Box Size: 7.4 x 26.6 Overall Size: 27 x 37 Folds to: 3.375 x 9.25

COVIDIEN

EEA™

Circular Stapler with Tri-Staple™ Technology

PT00132224 page 1 of 2 INSPIRATION

8. Darbinės dalies skersmuo: 28 mm

6. Instrumento darbinės dalies ilgis 22 cm

en

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using the product. It is not a reference to surgical techniques.

This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or reinsterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or reinterilize this device.

DESCRIPTION

1. Titaninės kabutės pagaminos iš stabiakampio formos vielos

The EEA™ circular stapler with Tri-Staple™ technology places a circular, triple-staggered row of titanium staples and excises the excess tissue, creating a circular anastomosis. Representing and/or orientation of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or reinterilize this device.

The EEA™ circular stapler with Tri-Staple™ technology is available in 2 shaft lengths, a standard 20 cm and an 31 cm. Additionally, the stapler is offered in 2 staple sizes, a medium/thick and extra thick. Please refer to the EEA™ circular stapler with Tri-Staple™ technology anvil gauge selection, tissue weight, knife/anvil gap selection, and knife/anvil height guide to determine the appropriate staple size for the patient. The EEA™ circular stapler with Tri-Staple™ technology is available in all regions, except Japan. The EEA™ circular stapler with Tri-Staple™ technology is available in all regions, except Japan.

* 31 cm staplers not cleared for sale in the U.S. market.

INDICATIONS

The EEA™ circular stapler with Tri-Staple™ technology has application throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in general surgical procedures.

CONTRAINDICATIONS

1. This device is not designed, sold, or intended for use except as indicated.
2. Do not use the stapler on any tissue that, in the opinion of the surgeon, will not be able to tolerate conventional suture material or conventional closure techniques.
3. Do not use the stapler with methods/thick staple size (purple) on any tissue that compresses to less than 1.5 mm in thickness. In such cases, the staple will not form adequately.
4. Do not use the stapler with methods/thick staple size (purple) on any tissue that will not comfortably compress to 2 mm in thickness. The instrument should not be used if unusual effort is required to turn the knob knob in order to visualize at least a portion of the green bar in the indicator window.
5. Do not use the stapler with extra thick staple size (black) on any tissue that will not comfortably compress to 3.0 mm in thickness. The instrument should not be used if unusual effort is required to turn the knob knob in order to visualize at least a portion of the green bar in the indicator window.
6. Do not use the stapler if the instrument is rusted to the point that the knob knob in order to visualize at least a portion of the green bar in the indicator window.
7. Do not use the stapler if the instrument is stretched or thinned out by introducing a cartridge that is too large for the diameter of the structure. Leakage and narrowing of the anastomosis could occur. Refer to the staple specification chart. Resulting sizes are available to evaluate the size of the structures.
8. Do not use the stapler unless there is sufficient tissue to allow proper inversion of tissue edges so staples can be placed securely in the inverted edges. The purse-string suture must be tied securely above the purse-string notch so the anvil/center rod assembly.
9. Do not use the stapler where adequacy of hemostasis cannot be verified visually after firing.

WARNINGS AND PRECAUTIONS

- Preoperative radiotherapy may result in changes to tissue. These changes may, for example, cause the tissue thickness to exceed the indicator range for the selected staple size. Careful consideration must be given to use of the surgical treatment the patient may have undergone and its corresponding selection of stapler size.
- Parenteral vasopressor drugs may cause the blood vessels to constrict. Use of these drugs may result in avoid excessive tissue within the closed anvil and cartridge, which could cause staple malformation or leakage.
- Cleaning the bowel has for the purse-string suture and the cartridge and anvil. Failure to clean the bowel may result in the cartridge and anvil is closed and cartridge, which could cause staple malformation or leakage.
- Make certain that the section of tissue to be stapled is free from any staple line disruptions, otherwise, the knife blade may not cut.

NOTE: If performing a triple stapling procedure, or when a white anvil tissue tip accessory is desired, select the appropriate anvil tissue tip accessory for the procedure.

1. If the sharp tip rarely applicable to the 31 and 25 mm staplers (2 staple rows), remove the anvil assembly (A). Attach the white sharp anvil tissue tip accessory (F) to the hollow shaft on the Tri-Staple™ anvil/center rod assembly (A). The anvil tissue tip accessory will lock into place.
2. A stainer may be placed through the hole at the tip of the anvil tissue tip accessory and tied into a loop. Once the structure has been pierced, unlock the white anvil tissue tip accessory by pressing the black release button on the anvil tissue tip accessory and replace it with the blunt tip. If performing triple stapling procedure, remove the anvil tissue tip accessory by grasping the suture loop and pulling the white anvil tissue tip accessory through the access cannula with an 8 mm diameter green Base O-ring.
4. The stapler is supplied with the integrated tract (J) in the fully retracted position and completely within the confines of the cartridge (K).

CAUTION: Avoid handling the top rim of the cartridge to prevent possible injury from the circular knife.

5. To open tissue, the instrument is inserted up to the closed lumen to be dissected, and the integrated tract (J) is extended by turning the knob (N) counterclockwise until the green bar is completely visible in the indicator window. Ensure the integrated tract is extended slowly adjacent to the locking staple line to avoid tissue buckling on the side of the integrated tract. The distance between the staple and the opening of the integrated tract (J) is determined by the amount of tissue between the staple line, but the enough to allow easy passage of the center rod of the anvil center rod assembly through the distal lumen during anastomosis.

CAUTION: When piercing tissue with the integrated tracar or anvil tracar tip accessory, keep the point and puncture site visualized at all times to prevent inadvertent damage to surrounding structures. Additionally, verify that the anvil tissue tip accessory is visible outside of the structure to be anastomosed. If the orange band is not visible, the Tilt-Top™ anvil may not be properly deployed.

6. Once the integrated tract (J) is fully extended, hold the Tilt-Top™ anvil and center rod assembly (A) of the grasping notch (C) with a grasping device (D) such as a Babcock. Push the Tilt-Top™ down from the Tilt-Top™ anvil and center rod assembly to the integrated tract by pushing firmly until the instrument shaft clicks into its fully seated position. This click will be audible. Manually inspect the attachment to ensure that the anvil and center rod assembly is properly attached to the instrument.
7. After attaching the anvil to the instrument, verify that the orange band on the instrument's integrated tract has been completely covered by the anvil center rod (this is approximating the anvil center rod assembly (A) and the integrated tract (J) of the instrument.
8. Applying gentle counter traction on the distal bowel during approximation may minimize excessive tissue [bend] incorporated into the barrel of the stapler. 7. Įdiegta apsauga nuo atsitiktinio panaudojimo

10. Do not turn the stapler unless there is sufficient tissue to allow anastomosis without tension.
11. Make certain that the counter-anvil and is closed and that the tissue between the purse-string suture and the anvil is cleared and the anvil is closed between the purse-string suture and the anvil is cleared and that the tissue between the purse-string suture and the anvil is cleared. The tissue

OPBEVARES VED STUETEMPERATUR. UNDGÅ LÆNGERE TIDS UDSÆTTELSE FOR HØJE TEMPERATURER.

fi

Tri-Staple™-teknologiaa sisältävä ympyränitoja

SEURAAVAT OHJEET ON LUETTAVA HUOLELLISESTI ENNEN TUOTTEEN KÄYTTÖÄ.

SÄILYTETTÄVÄ HUONEENLÄMMÖSSÄ. VÄLTETTÄVÄ PITKITTYNYTTÄ ALTISTUSTA KORKEILLE LÄMPÖTILOILLE.

el

Κυκλικός αναστομωτήρας με τεχνολογία Tri-Staple™

ΦΥΛΑΣΣΕΤΕ ΣΕ ΘΕΡΜΟΚΡΑΣΙΑ ΔΩΜΑΤΙΟΥ. ΑΠΟΦΕΥΓΕΤΕ ΤΗΝ ΠΑΡΑΤΕΤΑΜΕΝΗ ΕΚΘΕΣΗ ΣΕ ΥΨΗΛΕΣ ΘΕΡΜΟΚΡΑΣΙΕΣ.

pl

Stapler okrężny z technologią Tri-Staple™

PRZECHOWYWAĆ W TEMPERATURZE POKOJOWEJ. UNIKAĆ PRZEDŁUŻONEJ EKSPOZYCJI NA PODWYŻSZONE TEMPERATURY.

tr

Tri-Staple™ Teknolojili Dairesel Stapler

ODA SICAKLIĞINDA SAKLAYIN. UZUN SÜRE YÜKSEK SICAKLIKLARA MARUZ BIRAKMAKTAN KAÇININ.

ru

Циркулярный сшивающий аппарат с применением технологии Tri-Staple™

ХРАНИТЬ ПРИ КОМНАТНОЙ ТЕМПЕРАТУРЕ. ИЗБЕГАТЬ ДЛИТЕЛЬНОГО ВОЗДЕЙСТВИЯ ПОВЫШЕННОЙ ТЕМПЕРАТУРЫ.

cs

Kruhový stapler s technologií Tri-Staple™

SKLADUJTE PŘI POKOJOVÉ TEPLOTĚ. CHRAŇTE PŘED DELŠÍM VYSTAVENÍM ZVÝŠENÝM TEPLOTÁM.

hu

Tri-Staple™ technológiájú körvarrógép

A TERMÉK HASZNÁLATA ELŐTT FIGYELMESEN OLVASSA EL AZ ALÁBBI TUDNIVALÓKAT.

SZOBAHŐMÉRSÉKLETEN TÁROLANDÓ. NEM SZABAD HOSSZÚ IDEIG MAGAS HŐMÉRSÉKLETNEK KITENNI.

STERILE EO	**en:** Sterilized using ethylene oxide **fr:** Stérilisé à l'oxyde d'éthylène **de:** Mit Ethylenoxid sterilisiert **it:** Sterilizzato con ossido di etilene **es:** Esterilizado con óxido de etileno **pt:** Esterilizado com óxido de etileno **nl:** Gesteriliseerd met ethyleenoxide **sv:** Steriliserad med etylenoxid **da:** Steriliseret med ethylenoxid **fi:** Steriloitu etyleenioksidilla **el:** Αποστειρωμένο με οξείδιο του αιθυλενίου **pl:** Sterylizowano przy użyciu tlenku etylenu **tr:** Etilen oksit kullanılarak sterilize edilmiştir **ru:** Стерилизовано этиленоксидом **cs:** Sterilizováno ethylenoxidem **hu:** Etilén-oxiddal sterilizálva
Rx ONLY	**en:** Caution: U.S. Federal law restricts this device to sale by or on the order of a physician. ...
	en: Do not use if package is opened or damaged. ...
	en: Caution, consult accompanying documents ...
MR	**en:** MR Conditional ...
CE 0123	CE Mark

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Covidien llc, 15 Hampshire Street, Mansfield, MA 02048 USA.
EC REP Covidien Ireland Limited, IDA Business & Technology Park, Tullamore, Ireland.
www.covidien.com
+1 800 633 8766
+1 763 514 4000

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