

Product Introduction

QELC



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Description

QELC: Universal Endoscopic Linear Cutting Stapler and Single Use Loading Unit.

QELC can be reloaded 25 times for a total of 25 firings. (Unlike QOLC which is initially packed with a reload and ready to fire cartridge), it is disposable and multi-fire.



Stapler Structure



- 1. Instrument shaft,
- 2. Trigger,
- 3. Rotating lever,
- 4. Safety
- 5. Handle
- 6. Release knob
- 7. Speedometer

QELC Models



QELC L
(Length:260mm)

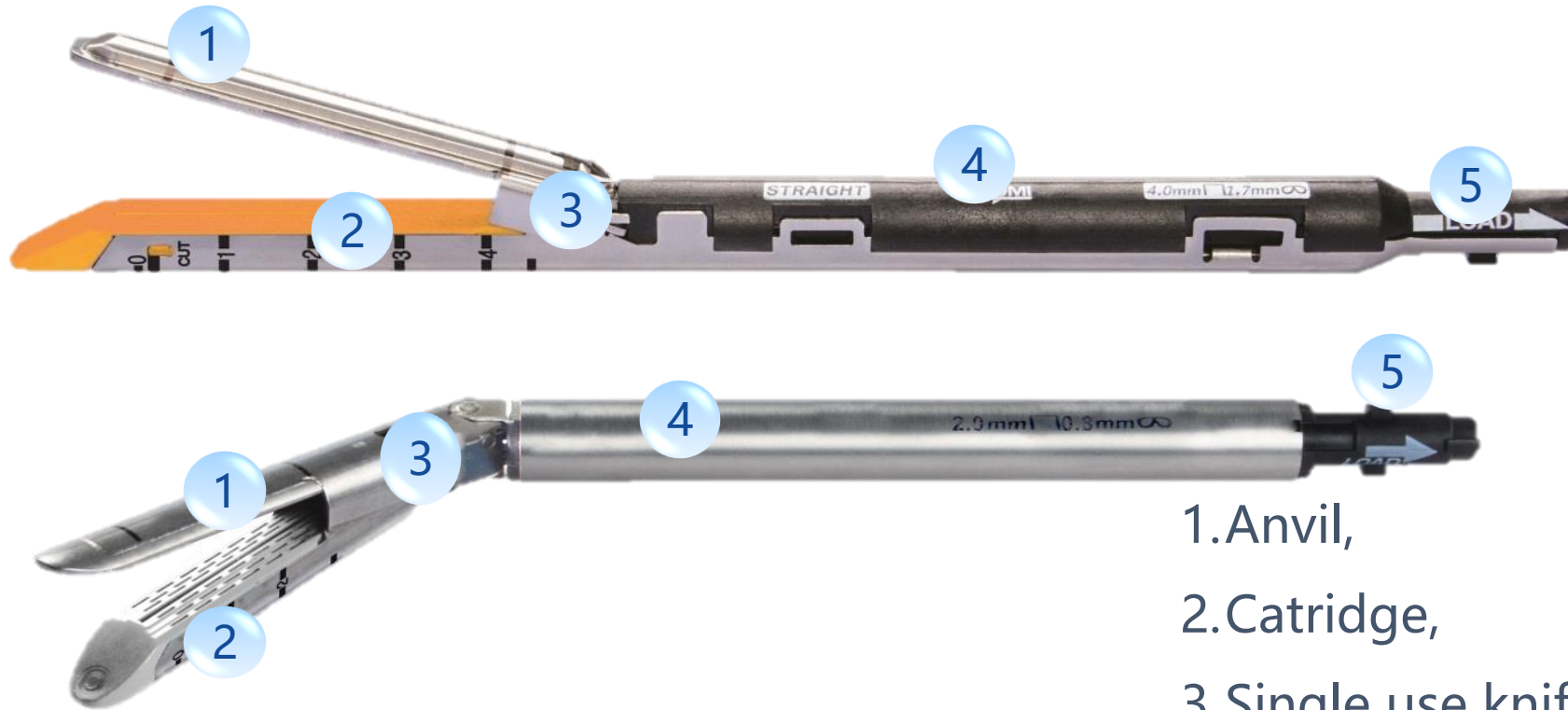


QELC
(Length:160mm)



QELC S
(Length:60mm)

Cartridge Structure



- 1. Anvil,
- 2. Cartridge,
- 3. Single use knife blade,
- 4. Cartridge shaft,
- 5. Loading device

Cartridge Models-L (1st generation)

Model	Total length	Suture Length	Staple Width	Staple Height	Color
QELC4525L	183±3	45±2	3.0±0.5	2.5±0.5	White
QELC4535L	183±3	45±2	3.0±0.5	3.5±0.5	Blue
QELC4540L	183±3	45±2	3.0±0.5	4.0±0.5	Gold
QELC4548L	193±3	45±2	3.0±0.5	4.8±0.5	Green
QELC6025L	199±3	60±2	3.0±0.5	2.5±0.5	White
QELC6035L	199±3	60±2	3.0±0.5	3.5±0.5	Blue
QELC6040L	199±3	60±2	3.0±0.5	4.0±0.5	Gold
QELC6048L	209±3	60±2	3.0±0.5	4.8±0.5	Green



L-Cartridge

Cartridge Models- R (2nd generation)

Model	Total length	Circumscribed circle diameter	Suture length	Staple width	Staple height	Color
QELC 4525R	217	12.5	45	3.0	2.5	White
QELC 4535R	217	12.5	45	3.0	3.5	Blue
QELC4548R	225	15.5	45	3.0	4.8	Green
QELC 6025R	233	12.5	60	3.0	2.5	White
QELC 6035R	233	12.5	60	3.0	3.5	Blue
QELC 6040R	233	12.5	60	3.0	4.0	Gold
QELC 6048R	241	15.5	60	3.0	4.8	Green



R- Cartridge

Cartridge Models- R (3rd generation)



Cartridge Models-A (4th generation)

Model	Suture Length	Staple Height	Forming Height	Color
QELC3025A	30±2	2.5±0.5	1.0	White
QELC4525A	45±2	2.5±0.5	1.0	White



A- Cartridge

Cartridge Models-B (4th generation)

Model	Suture Length	Staple Height			Forming Height			Color
		1 row	2 row	3 row	1 row	2 row	3 row	
QELC 4535B	45	3.0	3.5	4.0	1.4	1.6	1.8	Purple
QELC 4545B	45	4.0	4.5	5.0	1.8	2.0	2.2	Black
QELC 6035B	60	3.0	3.5	4.0	1.4	1.6	1.8	Purple
QELC 6045B	60	4.0	4.5	5.0	1.8	2.0	2.2	Black



B- Cartridge

Cartridge Models-C (4th generation)

Model	Suture length	Staple Height			Forming Height			Color
		1 row	2 row	3 row	1 row	2 row	3 row	
QELC 4535C	45	3.0	3.5	4.0	1.4	1.6	1.8	Purple
QELC 4545C	45	4.0	4.5	5.0	1.8	2.0	2.2	Black
QELC 6035C	60	3.0	3.5	4.0	1.4	1.6	1.8	Purple
QELC 6045C	60	4.0	4.5	5.0	1.8	2.0	2.2	Black



C- Cartridge

QELC- Cartridge Selection

30

Artery, Vein, Venous plexus, Bronchus etc.

45

Artery, Vein, Ligament, Omentum, Mesentery, Small intestine, Rectum, Bronchus, Lung parenchyma etc.

60

Stomach, Colon, Small intestine, Pulmonary fissure, Lung parenchyma etc.

QELC- Cartridge Selection

2.0	Artery, Vein, Venous plexus, Ligament, Omentum, Mesentery etc.
2.5	Artery, Vein, Venous plexus, Ligament, Omentum, Mesentery etc.
3.5	Stomach, Small intestine, Colon, Anastomosis, Bronchus, Lung parenchyma etc.
4.0	Stomach, Small intestine, Colon, Bronchus, Lung parenchyma etc.
4.8	Distal rectum, Pylorus, Trachea, Lung parenchyma etc.

Resumen

Rotate in 45° satisfice in variable clinical situation



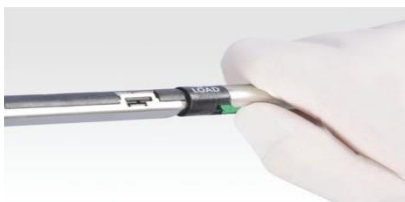
Release knob with new design

5

6

7

Stable safety for cartridge



4

Safety for avoiding mis-operation

3

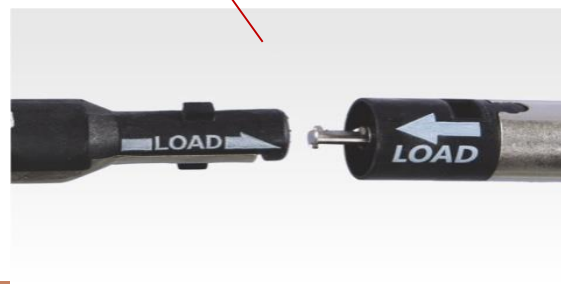
High strength metal shell
Ensure the strength of the instrument

2

1

Rotate system improved

Indicator for reloading of the cartridge



8

Handle with rubber coating



Contents

1. Description

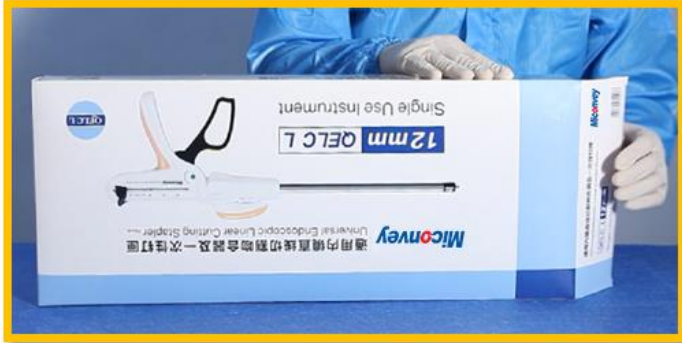
2. Operation

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Step 1: Instrument Preparing



1

- All instruments are sterilized by Co-60 gamma radiation before leaving the factory. The period of validity is 4 years, and the valid date is marked on each package. Do not use the expired instruments.



2

- Open the graphic carton, you will find instructions for use together with instrument in plastic packaging.

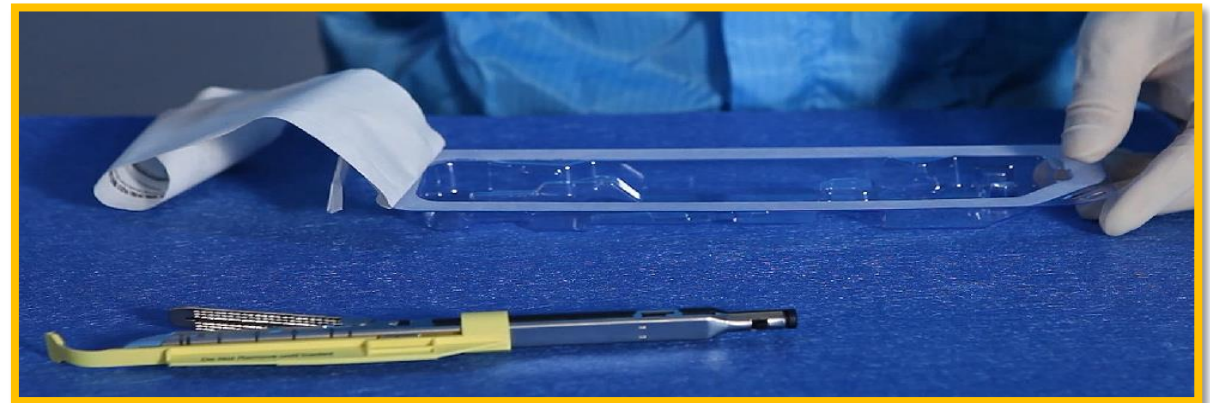


3

- Tear off dialysis paper along the arrow, and then take out the stapler.

Step 1: Instrument Preparing

- Take out the single use loading unit in the same way;
- And there is a protective cap on it.

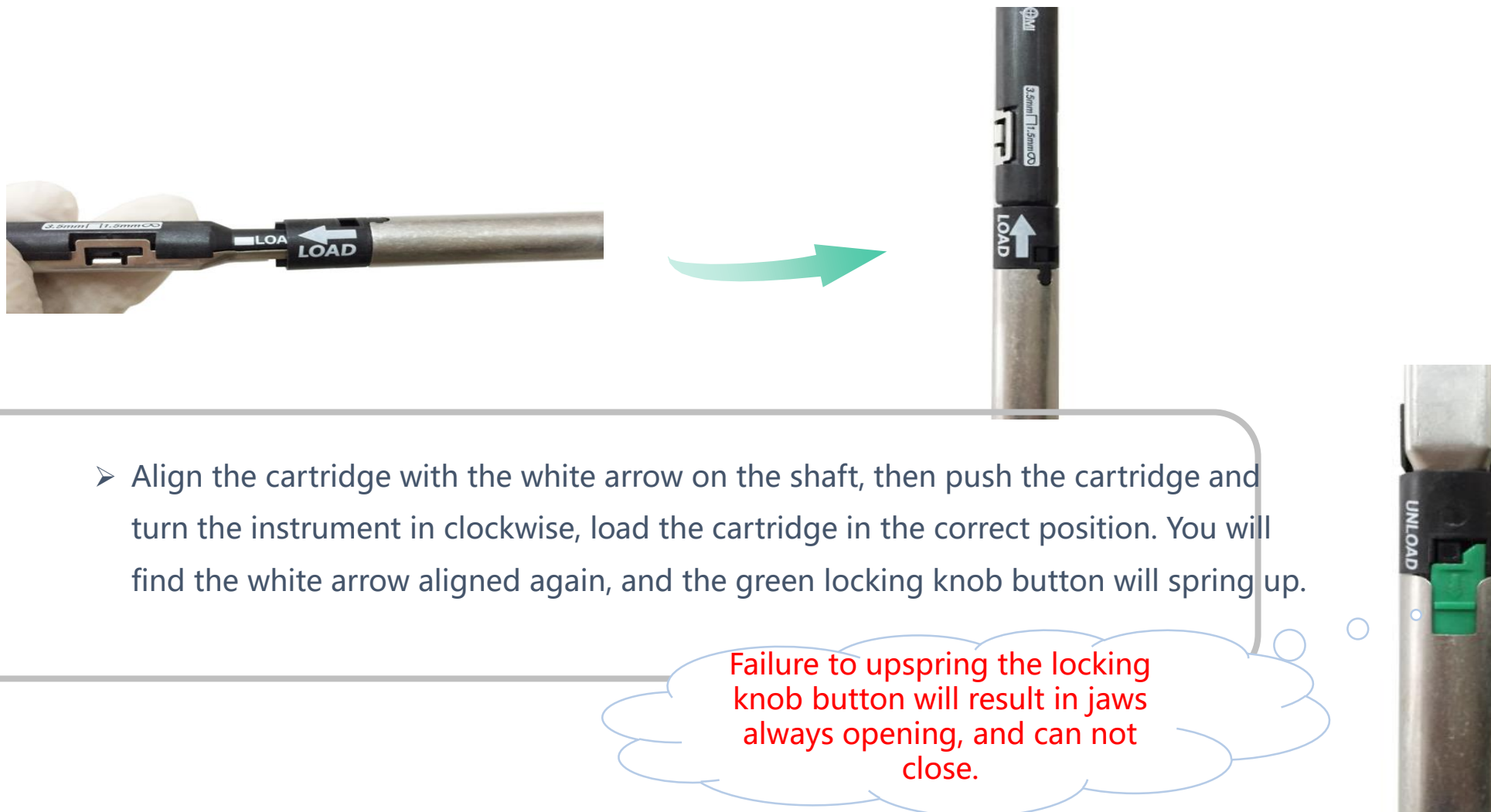


Step 2: Loading Cartridge



➤ Before each of cartridge loading, please clear the “gun” first.

Step 2: Loading Cartridge



Step 2: Loading Cartridge



➤ Take off the cartridge protective cap

Do Not Remove The Cap Until Loaded



Warnings and Precautions



The yellow protective cap is to avoid knife blade shifting during transportation or loading.

The shift of knife blade will cause the jaw being closed or opened incompletely.



Would rotate abnormality when press SULU into the designated place.

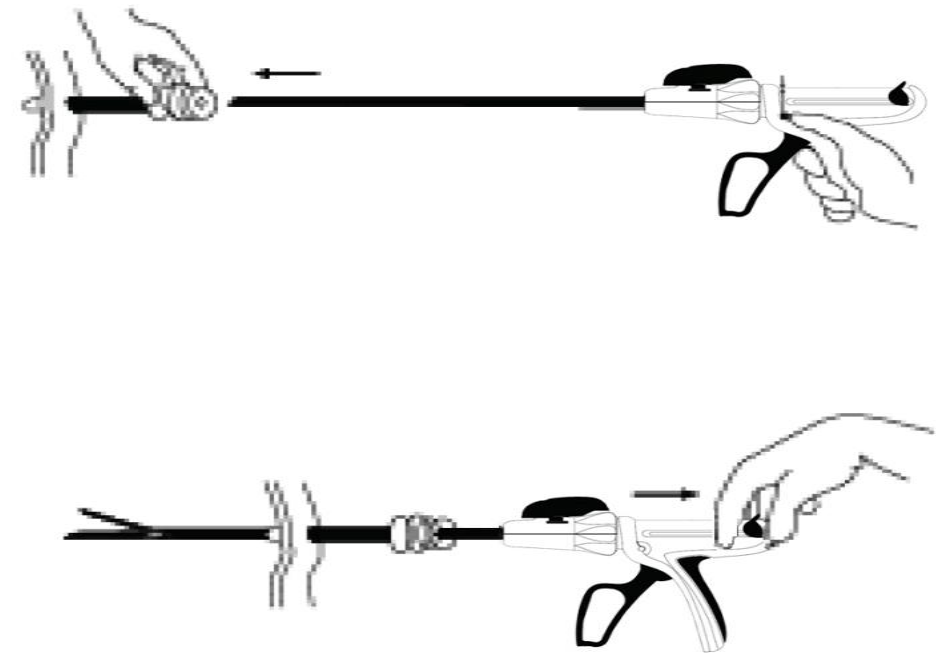
After loading, the jaw is closed or opened smaller obviously

Loading successfully, but failure to open the jaw after closing

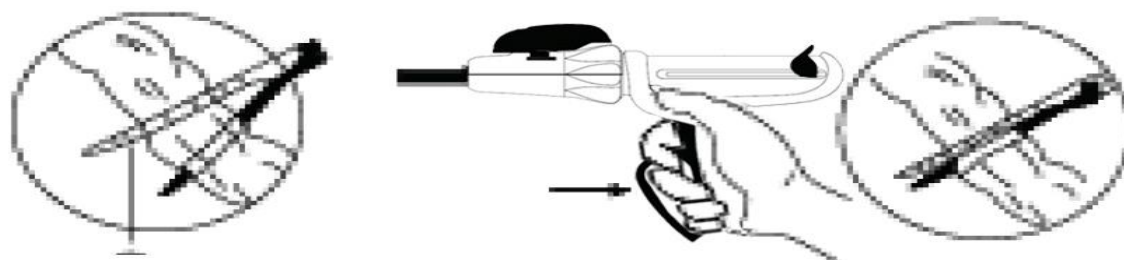
Management: Remove the SULU, reset the knife blade, **clear the stapler and reload the SULU.**

Step 3: Insert Into Body

- Pull the trigger to close the jaw of the cartridge.
- Insert stapler into a suitable trocar, or into a larger sized trocar through the converter.
- Inserting the cartridge into the body cavity completely, then pull the release button to open the jaw.



Step 4: Firing



- Make the instrument to clamp the target tissue, pull the trigger **once** to close the jaw and clamp the target tissue.
- If you want to readjust the position of the instrument to clamp the target tissue better, please pull the release button to open the jaw, or if use the 2nd generation stapler, the jaw also can be opened by pushing the firing trigger.

Caution: The target tissue could not be placed beyond the cutting mark.

Precautions

In case of the jaw cannot be closed: unload the cartridge, release the green button with finger, reload the cartridge after making sure the green button is released.

(Such situation can be caused by reusing of the instrument, so please use the instrument in single patient)



Step 4: Firing

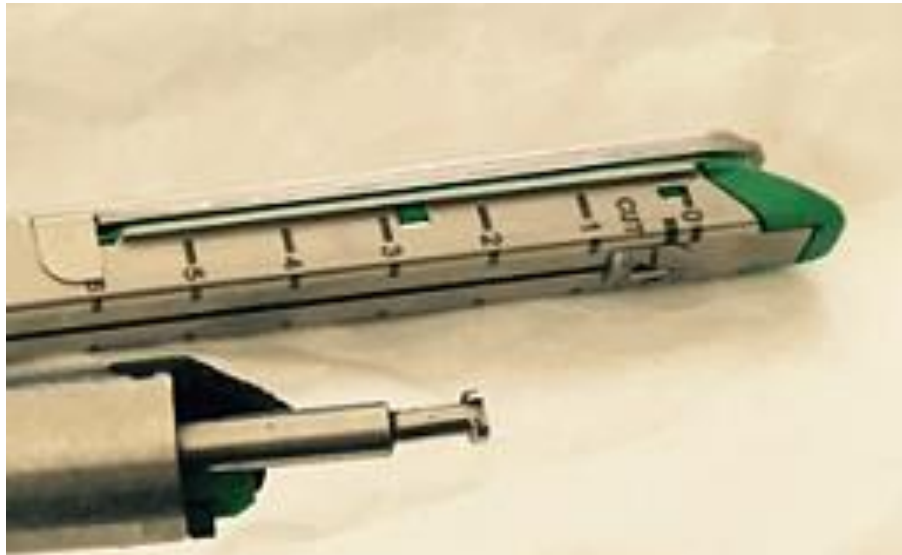


Before firing, press the green safety button from either side to make it released.



Precaution

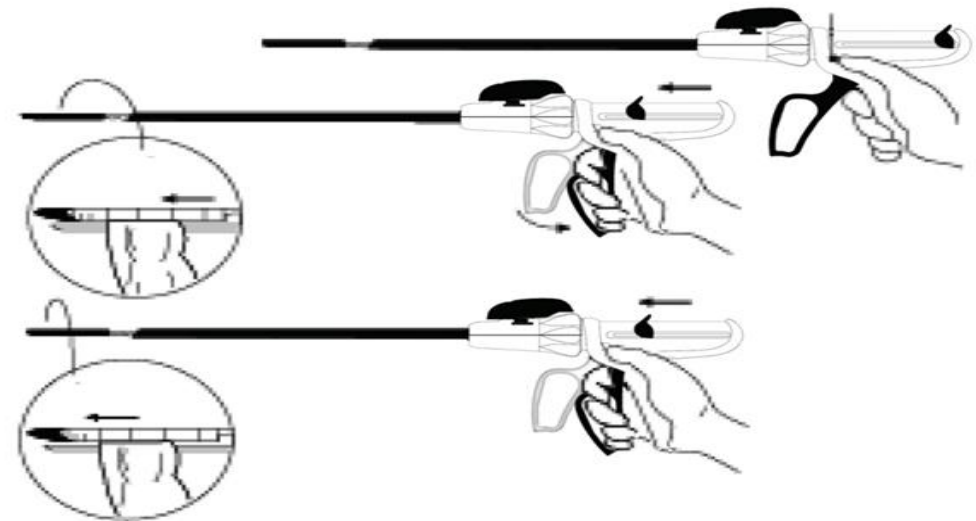
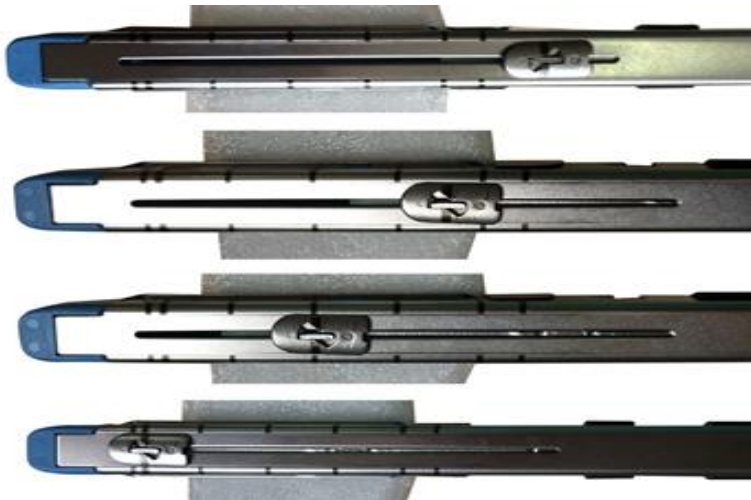
- Firing the instrument without releasing the safety would break the gun and lead the cartridge stuck on the tissue. You need to cut more tissues to take out the cartridge.



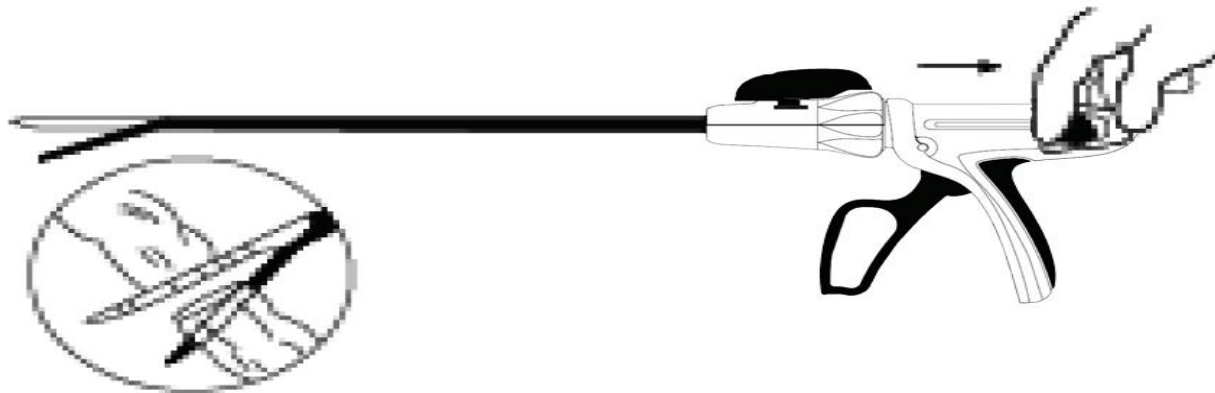
Step 4: Firing



Pull the trigger, and the firing times are based on the SULU length. QELC has to be fired till 'locked', which means the cutter should reach the terminal of the cartridge and the firing knob is locked to ensure the cartridge fired completely.



Step 5: Release the instrument



- After the instrument being fired completely, pull back the release button to the end to open the jaw, **In particular, when loading R-shape cartridge, you have to turn the articulating lever to ensure R-Cartridge in the original position firstly, then pull back the release button**
- Check whether there is any bleeding on the sutured tissue. **If so, using electrocautery instruments or manual suture to staunch the bleeding.**
- Close the jaw, and remove the stapler through the trocar, then remove the stapler from the body cavity and unload the cartridge.

Step 6: Remove and Unloading



- 'Clear the gun' , and make sure the jaw is in a fully opened position



- Push the locking knob and turn the cartridge in counterclockwise.

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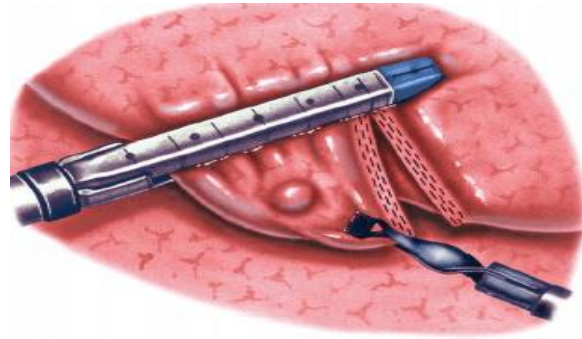


Indications

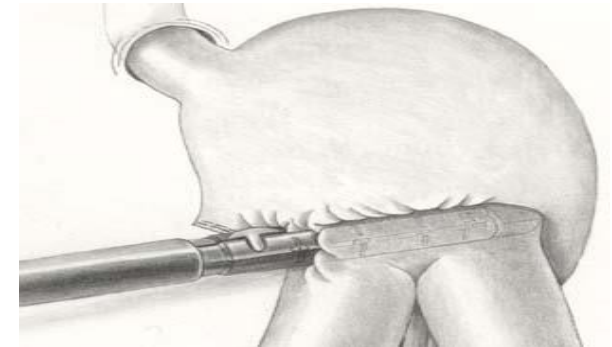
The MICONVEY® Universal Endoscopic Linear Cutting Stapler with Single Use Loading are widely applied in lung, bronchial tissue ,stomach and intestines both in **open and endoscopic surgery** such as **transection**, **resection** and **anastomosis**.



Transection



Resection



Anastomosis

Contraindications

- **The instrument should not be used on patient with:**
 - Gastrointestinal mucosa edema,
 - Thicker muscle layers or poor healing ability,
 - Suspected with cancer tissue remains.



Main Applications

➤ Thoracic Surgery

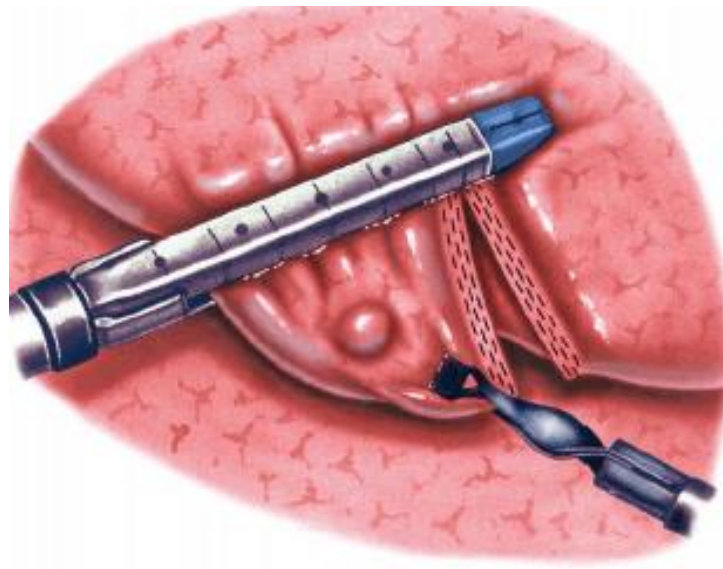
- Thoracoscopic pulmonary bulla resection
- Thoracoscopic lobotomy

➤ Gastrointestinal Surgery

➤ Laparoscopic Gastrectomy

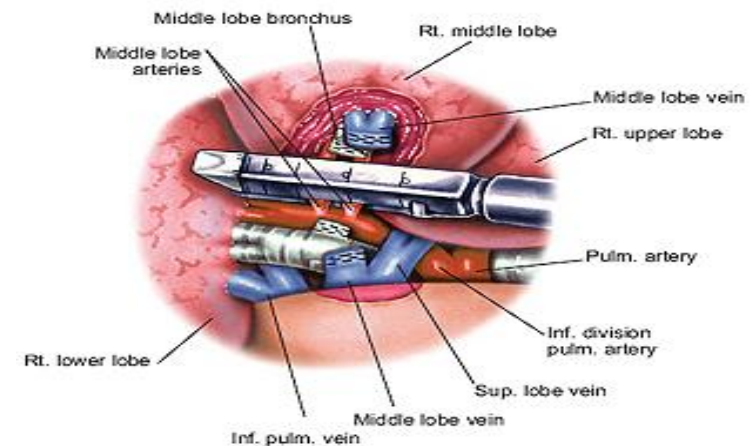
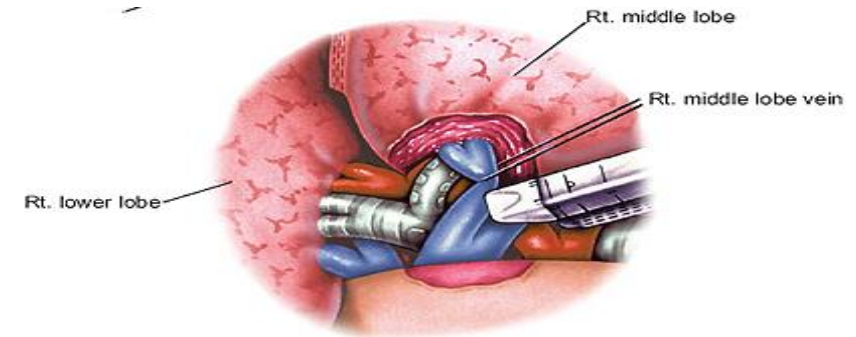
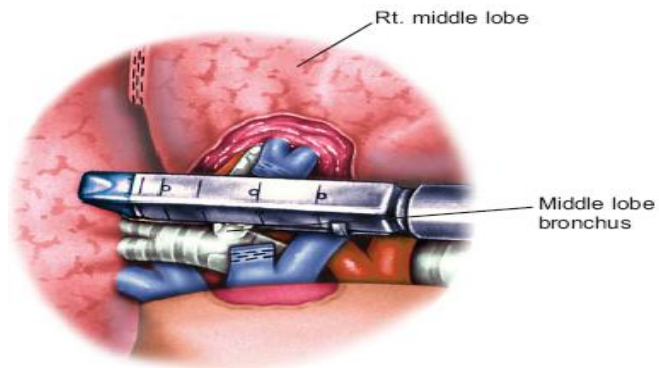
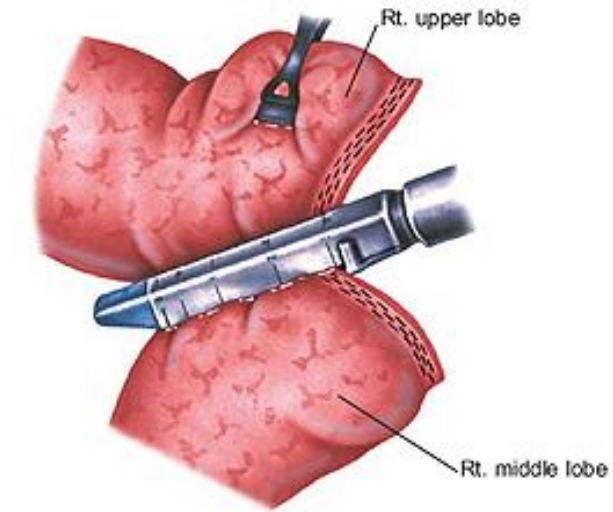
- Laparoscopic resection of the colon
- Laparoscopic lower anterior resection
- LGBP

Thoracoscopic Pulmonary Bulla Resection



STEPS	STAPLER	SULU	APPLICATION
1	QELC	4535/6035	Resect diseased lung tissues

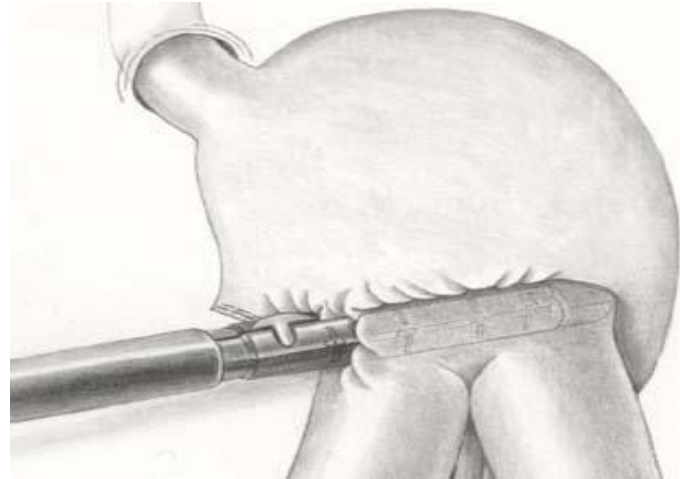
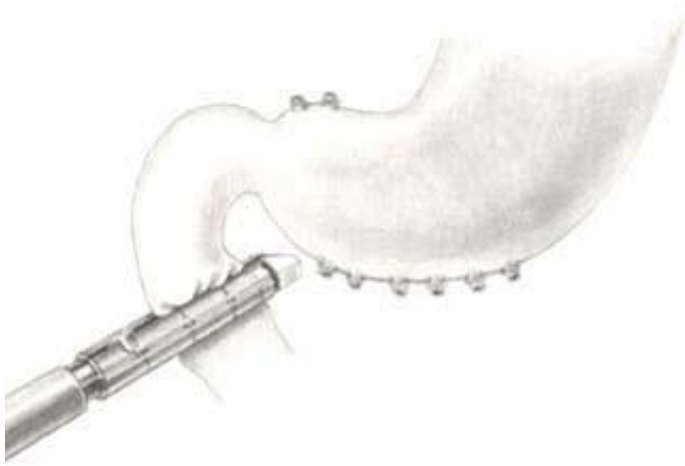
Thoracoscopic Lung Resection



Thoracoscopic Lung Resection

STEPS	STAPLER	SULU	APPLICATION
1	QELC	4535×2	Pulmonary fissure separation
2		3025×1	Resection of pulmonary vein
3		4535×1	Resection of bronchus
4		3025×1-2	Cut off the pulmonary artery

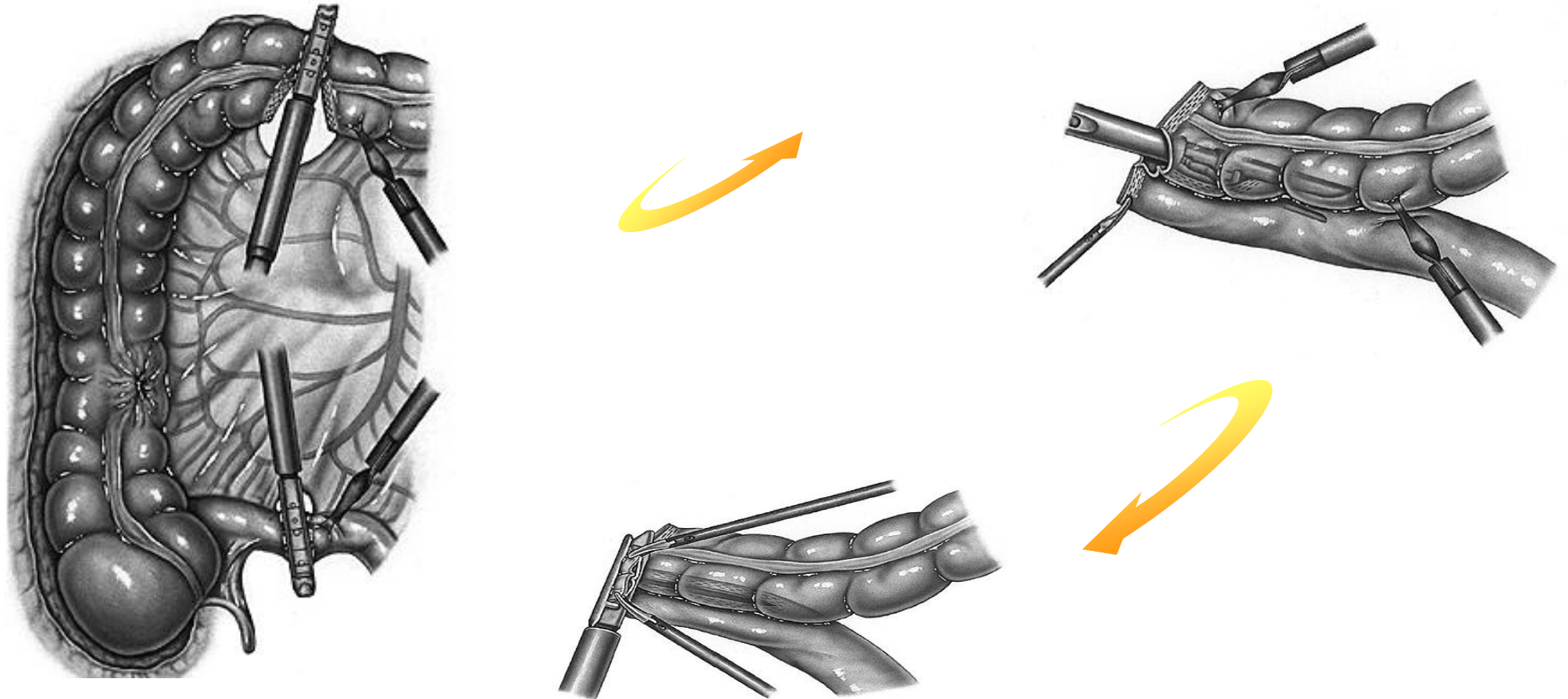
Endoscopic Billroth II



Endoscopic Billroth II

STEPS	STAPLER	SULU	APPLICATION
1	QELC	4535/6035×1	Resection of duodenum
2		6035×2	Resection of stomach
3		6035×1	Stomach-jejunum side to side anastomosis
4		4535×1	Close the incision

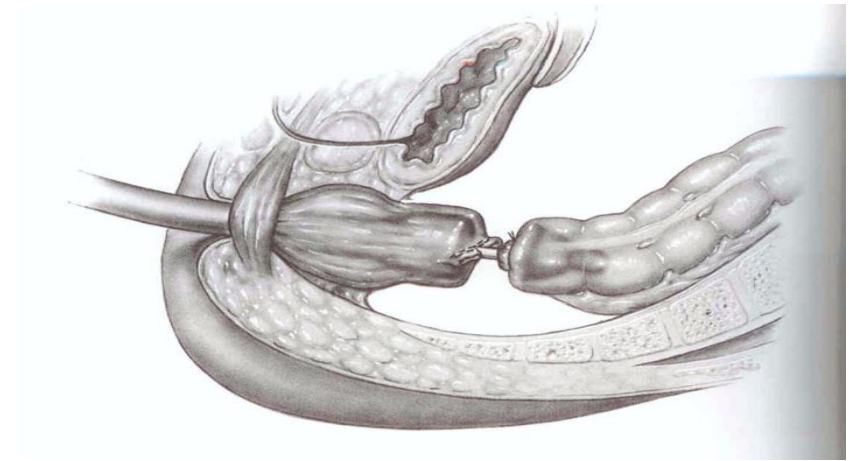
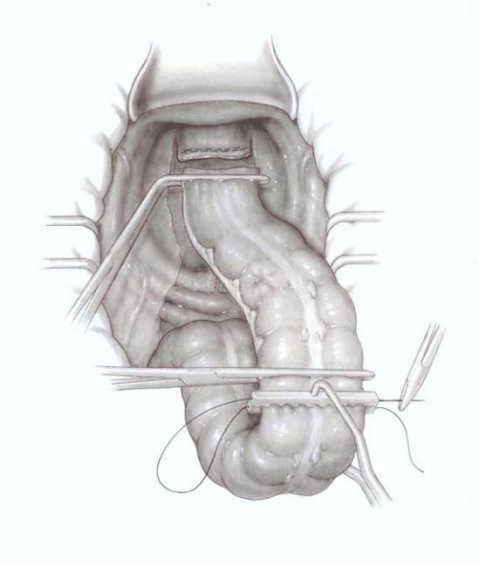
Laparoscopic Right Half Colon Resection



Laparoscopic Right Half Colon Resection

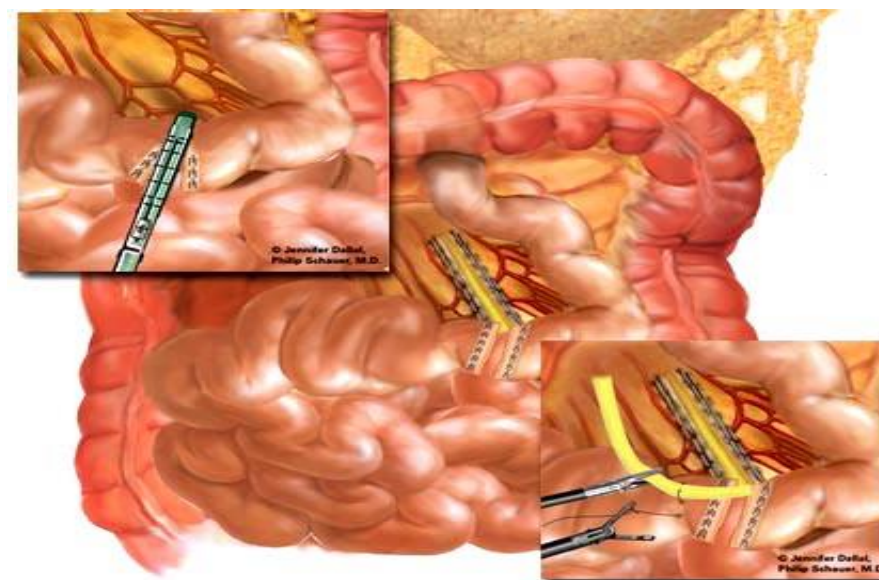
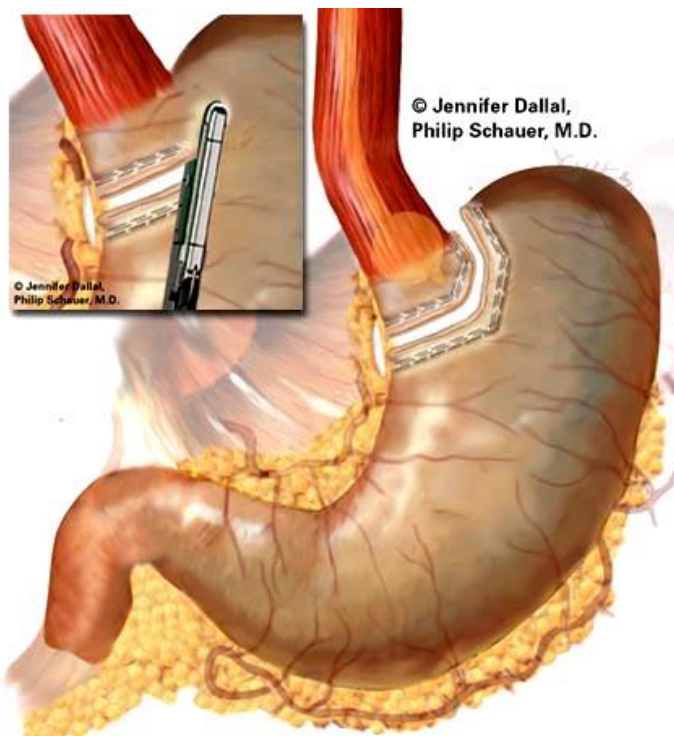
STEPS	STAPLER	SULU	APPLICATION
1	QELC	4535×1	Resection of terminal ileum
2		4535×1	Resection of transverse colon
3		6035×1	Ileum-colon side to side anastomosis
4		4535×1	Close the incision

Laparoscopic Colorectal Cancer Resection

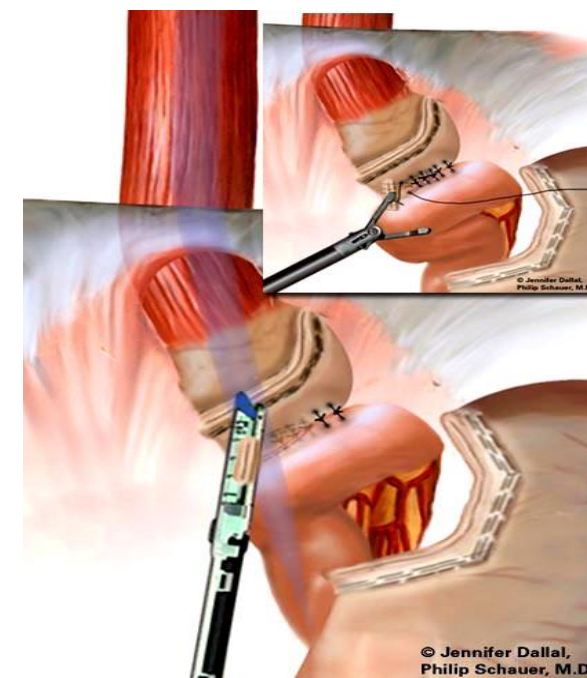
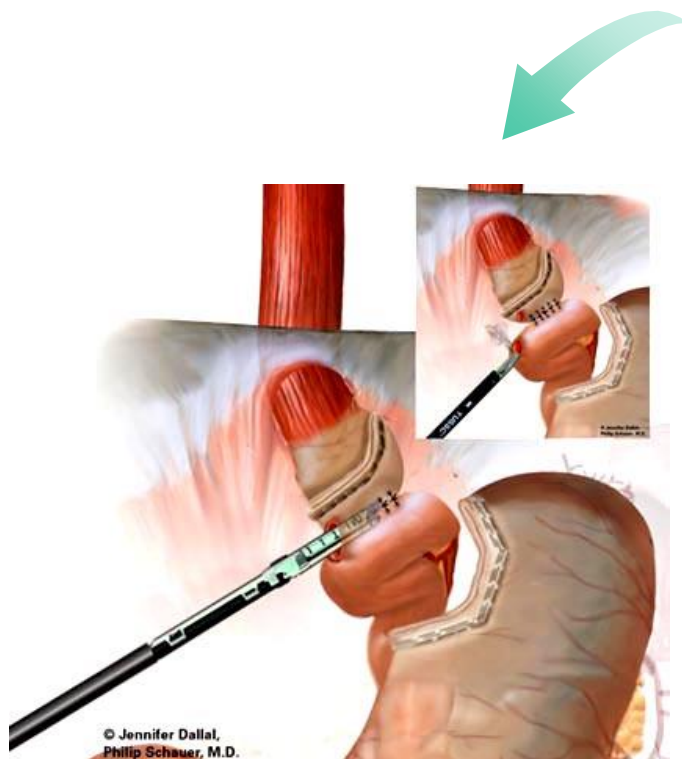
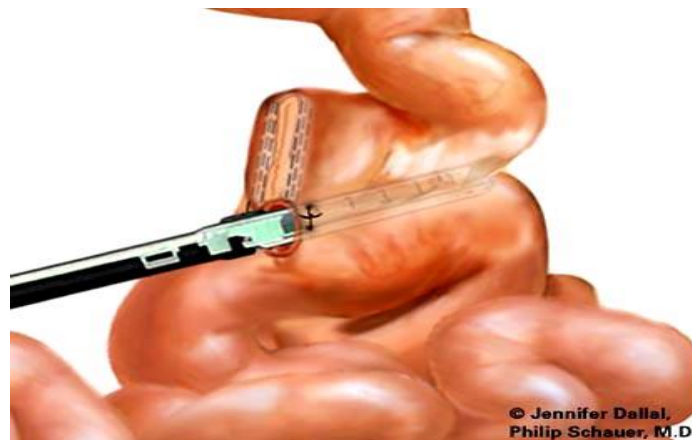


STEPS	STAPLER	SULU	APPLICATION
1	QELC	4535 × 1	Cut off the edge of tumor bowel loops

Endoscopic Roux-En-Y Surgery



Endoscopic Roux-En-Y Surgery



Endoscopic Roux-En-Y Surgery

STEPS	STAPLER	SULU	APPLICATION
1	QELC	6035 × 3	Make a small stomach pouch
2		4535 × 1	Resect jejunum
3		6035 × 1	Jejunum-jejunum end to side anastomosis
4		4535 × 1	Close the incision (jejunum)
5		6035 × 1	Stomach-jejunum side to side anastomosis
6		4535 × 1	Close the incision (stomach, jejunum)

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Difficult to reload the cartridge ?

- Clear the gun
- Align the white arrow

Abnormality after reloading the cartridge ?

- Clear the gun
- Unload the cartridge
- Clear the gun
- Reload the cartridge which following the instruction of reloading

FAQ

The jaw cannot be closed normally ?

- Check if the cartridge have been reloaded correctly
- Check if select the correct cartridge for the tissue

What is QELC technology ?

- GST™: Guiding Stapling Technology
- Disposable knife blade
- Smart anvil design
- Reinforced clamping force
- Intelligent staple

What is GST™ technology?

GST™: Guiding Stapling Technology. The spindle socket provides enough receiving area when staple leg is impacted, and guides the staple leg to the correct position. This ensures staple “B- shape” formation and avoids distortion caused by deviation.

FAQ

Does the knife blade get reused with each firing?

Absolutely not!

Every cartridge comes with a new sterile knife blade. Using a new knife for each firing ensures maximum sharpness , reduce risk of cross infection and cancer metastasis.

Does the knife cut beyond the last row of staples?

Absolutely not!

The staple line continues well beyond the cut line. Hemostasis first, then cutting is much safer. If cutting without stapling, it would cause bleeding.

FAQ

What is the shaft diameter of the QELC?

The shaft diameter of the QELC is 12mm. All cartridges, with the exception of the 4.8 reloads, are 12mm. The 4.8 cartridges (green) are 15mm.

FAQ

How many times can the QELC instrument be reloaded?

All three model: QELC, QELCS and QELC L, can be loaded and fired 25 times.

FAQ

Why do I have to squeeze the handle multiple times?

The QELC compresses tissue as it is fired. The tissue gap control mechanism predictably compresses tissue, while it simultaneously lays down a staple line and transects the tissue. To accomplish it, the instrument moves the tissue gap control mechanism 15mm with each squeeze, to physically pull the anvil and staple cartridge together to sequentially compress the tissue as it fires. This provides consistent staple formation even at the distal end of the cartridge.

FAQ

How do I know which staple size to use?

The 2.0mm cartridge (gray) should be used on tissue that can comfortably compress to 0.8 ± 0.1 . The 2.5mm cartridge (white) should be used on tissue that can comfortably compress to 1.0 ± 0.1 . The 3.5mm cartridge (blue) should be used on tissue that can comfortably compress to 1.5 ± 0.2 . The 4.0mm cartridge (gold) should be used on tissue that can comfortably compress to 1.7 ± 0.2 . The 4.8 cartridge (green) should be used on tissue that can comfortably compress to 2.0 ± 0.2 .

Thank you!

Miconvey Technologies Co., LTD

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✉ info@miconvey.com



EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60124974 0001

Report No.: 17062476 003

Manufacturer: Miconvey Technologies Co., Ltd.
No. 16, Fangzheng Avenue, Beibei District
400714 Chongqing
China

Products: Medical Devices

(see attachment for products included)

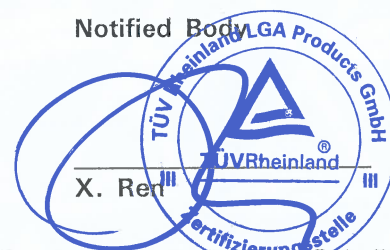
Replace Approval, Registration No.: HD 60116798 0001

Expiry Date: 2022-01-24

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-02-07

Date: 2018-02-07



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

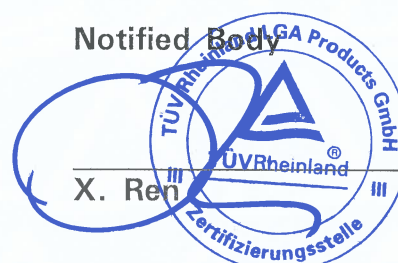
Registration No.: HD 60124974 0001
Report No.: 17062476 003

Manufacturer: Miconvey Technologies Co., Ltd.
No. 16, Fangzheng Avenue, Beibei District
400714 Chongqing
China

Products:

- Ultrasonic Surgical System (Generator, Handpiece Sterile Disposable Scalpel)
- Universal Endoscopic Linear Cutting Stapler and Single Use Loading Unit (Sterile)
- Disposable End-to-End Anastomosis Circular Stapler (Sterile)
- Linear Cutting Stapler and Single Use Loading Unit (Sterile)
- Disposable Hemorrhoidal Circular Stapler (Sterile)

Date: 2018-02-07



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Miconvey Technologies Co., Ltd.
No. 16, Fangzheng Avenue, Beibei District
400714 Chongqing
P.R. China

has established and applies a quality management system for medical devices
for the following scope:

Design and Development, Manufacture and Distribution of
Medical Devices
(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-02-21
Certificate Registration No.: SX 60145983 0001
An audit was performed. Report No.: 17062476 007
This Certificate is valid until: 2023-01-24

Certification Body



Date 2020-02-21



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60145983 0001
Report No.: 17062476 007

Organization: Miconvey Technologies Co., Ltd.
No. 16, Fangzheng Avenue, Beibei District
400714 Chongqing
P.R. China

Scope:

Products:

- Ultrasonic Surgical System (Generator, Handpiece, Sterile Disposable Scalpel)
- Universal Endoscopic Linear Cutting Stapler and Single Use Loading Unit (Sterile)
- Disposable End-to-End Anastomosis Circular Stapler (Sterile)
- Linear Cutting Stapler and Single Use Loading Unit (Sterile)
- Disposable Hemorrhoidal Circular Stapler (Sterile)

Certification Body



Date: 2020-02-21

