Box size: 4 x 11
Overall size: 18 x 28
Folds to: 3 x 9.333

COVIDIEN

Endo GIA™ Ultra
Universal, Universal Short, and Universal XL
Single Use Staplers

1029434

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BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical technique.

Before attempting to use this product, it is important that the surgeon thoroughly familiarize himself/herself with the operating technique for this product. Safe and subsequent patient benefit is dependent upon the surgeon's knowledge of the device and may include the use of conventional and patient selection. Do not reuse, reprocess or resterilize this device.

DESCRIPTION

The Endo GIA™ Universal Short, Endo GIA™ Universal and Endo GIA™ Ultra Universal XL staplers are designed to apply two rows of staples and simultaneously transect tissue between the rows of staples. The Endo GIA™ Universal XL and Endo GIA™ Ultra Universal XL staplers are designed to apply two rows of staples on each side of the transection line and to transect tissue between the rows of staples.

Each reload and buttress (if included) contains a single cartridge with staggered rows of 2.0mm, 2.5 mm, 3.0mm titanium staples.

Purple reload and Purple curved reload – two triple-staggered height progressive rows of 3.0mm, 3.5 mm and 4.0mm titanium staples

Black reload – two triple-staggered height progressive rows of 4.0mm, 4.5 mm and 5.0mm titanium staples

The Endo GIA™ Universal Short stapler is designed for open procedures only. All instructions, warnings, and precautions referring to trocars, or laparoscopic procedures, apply to the Endo GIA™ Universal and the Endo GIA™ Universal XL staplers only, and do not pertain to the Endo GIA™ Universal Short stapler.

The Endo GIA™ Universal Short, Endo GIA™ Ultra Universal Short, Endo GIA™ Universal and Endo GIA™ Ultra Universal XL staplers with reinforcement are of the single-use load units that are available in the 30 mm, 45 mm and 60 mm sizes.

The Endo GIA™ Ultra Universal and Endo GIA™ Universal XL staplers with either the Gray, Gas, or Purple single-use reload is designed for introduction and use through a 12 mm trocar sleeve, or larger, with the use of a curved tip. This does not pertain to the Endo GIA™ Ultra Universal Short stapler.

The Endo GIA™ Ultra Universal and Endo GIA™ Ultra Universal XL staplers with the Purple single-use reload is designed for introduction and use through a 15 mm trocar sleeve, or larger, with the use of a curved tip. This does not pertain to the Endo GIA™ Ultra Universal Short stapler.

The instrument may be reloaded and fired up to 3 times in a single operation.

NOTE: Each instrument can accommodate the 30 mm Height Gray, Gas, and Purple single-use reloads; the 45 mm Height Gray, Tan, Purple, Black reload and the 60 mm Height Tan, Purple, Black reload.

The curved tip on the distal end of the curved tip reload can be used to dissect and manipulate tissue/ vessels when locating space from subsequent firing and placement of staples.

The flexible introducer provided with the curved tip reload can be mounted on the curved tip and used to guide the curved underneath the instrument flute to its fully inserted.

COMPATIBILITY

Endo GIA™ Ultra Universal staplers are compatible with all Endo GIA™ Universal single-use loading units, all Endo GIA™ Reticulate™ single-use loading units and all Endo GIA™ single-use reloads with Tri-Staple™ technology.

When using the Endo GIA™ Universal Short, Endo GIA™ Ultra Universal Short, Endo GIA™ single-use loading units or with Endo GIA™ Reticulate™ single-use loading unit, refer to the instructions, contained therein, warnings and precautions contained in the Endo GIA™ Universal and Endo GIA™ Universal Ultra and XL refer to the loading instructions, unloading instructions and instructions for use contained in the Endo GIA™ Ultra Universal Short Reload.

All Endo GIA™ Universal and Ultra™ Universal staplers are compatible with all Endo GIA™ single-use reloads with Tri-Staple™ technology.

When using Endo GIA™ Universal and GIA™ Universal staplers with Endo GIA™ single-use reloads with Tri-Staple™ technology, refer to the instructions, contraindications and warnings & precautions contained in the Endo GIA™ Universal and Ultra and XL refer to the loading instructions, unloading instructions and instructions for use contained in the Endo GIA™ Universal & GIA™ Universal Ultra.

Compatibility of staples for reinforcement material for use with Endo GIA™ single-use reloads with Tri-Staple™ technology has not been determined.

INDICATIONS

The Endo GIA™ Universal Short, Endo GIA™ Ultra Universal Short, Endo GIA™ Universal XL staplers are indicated for use to transect and create hemostatic lines in tissue during open surgical procedures, including creation of anastomoses. It may be used for transection and resection of non-cutaneous, hepatic vasculature and biliary structures.

The Endo GIA™ Ultra Universal Short, Endo GIA™ Ultra Universal and Endo GIA™ Ultra Universal XL staplers when used with the Endo GIA™ curved tip single-use reloads can be used to blunt dissect or separate target tissue from other tissue.

CONTRAINDICATIONS

1. Do not use the Endo GIA™ Universal Short stapler for laparoscopic procedures.
2. Do not open the Endo GIA™ Ultra Universal Short stapler through a trocar, as the shaft of the handle will not fit through the trocar opening. Use the Endo GIA™ Ultra Universal.
3. Do not use Endo GIA™ Ultra single-use reloads on any trocar that compresses on into Size 5 mm or thicker, on any trocar that cannot comfortably compress to 12 mm or on the aorta.
4. Do not use Endo GIA™ Ultra single-use reloads on any trocar that is smaller than 12 mm in diameter, on any trocar that cannot comfortably compress to 12 mm or on the aorta.
5. Do not use the Endo GIA™ Purple reload on any trocar that compresses on into Size 12 mm or thicker, on any trocar that cannot comfortably compress to 12.5 mm or on the aorta.
6. The Endo GIA™ Ultra Universal Short, Endo GIA™ Ultra Universal and Endo GIA™ Ultra Universal XL instruments should not be used or reuse such as liver or spleen where compressibility is such that closure of the staples cannot be accomplished.

CONTRAINDICATIONS

Staples on Buttress Endo GIA™ Ultra Universal Short, Endo GIA™ Ultra Universal and Endo GIA™ Ultra Universal XL staplers with Tri-Staple™ technology:

1. Do not use on tissue that is not adequate to secure with buttress material.
2. Do not use on tissue that cannot be compressed to the thickness of the buttressed staples.
3. Do not use on tissue that is not adequate to secure with buttress material.
4. Do not use on tissue that cannot be compressed to the thickness of the buttressed staples.

Use of Endo GIA™ Ultra Universal Short, Endo GIA™ Ultra Universal and Endo GIA™ Ultra Universal XL staplers with Tri-Staple™ technology has not been determined for:

1. Patients undergoing chemotherapy or radiation therapy.
2. Patients with a history of bleeding disorders.
3. Patients who are immunosuppressed.
4. Patients who are malnourished.
5. Patients who have received a blood transfusion within 48 hours of surgery.
6. Patients who have had steroid therapy within 30 days of surgery.
7. Patients who have had chemotherapy within 7 days of surgery.
8. Patients who have had radiation therapy within 30 days of surgery.
9. Patients who have had an infection at the surgical site.
10. Patients who have had a bleeding disorder.
11. Patients who have had a platelet count of less than 100,000 platelets/mm3.
12. Patients who have had a platelet dysfunction.
13. Patients who have had a coagulation disorder.
14. Patients who have had a prothrombin time greater than 15 seconds.
15. Patients who have had a partial thromboplastin time greater than 40 seconds.
16. Patients who have had a bleeding time greater than 9 minutes.
17. Patients who have had a fibrinogen level less than 100 mg/dl.
18. Patients who have had a hematocrit less than 30%.
19. Patients who have had a hemoglobin level less than 10 g/dl.
20. Patients who have had a platelet count less than 100,000 platelets/mm3.
21. Patients who have had a white blood cell count greater than 15,000 cells/mm3.
22. Patients who have had a white blood cell count less than 3,000 cells/mm3.
23. Patients who have had a bilirubin level greater than 2.0 mg/dl.
24. Patients who have had a creatinine level greater than 2.0 mg/dl.
25. Patients who have had a BUN level greater than 40 mg/dl.
26. Patients who have had a SGOT level greater than 100 units/dl.
27. Patients who have had a SGPT level greater than 100 units/dl.
28. Patients who have had a total protein level less than 5.0 g/dl.
29. Patients who have had an albumin level less than 2.5 g/dl.
30. Patients who have had a total bilirubin level greater than 2.0 mg/dl.
31. Patients who have had a direct bilirubin level greater than 0.5 mg/dl.
32. Patients who have had a prothrombin time greater than 15 seconds.
33. Patients who have had a partial thromboplastin time greater than 40 seconds.
34. Patients who have had a bleeding time greater than 9 minutes.
35. Patients who have had a fibrinogen level less than 100 mg/dl.
36. Patients who have had a hematocrit less than 30%.
37. Patients who have had a hemoglobin level less than 10 g/dl.

WARNINGS

1. Do not use the Endo GIA™ Universal Short, Endo GIA™ Ultra Universal Short, Endo GIA™ Universal and Endo GIA™ Ultra Universal XL staplers for laparoscopic procedures.
2. Do not open the Endo GIA™ Ultra Universal Short stapler through a trocar, as the shaft of the handle will not fit through the trocar opening. Use the Endo GIA™ Ultra Universal.
3. Do not use Endo GIA™ Ultra single-use reloads on any trocar that compresses on into Size 5 mm or thicker, on any trocar that cannot comfortably compress to 12 mm or on the aorta.
4. Do not use Endo GIA™ Ultra single-use reloads on any trocar that is smaller than 12 mm in diameter, on any trocar that cannot comfortably compress to 12 mm or on the aorta.
5. Do not use the Endo GIA™ Purple reload on any trocar that compresses on into Size 12 mm or thicker, on any trocar that cannot comfortably compress to 12.5 mm or on the aorta.
6. The Endo GIA™ Ultra Universal Short, Endo GIA™ Ultra Universal and Endo GIA™ Ultra Universal XL instruments should not be used or reuse such as liver or spleen where compressibility is such that closure of the staples cannot be accomplished.

CONDITIONS

Staples on Buttress Endo GIA™ Ultra Universal Short, Endo GIA™ Ultra Universal and Endo GIA™ Ultra Universal XL staplers with Tri-Staple™ technology:

1. Do not use on tissue that is not adequate to secure with buttress material.
2. Do not use on tissue that cannot be compressed to the thickness of the buttressed staples.
3. Do not use on tissue that is not adequate to secure with buttress material.
4. Do not use on tissue that cannot be compressed to the thickness of the buttressed staples.

Use of Endo GIA™ Ultra Universal Short, Endo GIA™ Ultra Universal and Endo GIA™ Ultra Universal XL staplers with Tri-Staple™ technology has not been determined for:

1. Patients undergoing chemotherapy or radiation therapy.
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9. Patients who have had an infection at the surgical site.
10. Patients who have had a bleeding disorder.
11. Patients who have had a platelet count of less than 100,000 platelets/mm3.
12. Patients who have had a platelet dysfunction.
13. Patients who have had a coagulation disorder.
14. Patients who have had a prothrombin time greater than 15 seconds.
15. Patients who have had a partial thromboplastin time greater than 40 seconds.
16. Patients who have had a bleeding time greater than 9 minutes.
17. Patients who have had a fibrinogen level less than 100 mg/dl.
18. Patients who have had a hematocrit less than 30%.
19. Patients who have had a hemoglobin level less than 10 g/dl.
20. Patients who have had a platelet count less than 100,000 platelets/mm3.
21. Patients who have had a white blood cell count greater than 15,000 cells/mm3.
22. Patients who have had a white blood cell count less than 3,000 cells/mm3.
23. Patients who have had a bilirubin level greater than 2.0 mg/dl.
24. Patients who have had a creatinine level greater than 2.0 mg/dl.
25. Patients who have had a BUN level greater than 40 mg/dl.
26. Patients who have had a SGOT level greater than 100 units/dl.
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37. Patients who have had a hemoglobin level less than 10 g/dl.

PRECAUTIONS

1. Before using the stapler on the abdominal cavity, the surgeon should be familiar with the operating technique for this product.
2. Safe and subsequent patient benefit is dependent upon the surgeon's knowledge of the device and may include the use of conventional and patient selection.
3. Do not reuse, reprocess or resterilize this device.
4. Do not use the stapler on the applicator site, ensure that no obstructions, such as clips, are incorporated into the instrument jaws. Firing over an obstruction may result in incomplete cutting action and/or improperly formed staples.
5. To ensure proper performance of this device, read the instructions, such as clips, are incorporated into the instrument jaws. Firing over an obstruction may result in incomplete cutting action and/or improperly formed staples.
6. Endoscopic procedures should be performed only by physicians having adequate training and familiarity with the specific surgical procedure and the instrument. Improper use of any endoscopic procedure, consult the medical literature relative to technique, complications and hazards.
7. A thorough understanding of the principles involved in laser and electrosurgical procedures is essential to avoid shock and burn hazards to both patient and operating personnel, and damage to the instrument.
8. When Endoscopic instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure that only sterile components are used in the procedure.
9. The wrist must be completely rotated, open the tissue sleeve/ jaws to opening the reload within the body cavity. This does not pertain to the Endo GIA™ Ultra Universal Short stapler.
10. Do not grasp tissue with the open jaws of the stapler. Use the jaws for tissue only after grasping and stapling.
11. When manipulating tissue with the curved tip reload, avoid exerting excessive pressure on fragile structures with the curved tip of the reload.
12. To ensure that the curved tip reload can be inserted and removed from the trocar sleeve without damage to the trocar sleeve, the curved tip must be straightened as it is withdrawn from the trocar sleeve.
13. The instrument will cut and staple any structure included in the jaws. Do not attempt to cut or staple tissue that is to be left alive.
14. Before firing the stapler, ensure that the tissue is not twisted and that no structures, such as clips, are incorporated into the instrument jaws. Firing over an obstruction may result in incomplete cutting action and/or improperly formed staples.
15. Do not fire the stapler unless the jaws are completely closed. Proper alignment of the staple cartridge and anvil is assured when the jaws are completely closed.
16. Do not clamp instrument jaws for tissue manipulation.
17. Do not open the jaws of the stapler unless the jaws are completely closed. Proper alignment of the staple cartridge and anvil is assured when the jaws are completely closed.
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DESCRIPTION OF COMPONENTS

A) HOUSING
B) ACTUATION
C) CLOSURE OSCILLATION
D) CLOSURE / ROTATION KNOB
E) HANDPIECE & ROTATING NOSE
F) ANVIL
G) ANVIL RELEASE
H) CARTRIDGE
I) CARTRIDGE ALIGNMENT
J) CARTRIDGE RELEASE
K) CARTRIDGE RETAINER
L) CARTRIDGE RETAINER RELEASE
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Box size: 4 x 11
Overall size: 18 x 28
Folds to: 3 x 9.333
page 2 of 3, page 1 is 1029434, page 3 is non-printed

COVIDIEN

Endo GIA™ Ultra

Universal, Universal Short, and Universal XL
Single Use Staplers

1029435

FI

Kertakäyttöiset Universal-, Universal Short- ja Universal XL -niitojat

SISÄNKANNI ONVOIT ON LUOTTAVA KUKKULEUSSEN TOIMINTAAN KÄYTTÄE. TÄMÄSSÄ

Tämä käyttöohjeisto on tarkoitettu käyttäjälle. Sitä ei annella ilmoituksia mennettelä koskeva objektia. Tämä tuo vaikeutta, mutta on tärkeää, että käyttäjä ymmärtää kaikki tämän käyttöohjeen sisältämät ohjeet ja varoitukset. Lukemi jaksoissa ja tee ymmärtämisen sujuttelen on yhtaa tarvitsemaasi ja pohjoisliikkeen. Lukemi ja varoitukset, jotkissa ei ole tehdä sujuttelen.

KUVAUS

Endo GIA™ Ultra Universal, Endo GIA™ Ultra Universal ja Endo GIA™ Ultra Universal XL -niitat kumoa valmiit kahtiin niitin ennen lähtöä tehdyn kerrallaisilla kaksirivisillä, pitkittäisillä niitti- ja leikkausviivoilla. Tukkumi niitteen. Tukkumi niitin määrittelyä kahtiin niitin ennen lähtöä tehdyn kerrallaisilla kaksirivisillä, pitkittäisillä niitti- ja leikkausviivoilla. Tukkumi niitteen. Tukkumi niitin määrittelyä kahtiin niitin ennen lähtöä tehdyn kerrallaisilla kaksirivisillä, pitkittäisillä niitti- ja leikkausviivoilla. Tukkumi niitteen.

Kumma halvakäyttöä ja kumma kumma halvakäyttöä niitet tehdä kolmeistöistä aineitten kerrallaisilla niitti- ja leikkausviivoilla. Tukkumi niitteen.

Muuta halvakäyttöä niitet tehdä kolmeistöistä aineitten kerrallaisilla niitti- ja leikkausviivoilla. Tukkumi niitteen.

Endo GIA™ Ultra Universal Short -niitoja on saatavilla sen automaattisesta. Kaikki kuudentoista ja kuudentoista kuudentoista kuudentoista