH29A (n = 14) when firing into foam. P < 0.001.

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ΩΩBench test results may not necessarily be indicative of clinical performance.

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Product In-Service & Troubleshooting

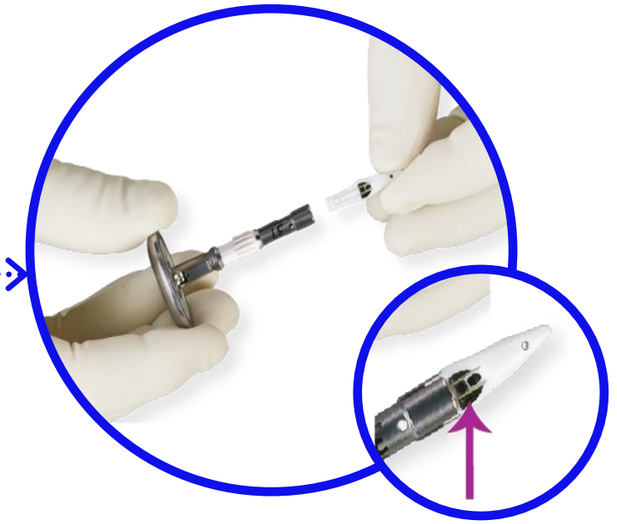
DEMONSTRATION: In-Service Steps†

Step 1 - Detach

This in-service guide is for both purple and black EEA™ reloads

Detach the yellow shipping wedge.

Remove anvil and trocar tip(s).



If the white trocar accessory is desired, it can be attached to the hollow shaft on Tilt-Top™ anvil/central rod assembly and removed after usage by depressing the black release button.

†Always refer to the Instructions For Use for complete instructions.

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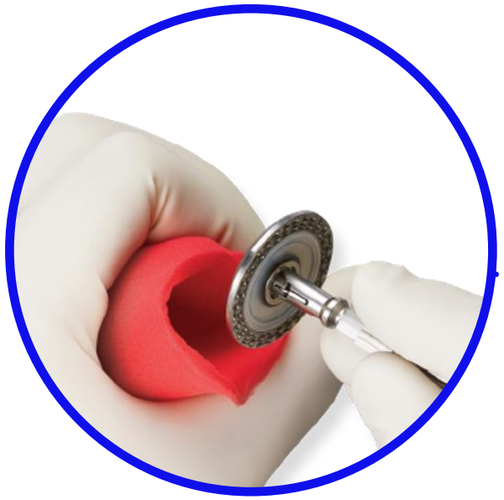
DEMONSTRATION: In-Service Steps†

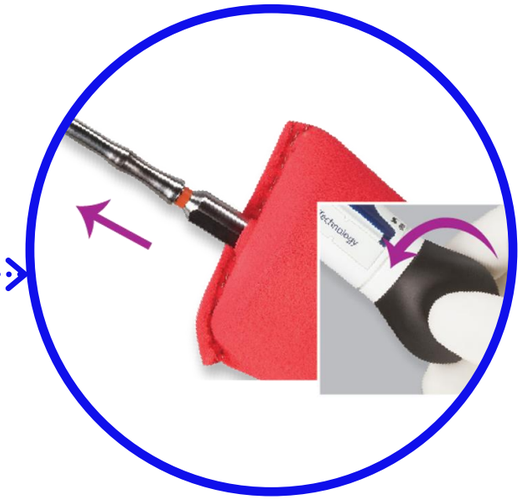
Step 2 – Set-up

This in-service guide is for both purple and black EEA™ reloads



Insert anvil.

Tighten the purse-string suture around the purse-string notch. To avoid excessive tissue within the closed anvil and cartridge, secure purse-string sutures no more than 2.5 mm from the cut edge of the tissue.



Insert the shaft into the closed lumen and extend the trocar until the tissue is pierced and the instrument shaft is fully extended. Orange band must be fully visible.

†Always refer to the Instructions For Use for complete instructions.

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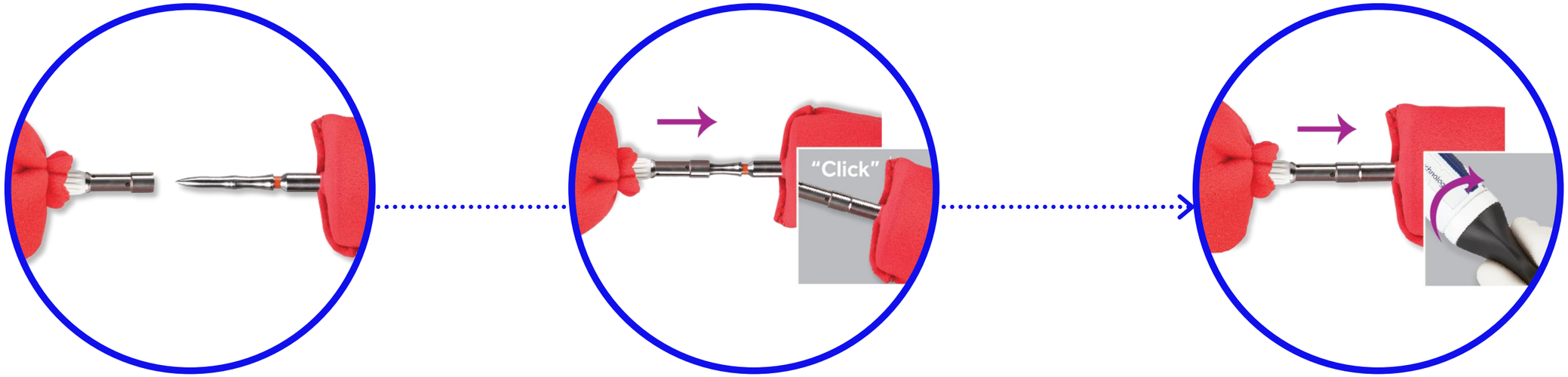
DEMONSTRATION: In-Service Steps†

Step 3 – Close

This in-service guide is for both purple and black EEA™ reloads



Attach anvil to trocar.

Tilt-Top™ anvil must click in its fully seated position and orange band must be completely covered.

Fully tighten with twist lever until the green bar is visible in the indicator window.

†Always refer to the Instructions For Use for complete instructions.

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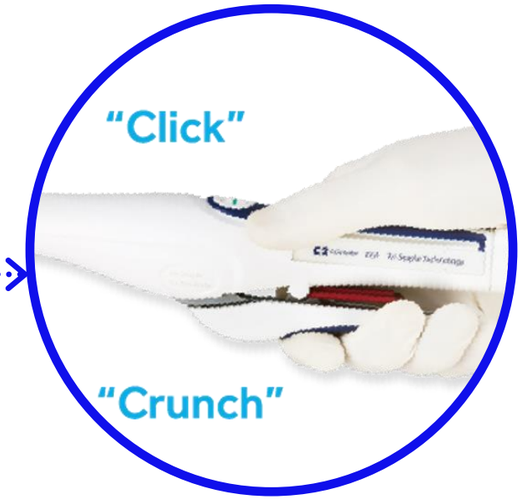
DEMONSTRATION: In-Service Steps†

Step 4 – Fire

This in-service guide is for both purple and black EEA™ reloads

Ready to fire indicator – green bar must be visible in the indicator window before releasing the safety lever and firing. This indicates that the stapler is ready to be fired.

Remove red safety lever. Red safety lever will only release when the green bar is visible.



Handle must be fully squeezed, until it comes in contact with the instrument body.

†Always refer to the Instructions For Use for complete instructions.

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DEMONSTRATION: In-Service Steps†

Step 5 – Open

This in-service guide is for both purple and black EEA™ reloads

Red safety needs to be reset for proper opening.

IMPORTANT: To ensure proper staple formation the handle should only be squeezed once.

Rotate twist lever two full turns counter-clockwise, stopping once an audible click is heard. Gently remove the instrument by pulling it straight out of the new anastomosis. Do not twist as the instrument is removed.

IMPORTANT: Relieve any tension by pushing the instrument slightly forward and then pulling straight out.

Inspect tissue specimens.

†Always refer to the Instructions For Use for complete instructions.

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Q&A

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