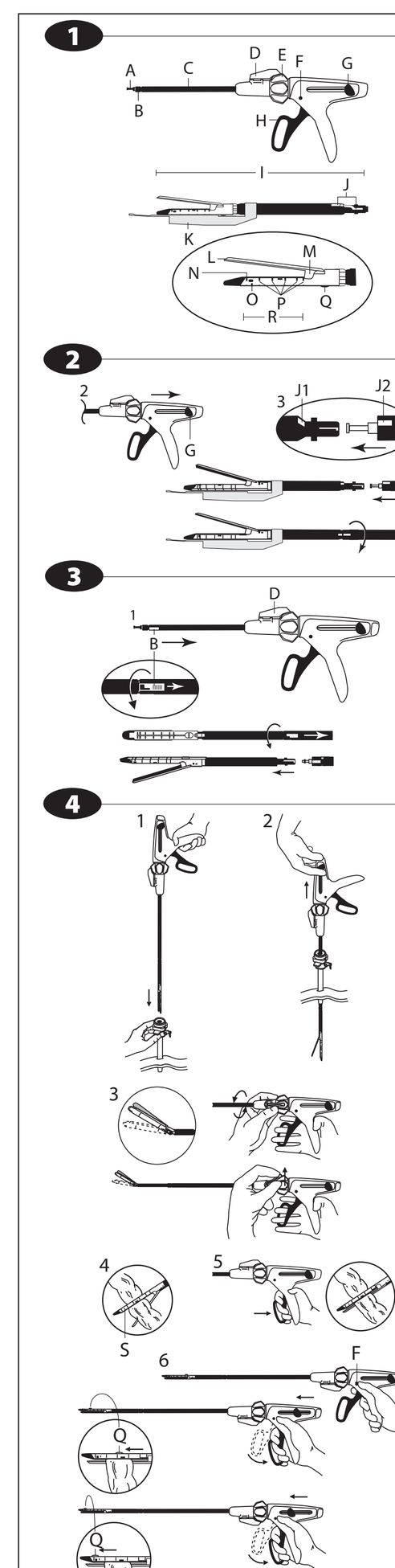
Box size: 3.88 x 9.56
Overall size: 18 x 28
Folds to: 3 x 7

COVIDIEN™

Endo GIA™

Universal Stapler and Loading Unit

1300840



5

	T	U	V	W
	Gray	30 mm, 45 mm	3 mm / 2 mm	.75 mm
	White	30 mm, 45 mm, 60 mm	3 mm / 2.5 mm	1.0 mm
	Blue	30 mm, 45 mm, 60 mm	3 mm / 3.5 mm	1.5 mm
	Green	45 mm, 60 mm	3 mm / 4.8 mm	2.0 mm

EN

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 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 resterilization of this device may create the risk of contamination and infection. Do not reuse, reprocess or resterilize this device.

DESCRIPTION

The Endo GIA™ universal and Endo GIA™ universal XL staplers place two, triple-staggered rows of titanium staples and simultaneously divides the tissue between the two, triple-staggered rows. The size of the staples is determined by the selection of the 2.0 mm, 2.5 mm, 3.5 mm or 4.8 mm single use loading unit. The Endo GIA™ universal staplers will accommodate any of the single use loading unit sizes that are available in the 30 mm, 45 mm and 60 mm lines.

The Endo GIA™ universal staplers with either the 2.0, 2.5, 3.5 single use loading unit is designed for introduction and use through a 12 mm trocar sleeve, or larger, with the use of a converter.

When using the Endo GIA™ universal staplers with the 4.8 single use loading unit, it must be inserted into a 15 mm trocar sleeve. The instrument may be loaded and fired up to 25 times in a single procedure.

NOTE: Each instrument can accommodate the 30-2.0, 2.5, 3.5 / 45-2.0, 2.5, 3.5, 4.8 / 60-2.5, 3.5, 4.8 mm loading units.

INDICATIONS

The Endo GIA™ universal staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis.

CONTRAINDICATIONS

1. Do not use the Endo GIA™ universal 2.0 mm staples on any tissue that compresses to less than .75 mm in thickness, on any tissue that cannot comfortably compress to 1.0 mm or on the aorta.
2. Do not use the Endo GIA™ universal 2.5 mm staples on any tissue that compresses to less than 1.0 mm in thickness, on any tissue that cannot comfortably compress to 1.5 mm or on the aorta.
3. Do not use the Endo GIA™ universal 3.5 mm staples on any tissue that compresses to less than 1.5 mm in thickness, on any tissue that cannot comfortably compress to 2.0 mm or on the aorta.
4. Do not use the Endo GIA™ universal 4.8 mm staples on any tissue that compresses to less than 2.0 mm in thickness, on any tissue that cannot comfortably compress to 2.0 mm or on the aorta.
5. The Endo GIA™ universal instrument should not be used on tissue such as liver or spleen where compressibility is such that closure of the instrument would be destructive.
6. Do not use the Endo GIA™ universal stapler where adequacy of hemostasis cannot be verified visually after applications.
7. These devices are provided STERILE and are intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT RESTERILIZE.

WARNINGS AND PRECAUTIONS

1. Preoperative radiotherapy may result in changes to tissue. These changes may, for example, cause the tissue thickness to exceed the indicated range for the selected staple size. Careful consideration should be given to any pre-surgical treatment the patient may have undergone and in corresponding selection of staple size.
2. Always include the combined thickness of the tissue and of any staple line reinforcement material in use when choosing the proper staple cartridge.
3. When using the Endo GIA™ universal instrument with a 4.8 single use loading unit, the instrument MUST be inserted into a 15 mm trocar. A smaller size trocar will not accept the 4.8 loading unit.
4. Always inspect the tissue thickness and select an appropriate staple size prior to application of the Endo GIA™ universal stapler.
5. Always close the jaws of the Endo GIA™ universal stapler prior to introducing and removing the stapler from the trocar sleeve.
6. After firing, always inspect the staple line for hemostasis. Minor bleeding may be controlled by electrocautery or manual sutures.
7. Placement of tissue proximal to the tissue stops (on the loading unit) may result in stapler malfunction. Any tissue extending beyond the cut mark will not be transected.
8. When using the stapler more than once during a SINGLE surgical procedure, be sure to remove the empty Endo GIA™ universal single use loading unit and load a new one. A safety interlock is provided that prevents an empty single use loading unit from being fired a second time. Do not attempt to override the safety interlock.
9. When positioning the stapler on the application 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.
10. Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. Prior to performance of any endoscopic procedures, consult the medical literature relative to techniques, complications and hazards.
11. A thorough understanding of the principles involved in laser and electrosurgical procedures is essential to avoid shock and burn hazards to both patient and operator(s), and damage to the instrument.
12. When endoscopic instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure that electrical isolation or grounding is not compromised.
13. The anvil must be completely visible, (past the trocar sleeve) prior to opening the loading unit within the body cavity.
14. When using a staple line buttressing material, follow the instructions provided by the manufacturer of the buttress material, as performance of the stapler may be affected when using buttress materials.
15. The instrument and single use loading unit are provided STERILE and are intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT RESTERILIZE.
16. Do not attempt to load loading unit while squeezing ring handle.

1 SCHEMATIC VIEW

A) PIN	J) LOAD ALIGNMENT INDICATORS
B) UNLOAD/UNLOCK BUTTON	K) SHIPPING WEDGE
C) SHAFT	L) ANVIL
D) ARTICULATING LEVER	M) TISSUE STOP
E) ROTATION COLLAR	N) END OF STAPLE LINE
F) GREEN BUTTON	O) END OF CUT LINE
G) BLACK RETURN KNOB	P) INCREMENT MARKINGS
H) HANDLE	Q) LOWER CLAMP BUTTON
I) LOADING UNIT (30, 45, 60)	R) STAPLE CARTRIDGE

2 LOADING

1. The loading unit is packaged in the open position. Do not attempt to close the loading unit.

WARNING: Select a loading unit with the appropriate staple size for the tissue thickness. Overly thick or thin tissue may result in unacceptable staple formation. Always include the combined thickness of the tissue and of any staple line reinforcement material in use when choosing the proper staple cartridge.

CAUTION: Do not attempt to remove the shipping wedge until the loading unit is loaded into the instrument.

2. Ensure that the black knobs on the instrument are pulled back completely and the articulation arm is in the neutral position.

G) BLACK RETURN KNOBS

3. To load the Endo GIA™ universal stapler with the appropriate loading unit, insert the pin located at the distal end of the instrument shaft into the loading unit. Ensure that the LOAD alignment indicator on the loading unit aligns with the LOAD alignment indicator on the shaft. Push the loading unit in and twist clockwise 45° relative to the instrument, so that the loading unit will lock into place. The LOAD alignment indicator on the instrument shaft will align with the LOAD alignment indicator on the loading unit.

J1) LOAD ALIGNMENT INDICATOR (LOADING UNIT)

J2) LOAD ALIGNMENT INDICATOR (SHAFT)

4. Remove the shipping wedge from the loading unit prior to inserting the instrument into the trocar.

CAUTION: Do not clamp instrument prior to removing shipping wedge.

5. To confirm proper loading, cycle the instrument after loading the loading unit. Squeeze the handle once to close the jaws of the loading unit. Pull back on the black return knobs and confirm that the loading unit jaws open fully.

3 UNLOADING

1. To unload a loading unit from the stapler, the articulating lever must be in the neutral position. Ensure that the jaws of the loading unit are open by pulling the black return knobs back completely. Pull the UNLOAD/UNLOCK button (located on the underside of the shaft) back towards the instrument, twist the loading unit counterclockwise 45° and remove the loading unit from the shaft of the instrument.

B) UNLOAD/UNLOCK BUTTON

D) ARTICULATING LEVER

4 INSTRUCTIONS FOR USE

NOTE: The jaws of the loading unit must be closed prior to introducing the instrument into the trocar sleeve. To do so, squeeze the handle.

1. Insert the Endo GIA™ universal stapler into an appropriately sized trocar sleeve, or larger, with the use of a converter.

CAUTION: The anvil must be completely visible, (past the trocar sleeve) prior to opening the loading unit within the body cavity.

The instrument shaft rotates 360° and articulates 22° and 45° in both directions with use of articulating lever.

NOTE: When using the Endo GIA™ universal instrument with a 4.8 single use loading unit, the instrument MUST be inserted into a 15 mm trocar. A smaller size trocar will not accept the 4.8 loading unit.

2. Once inside the body cavity, open the jaws of the instrument by pulling the black return knobs completely back.

CAUTION: Do not squeeze the instrument handle while pulling back the black knobs.

3. Apply the Endo GIA™ universal stapler across the tissue to be transected. Caution: Ensure that no obstructions (such as clips) are incorporated in the instrument jaws. Firing over an obstruction may result in incomplete cutting action and/or improperly formed staples.

The instrument will not cut tissue beyond the black cut mark indicated on the single use loading unit. More than one application of the Endo GIA™ universal stapler may be necessary for tissue exceeding the length of the loading unit (30 mm, 45 mm or 60 mm).

S) CUTMARK

CAUTION: Placement of tissue proximal to the tissue stops (on the loading unit) may result in stapler malfunction. Any tissue extending beyond the cut mark will not be transected.

4. Close the jaws of the instrument across the tissue to be transected by squeezing the handle completely. The stapler is equipped with a safety interlock; the instrument will not fire the staples and cut tissue unless the green button is pushed.

CAUTION: A safety interlock is provided that prevents an empty single use loading unit from being fired a second time. Do not attempt to override the safety interlock.

The jaws of the instrument may be repositioned on the tissue prior to firing by pulling the black return knobs completely back, allowing the jaws to open.

5. In order to fire the instrument, push the green button. Squeeze the handle sequentially until the oval clamp cover reaches the distal end of the cartridge slot, and the handle locks.

Sequential squeezes of the handle are required to fully fire the loading unit.

The total number of squeezes is relative to the length of the loading unit (30, 45 or 60).

FAILURE TO COMPLETELY FIRE THE LOADING UNIT WILL RESULT IN AN INCOMPLETE CUT AND/OR INCOMPLETE STAPLE FORMATION, WHICH MAY RESULT IN POOR HEMOSTASIS.

F) GREEN BUTTON

Q) LOWER CLAMP BUTTON

6. Once the instrument has been completely fired, open the jaws by pulling the black return knobs completely back. Gently remove the instrument from the tissue. The site should be checked for hemostasis following removal of the instrument. Minor bleeding may be controlled using electrocautery or manual sutures.

7. After completely firing the loading unit, close jaws of the instrument and remove the Endo GIA™ universal stapler from the body cavity to unload the single use loading unit from the instrument.

NOTE: Do not attempt to insert or remove the instrument from the trocar sleeve if the instrument is in the articulated position.

The Endo GIA™ universal may be loaded and fired up to 25 times in a single procedure.

5 STAPLE SPECIFICATIONS

T) COLOR

U) STAPLE LINE LENGTH

W) OPEN STAPLE SIZE

X) CLOSED STAPLE SIZE

AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.

FR

Agrafeuse universelle et unité de chargement

DE

Universal-Klammerninstrument und Ladevorrichtung

IT

Suturatrice meccanica universale e unità di caricamento

ES

Grapadora universal y unidad de carga

PT

Grampeador universal e unidade de caga

NL

Universele stapler en laadeenheid

SV

Universalstapler och magasin

DA

Universalstapler og engangsmagasin

FI

Yleisnitoja ja hakasyksikkö

EL

Καθολικό συρραπτικό και μονάδα γεμίσματος

PL

Uniwersalny stapler i wkład

TR

Universal Zımba Aleti ve Doldurma Birimi

RU

Универсальный степлер и загрузочное устройство

CS

Univerzální sešívačka a plnicí jednotka

Do not use if package is opened or damaged.
Ne pas utiliser en cas d'endommagement ou d'ouverture de l'emballage.
Bei geöffneter oder beschädigter Verpackung nicht verwenden.
Non utilizzare se la confezione è aperta o danneggiata.
No usar el dispositivo si la envoltura está abierta o dañada.
Não utilizar se a embalagem estiver aberta ou danificada.
Niet gebruiken als de verpakking beschadigd of geopend is.
Får ej användas om förpackningen är öppnad eller skadad.
Må ikke anvendes, hvis emballagen er åbnet eller beskadiget.
Ei saa käyttää, jos pakkaus on avattu tai vaurioitunut.
Μη χρησιμοποιείτε αν η συσκευασία έχει ανοιχτεί ή υποστεί ζημιά.
Nie stosować, jeżeli opakowanie zostało otwarte lub uszkodzone.
Ambalaj açılmış ya da zarar görmüşse kullanmayın.
Не использовать изделие, если упаковка вскрыта или повреждена.
Pokud je balení otevřené nebo poškozené, produkt nepoužívejte.

STERILE EO

Rx ONLY

Caution, consult accompanying documents

Upper temperature limit 130°F 54°C

Store at room temperature 86°F 30°C 59°F 15°C

CE 0123

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