Medtronic

Value analysis brochure (VAB)

Experience all-around confidence.

EEA™ circular stapler with Tri-Staple™ technology

An open manual circular stapler with the Tri-Staple™ technology advantage

Table of contents

Introduction 3

Technology overview 4

Features and benefits 6

Competitive comparison 7

In-service guide 8

FDA 510(k) clearance letter and instructions for use (IFU) 10

OrVil™ transoral circular stapler anvil ... 11

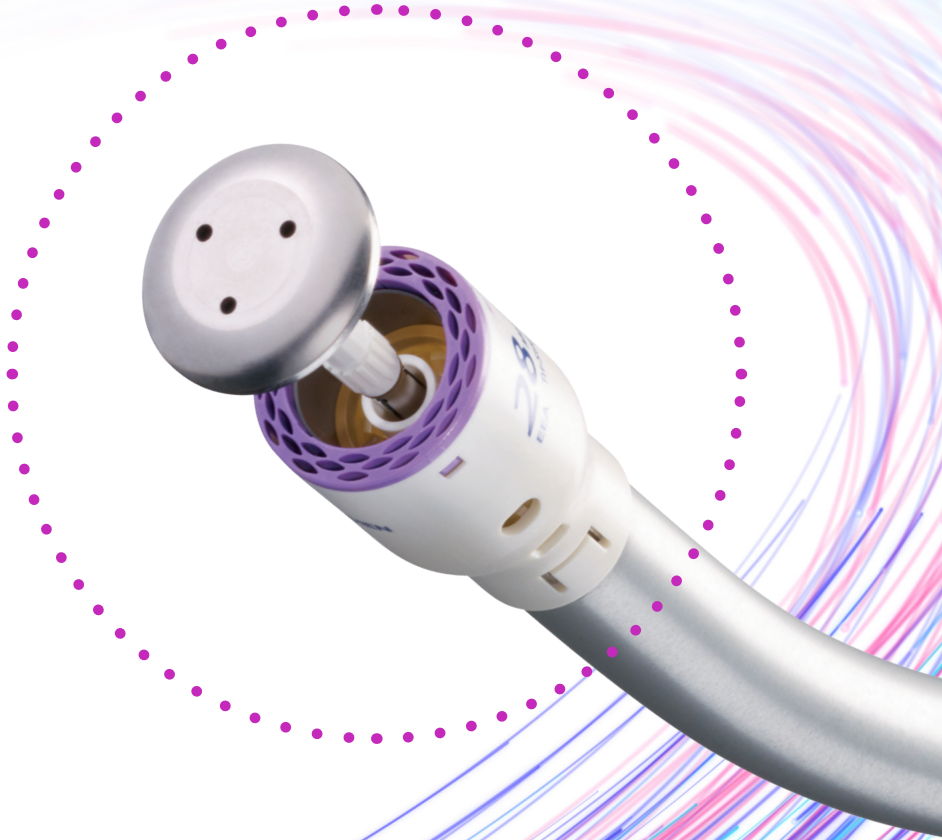
Ordering information 12

Confidence comes full circle.

Created to support anastomosis during your surgical procedures, the EEA™ circular stapler with Tri-Staple™ technology delivers three rows of staples with every firing. That extra row gives you – and your patients – greater security at the staple line.[†,‡,1] Its innovative design also allows for greater perfusion,[†,§,2] an essential factor for optimal healing[3] and prevention of anastomotic leaks.[◊,4]

Tissue thickness varies – but performance shouldn't.

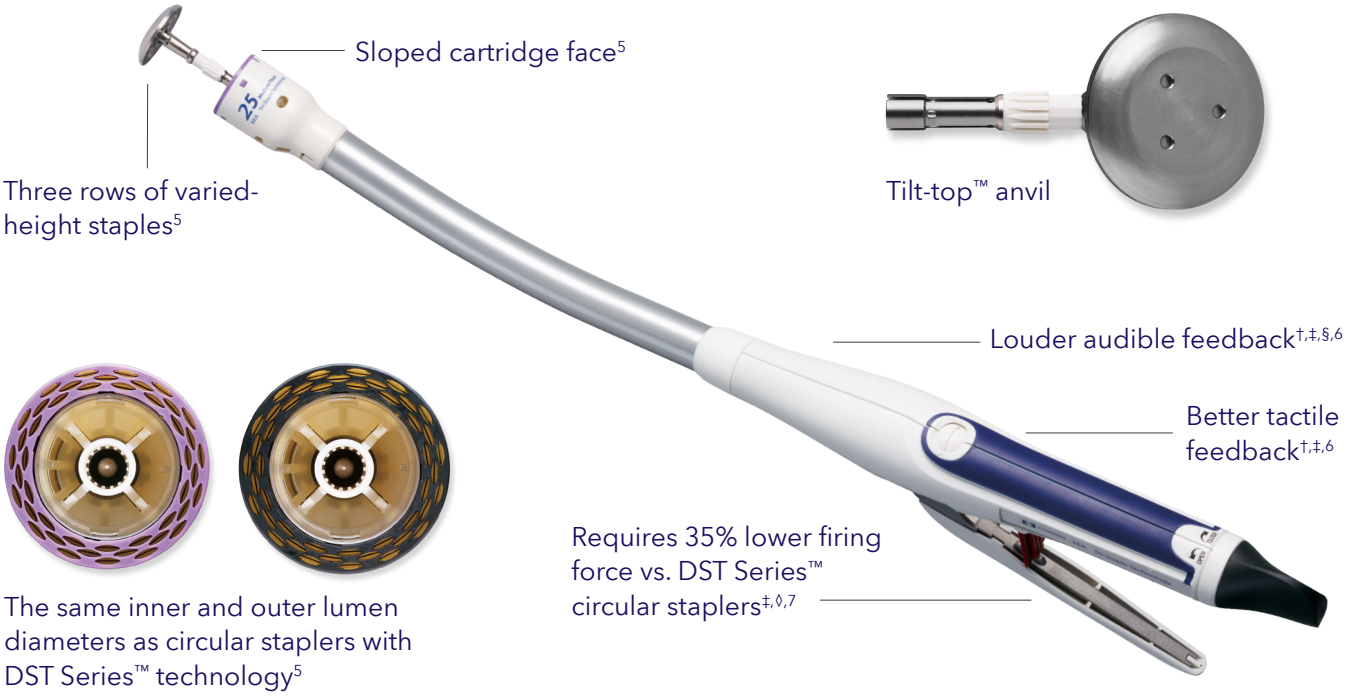
The pairing of Tri-Staple™ technology with the EEA™ circular stapler marks an evolution in open manual circular stapling, one that provides you with consistent performance[¶,5] for consistent confidence.



† Preclinical results may not correlate with clinical performance in humans. ‡ Based on tensile strength testing comparing TRIEEA31XT and CDH31P (n = 10, P = 0.002). § Compared to the Ethicon 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). ◊ In univariate analysis, blood flow decrease was related to the occurrence of anastomotic leak (no leak: n = 47, 5.56% reduction; leak: n = 8, 14.45% reduction. P = 0.001) following rectal anastomosis. ¶ Bench test results may not necessarily be indicative of clinical performance.

A familiar design, enhanced by Tri-Staple™ technology

The EEA™ circular stapler with Tri-Staple™ technology is a thoughtful evolution above its DST Series™ predecessors, maintaining important design elements while enhancing others.



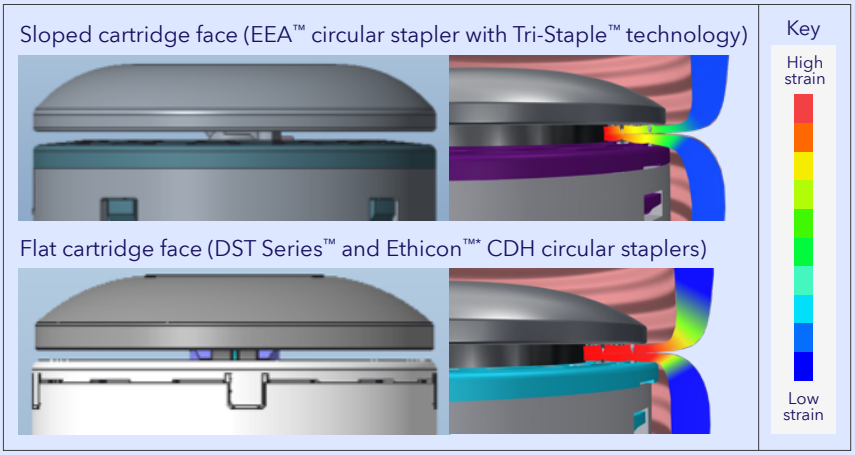
The EEA™ circular stapler with Tri-Staple™ technology has

3 rows of varied-height staples

Circular staplers with DST Series™ technology have

2 rows of staples

The EEA™ circular stapler's sloped cartridge face delivers less stress on tissue compared to flat-faced cartridges during compression and clamping.◊,¶,8



† Preclinical results may not correlate with clinical performance in humans. ‡ Compared to EEA™ circular staplers with DST Series™ technology. § 10 out of 11 surgeons surveyed agreed. ◊ Bench test results may not necessarily be indicative of clinical performance. ¶ 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.

Technology overview

A legacy redefined.

EEA™ circular stapler with Tri-Staple™ technology

EEA™ circular stapler with DST Series™ technology

Greater perfusion.[†,‡,2] Fewer leaks.[†,§,9]

Perfusion is essential for optimal healing of the anastomosis[3] and for preventing anastomotic leaks.[◊,4] By delivering three rows of varied-height staples with a sloped cartridge face,[5] the EEA™ circular stapler with Tri-Staple™ technology provides benefits that can increase your confidence in greater leak protection.[†,§,10]

Greater perfusion
into the staple line[†,‡,2]

Less stress on tissue
during compression and clamping[¶,#,8]

Consistent staple performance
over a broad range of tissue thicknesses[¶,5]

Lower removal forces
with a tilting anvil design[¶,Δ,11]

More security
than the Ethicon Circular™* Powered stapler[†,∞,1]

† Preclinical results may not correlate with clinical performance in humans. ‡ Compared to the Ethicon 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). § Based on leak testing in an in vivo canine model comparing TRIEEA25XT to Ethicon™* CDH25P (n = 9; P = 0.002), where 50 mmHg represented a maximum expected colonic pressure. ◊ In univariate analysis, blood flow decrease was related to the occurrence of anastomotic leak (no leak: n = 47, 5.56% reduction; leak: n = 8, 14.45% reduction. P = 0.001) following rectal anastomosis. ¶ Bench test results may not necessarily be indicative of clinical performance. # 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. Δ Based on testing in simulated tissue media comparing TRIEEA25XT and CDH25P (n = 6; P < 0.001). ∞ Based on tensile strength testing comparing TRIEEA31XT and CDH31P (n = 10, P = 0.002).

Competitive comparison

Gain an edge over other staplers, both manual and powered.

EEA™ circular stapler with Tri-Staple™ technology vs. Ethicon Circular™* Powered stapler

- **80%** fewer leaks[†,‡,10]
- **140%** greater perfusion into the staple line[†,§,2]
- **20%** greater staple line security[◊,¶,1]
- **52%** thinner anvil[#,12]
- **78%** lower removal forces[◊,Δ,11]

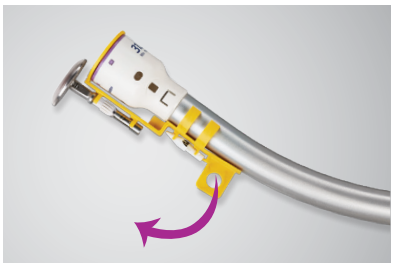
EEA™ circular stapler with Tri-Staple™ technology vs. Ethicon™* CDH manual stapler

- **31%** greater leak pressure[†,∞,13]
- **63%** more staples in the same lumen diameter[††,14]
- **Less stress** on tissue during compression and clamping[◊,‡‡,§§,8]
- **62% lower firing force**[◊,††,7]
- **Louder** audible feedback[◊,§§,7]

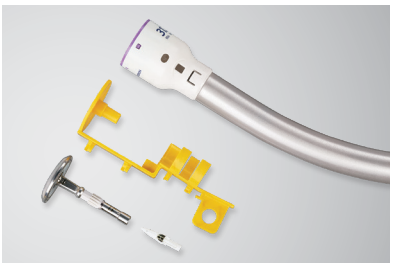
† Preclinical results may not correlate with clinical performance in humans. ‡ Based on leak testing in an in vivo canine model comparing TRIEEA25XT to Ethicon™* CDH25P (n = 9; P = 0.023), where 50 mmHg represented a maximum expected colonic pressure. § Based on staple-line vascularity analysis using MicroCT in an in vivo canine model (CDH31P: n = 13; TRIEEA31XT: n = 15. P = 0.007). ◊ Bench test results may not necessarily be indicative of clinical performance. ¶ Based on tensile strength testing comparing TRIEEA31XT and CDH31P (n = 10, P = 0.002). # Based on comparison of TRIEEA28MT (n = 5) and CDH29P (n = 5). Δ Based on testing in simulated tissue media comparing TRIEEA25XT and CDH25P (n = 6; P < 0.001). ∞ Based on leak pressure testing in excised porcine tissue comparing TRIEEA31XT to Ethicon™* CDH29A (n = 20; P = 0.009). †† Compared to Ethicon™* CDH circular staplers. ‡‡ 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.

In-service guide

1. Detach



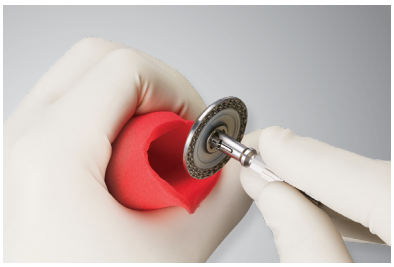
Detach the yellow shipping wedge.



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.

2. Set-up

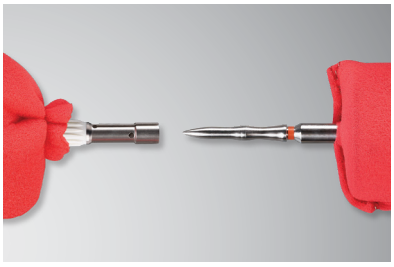


Insert anvil.

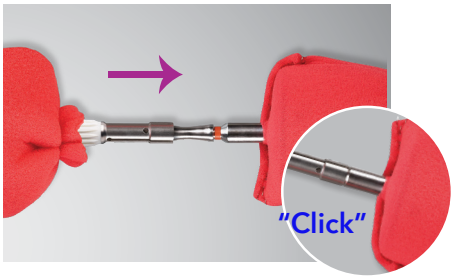
Tighten purse-string suture around purse-string notch. To avoid excessive tissue within the closed anvil and cartridge, secure purse-string sutures no more than 2.5 mm from the cut edge of the tissue.

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

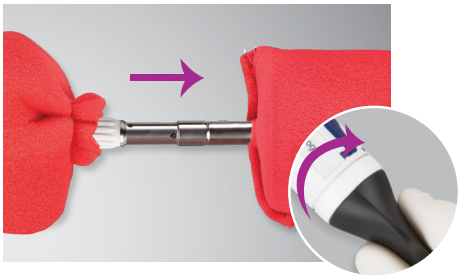
3. Close



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 knob until the green bar is visible in the indicator window.

4. Fire

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 instrument body.

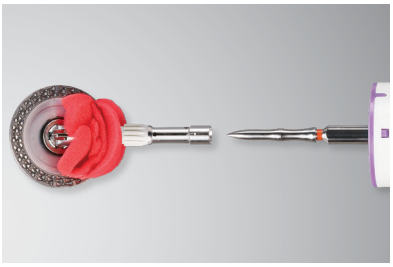
5. Open

Red safety needs to be reset for proper opening.

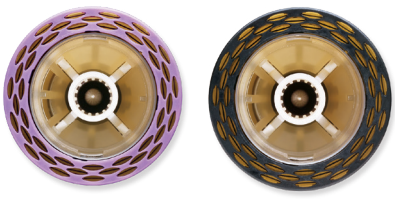
IMPORTANT: To ensure proper staple formation, the handle should only be squeezed once.

Rotate twist knob 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.

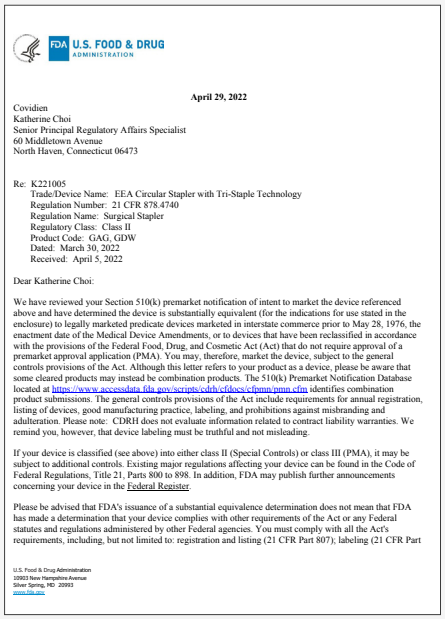


In-service guide is for both purple and black EEA reloads

IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings, and precautions.

FDA 510(k) clearance letter and instructions for use (IFU)

FDA 510(k) clearance letter (K221005)



April 29, 2022

Covidien
Katherine Choi
Senior Principal Regulatory Affairs Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K221005
Trade/Device Name: EEA Circular Stapler with Tri-Staple Technology
Regulation Number: 21 CFR 878.4740
Regulation Name: Surgical Stapler
Regulatory Class: Class II
Product Code: GAG, GDW
Dated: March 30, 2022
Received: April 5, 2022

Dear Katherine Choi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

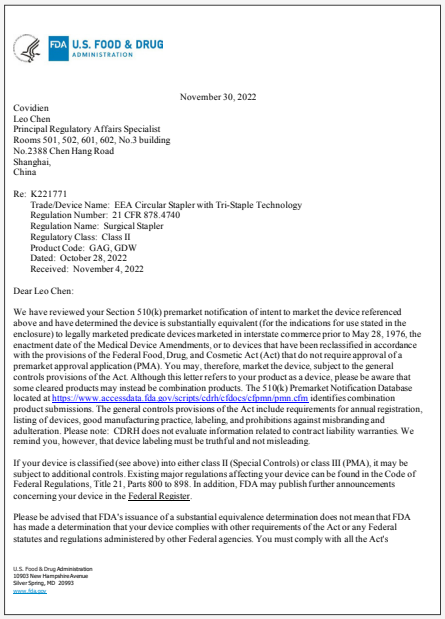
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

The 510(k) letter only confirms the device's legal market status in the U.S. and should not be interpreted as an FDA approval or endorsement of the product.

FDA 510(k) clearance letter (K221771)



November 30, 2022

Covidien
Leo Chen
Principal Regulatory Affairs Specialist
Rooms 501, 502, 601, 602, No.3 building
No.2388 Chen Hang Road
Shanghai,
China

Re: K221771
Trade/Device Name: EEA Circular Stapler with Tri-Staple Technology
Regulation Number: 21 CFR 878.4740
Regulation Name: Surgical Stapler
Regulatory Class: Class II
Product Code: GAG, GDW
Dated: October 28, 2022
Received: November 4, 2022

Dear Leo Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

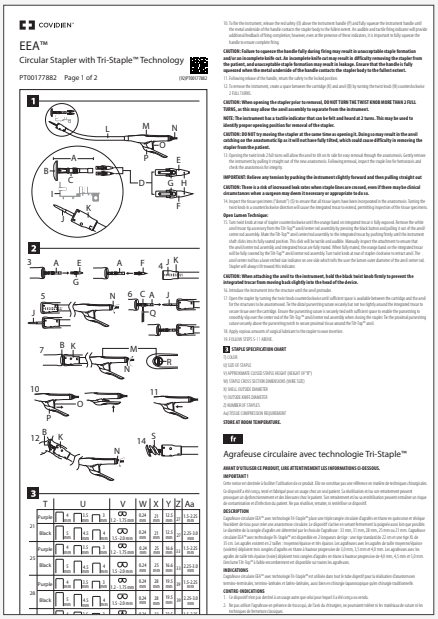
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

The 510(k) letter only confirms the device's legal market status in the U.S. and should not be interpreted as an FDA approval or endorsement of the product.

Instructions for use (IFU)



COVIDIEN

EEA™
Circular Stapler with Tri-Staple™ Technology

PT001778B2 Page 1 of 2

IMPORTANT!

DESCRIPTION

INDICATIONS

CONTRAINDICATIONS

fr

Agrafeuse circulaire avec technologie Tri-Staple™

IMPORTANT !

DESCRIPTION

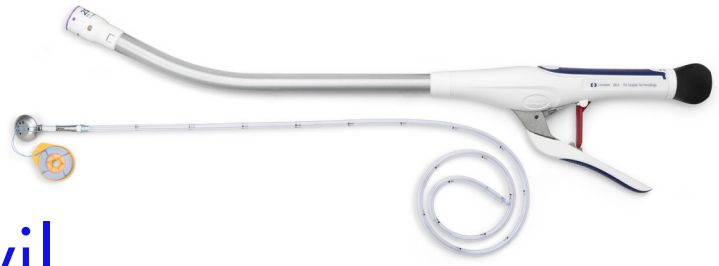
INDICATIONS

CONTRE-INDICATIONS

The IFU image current as of 06/2025 when this brochure was approved by Medtronic. For the most current IFU(s), please scan QR code or contact your sales rep.

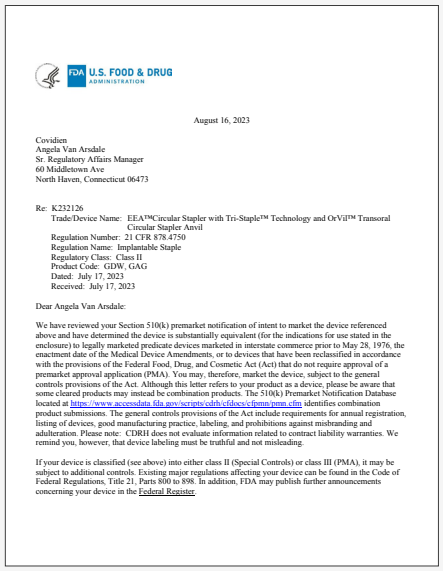
EEA™ circular stapler accessory

OrVil™ transoral circular stapler anvil



Available on certain sizes of the EEA™ circular stapler, the OrVil™ transoral circular stapler anvil offers another approach for deploying Tri-Staple™ technology in applications throughout the alimentary tract for the creation of anastomoses.[15]

View FDA 510(k) clearance letter



U.S. FOOD & DRUG ADMINISTRATION

August 16, 2023

Covidien
Angela Van Arsdale
Sr. Regulatory Affairs Manager
60 Middletown Ave
North Haven, Connecticut 06473

Re: K232126
Trade/Device Name: EEA™Circular Stapler with Tri-Staple™ Technology and OrVil™ Transoral Circular Stapler Anvil
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: July 17, 2023
Received: July 17, 2023

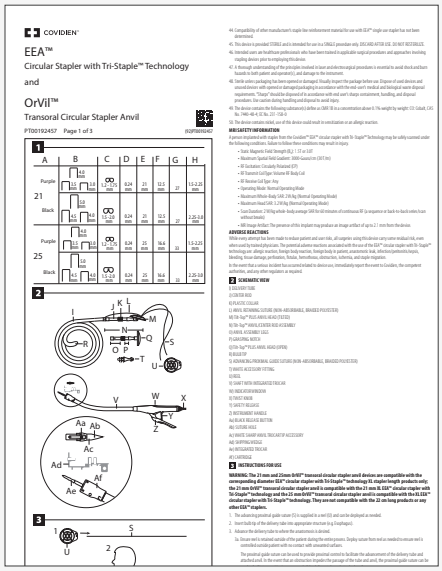
Dear Angela Van Arsdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

The 510(k) letter only confirms the device's legal market status in the U.S. and should not be interpreted as an FDA approval or endorsement of the product.

View instructions for use (IFU)



COVIDIEN

EEA™
Circular Stapler with Tri-Staple™ Technology
and
OrVil™
Transoral Circular Stapler Anvil

IFU image current as of 06/2025 when this brochure was approved by Medtronic. For the most current IFU(s), please scan QR code or contact your sales rep.

View in-service guide

Medtronic

In-service guide

EEA™ circular stapler with Tri-Staple™ technology and OrVil™ transoral circular stapler anvil

Visit **medtronic.com/EEAwithTriStaple** to view in-service guide and videos.

Ordering information

Order code	Description	Lumen size	Color	Staple size (inner to outer row)	Tissue type	Units per box
TRIEEAXL21MTORVIL	EEA™ circular stapler XL length with Tri-Staple™ technology and OrVil™ transoral circular stapler anvil	21 mm	Purple	3.0 mm, 3.5 mm, 4.0 mm	Medium/thick	3
TRIEEAXL21XTORVIL	EEA™ circular stapler XL length with Tri-Staple™ technology and OrVil™ transoral circular stapler anvil	21 mm	Black	4.0 mm, 4.5 mm, 5.0 mm	Extra thick	3
TRIEEAXL25MTORVIL	EEA™ circular stapler XL length with Tri-Staple™ technology and OrVil™ transoral circular stapler anvil	25 mm	Purple	3.0 mm, 3.5 mm, 4.0 mm	Medium/thick	3
TRIEEAXL25XTORVIL	EEA™ circular stapler XL length with Tri-Staple™ technology and OrVil™ transoral circular stapler anvil	25 mm	Black	4.0 mm, 4.5 mm, 5.0 mm	Extra thick	3

Ordering information

Bring greater leak protection to your procedures.†,‡,10

Contact your Medtronic representative or visit us at **medtronic.com/EEAwithTriStaple** to explore the advantages of the EEA™ circular stapler with Tri-Staple™ technology

Ordering information

Order code	Description	Lumen size	Color	Staple size (inner to outer row)	Tissue type	Units per box
TRIEEA21MT	EEA™ circular stapler with Tri-Staple™ technology	21 mm	Purple	3.0 mm, 3.5 mm, 4.0 mm	Medium/thick	3
TRIEEA21XT	EEA™ circular stapler with Tri-Staple™ technology	21 mm	Black	4.0 mm, 4.5 mm, 5.0 mm	Extra thick	3
TRIEEAXL21MT	EEA™ circular stapler XL length with Tri-Staple™ technology	21 mm	Purple	3.0 mm, 3.5 mm, 4.0 mm	Medium/thick	3
TRIEEAXL21XT	EEA™ circular stapler XL length with Tri-Staple™ technology	21 mm	Black	4.0 mm, 4.5 mm, 5.0 mm	Extra thick	3
TRIEEA25MT	EEA™ circular stapler with Tri-Staple™ technology	25 mm	Purple	3.0 mm, 3.5 mm, 4.0 mm	Medium/thick	3
TRIEEA25XT	EEA™ circular stapler with Tri-Staple™ technology	25 mm	Black	4.0 mm, 4.5 mm, 5.0 mm	Extra thick	3
TRIEEAXL25MT	EEA™ circular stapler XL length with Tri-Staple™ technology	25 mm	Purple	3.0 mm, 3.5 mm, 4.0 mm	Medium/thick	3
TRIEEAXL25XT	EEA™ circular stapler XL length with Tri-Staple™ technology	25 mm	Black	4.0 mm, 4.5 mm, 5.0 mm	Extra thick	3
TRIEEA28MT	EEA™ circular stapler with Tri-Staple™ technology	28 mm	Purple	3.0 mm, 3.5 mm, 4.0 mm	Medium/thick	3
TRIEEA28XT	EEA™ circular stapler with Tri-Staple™ technology	28 mm	Black	4.0 mm, 4.5 mm, 5.0 mm	Extra thick	3
TRIEEAXL28MT	EEA™ circular stapler XL length with Tri-Staple™ technology	28 mm	Purple	3.0 mm, 3.5 mm, 4.0 mm	Medium/thick	3
TRIEEAXL28XT	EEA™ circular stapler XL length with Tri-Staple™ technology	28 mm	Black	4.0 mm, 4.5 mm, 5.0 mm	Extra thick	3
TRIEEA31MT	EEA™ circular stapler with Tri-Staple™ technology	31 mm	Purple	3.0 mm, 3.5 mm, 4.0 mm	Medium/thick	3
TRIEEA31XT	EEA™ circular stapler with Tri-Staple™ technology	31 mm	Black	4.0 mm, 4.5 mm, 5.0 mm	Extra thick	3
TRIEEAXL31MT	EEA™ circular stapler XL length with Tri-Staple™ technology	31 mm	Purple	3.0 mm, 3.5 mm, 4.0 mm	Medium/thick	3
TRIEEAXL31XT	EEA™ circular stapler XL length with Tri-Staple™ technology	31 mm	Black	4.0 mm, 4.5 mm, 5.0 mm	Extra thick	3
TRIEEA33MT	EEA™ circular stapler with Tri-Staple™ technology	33 mm	Purple	3.0 mm, 3.5 mm, 4.0 mm	Medium/thick	3
TRIEEA33XT	EEA™ circular stapler with Tri-Staple™ technology	33 mm	Black	4.0 mm, 4.5 mm, 5.0 mm	Extra thick	3
TRIEEAXL33MT	EEA™ circular stapler XL length with Tri-Staple™ technology	33 mm	Purple	3.0 mm, 3.5 mm, 4.0 mm	Medium/thick	3
TRIEEAXL33XT	EEA™ circular stapler XL length with Tri-Staple™ technology	33 mm	Black	4.0 mm, 4.5 mm, 5.0 mm	Extra thick	3
TRIEEAXL21MTORVIL	EEA™ circular stapler XL length with Tri-Staple™ technology and OrVil™ transoral circular stapler anvil	21 mm	Purple	3.0 mm, 3.5 mm, 4.0 mm	Medium/thick	3
TRIEEAXL21XTORVIL	EEA™ circular stapler XL length with Tri-Staple™ technology and OrVil™ transoral circular stapler anvil	21 mm	Black	4.0 mm, 4.5 mm, 5.0 mm	Extra thick	3
TRIEEAXL25MTORVIL	EEA™ circular stapler XL length with Tri-Staple™ technology and OrVil™ transoral circular stapler anvil	25 mm	Purple	3.0 mm, 3.5 mm, 4.0 mm	Medium/thick	3
TRIEEAXL25XTORVIL	EEA™ circular stapler XL length with Tri-Staple™ technology and OrVil™ transoral circular stapler anvil	25 mm	Black	4.0 mm, 4.5 mm, 5.0 mm	Extra thick	3

† 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 = 0.002), where 50 mmHg represented a maximum expected colonic pressure.

1. Based on internal report #RE00342843, Staple line security test comparing EEA™ circular stapler with Tri-Staple™ technology (TRIEEA31XT) and Echelon Circular™* powered stapler (CDH31P). June 2021.
2. Based on internal report #RE00330708 rev 1, Perfusion analysis for circular staplers, comparing EEA™ circular stapler with Tri-Staple™ technology. May 13, 2021.
3. Smallwood N, Mutch MG, Fleshman JW. The failed anastomosis. In: *Complexities in Colorectal Surgery: Decision-Making and Management.* New York, NY: Springer Science and Business Media; 2014:277–304.
4. Vignali A, Gianotti L, Braga M, Radaelli G, Malvezzi L, Di Carlo V. Altered microperfusion at the rectal stump is predictive for rectal anastomotic leak. *Dis Colon Rectum.* 2000;43(1):76–82.
5. Based on internal test report #RE00069039 rev 5.1, EEA™ circular stapler with Tri-Staple™ technology design verification report. Sept. 29, 2020.
6. Based on internal test report #RE00073061, Tulip formative evaluation summary. Nov. 25, 2016.
7. Based on internal test report #RE00183973_B, Firing force and audible feedback test report. July 2020.
8. Based on internal test report #RE00200393 rev 2, Comparison of circular staplers: tissue compression profiles as determine by 2-D static axisymmetric finite element analysis (FEA). June 17, 2021.
9. Based on internal report #RE00318260 rev 1, Comparative leak testing for EEA™ circular stapler with Tri-Staple™ technology and Ethicon™* CDH. April 2021.
10. Based on internal report #RE00365456, Comparative in vivo leak testing for EEA™ circular staplers with Tri-Staple™ technology (TRIEEA25XT) and Ethicon Echelon Circular™* Powered stapler (CDH25P). Dec. 21, 2021.
11. Based on internal report #RE00354964, Device removal force for EEA™ circular stapler with Tri-Staple™ technology vs. Echelon Circular™* powered stapler. January 7, 2022.
12. Based on internal report #RE00337611, Anvil height weight stapler length – comparing TRIEEA28MT to Ethicon CDH29A and CDH29P. June 2021.
13. Based on internal report #RE00318260 rev 2, Comparative leak testing for EEA™ circular stapler with Tri-Staple™ technology and Ethicon™* CDH. April 2021.
14. Based on internal test report #RE00276578 rev B, EEA™ circular stapler with Tri-Staple™ technology compared to the top five two-row circular staplers in the markets for number of staples in the circular staplers. March 29, 2021.
15. EEA™ Circular Stapler with Tri-Staple™ Technology and OrVil™ Transoral Circular Stapler Anvil [instructions for use]. Mansfield, MA: Covidien; 2023.

Medtronic