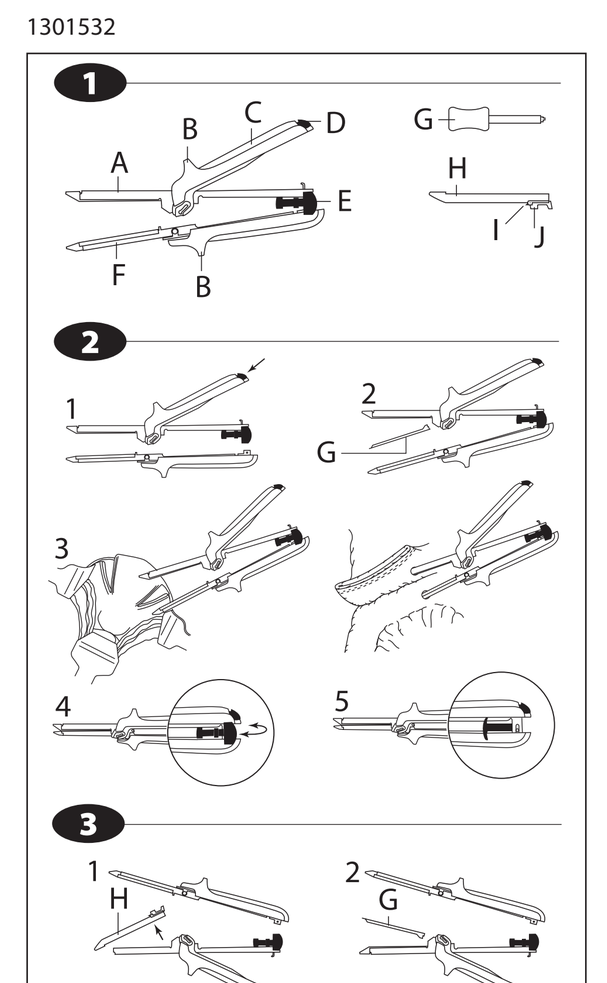
Box size: 4.81 x 13.06
Overall size: 18 x 22
Folds to: 3 x 7.333

COVIDIEN™

GIA™ and SGIA™ Auto Suture™ Stapler with DST Series™ Technology

1301532



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	K	L	M	N	O	P	Q
	GIA6025S	GIA6025L	60 mm	WHITE	2.84 mm / 2.5 mm	1 mm	1 mm
		GIA6038L	60 mm	BLUE	2.84 mm / 3.8 mm	1.5 mm	1.5 mm
		GIA6048L	60 mm	GREEN	2.84 mm / 4.8 mm	2 mm	2 mm
	GIA6038S	GIA6025L	60 mm	WHITE	2.84 mm / 2.5 mm	1 mm	1 mm
		GIA6038L	60 mm	BLUE	2.84 mm / 3.8 mm	1.5 mm	1.5 mm
		GIA6048L	60 mm	GREEN	2.84 mm / 4.8 mm	2 mm	2 mm
	GIA6048S	GIA6025L	60 mm	WHITE	2.84 mm / 2.5 mm	1 mm	1 mm
		GIA6038L	60 mm	BLUE	2.84 mm / 3.8 mm	1.5 mm	1.5 mm
		GIA6048L	60 mm	GREEN	2.84 mm / 4.8 mm	2 mm	2 mm
	SGIA6038S		60 mm	BLUE	2.84 mm / 3.8 mm	1.5 mm	1.5 mm
	GIA8038S	GIA8038L	80 mm	BLUE	2.84 mm / 3.8 mm	1.5 mm	1.5 mm
		GIA8048L	80 mm	GREEN	2.84 mm / 4.8 mm	2 mm	2 mm
	GIA8048S	GIA8038L	80 mm	BLUE	2.84 mm / 3.8 mm	1.5 mm	1.5 mm
		GIA8048L	80 mm	GREEN	2.84 mm / 4.8 mm	2 mm	2 mm
	GIA10038S	GIA10038L	100 mm	BLUE	2.84 mm / 3.8 mm	1.5 mm	1.5 mm
		GIA10048L	100 mm	GREEN	2.84 mm / 4.8 mm	2 mm	2 mm
	GIA10048S	GIA10038L	100 mm	BLUE	2.84 mm / 3.8 mm	1.5 mm	1.5 mm
		GIA10048L	100 mm	GREEN	2.84 mm / 4.8 mm	2 mm	2 mm

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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 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 patient infection. Do not reuse, reprocess or resterilize this device.

DESCRIPTION

The GIA™ stapler with DST Series Technology™ places two double staggered rows of titanium staples and simultaneously cut and divide tissue between the two double rows. The staplers and single use loading units (SULU) are available in 60 mm, 80 mm, and 100 mm lengths. The SGIA™ 60 knifeless stapler places two double staggered rows of titanium staples. The SGIA™ knifeless stapler with DST Series Technology™ is available in 60 mm only.

The staplers are available in three staple sizes to accommodate various tissue thicknesses: 2.5 mm, 3.8 mm and 4.8 mm. The SGIA™ knifeless stapler is available in 3.8 mm staple size only. Please refer to the "SPECIFICATION CHART" for availability of staple sizes and cartridge lengths.

Each stapler may be reloaded up to 7 times for a total of 8 firings per instrument. The SGIA™ stapler is not reloadable.

INDICATIONS

The reloadable staplers and the knifeless stapler have applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis.

CONTRAINDICATIONS

1. The instrument should not be used on tissue such as liver or spleen where compressibility is such that closure of the instrument would be destructive.
2. Tissue thickness should be carefully evaluated before firing any stapler. Refer to "SPECIFICATION CHART" and the "Tissue Compression Requirements" section. "Tissue Compression Requirement" refers to the tissue compression requirement for each staple size. If the tissue can not comfortably compress to the specified minimum requirement, or compresses to less than this requirement, the tissue may be too thick or too thin for the selected staple size.

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. The SGIA™ 60 knifeless stapler contains no knife.
3. The GIA™ 60, 80 and 100 staplers are designed to be fully disposable and should not be fired more than 8 times per instrument. Additional applications may cause improperly formed staples resulting in leakage or disruption of the staple line.
4. The SGIA™ 60 stapler places four parallel rows of staples. Never manually divide between the rows of staples. If division is desired, the GIA™ 60 mm, 80 mm, or 100 mm instrument is recommended.
5. When using the instrument more than once during the same procedure, be sure that the anvil is clear of tissue, blood and staples following each application.
6. When used in the abdomen, make sure no omental or mesenteric vessels are caught between the cartridge and anvil assembly prior to locking the instrument.
7. The GIA™ 60, 80 and 100 staplers are provided STERILE and are intended for multiple use during a SINGLE procedure. The SGIA™ 60 knifeless stapler is also provided sterile and is intended for SINGLE use. DISCARD AFTER USE. DO NOT RESTERILIZE.
8. The SULU's are provided STERILE and are intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT RESTERILIZE.
9. If using a reinforcement product, include the thickness of the respective product into the overall tissue thickness to determine the appropriate staple size that will be applied.
10. Ensure to select a SULU with the appropriate staple size for the tissue thickness. Overly thick or thin tissue may result in unacceptable staple formation.
11. After firing, always inspect the staple line for hemostasis. Minor bleeding can be controlled by electrocautery or manual sutures. At the surgeon's discretion, a laparotomy or thoracotomy may be performed.
12. Failure to advance the handle completely may result in incomplete staple formation, which may compromise the integrity of the staple line.
13. Do not rotate the firing knob during firing. Rotating the knob during firing may cause damage and possible instrument malfunction.

1 SCHEMATIC VIEW

A) CARTRIDGE FORK
B) SHOULDER
C) LOCKING LEVER HANDLE-CARTRIDGE
D) RELEASE BUTTON-CARTRIDGE
E) FIRING KNOB
F) ANVIL FORK
G) SHIPPING WEDGE (TOP VIEW)
H) SINGLE USE LOADING UNIT (SULU)
I) KNIFE BLADE ASSEMBLY
J) SAFETY LOCKOUT (BLACK FOR SGIA™)

INSTRUCTIONS FOR USE

2 FIRING INSTRUCTIONS

CAUTION: Ensure to select a SULU with the appropriate staple size for the tissue thickness. Overly thick or thin tissue may result in unacceptable staple formation.

1. Open the instrument by pushing in on the release button on the cartridge fork lever handle (located at end of instrument).
2. Remove the shipping wedge from SULU channel by lifting and pulling it out at the finger tabs. (Remove shipping wedge after SULU is fully loaded. SULU will "float" up and down in final loaded position.)

G) SHIPPING WEDGE

3. Position the tissue to be stapled between the instrument cartridge and anvil fork; or, if the tissue is to be anastomosed, place the cartridge fork in one lumen and the anvil fork into the other lumen as appropriate. Align tissue edges equally on cartridge and anvil. This may be accomplished with the instrument halves separated or hinged at the rear. Close the instrument by moving the lever handle towards the instrument body until the audible click is heard.
4. With the instrument securely closed, rotate the firing knob to either side of the instrument.

NOTE: In its pre-fire position, the firing knob should rotate to either side of the instrument.

5. Place a thumb behind the firing knob and two fingers on the instrument shoulders. Fire the instrument by sliding the firing knob forward to a complete stop.

CAUTION: Do not rotate the firing knob during firing. Rotating the knob during firing may cause damage and possible instrument malfunction.

CAUTION: Failure to advance the handle completely may result in incomplete staple formation, which may compromise the integrity of the staple line.

6. After firing, return firing knob all the way back to its pre-fire position.
7. Push in the cartridge release button to open the instrument (refer to step 1). Remove the instrument from the surgical site.

CAUTION: After firing, always inspect the staple line for hemostasis. Minor bleeding can be controlled by electrocautery or manual sutures. At the surgeon's discretion, a laparotomy or thoracotomy may be performed.

NOTE: When a fired instrument is opened, the lockout device will deploy. The safety lockout prevents clamping of the instrument with a SULU that has been fired. (The safety lockout for the SGIA™ is black.)

3 RELOADING INSTRUCTIONS

1. To remove the fired SULU, separate the instrument halves. Holding the cartridge-half of the instrument, grasp the proximal end of the SULU tabs and pull up and out to remove SULU from instrument.

H) SULU

2. To place a new SULU into the instrument, hold the SULU by the proximal end tabs and insert into the cartridge fork at a 30 to 45 degree angle from the distal end down until snap into place. Remove shipping wedge after SULU is fully loaded. SULU will "float" up and down in final loaded position.

G) SHIPPING WEDGE

CAUTION: Ensure to select a SULU with the appropriate staple size for the tissue thickness. Overly thick or thin tissue may result in unacceptable staple formation.

CAUTION: The reloadable staplers should only be reloaded seven (7) times per instrument for a total of eight (8) firings. The SGIA™ stapler is not reloadable.

4 SPECIFICATION CHART

K) INSTRUMENT REORDER CODES
L) SULU REORDER CODES
M) STAPLE LINE LENGTH
N) SULU COLOR
O) OPEN STAPLE SIZE
P) CLOSED STAPLE SIZE (TYPICAL)
Q) TISSUE COMPRESSION REQUIREMENT

AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.

FR
Agrafeuses avec technologie DST Series™

DE
Klammerinstrument mit DST Series™-Technologie

IT
Suturatrice a punti metallici con tecnologia DST Series™

ES
Grapadora con tecnología DST Series™

PT
Grampeador com tecnologia DST Series™

NL
Stapler met DST Series™-technologie

SV
Stapler med DST Series™-teknik

DA
Stapler med DST Series™-teknologi

FI
Nitoja, jossa on DST Series™ -tekniikkaa

EL
Συρραπτικό με τεχνολογία DST Series™

PL
Stapler z technologią DST Series™

TR
DST Series™ Teknolojisine sahip Zımba Aleti

RU
Сшивающие аппараты с технологией DST Series™

CS
Stapler s technologií DST Series™

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 используйте изделие, если упаковка вскрыта или повреждена.
Pokud je balení otevřené nebo poškozené, produkt nepoužívejte.

STERILE EO
Rx ONLY

Caution, consult accompanying documents
130°F 54°C Upper temperature limit
86°F 30°C 59°F 15°C Store at room temperature
CE 0123

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