360-DEGREE STAPLE LINE SECURITY. FOR ALL AROUND CONFIDENCE.

EEA™ Circular Stapler with Tri-Staple™ Technology
# Table of Contents

1. **Introduction**

2. **Features and Benefits**
   - Tri-Staple™ Technology in Circular Stapling Overview
   - Product Enhancements

3. **Competitive Comparison**

4. **In-Service Guide**

5. **Ordering Information**

6. **510(k) Clearance**

7. **References**
SECURITY MATTERS

EEA™ Circular Stapler with Tri-Staple™ Technology

Anastomotic leaks are bad for patients — and for your hospital.

6.2% colorectal leak rate\textsuperscript{1,†}

$28,597 average cost per leak\textsuperscript{1,†}

>162,000 annual global leaks\textsuperscript{2}

>4.6B annual hospital cost\textsuperscript{2}

\textsuperscript{†}Based on U.S. data
MORE ROWS OF STAPLES. MORE SECURITY.

Secure staple lines. You count on them. So do your patients.

That’s why we’ve given our EEA™ circular stapler the advantages of Tri-Staple™ technology. Now you can have:

- Three rows of varied height staples for 30 percent more security compared to two-row staplers.
- Consistent performance over a broad range of tissue.
- A sloped cartridge face for less stress on tissue during compression and clamping compared to flat cartridge faces.
- Improved audible and tactile feedback.
- Potentially greater perfusion into the staple line vs. two row flat cartridge circular staplers.

†Preclinical results may not correlate with clinical performance in humans.
‡Based on the addition of a third row of staples in the EEA™ circular stapler with Tri-Staple™ technology, as compared to predicate two-row device designs.
§Refers to the healing period (generally through day 28) that was evaluated in multiple preclinical (canine) survival studies designed to assess device safety and efficacy.
Ω16 out of 19 surgeons surveyed agreed.
††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.
EASIER TO FIRE. EASIER TO HEAR AND FEEL WHEN YOU DO.

- Sloped cartridge face
- Three rows of varied height staples
- Same inner and outer lumen diameters as circular staplers with DST Series™ technology
- Better audible and tactile feedback
- Tilt-top™ anvil facilitates removal
- Includes 30% more staples in the staplers of the same lumen diameters

†Compared to two-row circular staplers.
‡16 out of 19 surgeons surveyed agreed.
A LEGACY REDEFINED.

EEA™ Circular Stapler with Tri-Staple™ Technology

- Lipless design
- Stronger tilt spring
- Tapered surface to enhance ability to tilt
- Diameter size designation (the anvil tilts toward this label)
- Smooth transition between anvil and trocar
- Grasping notch
- Purse-string notch

EEA™ Circular Stapler with DST Series™ Technology

- Lip
- Tissue donut can get trapped and prevent tilting
- Grasping notch
- Purse-string notch
- No diameter size designation
- Stepped transition between anvil and trocar
CIRCULAR STAPLING LOOKED AT FROM DIFFERENT ANGLES.

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

- 3 ROWS of varied height staples\(^6\)

The EEA™ stapler with DST Series™ technology and the Ethicon™ ILS stapler have:

- 2 ROWS of staples

The EEA™ circular stapler with Tri-Staple™ technology has a sloped cartridge face.

The EEA™ stapler with DST Series™ technology and the Ethicon™ ILS stapler have a flat cartridge face.

Compared to two-row circular staplers, the EEA™ device with Tri-Staple™ technology provides:

- 30% MORE SECURITY at the staple line during the critical healing period\(^3–5,1+3\)
- 14% REDUCTION in firing force vs. circular staplers with DST Series™ technology\(^15,Ω\)

The sloped cartridge face of Tri-Staple™ technology delivers less stress on tissue compared to flat-faced cartridges like the Ethicon™ ILS stapler during compression and clamping.\(^10,§\)

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\(\dagger\) Based on the addition of a third row of staples in the EEA™ circular stapler with Tri-Staple™ technology, as compared to predicate two-row device designs.  
\(\ddagger\) Refers to the healing period (generally through day 28) that was evaluated in multiple preclinical (canine) survival studies designed to assess device safety and efficacy.  
\(\S\) Preclinical results may not correlate with clinical performance in humans.  
\(Ω\) Compared to two-row circular staplers.  
\(§\) Preclinical results may not correlate with clinical performance in humans.
**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.

**SETUP**

- Insert anvil.
- Tighten Purstring™ around Purstring™ notch.
- Extend trocar. Orange band must be visible.

**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.
FIRE
Ready to fire indicator. The green bar must be visible in the indicator window before releasing the safety lever and firing.

Flip the red safety lever.

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

OPEN
Red safety needs to be reset for proper opening.

Rotate twist knob two full turns counterclockwise, stopping when a click is heard.

Inspect tissue specimens.

“Click”

“Crunch”

IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings, and precautions.
<table>
<thead>
<tr>
<th>Reorder Code</th>
<th>Product Description</th>
<th>Color</th>
<th>Staple Size (Inner to Outer Row)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRIEEA28MT</td>
<td>EEA™ Circular Stapler with Tri-Staple™ Technology 28 mm Medium/Thick</td>
<td>Purple</td>
<td>3.0 mm, 3.5 mm, 4.0 mm</td>
</tr>
<tr>
<td>TRIEEA28XT</td>
<td>Black EEA™ Circular Stapler with Tri-Staple™ Technology 28 mm Extra Thick†</td>
<td>Black</td>
<td>4.0 mm, 4.5 mm, 5.0 mm</td>
</tr>
<tr>
<td>TRIEEA31MT</td>
<td>EEA™ Circular Stapler with Tri-Staple™ Technology 31 mm Medium/Thick</td>
<td>Purple</td>
<td>3.0 mm, 3.5 mm, 4.0 mm</td>
</tr>
<tr>
<td>TRIEEA31XT</td>
<td>Black EEA™ Circular Stapler with Tri-Staple™ Technology 31 mm Extra Thick†</td>
<td>Black</td>
<td>4.0 mm, 4.5 mm, 5.0 mm</td>
</tr>
<tr>
<td>TRIEEAXL33MT</td>
<td>EEA™ Circular Stapler XL Length with Tri-Staple™ Technology 33 mm Medium/Thick</td>
<td>Purple</td>
<td>3.0 mm, 3.5 mm, 4.0 mm</td>
</tr>
<tr>
<td>TRIEEAXL33XT</td>
<td>Black EEA™ Circular Stapler XL Length with Tri-Staple™ Technology 33 mm Extra Thick†</td>
<td>Black</td>
<td>4.0 mm, 4.5 mm, 5.0 mm</td>
</tr>
</tbody>
</table>

†Black cartridges currently not available in the United States.
February 16, 2018

Covidien
Sarah Tang
Sr. Regulatory Affair Specialist
Rooms 501, 502, 601, 602 No.3 building
No.2388, Chen Hang Road
Min Hang District, Shanghai, 201114 Cn

Re: K172361
   Trade/Device Name: EEA Circular Stapler with Tri-Staple Technology
   Regulation Number: 21 CFR 878.4750
   Regulation Name: Implantable Staple
   Regulatory Class: Class II
   Product Code: GDW
   Dated: August 2, 2017
   Received: August 4, 2017

Dear Sarah Tang:

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. 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 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);
and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
LESS STRESS ON TISSUE.
MORE SECURE STAPLE LINES.³⁻⁵,†

LESS STRESS
GREATER PERFUSION
CONSISTENT PERFORMANCE

Call your sales representative for more information about the EEA™
circular stapler with Tri-Staple™ technology.

Visit us at medtronic.com/covidien

[3] Preclinical results may not correlate with clinical performance in humans.
[4] 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.

2. Based on internal analysis of MICI marker model for colorectal procedures multiplied by leak rate and average cost.
3. Based on internal test report #2128-194. Comparison of EEA™ circular stapler with Tri-Staple™ technology to EEA™
4. Based on internal test report #RE00036703, Pilot comparison of EEA™ circular stapler with Tri-Staple™ technology to
5. Based on internal test report #2128-097. Evaluation of early wound healing events in gastrojejunosomies and colonic
6. Based on internal test report #RE00069309. EEA™ circular stapler with Tri-Staple™ technology design verification
11. Based on internal test report #PCG-30. Comparison of circular staplers: tissue compression profiles as determine by
12. Based on extrapolation of perfusion studies performed for Endo GIA™ with Tri-Staple™ technology: internal test report
13. Zhang J. The use of the language “EEA™ circular stapler with Tri-Staple™ technology has 30 percent more staples
    in the staplers of the same lumen diameters as compared to two row circular staplers” in marketing materials

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