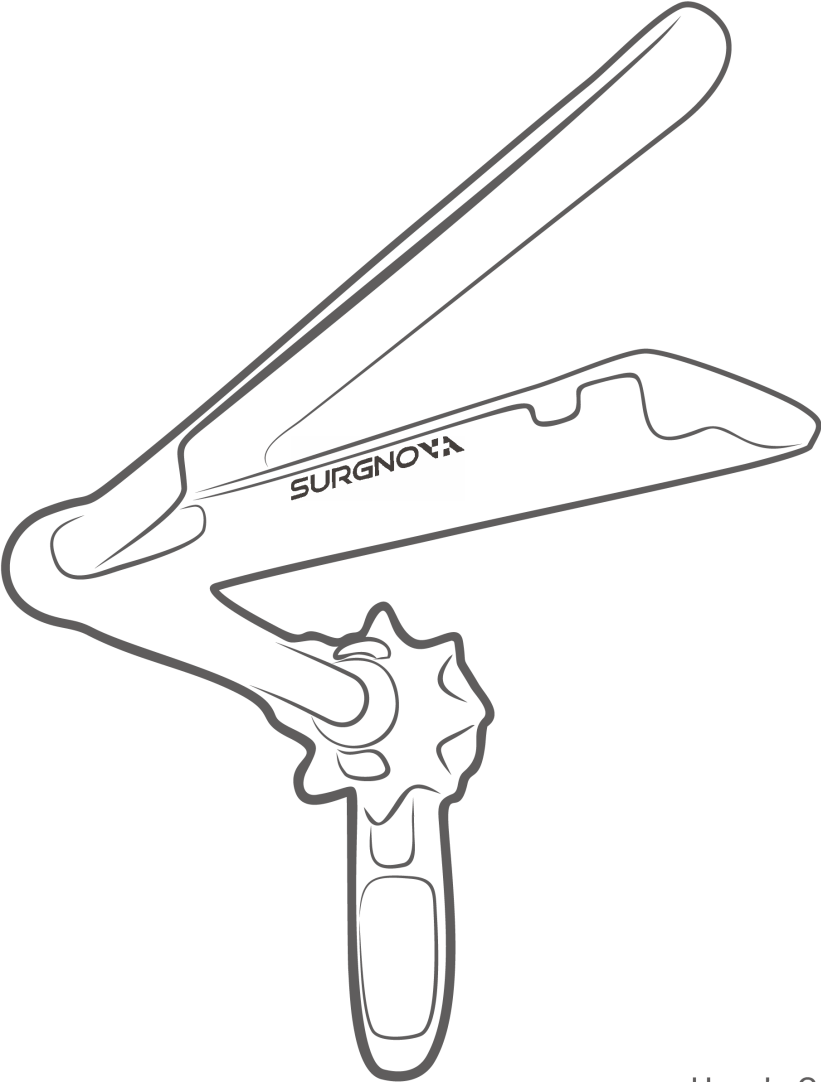


Alligator™

SURGNOVA
HEALTHCARE TECHNOLOGIES

Powered Endoscopic Staplers



Contents

1	Introduction	1
1.1	Important Tip	1
1.2	Warning, Caution and Tip	1
1.3	Symbols	2
2	Product Overview	4
2.1	System Components	4
2.2	Intended Use	4
2.3	Intended User	4
2.4	Intended Patient Population	4
2.5	Applicable Disease or Condition	4
2.6	Contraindications	5
2.7	Clinical Benefits	5
2.8	Working Principle	5
2.9	Specifications	5
2.10	Package Contents	8
3	Powered Endoscopic Staplers	9
3.1	Powered Endoscopic Stapler	9
3.2	Linear Cutter Reloads	11
3.3	Battery Pack	12
4	Instructions for Use	12
4.1	System Installation	13
4.1.1	Installing the Battery Pack	13
4.1.2	Loading of the Linear Cutter Reloads	14
4.2	Operation	15
4.3	Reloading of the Linear Cutter Reloads	18
4.4	Manual Mechanism Operation	19
4.4.1	Manual Override Mechanism	19
4.4.2	Manual Straight Mechanism	20
4.5	Descriptions of the Indicator	21
5	Maintenance	22
6	Transport and Storage	22
6.1	Transport	22
6.2	Storage	22
7	Disposal	23
8	Trouble Shooting	24
9	Electromagnetic Compatibility	26

1 Introduction

1.1 Important Tip

This user manual describes the proper operation and maintenance of the Powered Endoscopic Staplers manufactured by Surgnova Healthcare Technologies (Zhejiang) Co., Ltd. Any incorrect operation during use may cause instrument damage or personal injury. Surgnova will not be responsible for any personal injury or instrument damage caused by improper use of the instrument. Please read all the instructions, warnings, cautions and tips provided in this manual, and do not attempt to operate the instrument before fully reading and understanding the instructions.

1.2 Warning, Caution and Tip

The safety instructions included in this user manual help users identify potential risks and avoid them. Please read through and understand all instructions before use. The Safety Instructions included in this manual are divided into "WARNING", "CAUTION" and "TIP":



WARNING

Indicates a potentially hazardous situation that may cause serious instrument damage or personal casualty if not avoided.



CAUTION

Indicates a potential safety hazard that may cause instrument damage or personnel injury if not avoided.

TIP

Indicates annotation to operation or recommendation on maintenance; mistakes may be caused if they are not followed.

1.3 Symbols

The following is a list of the symbols used on the instrument and labels:

	Type CF applied part
	Do not reuse
	Serial number
	Batch code
	Catalogue number
	Manufacturer
	Country of manufacture
	Use-by date
	Fragile, handle with care
	This way up
	Keep dry
	Do not use if the package is damaged and consult instructions for use.
	The battery pack should be disposed of according to local regulation for disposal of electronic equipments.
	Temperature Limitation

	Humidity Limitation
	Atmospheric Pressure Limitation
	Refer to instruction manual
	MR Conditional
	General Warning Sign
	Caution
	Sterilized using ethylene oxide, single sterile barrier system with protective packaging inside.
	Sterilized using ethylene oxide, single sterile barrier system.
	Sterilized using irradiation, single sterile barrier system.
	Authorized representative in the European Community
	European union approval
	Medical device
	UK Conformity Assessed

 CAUTION

- Be familiar with the symbols above, and understand them before using the instrument.

2 Product Overview

2.1 System Components

The Powered Endoscopic Staplers are composed of the Powered Endoscopic Stapler, Linear Cutter Reloads and Non-rechargeable Battery Pack. The Non-rechargeable Battery Pack must be installed in the Powered Endoscopic Stapler before use.

Table 2-1: Composition of Powered Endoscopic Staplers

Composition	Model
Powered Endoscopic Stapler	OES45-260, OEC45-360, OEL45-460, OES60-260, OEC60-360, OEL60-460
Linear Cutter Reloads	OCR4520, OCR4525, OCR4530, OCR4535, OCR4538, OCR4540, OCR6025, OCR6030, OCR6035, OCR6038, OCR6040
Non-rechargeable Battery Pack	NBP12R

2.2 Intended Use

The Powered Endoscopic Staplers are intended for transection, resection and/or creation of anastomoses. It is mainly suitable for open or minimally invasive general surgery, obstetrics and gynecology, urology, thoracic surgery and pediatric surgery. It can also be used for transection and resection liver parenchyma (hepatic vascular system and biliary structure), pancreas, kidney and spleen.

2.3 Intended User

The Powered Endoscopic Staplers are intended for use only by qualified medical professionals trained in particular technique and surgical procedure to be performed.

2.4 Intended Patient Population

The Powered Endoscopic Staplers is applicable for pediatric and adult patient population.

2.5 Applicable Disease or Condition

The Powered Endoscopic Staplers are suitable for liver, lung, kidney, spleen, and digestive tract tissues such as stomach and intestine.

2.6 Contraindications

The Powered Endoscopic Staplers are not recommended for the following conditions:

- Do not use the stapler on the aorta.
- Do not use the stapler on ischemic or necrotic tissue.
- Do not use the stapler and the linear cutter reloads on major vessels without making provision for proximal and distal control.
- Tissue thickness should be carefully evaluated before the stapler is fired. Please refer to the table **Linear Cutter Reloads Model** for the tissue compression requirements (the closed staple height) of each specification. Tissue may be too thick or too thin for the selected staple size if it cannot be compressed to the closed staple height or is easily compressed to less than the closed staple height.
- Do not use the stapler when there is a contraindication for surgical anastomosis.

2.7 Clinical Benefits

The Powered Endoscopic Staplers could be used with following clinical benefits:

- Less operative time
- Decreased intraoperative blood loss
- Reduced length of hospital stay
- Reduced postoperative drainage
- Improved anastomosis success rate.

CAUTION

- Use of this product may cause the following side effects: post-operative bleeding, leakage complication, intra-abdominal abscess, pulmonary complication, wound infection and anastomotic leakage.

2.8 Working Principle

The Powered Endoscopic Stapler fires the six rows of parallel staggered staples that are preset in the Linear Cutter Reloads through the mechanical transmission into the aligned tissue to be anastomosed. The staples are blocked by the anvil ahead after passing through the tissue and bend inward forming "B" shape staggered arrangement, and then the tissue is anastomosed together. Since the small blood vessels can pass through the "B" shaped anastomotic gap, the blood supply to the anastomotic site and its distal end is not affected.

2.9 Specifications

Power Supply

Voltage input: 12+2 0V DC

Margin of Error: $\pm 10\%$

Operation, Transport and Storage

	Operation	Transport and Storage
Temperature	10°C ~ 40°C (50°F ~ 105°F)	-20°C ~ 55°C (-4°F ~ 131°F)
Humidity	30% RH ~ 75% RH(Non-condensing)	10% RH ~ 80% RH(Non-condensing)
Atmospheric Pressure	700hPa ~ 1060hPa	700hPa ~ 1060hPa

Type of Protection against Electric Shock

Internal power supply instrument

Degree of Protection against Electric Shock

Type CF Applied Part

Degree of Protection against Ingress of Water

IPX0

Method of Disinfection and Sterilization

Powered Endoscopic Stapler: Sterilized using ethylene oxide

Linear Cutter Reloads: Sterilized using ethylene oxide

Non-rechargeable Battery Pack: Sterilized using irradiation

Mode of Operation

Continuous

Date of Manufacture

Is shown in the label

MRI Safety Information

 MR Conditional	
A patient with the "Powered Endoscopic Staplers" may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient. Additional MRI Safety information may be found at https://www.surgnova.com/	
Parameter	Condition of Use/Information
Device Name	Powered Endoscopic Staplers
Static Magnetic Field Strength(B_0)	1.5T, 3T
Static Magnetic Field Strength(B_0) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient (SFG)	40 T/m (4,000 gauss/cm)
RF Polarization	Circular Polarized (CP)
RF Transmit Coil	Any Transmit RF coil may be used.
RF Receive Coil	Any Receive coil may be used.
MR System (RF) Operating Modes or Constraints	Normal Operating Mode
Whole-Body Averaged SAR	Normal Operating Mode
Head SAR	Normal Operating Mode

Scan Duration	60 minutes of continuous RF exposure (a sequence or back-to-back series/scan without breaks) followed by a wait time of 15 minutes before resuming scanning
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Powered Endoscopic Stapler Model

Stapler Model	Shaft Length	Staple Line Length	Cutting Length
OES45-260	260 mm	45 mm	38 mm
OEC45-360	360 mm	45 mm	38 mm
OEL45-460	460 mm	45 mm	38 mm
OES60-260	260 mm	60 mm	54 mm
OEC60-360	360 mm	60 mm	54 mm
OEL60-460	460 mm	60 mm	54 mm

Linear Cutter Reloads Model

Reloads Model	Staple Line Length	Cutting Length	Open Staple Height	Closed Staple Height	Reloads Color	Number of Staples
OCR4520	45 mm	38 mm	2.0 mm	0.75 mm	Grey	66
OCR4525	45 mm	38 mm	2.5 mm	1.0 mm	White	66
OCR4530	45 mm	38 mm	3.0 mm	1.3 mm	Bronze	66
OCR4535	45 mm	38 mm	3.5 mm	1.5 mm	Blue	66
OCR4538	45 mm	38 mm	3.8 mm	1.8 mm	Gold	66
OCR4540	45 mm	38 mm	4.0 mm	2.0 mm	Green	66
OCR6025	60 mm	54 mm	2.5mm	1.0 mm	White	90
OCR6030	60 mm	54 mm	3.0mm	1.3 mm	Bronze	90
OCR6035	60 mm	54 mm	3.5mm	1.5 mm	Blue	90
OCR6038	60 mm	54 mm	3.8mm	1.8 mm	Gold	90
OCR6040	60 mm	54 mm	4.0mm	2.0 mm	Green	90

CAUTION

- When inserting and removing the Stapler, the jaws must be in a straight line with the shaft, otherwise it may be difficult to insert or remove the Stapler, which may cause damage to the Stapler.

Compatibility of the Stapler and the Reloads

Stapler Model	Reloads Model
OES45-260	OCR4520
	OCR4525
OEC45-360	OCR4530
	OCR4535
OEL45-460	OCR4538
	OCR4540
OES60-260	OCR6025
	OCR6030
OEC60-360	OCR6035
	OCR6038
OEL60-460	OCR6040

WARNING

- The stapler should be used with compatible reloads manufactured by Surgnova Healthcare Technologies (Zhejiang) Co., Ltd. Use of components produced by other manufactures may lead to instrument malfunction and/or damage.

2.10 Package Contents

Table 2-2: Package Contents of Powered Endoscopic Stapler

NO.	Contents	Model	Qty.
1	Powered Endoscopic Stapler	Refer to the Label	1
2	Non-rechargeable Battery Pack	NBP12R	1
3	User's Guide	/	1

Table 2-3: Package Contents of Linear Cutter Reloads

NO.	Contents	Model	Qty.
1	Linear Cutter Reloads	Refer to the Label	12
3	User's Guide	/	1

3 Powered Endoscopic Staplers

Powered Endoscopic Staplers are disposable products for single patient use only. And the Stapler can be used for tissue cutting and anastomosis at the same time. The part of the Stapler that is in constant contact with the human body is the staple, which is made of titanium.

3.1 Powered Endoscopic Stapler

The Powered Endoscopic Stapler can rotate bi-directionally and the rotation angle is not restricted. It can also articulate bi-directionally and the maximum articulation angle is $\pm 45^\circ$. The Stapler's lock-out feature is designed to prevent a reload that has been used, improperly installed or missing sled from being reloaded and prevent Stapler from being fired without reload. The structure of the Stapler is shown in below:

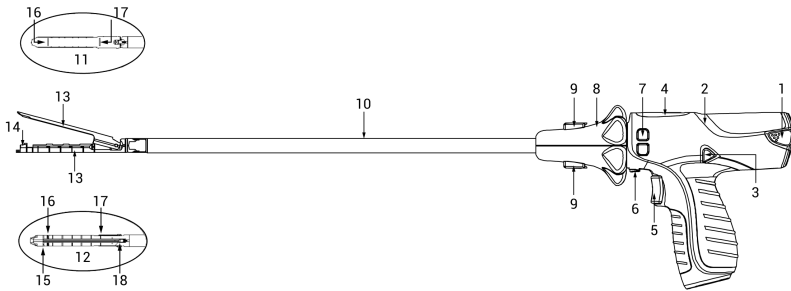


Fig. 3-1: Structure of the Powered Endoscopic Stapler

No.	Feature
1	Battery Pack Cover
2	Status Indicator
3	Safety Button / Safety Button Indicator
4	Manual Override Mechanism
5	Close / Fire Button
6	Open / Reverse Button
7	Articulation Button
8	Rotary Joint

No.	Feature
9	Manual Straight Mechanism
10	Shaft
11	Anvil
12	Cartridge
13	Jaws
14	Reload Slot
15	Staple Line
16	Cut Line
17	Proximal Black Line
18	Knife Blade Indicator

 WARNING

- The Powered Endoscopic Stapler is a single-patient-use instrument that can only be used for a single procedure.
- The Powered Endoscopic Stapler must be used with the Linear Cutter Reloads.

TIP

- In a single operation, the Stapler can be reloaded up to 12 times for a maximum of 12 firings. When the number of use reaches 12, the Status Indicator on the top of the Stapler will flash red, indicating that the Stapler cannot be used any more.

3.2 Linear Cutter Reloads

The Powered Endoscopic Stapler is packaged without the Linear Cutter Reloads and must be loaded before use. There are six rows of staggered staples in the Linear Cutter Reloads, and three rows on each side of the cutting line. The Staple Retaining Cap is used to protect the point of the staple during the transport.

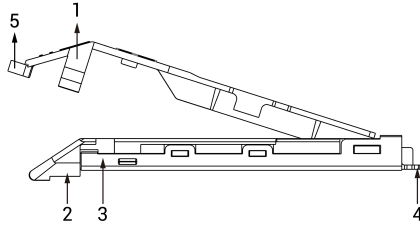


Fig. 3-2: Structure of the Linear Cutter Reloads

No.	Feature
1	Staple Retaining Cap
2	Reload Gripping Surface
3	Reload Alignment Tab
4	Sled
5	Spike

WARNING

- The Linear Cutter Reloads are sterile products for single use.

3.3 Battery Pack

The non-rechargeable battery pack is packaged separately in a sterile heat-sealed bag. And the Battery Pack must be installed before use. Please refer to Section 7 "Disposal" for specific requirements on battery pack disposal. Specifications of the non-chargeable battery pack are shown below.

Table 3-1 Specifications of non-rechargeable battery pack

Model	NBP12R
Voltage	12 ^{±2} V DC
Power	1500 mAh
Sterilization method	Sterilized using irradiation

CAUTION

- The non-rechargeable battery pack is a sterile product. Do not use the battery if the package is damaged.

4 Instructions for Use

The instrument should be examined according to the following suggested content before being put into use.

WARNING

- The instrument should be used only by trained medical professionals with specific expertise and relevant surgical trainings. Please carefully review the relevant medical literature on techniques, complications and risks before the operation.
- Do not assemble or use the Stapler and the reload produced by different manufacturer.
- If other technologies (such as electrocautery) are required during the operation, please follow the cautions stated by the original equipment manufacturer to avoid the hazards associated with their use.
- Selection of the reload should consider the patient's current condition and any preoperative treatment such as radiotherapy the patient may have undergone. Certain conditions and preoperative treatments may lead to changes in target tissue thickness, texture, and toughness. Appropriate reload should be selected based on the actual situation.
- Do not use any type of battery other than the battery pack provided by Surgnova, otherwise it may increase electromagnetic emissions or decrease electromagnetic immunity of the Stapler.
- Avoid using the Stapler in close proximity or stacking with other equipment. If it is unavoidable, the position between the Stapler and other equipment should be confirmed to ensure that all equipment can work normally.
- The Stapler and reload are all packaged and sterilized before delivery. They are disposable and cannot be reused, reprocessed or resterilized. Reuse, reprocessing, or resterilization may compromise the structural integrity of the Stapler and cause the failure of the Stapler, even may create a risk of contamination and/or cause infection or crossinfection, including but not limited to, the transmission of infectious diseases. Contamination may lead to injury, illness, or death.

- Any component of the Powered Endoscopic Staplers cannot be changed without the authorization of Surgnova.
- Verify that the Stapler model matches the Reloads model to be used (please refer to the **Compatibility of the Stapler and the Reloads** in the user's guide for details).
- Once the package of the Stapler is opened, whether used or not, the instrument should not be sterilized again.
- The instrument is not resistant to water ingress and is classified as IPX0.
- The operation of the Stapler should be strictly in accordance with the instructions to avoid accident injuries caused by improper use.
- If any serious incident has occurred in relation to the product, the user and/or patient should report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

4.1 System Installation

4.1.1 Installing the Battery Pack

1. Scrubbed Person removes the Stapler from the sterile package under the sterile conditions and open the Battery Pack Cover in the direction of the arrow shown in Fig. 4-1.

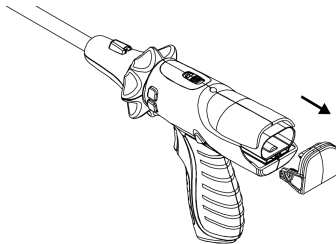


Fig. 4-1: Open the Battery Pack Cover

2. Circulating Person unpacks the battery pack using sterile technique. And then, scrubbed person aligns the battery pack with the groove behind the Stapler, and then inserts the battery pack in the direction indicated by the arrow on the battery pack, as shown in Fig. 4-2, be careful not to touch the Stapler. Make sure the battery pack is completely inserted into the Stapler.

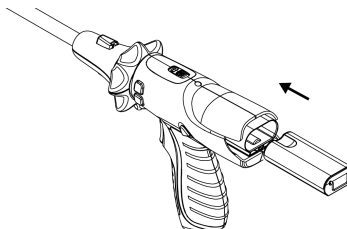


Fig. 4-2: Battery Pack Installation

3. Scrubbed Person firmly closes the battery pack cover without touching the battery pack, as shown in Fig. 4-3. When the battery pack cover is installed, the status indicator on the top of the Stapler is green.

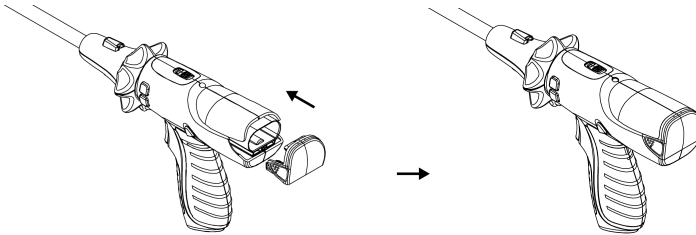


Fig. 4-3: Close the Battery Pack Cover

TIP

- If the status indicator is dark after installing the battery pack cover, please make sure that the battery pack is installed firmly in place and the Stapler is powered on. If the status indicator light is still dark, the battery pack is abnormal. Please replace the battery pack with a new one, and deliver it to after-sales service after the operation.
- The Stapler must be used within 10 hours after insertion of the battery pack (Please refer to Section 7 "Disposal" for battery pack disposal requirements).

4.1.2 Loading of the Linear Cutter Reloads

1. Remove the reload from the sterile package. Check whether the Staple Retaining Cap and Sled are intact. If there is any dislocation, defect or missing, please replace the reload with a new one, and deliver it to the after-sales service after the operation.
2. Make sure that the jaws are open before installing the reload. If the jaws are closed, press the Open Button to open the jaws.
3. Slide the reload into the bottom of the reload cartridge from the middle of the reload cartridge until the reload alignment tab is stuck in the reload alignment slot. After firmly installing the reload to the designated position, a "snap" sound will be heard and then remove the protective cap of the reload and keep it for disassembling. The specific steps as shown in Fig. 4-4.

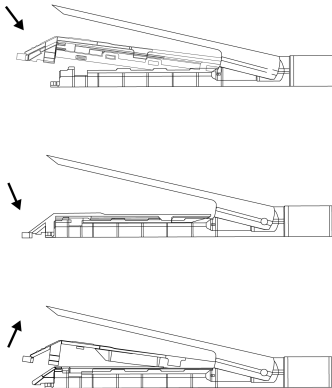


Fig. 4-4: Reload Installation

4. Please moisten and clean the jaws with saline or iodophor after installing the reloads.

CAUTION

- Tissue thickness should be carefully evaluated before using the Stapler (please refer to **Linear Cutter Reloads Model** to select a suitable reload). Do not use the stapler to staple tissues outside of the labeled limits of tissue thickness.
- After removing Staple Retaining Cap, the surface of the reload should be re-checked. If any abnormality is found (If colored Sled is visible, the reload may not contain staples), the reload should be replaced with a new one, and should be delivered to after-sales service after the operation.
- Do not remove the protective cap before loading of the Linear Cutter Reloads.

4.2 Operation

1. Make sure that the reload is positioned correctly, long press the Close Button to close the jaws, and then insert the Stapler into the body cavity through a trocar of 12mm and above. The jaws must be visible when passing through the trocar (operating under the endoscopy).
2. After entering the body cavity, press the Open Button to open the jaws. The articulation button (left or right) can be triggered to adjust the jaw angle as needed.

Note: The jaws can articulate from 0° to 45° to the left (by pressing lower articulation button on the left or upper articulation button on the right) or right (by pressing upper articulation button on the left or lower articulation button on the right). When the maximum angle is reached, the deflection cannot continue.

3. If necessary, using the index finger to adjust the rotary joint. The jaws will be free to rotate in any direction around the shaft.
4. Place the jaws around the target tissue.

5. After confirming the position of the jaws is correct, long press the Close Button to close the jaws. After the jaws are fully closed, the safety button indicator flashes blue.

6. After confirming the correct position of the jaws, press the safety button (left or right) to enable the fire button. After the safety button is pressed, the blue safety indicator will get into the always-on state from the flashing state.

Note: The safety button must be pressed before firing. Do not press the safety button unless all of the above conditions are confirmed. Otherwise, the Stapler may be misfired. If the Stapler is misfired, please return the Stapler following the instructions step 8 - 11 given in this section. Then remove the reload and reload a new one (refer to the section "Reloading of the Linear Cutter Reloads").

7. Long press the Fire Button to start the procedure with sound of motor. Keep holding the Fire Button until the anastomosis is completed.

Note: When no reload or used reload is installed, long press the Close Button to close the jaws, the Stapler will prevent the firing, and the safety button indicator will not flash. At this time, long press the Fire Button to fire will issue a warning (the status indicator flashes red twice). Please do not repeatedly press the Fire Button, otherwise the Stapler will be disabled after 4 continuous warnings, and the indicator will be red.

8. After the anastomosis, press the Reverse Button to reverse the knife and open the jaws.

9. Gently pull the Stapler away from the amputated tissue to ensure that the tissue has been completely released from the jaws.

10. Keep the jaws open before removing the Stapler, and move the jaws away from any object in the body cavity within the range of visibility. If the jaws are articulated, long press the articulation button to get the jaws return to the straight position (on the same line with the shaft).

11. Long press the Close Button to close the jaws and take the Stapler out from the body cavity through the trocar.

CAUTION

- When inserting and removing the Stapler, the jaws must be in a straight line with the shaft, otherwise it may be difficult to insert or remove the Stapler, which may cause damage to the Stapler.
- Avoid clamping and unclamping of delicate structures such as venous structures and bile ducts to prevent tissue damage.
- Visually inspect the staple line prior to firing to ensure that there are no unintended anatomic structures included within the staple line.
- Ensure that the tissue lies flat and is positioned properly between the jaws. "Mass or nodule" tissue along the reload may result in incomplete staple.
- After ensuring the position of the jaws, it is necessary to check and ensure that there is no stent, guide wire or other obstruction in the covered area of the reload of the target tissue, otherwise, it may lead to incomplete cutting and anastomosis, poor formed staple, or the jaws that cannot be opened after anastomosis.
- Make sure that the tissue does not exceed (or extrude) the proximal black line of the Stapler. If the tissue

extrudes outside the black line, it may be cut without anastomosis.

- The staplers have ***built-in safety mechanism*** for limiting operation when underlying tissues are outside the predefined thickness. If the status indicator flashes red twice (once a second) and the jaws cannot be closed properly, it means that the target tissue is outside the range of safe anastomosis of the Stapler. At this time, open the jaw, reposition the instrument, and take a smaller amount of tissue. If they are still unable to be closed, please check again if the reload matches the tissue thickness (please refer to Linear Cutter Reloads Model to select a suitable reload). If the reload is confirmed to be correctly selected, stop using the Stapler immediately.
- In the firing process, if the knife stops on account of the too thick tissue, you should release the Fire Button immediately, and press the Reverse Button to reverse the knife and open the jaws. Close the jaws again after leaving the tissue, take the Stapler out from the body cavity through the trocar and reload with another one of proper height. A smaller volume of tissue should be chosen at the next firing.
- Crossed staple lines may lead to higher risk of leak rates, even if there may be clinical circumstances when a surgeon may deem it necessary or appropriate to do so.
- If the jaws are not open after pressing the Reverse Button, please first observe the knife. If it has returned to the position enabling jaws to be opened, please gently lift the anvil to make jaws open. If the knife has not returned, please check whether the battery pack is firmly installed. If the jaws are still not open while the Stapler is in the power-on state, the manual override mechanism should be activated (see 4.4.1 "***Manual Override Mechanism***").
- If long press the articulation button but there is no corresponding articulation, the articulation direction should be checked first. If articulation cannot be performed in either direction, please ensure that the battery pack is firmly installed in place. If the jaws are still unable to articulate when the Stapler is in the power-on state, the manual straight mechanism should be activated (see 4.4.2 "***Manual Straight Mechanism***"). After the jaws are returned to the straight position, stop using it.
- The articulation can only be triggered when the jaws are open.
- If the firing cannot be stopped after the Fire Button is released, please press the Reverse Button or the safety button quickly.
- No matter whether the Fire Button is released or not, pressing the Reverse Button will stop the firing during the Stapler firing.
- After closing, the safety button indicator will flash blue. The safety button must be pressed before firing, and then the safety button indicator will change from flashing blue to constant blue.
- Once the safety button is pressed during the firing, reversing or articulation, the stapler will stop the operation immediately. Do not press the safety button again before ensuring the device and target tissue are in normal condition.
- If the firing function is not available, please replace the Stapler with a new one, and deliver it to after-sales service after the operation.
- If the sterile package of the product is damaged, stop using the product and replace it with a new one.
- Avoid partially firing the Stapler. Incomplete firing may result in poor formed staple, incomplete cutting line,

anastomotic bleeding or difficulty removing the device.

- Check the staple for bleeding and venting, and whether the staple is well formed. If there is any sign of bleeding/venting, appropriate measures should be taken.
- Do not press the safety button until the Stapler is ready to fire.
- Do not rotate the rotary joint when the jaws clamp the tissue.

TIP

- When passing through the trocar, avoid accidentally triggering any buttons.
- Interruption of anastomosis requires the operator to release the Fire Button or press the safety button. Restore anastomosis needs repressing the safety button and then long press the Fire Button again.
- Once the Reverse Button is pressed to return the knife, the reload cannot be continued to use again.
- As the resistance to the Stapler increases, the motor will gradually slow down.
- Instrument that has been exposed to body fluids should be specially disposed to prevent biological contamination.

4.3 Reloading of the Linear Cutter Reloads

1. Press the Open Button to open the jaws.
2. Insert the spike or pointed tools such as forceps between the reloadslot, and pry the reload in the direction shown in Fig. 4-5 until it is separated from the Stapler. Discard the disassembled and used reload.

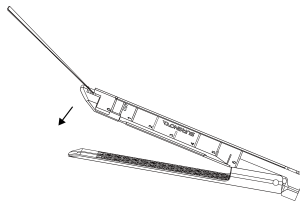


Fig. 4-5: Reload Removal

3. Reload a new reload according to the section 4.1.2 "Loading of the Linear Cutter Reloads".



WARNING

- Before reloading the reload, hold the Stapler in a vertical position, immerse the jaws in the saline solution, shake them vigorously, and then wipe the inside and outside surfaces of the jaws to remove the staples left in the Stapler. The Stapler can be used only after visual inspection to confirm that there are no staples in the jaws.

TIP

- Before removing the reload, make sure that the jaws are open.

4.4 Manual Mechanism Operation

The manual mechanism consists of two parts, one (at the top of the Stapler) for reversing and the other one (at the rotary joint) for articulation.

WARNING

- When the manual mechanism is activated, the stapler is disabled and cannot be used for any subsequent firings.

CAUTION

- Do not use excessive force when operating the manual mechanism to prevent the jaws from causing tissue damage in the body.

4.4.1 Manual Override Mechanism

Push the slide of the emergency gear cover on the top of the stapler toward the jaws until the button can no longer move forward, release the button at this time, and then open the manual override cover. After opening the manual override cover, lift the folding handle upward until it is fully straight (there will be a click when it is fully straight), and move the lever back and forth until the jaws are fully open. The specific operation is shown in Fig. 4-6.

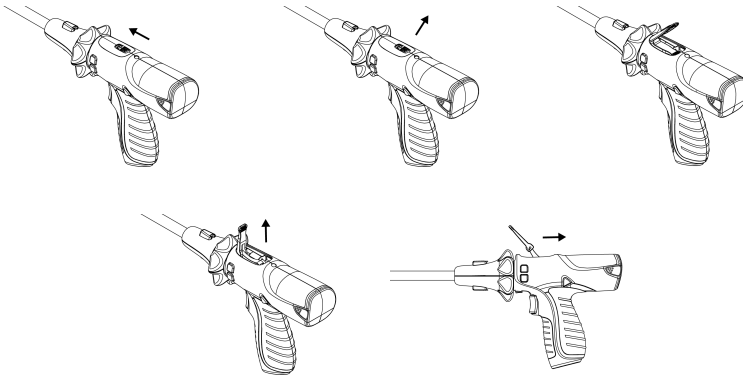


Fig. 4-6: Manual Override Mechanism Operation

CAUTION

- After the manual override cover is opened for use, it cannot be reattached to the handle of the Stapler.

4.4.2 Manual Straight Mechanism

Please observe the knife before activating the manual straight mechanism. If the knife has reversed to the position enabling jaws to be opened, the articulation emergency could be started. If the knife has not returned, please press the Reverse button or use the manual override mechanism to reverse the knife until jaws be fully opened. (See 4.4.1 "Manual Override Mechanism").

Disassemble the manual articulation caps covered on the rotary joint, and then the manual articulation levers will be exposed. Move the levers towards the handle cushioned with folded gauze until it can no longer be moved. At the same time, the jaws are articulated back to the straight position, as shown in Fig. 4-7.

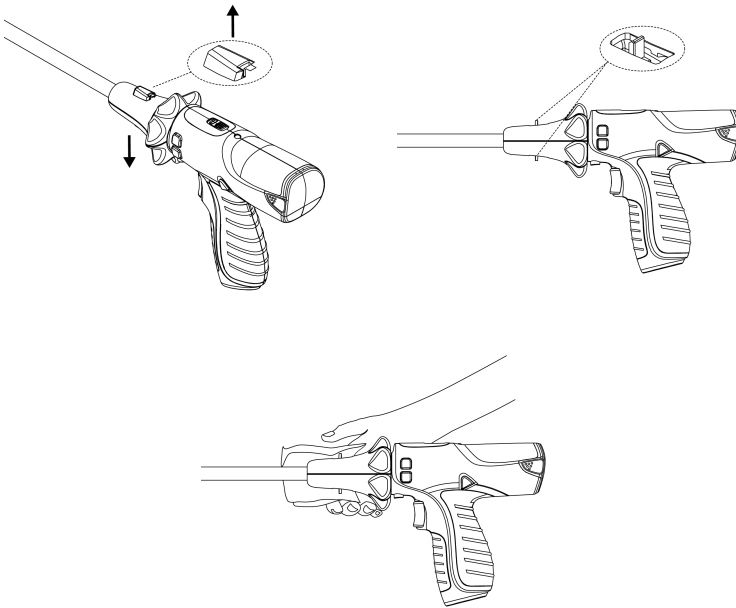


Fig. 4-7: Enable the Emergency Gear for Deflection

CAUTION

- Make sure the jaws are away from the tissue before using manual straight mechanism.

4.5 Descriptions of the Indicator

The Status Indicator is on the top of the Stapler, and its descriptions are as follow:

Table 4-1: Descriptions of Status Indicator

Status	Type	Description
Dark	Tip	The Stapler is in the power-off state.
Green	Tip	The battery pack is installed in place and the Stapler is working well.
The Status Indicator flashes red twice and then turns green	Tip	Overcurrent, the current exceeds the use threshold; the Stapler can be used normally.
Flashing Red (The Status Indicator flashes red once every two seconds, the flashing frequency is 0.5Hz)	Tip	The battery pack is too low for the next firing and needs to be replaced.
Flashing Red (The Status Indicator flashes red once a second, the flashing frequency is 1Hz)	Tip	Overcurrent four times continuously or 12 firings; the Stapler cannot be fired again.
Red	Tip	All functions of the Stapler are disabled and the emergency gear must be activated to remove the Stapler from the patient.

TIP

- When the overcurrent protection in the process of Stapler reverse / left articulation / right articulation is continuously triggered, the first three status indicators will flash red at 1Hz frequency for 2 times, then immediately turn green. After the fourth trigger, the status indicator will continue to flash red at a frequency of 1Hz.

The Ssfety Button Indicator is under the safety button on both side of the Stapler, and its descriptions are as follow:

Table 4-2: Descriptions of Safety Button Indicator

Status	Type	Description
Flashing Blue (the flashing frequency is 1Hz)	Tip	The jaws have been closed. If the position is confirmed, press the safety button to release the insurance.
Blue	Tip	Insurance has been released. Ready to fire.

5 Maintenance

Powered Endoscopic Staplers are disposable with no maintenance requirements.

There are no user-serviceable parts on this instrument. If any failure occurs, it should be sent to Surgnova Healthcare Technologies (Zhejiang) Co., Ltd. for maintenance.

WARNING

- Powered Endoscopic Stapler and the Linear Cutter Reloads are sterile products, which have been sterilized with ethylene oxide and cannot be sterilized again.

TIP

- Please contact Surgnova directly if you need the circuit diagram of the instrument and the list of components. And Surgnova will provide the circuit diagram and / or other technical documents in whole or in part according to your needs.

6 Transport and Storage

6.1 Transport

If the instrument needs to be transported, it shall be transported according to the requirements of the order contract. In the process of transportation, it must be protected from severe impact, rain and exposure to the sun. Avoid violent vibration and damp environment when transporting and handling instrument. The instrument shall be installed on a level stable surface which is dry, ventilated and free from direct sunlight. The transportation environment requirements of the Staplers are shown in the Section 2.9.

6.2 Storage

The instrument should be stored in a room with no corrosive gas, no irritating odor and good ventilation. The storage environment requirements of the Staplers are shown in the Section 2.9.

7 Disposal

Please dispose of the Powered Endoscopic Stapler and the Linear Cutter Reloads respectively after using the instrument 12 times or after one operation. For specific disposal methods, refer to the local laws and regulations on waste disposal of the Powered Endoscopic Stapler and the Linear Cutter Reloads.

Remove the battery pack after it has been installed to the Stapler for 24 hours, and then dispose of the battery pack in accordance with regional laws and regulations.



WARNING

- The battery pack may present a fire hazard if mistreated. Do not disassemble, heat above 100°C, autoclave, crush, puncture, short external contacts or recharge.
- Do not sterilize or disinfect the battery pack by using any high-temperature and high-pressure technique.
- Do not charge the battery pack.
- Battery pack should not be submerged in water or cleaning solutions.

TIP

- The battery pack as a whole does not need to be disassembled.

8 Trouble Shooting

If any malfunction occurs during use of the Stapler, please check all items listed in the following table for troubleshooting first. . If you cannot solve the malfunction, please contact Surgnova Healthcare Technologies (Zhejiang) Co., Ltd. for maintenance.

Table 8-1: Failure List

Problem	Possible Cause	Solution
The jaws cannot close when clamping the tissues.	The battery pack is loosened.	Check if the battery pack is firmly installed in place.
	The selected reload model does not match the thickness of the target tissue.	Stop using the reload immediately and replace it with another proper one for operation.
	The tissues are too thick and the volume is too much.	Select the small volume of thinner tissues for anastomosis.
The anastomosis is stopped before reaching the end point.	The battery pack is loosened.	Check if the battery pack is firmly installed in place.
	The selected reload model does not match the thickness of the target tissue.	Reverse the knife immediately, open the jaws and replace the reload with another proper one for operation.
	The tissues are too thick and the volume is too much.	Reverse the knife immediately, open the jaws, and replace the reload with a new one. Select a small volume of thinner tissues for anastomosis.
When the anastomosis completes or is interrupted, pressing the Reverse Button cannot make the jaws open.	The battery pack is loosened.	Check if the battery pack is firmly installed in place.
	The knife cannot be reversed.	Start the manual override mechanism (see 4.4.1 "Manual Override Mechanism").

Problem	Possible Cause	Solution
Pressing the deflection button cannot make the jaws articulate.	The battery pack is loosened.	Check if the battery pack is firmly installed in place.
	Mechanical failure.	Start the emergency gear for deflection (see 4.4.2 "Manual Straight Mechanism").
The status indicator flashes red twice (once a second).	The tissues are too thick during closing the jaws.	Stop using the reload immediately and replace it with another proper one for operation.
The status indicator flashes red twice (once a second).	Unloaded the reload or the reload has been used.	Loading a new reload.
	Excessive resistance during cutting and anastomosis.	Immediately return the knife and open the jaws to check if there are hard objects at the cutting and anastomosis sites, and check if there are residual hard objects in the jaws.
	Excessive resistance when deflecting left / right.	Check if there is a hard object in the deflection direction.
The status indicator flashes red all the time (once every two seconds).	Low Battery	Replace the battery pack.
The status indicator flashes red all the time (once a second).	The Stapler has been fired 12 times.	Replace the Stapler.
	The Stapler has overcurrent 4 times continuously.	Replace the Stapler.
The status indicator keeps red.	Mechanical failure.	Replace the Stapler.
Status indicator is dark.	The Stapler is not powered.	Check if the battery pack is installed.

9 Electromagnetic Compatibility

Powered Endoscopic Staplers need special precautions regarding EMC and put into service according to the EMC information provided in the user manual; Powered Endoscopic Staplers conform to this IEC 60601-1-2 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:



WARNING

- Powered Endoscopic Staplers with Following ESSENTIAL PERFORMANCE are intended used in Professional healthcare facility environment except for the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

ESSENTIAL PERFORMANCE: Power-driven articulation, Power-driven firing, 12 times anastomosis and cutting.

- Use of Powered Endoscopic Staplers adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, Powered Endoscopic Staplers and the other equipment should be observed to verify that they are operating normally.
- The use of accessoriess other than those specified or provided by the manufacturer of Powered Endoscopic Staplers could result in increased electromagnetic emissions or decreased electromagnetic immunity of this instrument and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the stapler, including cables specified by the manufacturer. Otherwise, degradation of the performance of Powered Endoscopic Staplers could result.
- Powered Endoscopic Staplers are designed compatible with high frequency surgical equipment; The condition includes working or standby in close proximity to high frequency surgical equipment.

EMI Compliance Table (Table 9-1)

Table 9-1: Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Home healthcare environment

EMS Compliance Table (Table 9-2 to 9-3)

Table 9-2: Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to Table 9-3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 9-3: Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

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