User Manual

————Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit

Drafted by:	Date:
Reviewed by :	Date:
Approved by:	Date:

Contents

1. Preface

⚠Please read all information carefully before using the product.

1.1. Important statement

This instruction is intended to assist in the use of Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit, and it is not a reference to surgical techniques.This product is designed, tested and manufactured for single surgical use. If reused or reprocessed, the device may fail to function and may cause injury or cross-infection to the patient. Please do not reuse or process this product.

1.2. Version Statement

The 02 version is revised in Jun. 2025

Document No.: 536000100

2. Product introduction

2.1. Product name

Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit

2.2. Main structure and composition of the product

2.2.1 The Powered Endoscopic Linear Cutting Stapler（hereinafter referred to as " powered stapler "）is mainly composed of anvil jaw, steering casing pipe, sealing ring fixing ring, casing pipe, cartridge jaw, knob, knife reverse switch, reset button, primary lithium battery pack, firing trigger, firing safety switch, closing trigger, handle, knife and casing seal(see figure2-1Structure of Powered Endoscopic Linear Cutting Stapler), adopt independent packaging.

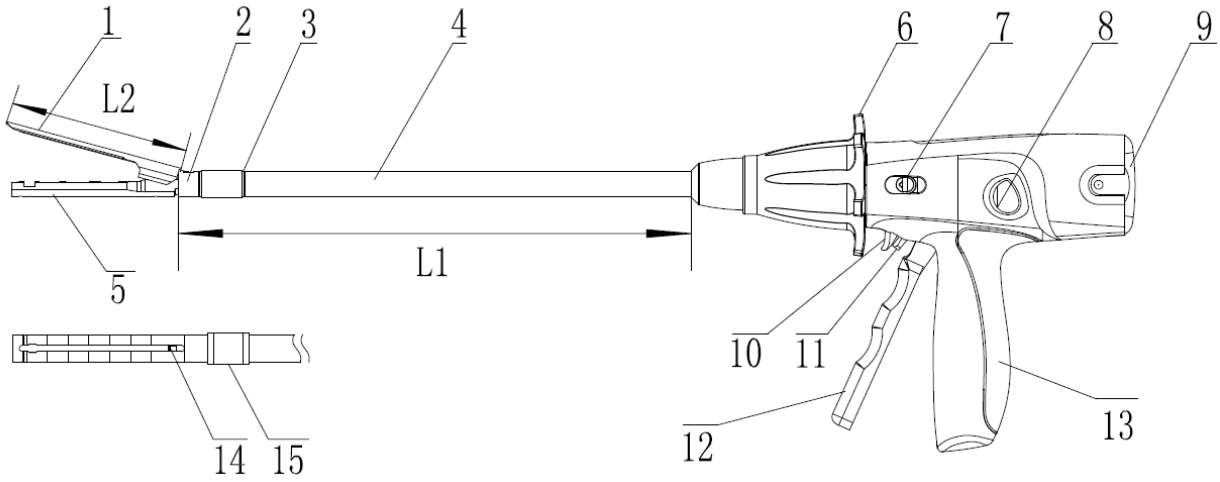
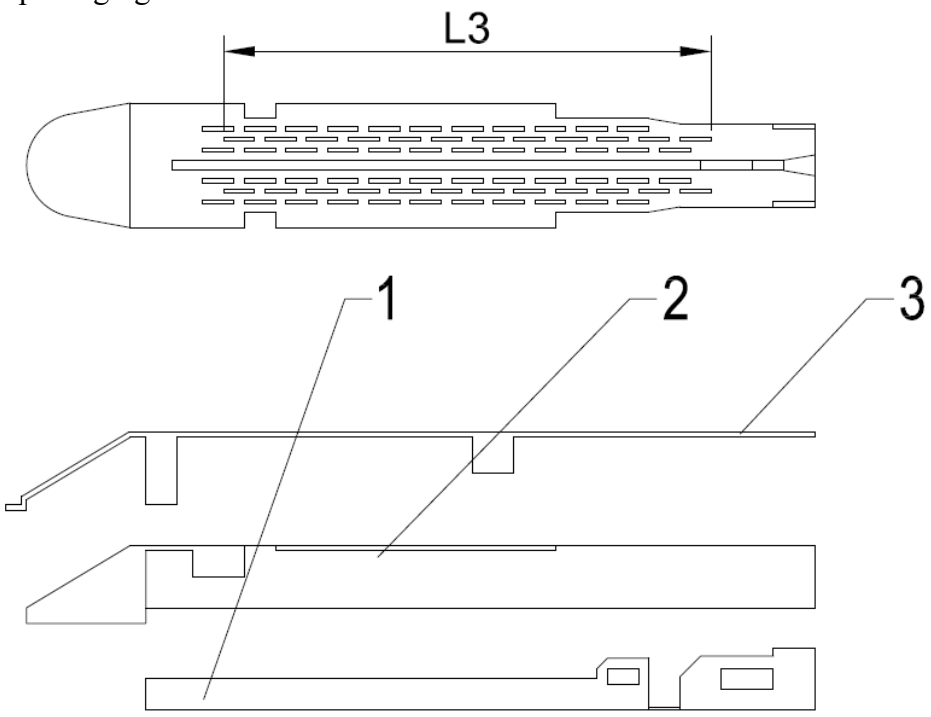


Figure 2-1: Structure of Powered Endoscopic Linear Cutting Stapler

(1. Anvil Jaw, 2. Steering Casing Pipe, 3. Sealing Ring Fixing Ring, 4. Casing Pipe, 5.Cartridge Jaw, 6.Knob, 7.Knife Reverse Switch, 8.Reset Button, 9.Primary Lithium Battery Pack, 10.Firing Trigger, 11.Firing Safety Switch, 12.Closing Trigger, 13.Handle, 14.Knife, 15.Casing Seal)

2.2.2 Single Use Loading Unit（hereinafter referred to as "cartridge"）is mainly composed of cartridge bracket, cartridge and cartridge protective cover(see Structure of Cartridge).adopt

independent packaging.



2-2: Structure of Cartridge

(1. Cartridge Bracket, 2. Cartridge, 3. Cartridge Protective Cover)

2.3. Model and Specification

2.3.1 Model and dimensions of Powered Endoscopic Linear Cutting Stapler is shown in Table 2-1.

Table 2-1 Model and dimensions of Powered Endoscopic Linear Cutting Stapler

Model	Length of Anvil(L2)	Length of shaft(L1)	Tolerance
ES190-60E	90mm	190mm	±5mm
ES190-45E	75mm	190mm	
ES250-60E	90mm	250mm	
ES250-45E	75mm	250mm	
ES350-60E	90mm	350mm	
ES350-45E	75mm	350mm	

2.3.2 Model and dimensions of cartridge is show in Table2-2.

Table 2-2 Model and dimensions of cartridge

Model	Length of anastomosis (L3)	Tolerance	Ti staple height	Colour	Tolerance
ESA60-2.6	60mm	±2.0mm	2.6mm	White	±0.2mm

Model	Length of anastomosis (L3)	Tolerance	Ti staple height	Colour	Tolerance
ESA60-3.6	60mm		3.6mm	Blue	
ESA60-3.8	60mm		3.8mm	Golden	
ESA60-4.1	60mm		4.1mm	Green	
ESA60-4.2	60mm		4.2mm	Black	
ESA45-2.6	46mm		2.6mm	White	
ESA45-3.6	46mm		3.6mm	Blue	
ESA45-3.8	46mm	±2.0mm	3.8mm	Golden	±0.2mm
ESA45-4.1	46mm		4.1mm	Green	
ESA45-4.2	46mm		4.2mm	Black	

2.4. Coordination with auxiliary devices

When this product is used in endoscopic surgery, it is recommended to match the specifications of the Trocar(Trocar diameter:φ= 12.8mm).

Note: the above specifications of Trocar are only recommended and can be changed according to the situation. When the converter is used, a Trocar with larger specification shall be used.

2.5. Material

Table 2-3: Materials used for main parts

Parts	Material Grade
Anvil	20Cr13
Cartridge jaw	05Cr17Ni4Cu4Nb
Steering casing pipe	06Cr19Ni10
Casing pipe	06Cr19Ni10
Casing seal	TPU
Sealing ring fixing ring	Aluminum alloy 6061
Knife	30Cr13
Ti staple	TA2G
Cartridge	PA

Table 2-4:Ti Staple Chemical Component

Element	Fe (w/%)	C (w/%)	H (w/%)	N (w/%)	O (w/%)	Ti
Content	0.071	0.014	0.0061	< 0.0050	0.14	Residue

2.6. Product performance

1) The anastomotic stoma after anastomosis shall be able to withstand not less than 3.6 × At 10^3pa pressure, the water leakage shall not exceed 10 drops within 15s.
2) The cutting edge of the knife shall be sharp and the cutting force shall not be greater than

0.80N.

3) The hardness of the knife shall not be less than 377$HV_{0.2}$。
4) The peel strength of the package seal of the powered stapler and cartridge shall not be less than 0.10N/mm. The two contact surfaces after stripping shall be smooth, continuous and uniform without delamination or tear.
5) The powered stapler and cartridge shall be sterile after being sterilized with ethylene oxide.

2.7. Intended Purpose

Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit are intended for transection, resection, and/or creation of anastomoses in multiple open or minimally invasive general. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen.

2.8. Patient populations

Adult patients requiring the resection and transection of tissue and creation of anastomosis during surgery.

2.9. Intended user

The Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit should only be used by a surgeon, who has received the training on surgical operation. Before use, the operator should have a full understanding of the using instruction, warnings and precautions.

2.10. MRI Safety information

Non-clinical tests have proved that instrument is safe under the following conditions.Failure to follow these conditions may result in injury.

Static Magnetic Field Strength(Bo)	1.5T or 3.0T
RF Excitation	Circularly Polarized(CP)
RF Transmit Coil Type	Volume RF body coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2W/kg (Normal Operating Mode）
Maximum Head SAR	3.2W/kg
Scan Duration	Under the scan conditions defined,patient can be scanned continuously for 60 minutes

3. Operation

3.1. Usage method

Please use the device according to the following instructions and figure. In order to facilitate understanding, the nomenclature to which the actual operation is applied are marked in more detail according to the structural diagram.

The nomenclature used for actual operation in Figure 3-1 are as follows:

1) Closing Trigger; 2) Firing Safety Switch; 3) Firing Trigger; 4) Reset Button; 5) Primary Lithium Battery Pack; 6) Battery Pack Release Tap; 7) Manual Operation Manhole Cover Panel; 8) Knife Reverse Switch; 9) Knob Fin; 10) Knob; 11) Anvil Jaw; 12) Cartridge Jaw; 13) Cartridge Alignment Slot; 14) Cartridge Clamping Surface; 15) Cartridge Protective Cover; 16) Cartridge; 17) Staple Line; 18) Cut Line; 19) Proximal Scale Line; 20) Knife Blade Indicator;

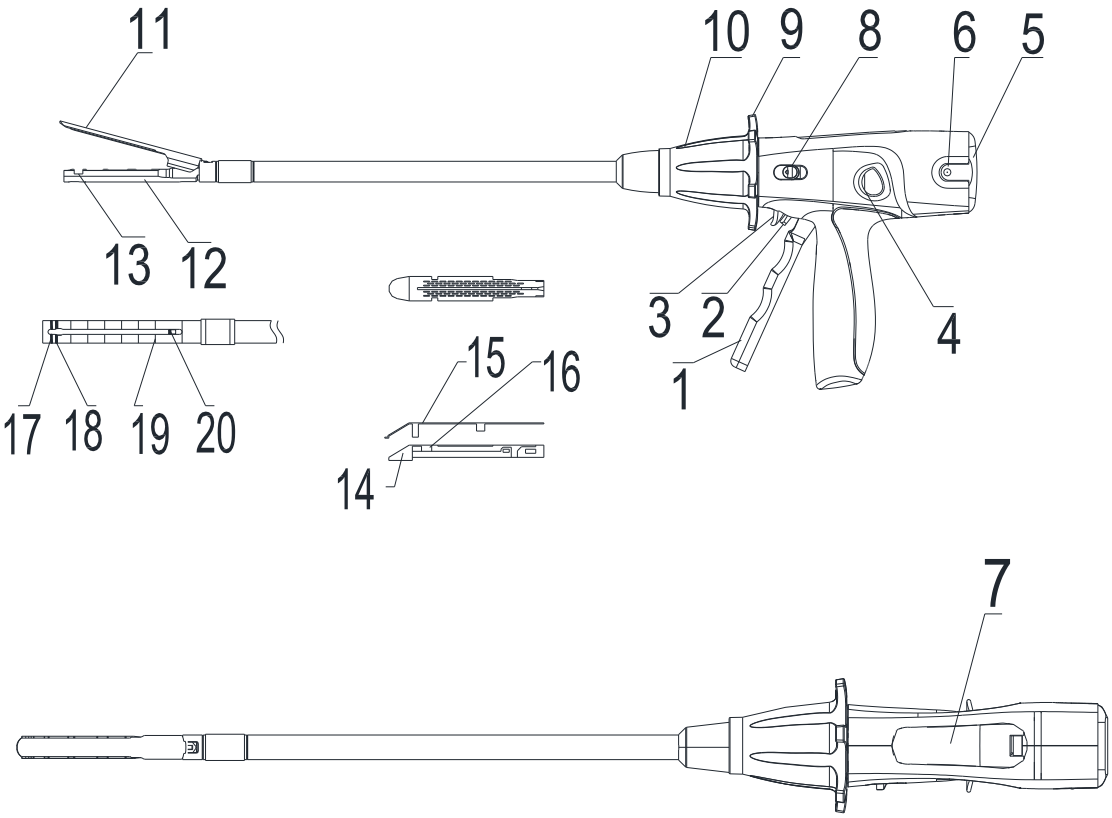
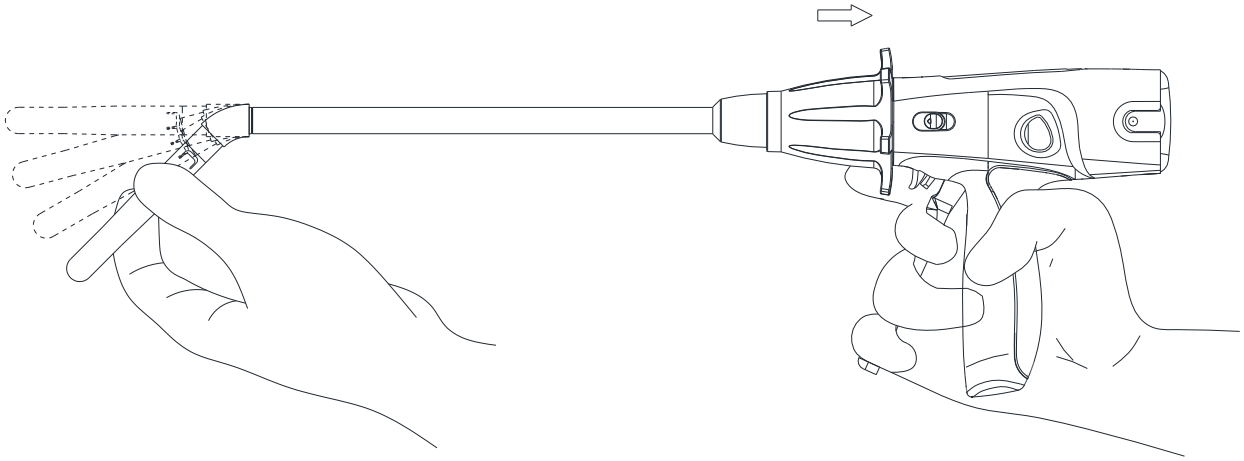


Figure 3-1



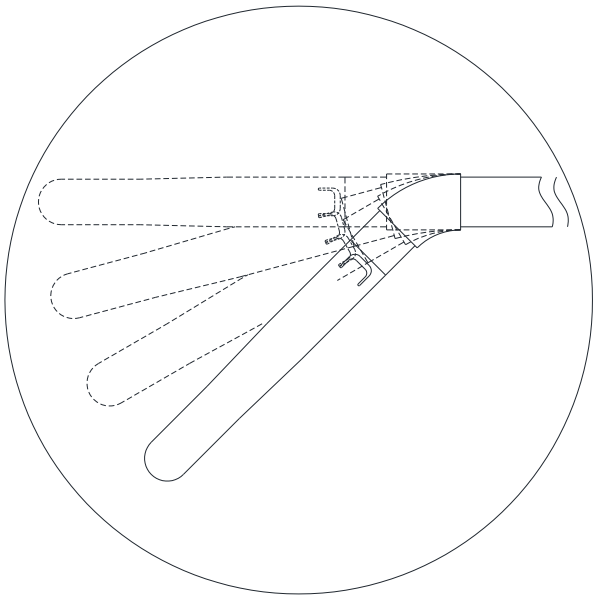


Figure 3-2

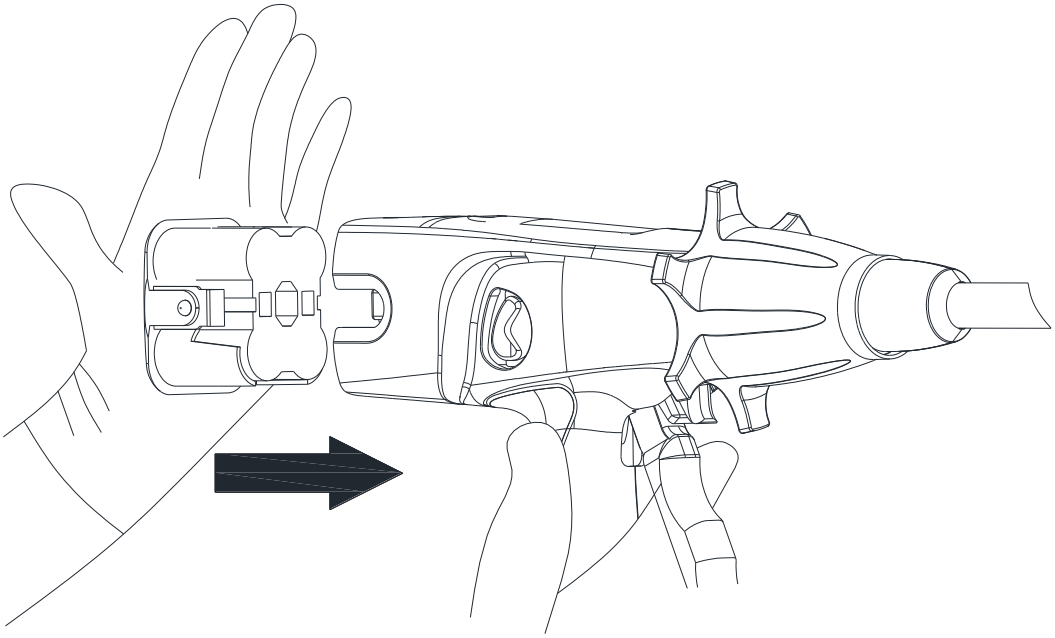


Figure 3-3

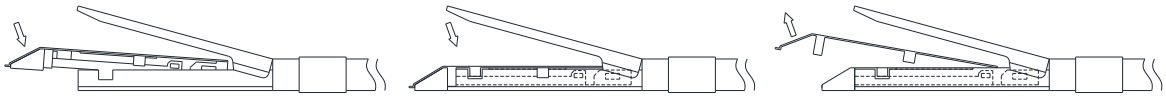


Figure 3-4

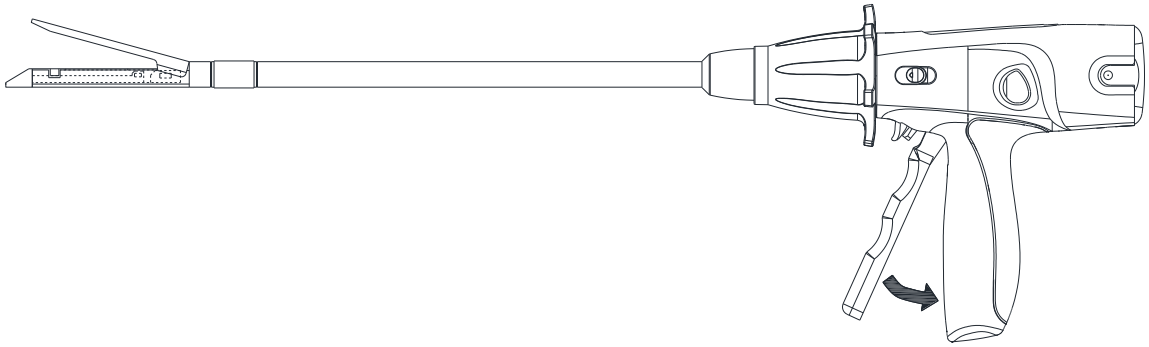


Figure 3-5

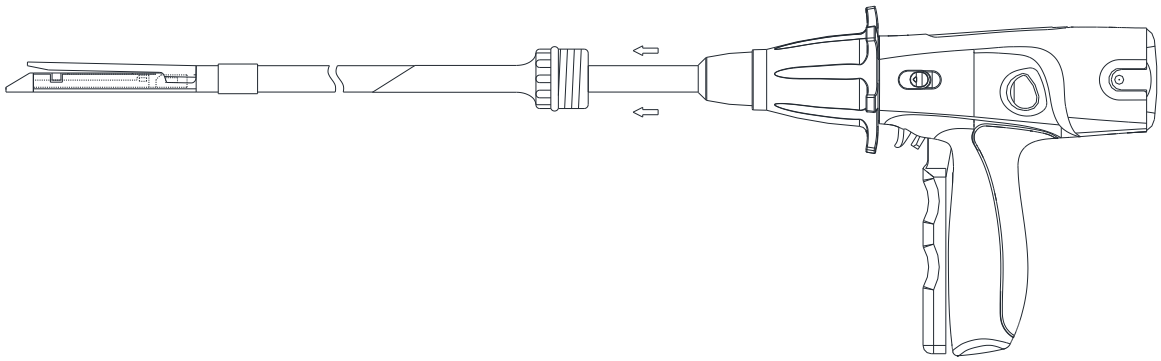


Figure 3-6

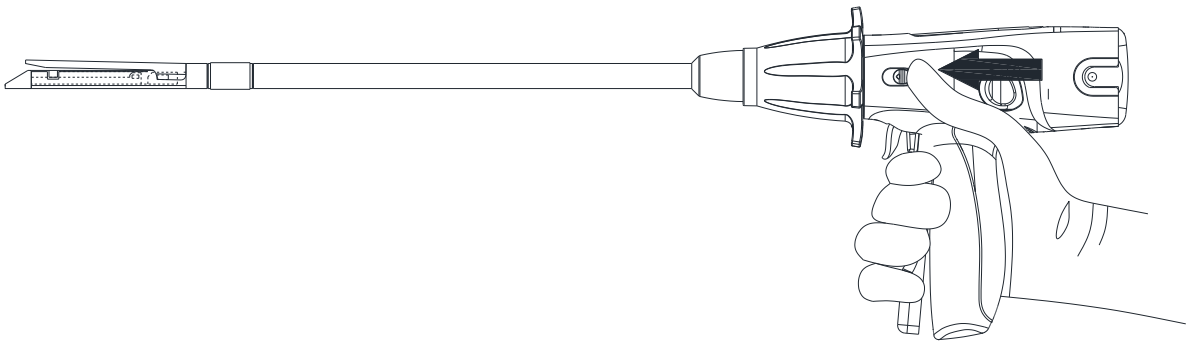


Figure 3-7

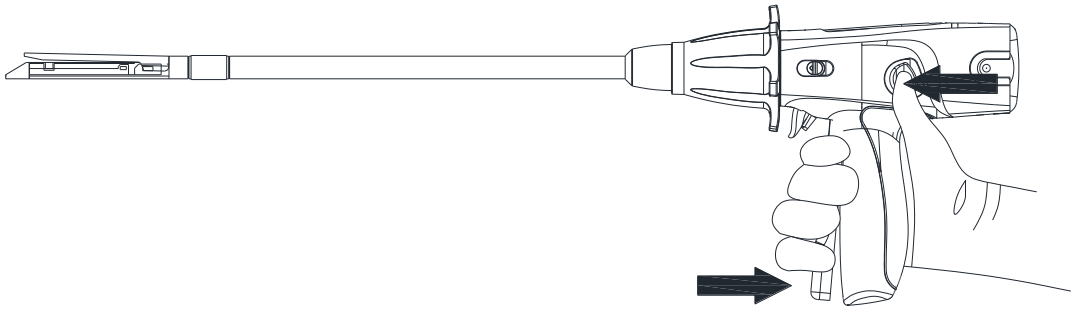


Figure 3-8

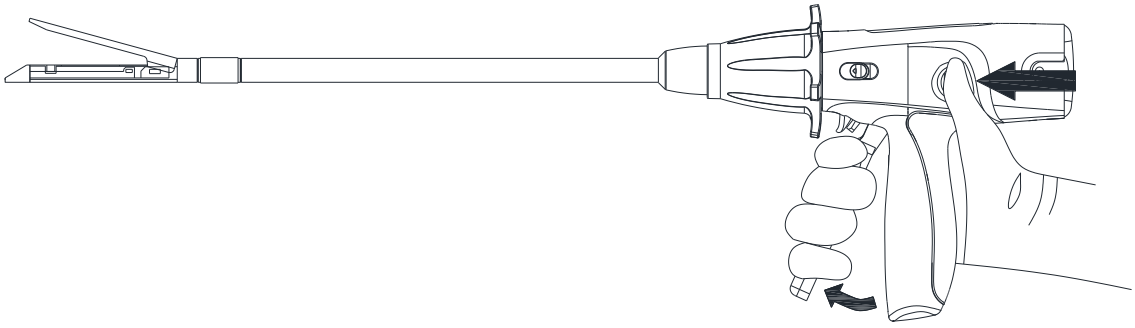


Figure 3-9

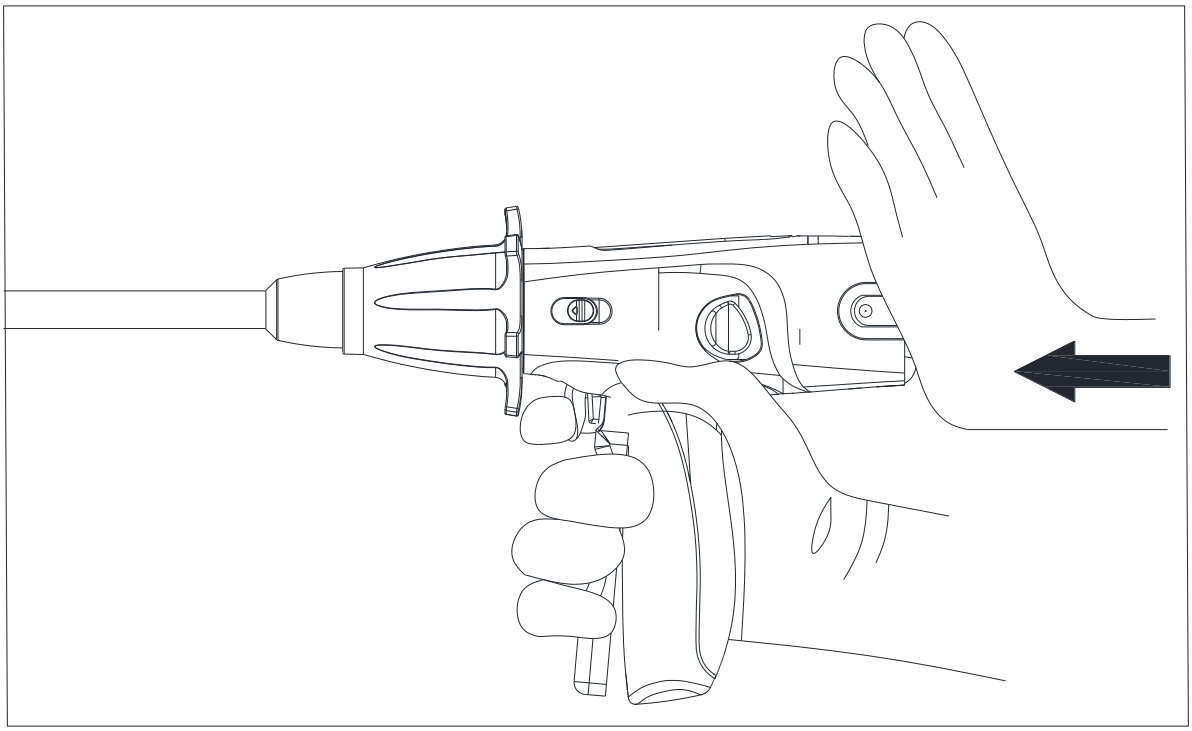
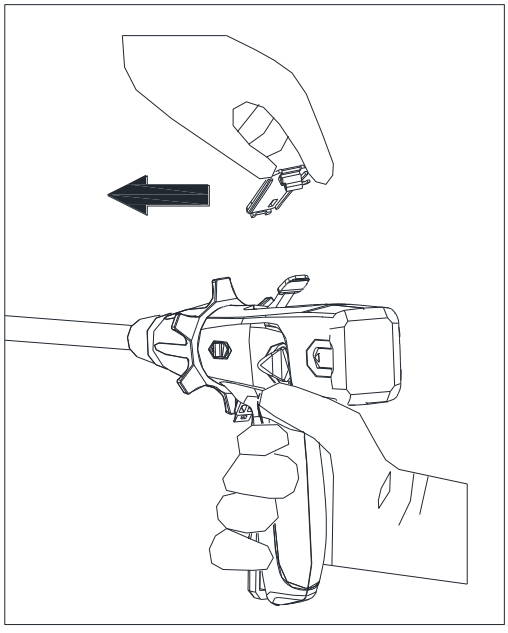
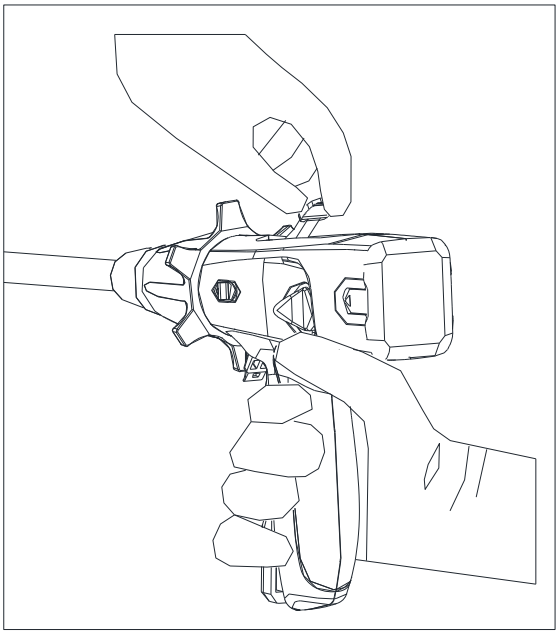
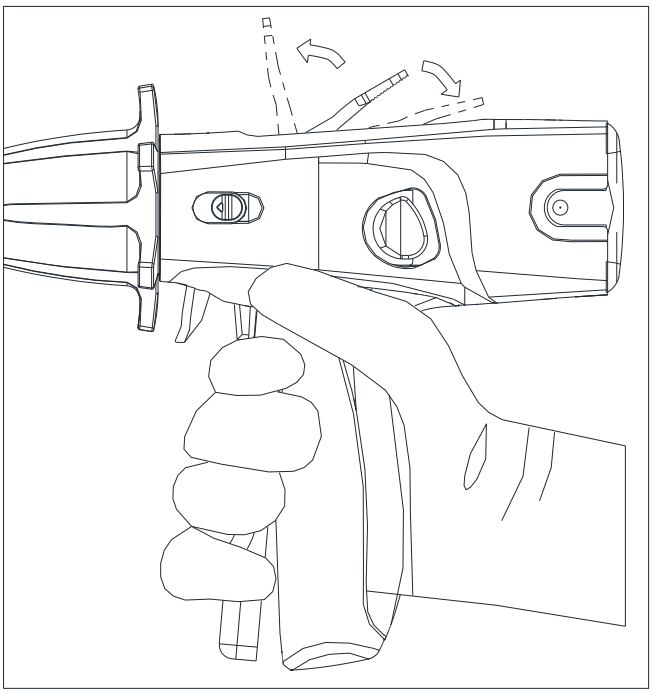


Figure 3-10







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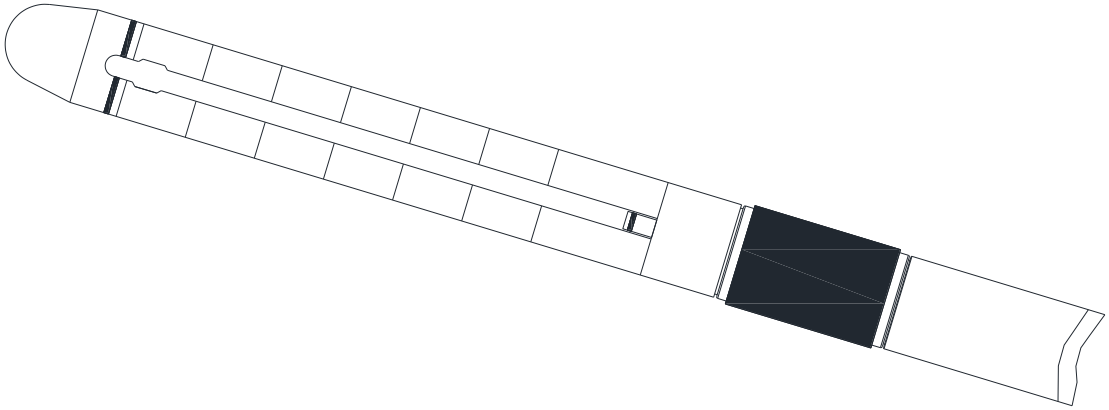

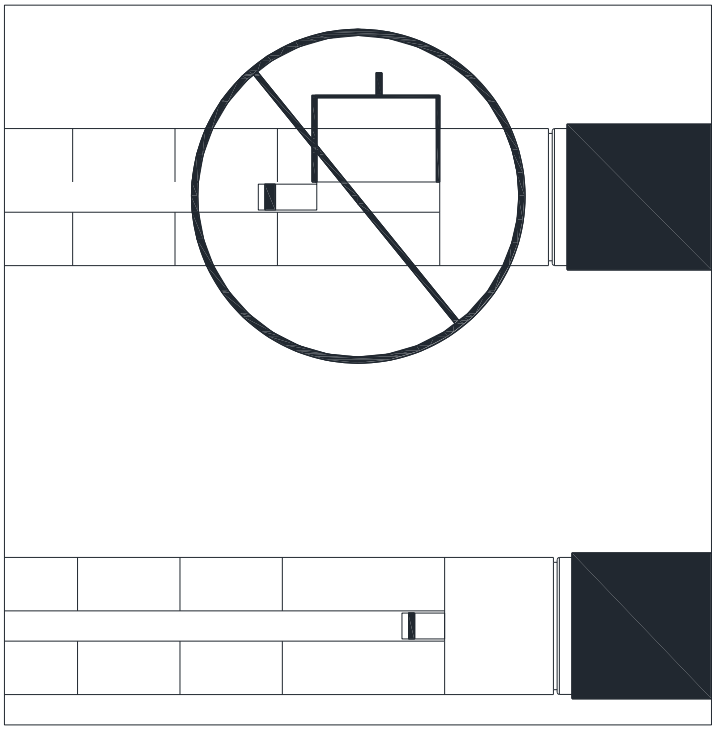

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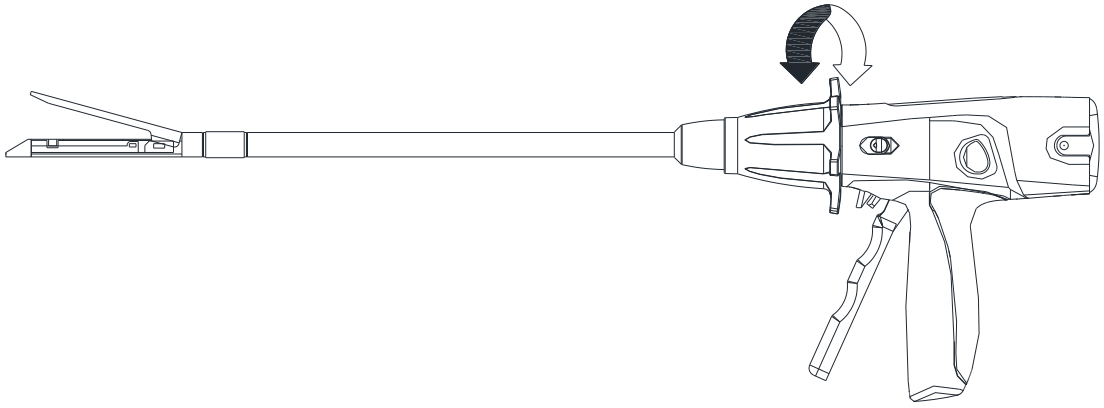


Figure 3-13

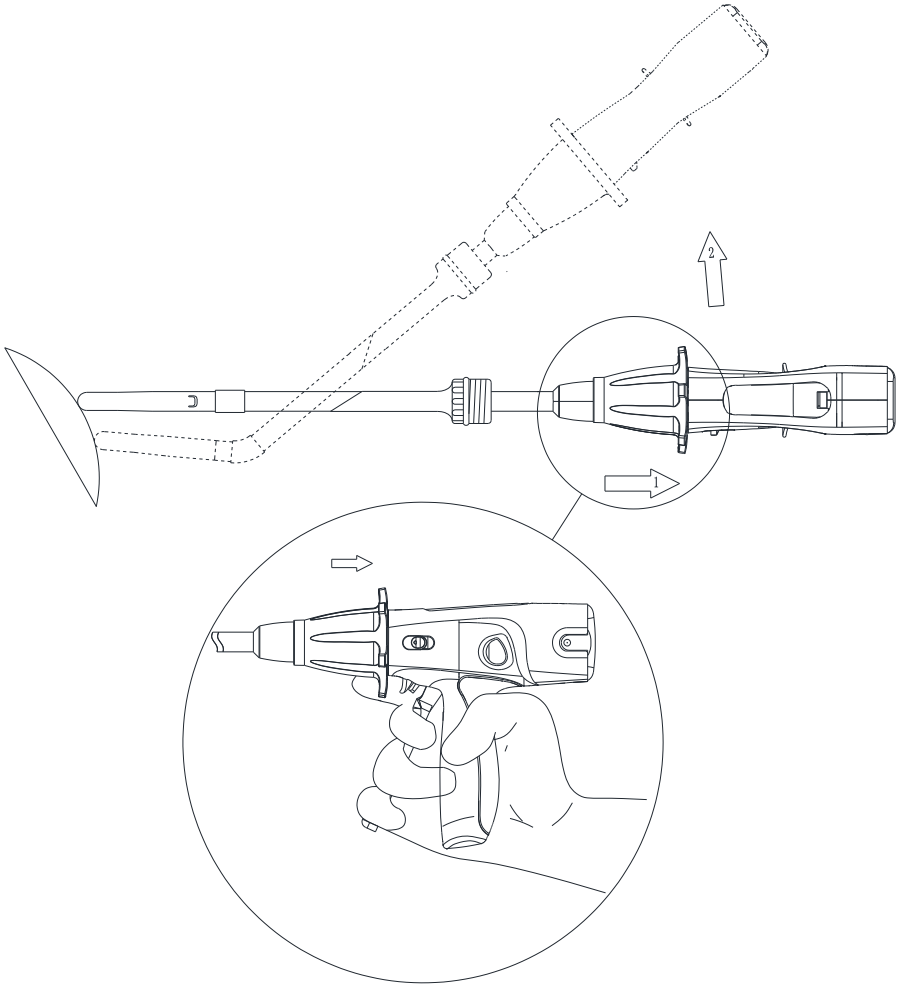


Figure 3-14

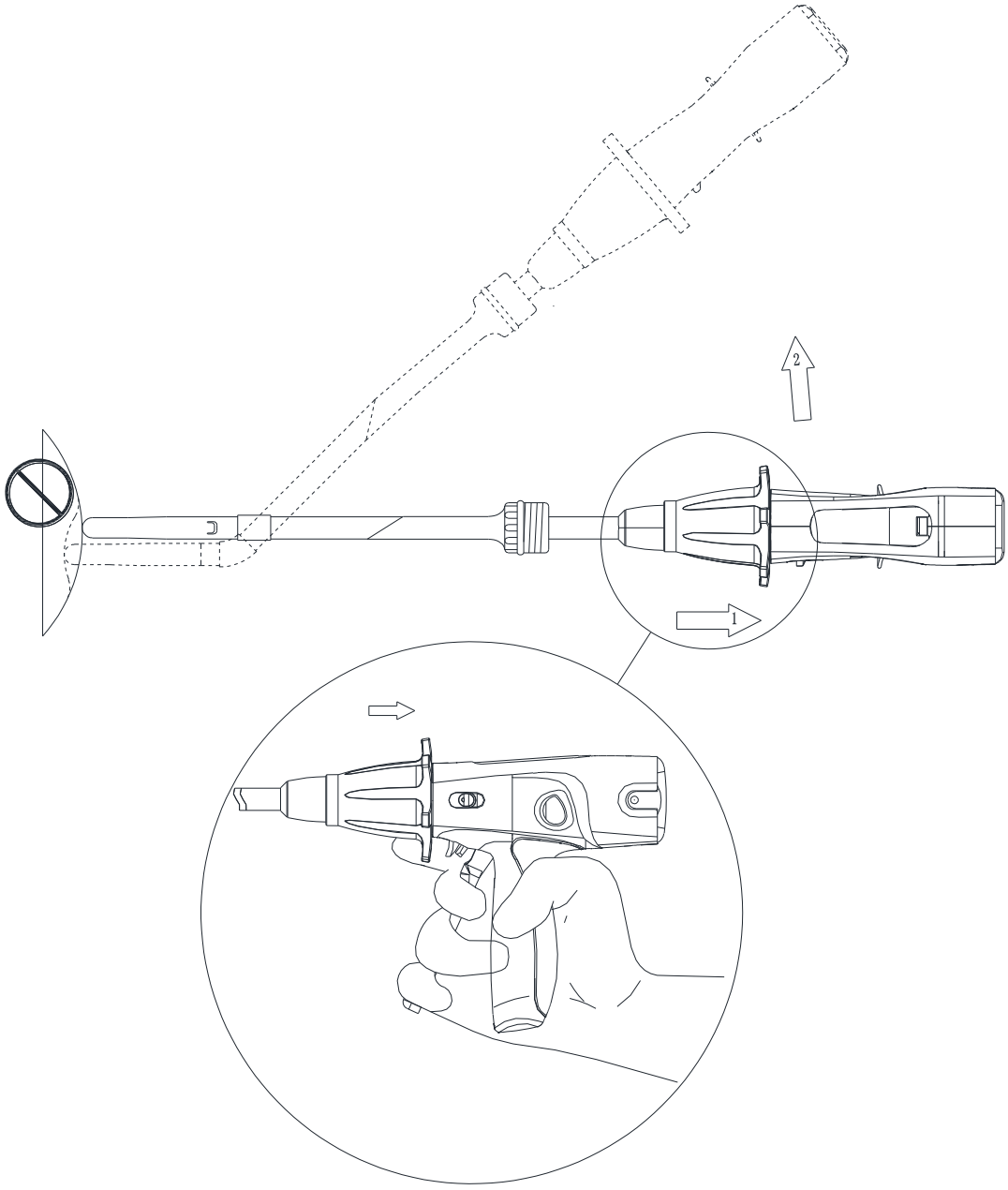


Figure 3-15

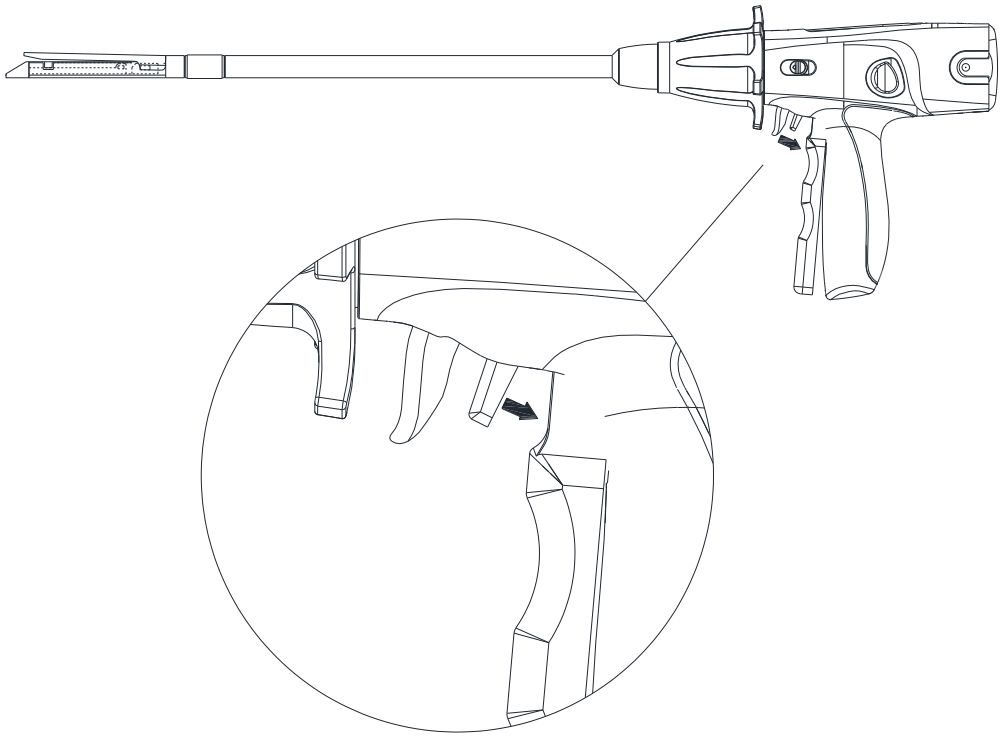


Figure 3-16

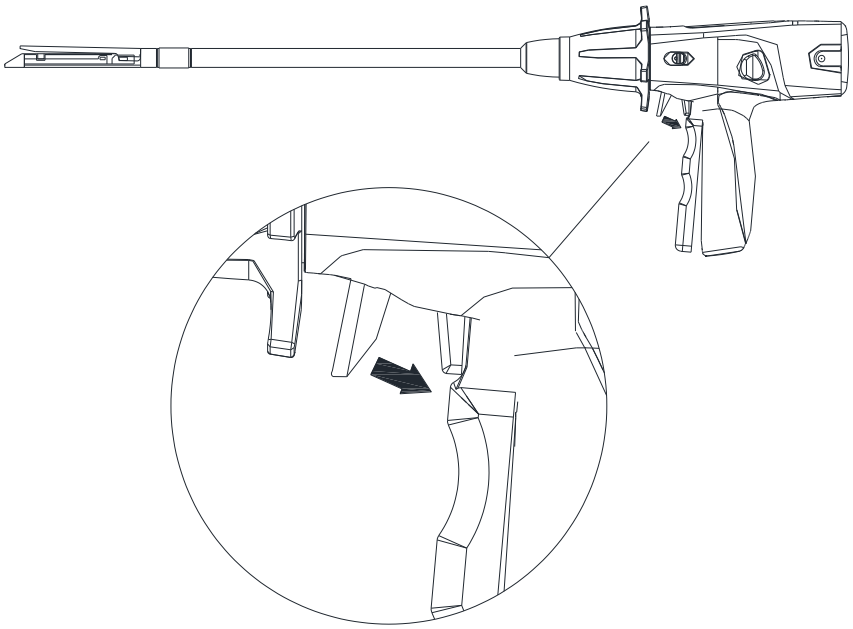


Figure 3-17

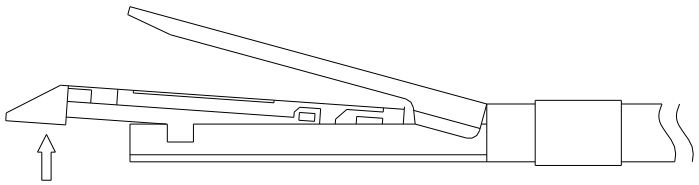


Figure 3-18

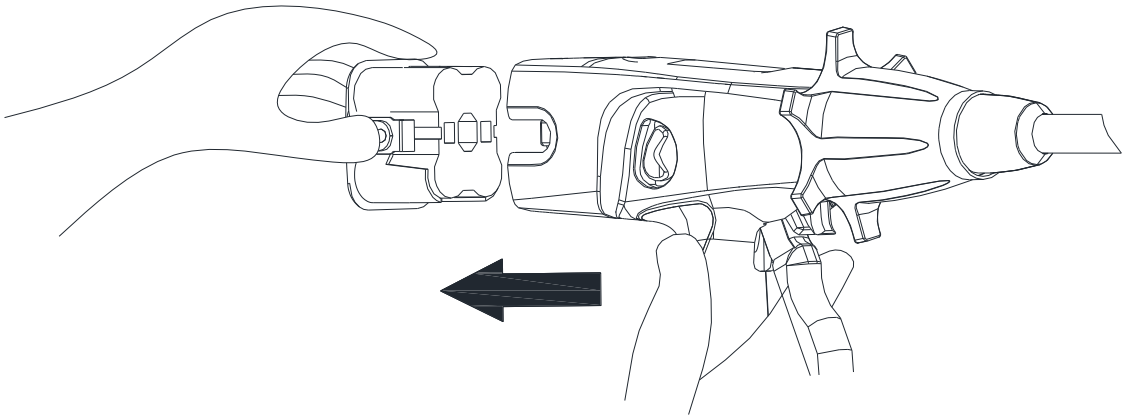


Figure 3-19

3.2. Familiar with device operation

1) Confirm that the size of the cartridge matches the device to be used (For example, ES 60 series devices are matched with ESA 60 series cartridge);
2) Become familiar with the bending action of the device by pulling on the fin on the knob with your index finger, and bending the device jaw at the front end of the device with the other hand(Figure 3-2).When the lateral pressure is applied in either direction, the device jaw will bend to the maximum angle of 45 degrees, at which point the bending resistance increases to signal the end of the bending arc. Maintain the lateral pressure while releasing the knob to lock the angle of the shaft. After locking the jaw, release the lateral pressure. Release the knob before reaching the end of the bending arc, and the device jaws will also be locked at an angle of about 15-30 degrees. To return the device jaw to the straight position, pull on the fin of the knob to release the bending angle locking action, and the device jaw will return automatically.
3) Before using the device, please confirm the compatibility of all devices and accessories (refer to **Warnings and Precautions**).

3.3. Install the cartridge for the device

1) Remove the device, primary lithium battery pack and cartridge from their respective

packages by aseptic operation.

2) Install the primary lithium battery pack. The primary lithium battery pack must be installed before use. Insert the primary lithium battery pack by lining up the release plate on the battery pack with the slot on the rear of the device. The primary lithium battery pack can be inserted in either direction without up and down (Figure 3-3). Ensure that the primary lithium battery pack is fully inserted into the device. When the primary lithium battery pack is fully inserted, a "click" can be heard.
3) **Note:** The device must be used within 12 hours after the primary lithium battery pack is inserted. Refer to the **Primary Lithium Battery Pack Disposal** section for primary lithium battery pack disposal instructions.
4) Before installing the cartridge, ensure that the device is in the open position (Figure 3-1).
5) Examine whether there is a cartridge protective cover on the cartridge. If cartridge protective cover is not in place, the cartridge shall be discarded.

Warning:

a) The cartridges are sterilized before leaving the factory and provided in a sterile state. The initial packaging (i.e. sterile packaging) shall be checked before use. If the initial packaging is damaged, it is prohibited to use.
b) Loading a cartridge with improper size or model into the device (for example, loading a 60mm cartridge onto a 45mm device) may only remove the tissue and not anastomose.

Note:

a) Before using the device, the tissue thickness must be carefully evaluated. Refer to the table 2-2 to select the appropriate cartridge.
b) The appropriate cartridge should be selected according to the total thickness of tissue and staple line reinforcement material. The use of staple line reinforcement material with the device may require greater firing force and may reduce the number of times the device can be fired. When using staple line reinforcement materials, follow the instructions of the material manufacturer.

6) Place the new cartridge against the bottom of cartridge jaw and insert it in a sliding manner until the cartridge alignment stops in the cartridge alignment slot. Clamp the cartridge firmly in place, remove the cartridge protective cover and discard it. The device is now fitted with Ti staple and can be used immediately (Figure 3-4).

Note:

After removing the cartridge protective cover, observe the surface of the new cartridge. If the color mark can be seen, the cartridge must be replaced (If color marks can be seen, there may be no Ti staple in the cartridge).

3.4. Use of device

1) Close the device jaws by squeezing the closing trigger until it locks into place (Figure 3-5). Hearing a "click" indicates that the closing trigger and the jaw have been locked in place.

When the device jaws are closed, the red firing safety switch and firing trigger are exposed.
Note: Do not pull the red firing safety switch or firing trigger at this time. The device may be partially or completely fired and will needs to be reloaded before being used on the tissue.

2) The device is inserted into the body cavity through an appropriately sized Trocar or through body surface incision (Figure 3-6). When using the Trocar, the device jaws must be closed and passes through the Trocar sleeve before opening the device jaw.

Note: When placing the device through the Trocar or incision, avoid inadvertently pulling the red firing safety switch and firing trigger. The device may be partially or completely fired and will needs to be reloaded before being used on the tissue. If the device has been partially fired, take out the device, slide the knife reverse switch forward to return the knife to the original position (Figure 3-7). To open the jaws, squeeze closing trigger, and then simultaneously press the reset button on either side of the device (Figure 3-8). Slowly release the closing trigger while maintaining pressure on the reset button (Figure 3-9). Remove the cartridge and insert a new cartridge (see Device Reloading).

Note: At any time, if the knife reverse switch does not return the knife to the original point and the jaw does not open:

a) First, ensure that the primary lithium battery pack is firmly installed and that the device has power (Figure 3-10); then, try the knife reverse switch again (Figure 3-7).

b) If the knife still does not reset, use the manual override. After the manual override is used, the device is disabled and cannot be used for any subsequent firing. To use the manual override, remove the manual operation manhole cover panel on the top of the device. At this time, the manual knife return rod is exposed, and move the rod forward and backward until it cannot be moved (Figure 3-11). The knife is now at the original point. It can be confirmed by observing the position of the knife blade indicator on the bottom of the cartridge jaw (Figure 3-12). Discard the device.

3) Once the device enters the body cavity, squeeze the closing trigger, and then simultaneously press the reset button on either side of the device (Figure 3-8). While maintaining the pressure on the reset button, slowly release the closing trigger, reopen the jaw, and return the closing trigger to the original position (Figure 3-9).

4) If necessary, use your index finger to push the fin of the knob downward or upward and rotate the device jaw. The device shaft will rotate freely in either direction (Figure 3-13).

5) When bending the device jaw in the body cavity, select an appropriate surface (a body structure, organ or another device) as the contact surface, bend the device jaw and ensure that it is within the field of vision. Place the transverse side of the device jaw opposite to the desired joint direction against the contact surface (the device jaw must be open to bend the device) (Figure 3-14).

Warning: Do not attempt to bend by pressing the front of the device jaw against the contact surface, as tissue damage or tissue trauma may be caused (Figure 3-15). Pull back the fin of the knob with your index finger, sweep to the side of the joint, and gently push the device handle to the contact surface. During this action, the device jaws should always be against the contact surface. After reaching the required bending angle, release the knob to lock the bending angle (the device is only locked at the predetermined angles of 15 degrees, 30 degrees and 45 degrees).
Note: The maximum bending angle that the device can reach is 45 degrees. When using body structures or organs as contact surfaces, particular attention should be placed to the visual and tactile feedback information received from the device. When the maximum angle is reached, the resistance will increase indicating that the maximum angle has been reached. Avoid exerting excessive pressure on the tissue, as it may cause tissue damage or tissue trauma.

6) Position the device around the tissue to be anastomosed.

Note: Ensure that the tissue is placed flat between the device jaws and in a properly position. If the tissue is folded along the cartridge, especially at the fork of the device jaw, the staple line may be incomplete.
The scale mark on the distal end of the anvil and the cartridge jaw represents the distal end of the staple line, and the scale mark with "CUT" on the cartridge jaw represents the cut line of the device (Figure 3-1).
Note: When positioning the device at the application site and ensure that there are no obstructions such as clips, stents,guide wires,etc. within the device jaw. Firing over an obstruction may result in incomplete cutting, poor stapling and / or inability to open the device jaws.

7) After positioning the device jaw, squeeze the closing trigger towards the handle until it is locked, so as to close the device jaw. Hearing or feeling a "click" indicates that the closing trigger and device jaws have been locked (Figure 3-5). When the device jaws are closed, the red firing safety switch and firing trigger are exposed. After closing and before firing,holding the jaw in place for 15 seconds may result in better compression and staple forming.

Note:

a) Ensure that the tissue does not extend (extruded) proximal to the proximal scale line on the device (Figure 3-1). Tissue squeezed beyond the proximal scale line of the device may only be removed without anastomosed.
b) If the closing trigger is difficult to lock, **reposition the device and clamp less tissue.** Ensure that the correct cartridges are selected (refer to **Model and size of cartridge table**).
c) If the closing trigger cannot work and the device jaw cannot clamp the tissue, the device shall not be fired. Remove the device and do not continue to use it.

8) Pull back the red firing safety switch so that the firing trigger can be pulled. (Figure 3-16)

9) Pull the firing trigger to fire the device. At this time, the motor starting sound will be heard (Figure 3-17). Continue to press the firing trigger until the motor stops (audible feedback). Alternatively, for enhance tissue compression, the user can pulse pull the firing trigger throughout the firing cycle until the crosscutting is completed.

Note:

a) Since the motor will stop when it is stall, it is important to conduct a visual inspection to confirm that the Knife Blade Indicator on the bottom surface of the cartridge jaw reaches the cutting end.

b) When trying to clamp too much tissue between the jaws, or clamping too dense / thick tissue before the jaws, forcing the trigger to complete the firing may cause the motor to stall and the knife to stop. If this happens, release the firing trigger, slide forward to the reversing switch, remove the device and reload (Figure 3-7). Then, position the device at the part with less tissue, or use a more suitable cartridge (please refer to **Model and size of cartridge table**).

10) To complete the firing action, release the firing trigger to activate the motor and automatically reset the knife to the original position where the knife will stop. In this position, the device is locked until the jaws are opened and re-closed.

Note: If it is necessary to interrupt the firing action, or if it is inadvertently interrupted due to releasing the firing trigger during firing, pull the firing trigger again to continue. The cutting state can be determined by observing the knife blade indicator on the bottom surface of the cartridge jaw at the beginning and end of firing (Figure 3-1). Once the knife reaches the end of the firing, releasing the firing trigger and the knife will automatically reset to the original position.

Note: If the device is locked, the motor will stop. Release the firing trigger and slide the knife reverse switch forward to reset it to the original position (Figure 3-7). In this position, the device should be removed, opened and reloaded to continue. To open the jaws, squeeze the closing trigger, and then simultaneously press the reset button on either side of the device (Figure 3-8). Slowly release the closing trigger (Figure 3-9) while maintaining pressure on the reset button. Please follow the instructions for reloading the device.

Note: At any time, if the reversing switch does not return the knife to the original point and the jaw does not open:

a) First, ensure that the primary lithium battery pack is firmly installed and that the device has power (Figure 3-10); then, try the knife reverse switch again (Figure 3-7).

b) If the knife still does not reset, use the manual override. After the manual override system is used, the device is disabled and cannot be used for any subsequent firing. To use the manual override, remove the manual operation manhole cover panel on

the top of the device. At this time, the manual knife return rod is exposed, and move the rod forward and backward until it cannot be moved (Figure 3-11). The knife will is now be at the original point. It can be confirmed by observing the position of the knife blade indicator on the bottom of the cartridge jaw (Figure 3-12). Discard the device.

Note:

a) Incomplete firing may result in malformed staples, incomplete cut lines, bleeding or difficulty in removing the device.

b) The use of staple line reinforcement material with the device may reduce the number of shots of the device. When using staple line reinforcement materials, the instructions of the material manufacturer shall be followed.

c) Cross suture may shorten device life.

d) If the firing mechanism does not work, do not continue to use the device.

11) To open the jaws, squeeze closing trigger, and then simultaneously press the reset button on either side of the device (Figure 3-8). Slowly release the closing trigger while maintaining pressure on the reset button (Figure 3-9).

Note: After pressing the reset button, the jaw does not open automatically. First ensure that the knife is at the origin position. The position of the knife can be confirmed by observing the knife blade indicator on the bottom surface of the cartridge jaw (Figure 3-12). If the knife blade indicator is not at the origin position or the position of the knife cannot be confirmed, slide the knife reverse switch and start the motor to reset the knife to the origin position (Figure 3-7). Using the reset button, try to open the jaws again. If the jaw cannot be opened at this time, gently pull the closing trigger upward away from the handle until both firing trigger and closing trigger return to their original position.

12) Gently pull the device away from the severed tissue to ensure that it is released from the device jaws. Check the anastomotic line to see whether the hemostasis / air sealing effect and the Ti staple are properly formed. Minor bleeding can be treated by electrocautery, manual suture or other appropriate methods.

13) Before taking out the device, keep the device jaw away from all obstacles in the body cavity, keep the device jaw open and within the field of vision, and pull the fin of the knob , and the device jaw will automatically return to the straight position.

14) To remove the device from the body cavity, squeeze the closing trigger until it is locked, so as to close the device jaw (Figure 3-5). Completely remove the device with the device in the closed position.

3.5. Device Reloading

1) Remove the cartridge from the package by aseptic operation.

2) Before installing the cartridge, ensure that the device is in the open position (Figure 3-1).

3) Push the cartridge upward (towards the anvil) to unsnap it from the cartridge jaw. Remove and discard the used cartridge (Figure 3-18).

Note: Before reloading the cartridge for the device, flush and wipe the surface of the anvil and cartridge jaw with sterile solution to eliminate unused Ti staples from the device. The device shall not be used until there is no Ti staple on the surface of the anvil and cartridge jaw through visual inspection.

4) Check whether there is a cartridge protective cover on the new cartridge. If there is no cartridge protective cover on the cartridge, discard the new cartridge.

Note:

a) Before using the device, the thickness of the tissue must be carefully evaluated. For information on the correct selection of cartridge, please refer to the **Model and size of cartridge table**

b) The appropriate cartridge should be selected according to the total thickness of tissue and staple line reinforcement material. The use of staple line reinforcement material with the device may require greater firing force and may reduce the number of times the device can be fired. When using staple line reinforcement materials, follow the instructions of the material manufacturer.

Note:

Loading a cartridge with improper size or model into the device (for example, loading an ESA60 series cartridge onto an ES 45 series device) may only remove the tissue and not anastomose.

5) Place the new cartridge against the bottom of cartridge jaw and insert it in a sliding manner until the cartridge alignment stops in the cartridge alignment slot. Clamp the cartridge firmly in place, remove the cartridge protective cover and discard it. The device is now fitted with Ti staple and can be used immediately (Figure 3-4).

Note:

After removing the cartridge protective cover, observe the surface of the new cartridge. If the color mark can be seen, the cartridge must be replaced (If color marks can be seen, there may be no Ti staple in the cartridge assembly).

3.6. Primary Lithium Battery Pack Disposal

- The battery pack does not need to be kept in the device. After it is removed from the device, it can be directly put into the battery recycling bin or normal waste stream according to your local regulations.
- Before installation into the device, if the primary lithium battery pack needs to be disposed of prior to installation into the device (for example, if the product exceeds the validity period indicated on the package, throw away the primary lithium battery pack).
- After the device is used, the primary lithium battery pack must be removed from the device before disposal.
- If the primary lithium battery pack requires decontamination before disposal, please handle it according to the relevant regulations of the hospital.
- To remove the primary lithium battery pack, squeeze the battery pack release tap and pull

the primary lithium battery pack back in a straight line (Figure 3-19).

- Note: It is not necessary to disassemble the primary lithium battery pack.

Note: Do not use the hospital autoclave to sterilize or disinfect the primary lithium battery pack. The stapler and battery after use shall be disposed of in accordance with the regulations on the management of medical waste.

4. Warnings and Precautions

- Avoid use of the Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, monitor the Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit and the other equipment to ensure normal operation.
- Class A device is intended to be used in an industrial environment. Due to the radiation disturbance of stapler, it may be potentially difficult to ensure electromagnetic compatibility in other environments.
- When used with the endoscope of CF application part, this product should be discontinued when the function of the endoscope is lost.
- If the endoscope of CF application part is used, we should choose to use the stapler endoscope accessory that minimizes the total patient leakage current.
- The stapler cannot be used simultaneously with high-frequency surgical device.
- The stapler should be avoided in case of explosive gas.
- Ti staple 2.6 model for Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit cannot be used for tissues with a thickness of less than 1.0mm after compression or tissues and organs that cannot be properly compressed to 1.5.
- Ti staple 3.6 model for Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit cannot be used for tissues with a thickness of less than 1.5mm after compression or tissues and organs that cannot be properly compressed to 1.8.
- Ti staple 3.8 model for Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit cannot be used for tissues with a thickness of less than 1.8mm after compression or tissues and organs that cannot be properly compressed to 2.0.
- Ti staple 4.1 model for Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit cannot be used for tissues with a thickness of less than 2.0mm after compression or tissues and organs that cannot be properly compressed to 2.3.
- Ti staple 4.2 model for Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit cannot be used for tissues with a thickness of less than 2.3mm after compression or tissues and organs that cannot be properly compressed to 2.6.

Suggestion:

- When stapler is used with other ME device, potential safety hazards caused by joint use shall be avoided.
- Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit can only be performed by personnel who have received sufficient training and are familiar with

minimally invasive surgery. Before performing any minimally invasive surgery, please consult the medical literature relative to techniques, complications and related risks of minimally invasive surgery.

- The diameter of minimally invasive devices produced by different manufacturers may vary. When minimally invasive devices and accessories produced by different manufacturers are used in the same operation, the compatibility of devices and accessories must be confirmed before operation.
- When using other technologies (e.g. electrocautery) in operation, follow the precautions recommended by the original equipment manufacturer to avoid use related injuries.
- Failure to follow the instructions correctly may lead to serious surgical consequences, such as leakage or cracking.
- Check the package for damage during transportation. Do not use device if the package is damaged.
- Each device can be fired up to 12 times. Do not load the device more than 12 times. The use of the device with staple line reinforcement may reduce the number of firings.
- Loading a cartridge with improper size or model into the device (for example, loading an ESA60 series cartridge onto an ES 45 series device) may only remove the tissue and not anastomose.
- The tissue thickness should be carefully evaluated before using the cartridge. For information on the correct selection of cartridge, refer to the **Model and size table of cartridge.**
- The appropriate cartridge should be selected according to the total thickness of tissue and staple line reinforcement material. The use of staple line reinforcement material on the device may require greater firing force and may reduce the number of times the device can be fired. When using staple line reinforcement materials, follow the instructions of the material manufacturer.
- Before use, remove the cartridge protective cover and observe the surface of the new cartridge. If the color mark can be seen, the cartridge must be replaced (If color marks can be seen, there may be no Ti staple in the cartridge).
- In order to insert and remove the device with joint head, the jaw of the device must be kept in a straight position and parallel to the shaft of the device. Failure to keep the jaws of the device in a straight line position will result it difficult to insert or remove the device, and may cause damage to the device.
- When placing the device through the Trocar or incision, avoid inadvertently pulling the red firing safety switch and firing trigger. The device may be partially or completely fired and will needs to be reloaded before being used on the tissue.
- Do not attempt to bend by pressing the front of the device jaw against the contact surface, as tissue damage or tissue trauma may be caused.
- The maximum bending angle that the device can reach is 45 degrees. When using body

structures or organs as contact surfaces, particular attention should be placed to the visual and tactile feedback information received from the device. When the maximum angle is reached, the resistance will increases, indicating that the maximum angle has been reached. Avoid exerting excessive pressure on the tissue, as it may cause tissue damage or tissue trauma.

- Ensure that the tissue is placed flat between the device jaws and in a properly position. If the tissue is folded along the cartridge, especially at the fork of the device jaw, the anastomotic line may be incomplete.
- Position the device at the application site and ensure that there are no obstructions such as clips, stents,guide wires,etc.within the device jaw. Firing over an obstruction may result in incomplete cutting, poor stapling and / or inability to open the device jaws.
- Ensure that the tissue does not extend (extruded) proximal to the proximal scale line on the device. Tissue squeezed beyond the proximal scale line of the device may only be removed without anastomosed.
- If the closing trigger is difficult to lock, **reposition the device and clamp less tissue.** Ensure that the correct cartridges are selected (refer to **Model and size of cartridge table**).
- If the closing trigger cannot work and the device jaw cannot clamp the tissue, the device shall not be fired. Remove the device and do not continue to use it.
- The use of staple line reinforcement material with the device may require increased force to close. When using staple line reinforcement materials, the instructions of the material manufacturer shall be followed.
- When trying to clamp too much tissue between the jaws, or clamping too dense / thick tissue before the jaws, forcing the trigger to complete the firing may cause the motor to stall and the knife to stop. If this happens, release the firing trigger, slide forward to the reversing switch, remove the device and reload (Figure 3-7). Then, position the device at the part with less tissue, or use a more suitable cartridge (please refer to **Model and size of cartridge table**).
- Since the motor will stop when it is stall, it is important to conduct a visual inspection to confirm that the Knife Blade Indicator on the bottom surface of the cartridge jaw reaches the cutting end.
- If the device is locked, the motor will stop. Release the firing trigger and slide the knife reverse switch forward to reset it to the original position (Figure 3-7). In this position, the device should be removed, opened and reloaded to continue.
- After the manual override system is used, the device is disabled and cannot be used for any subsequent firing. To use the manual override, remove the manual operation manhole cover panel on the top of the device. At this time, the manual knife return rod is exposed, and move the rod forward and backward until it can not be moved (Figure 3-11). The knife will now be at the original point. It can be confirmed by observing the position of the knife blade indicator on the bottom of the cartridge jaw (Figure 3-12). Discard the device.

- Incomplete firing may result in malformed staples, incomplete cut lines, bleeding or difficulty in removing the device.
- If the firing mechanism does not work, do not continue to use the device.
- After pressing the reset button, the jaw does not open automatically. First ensure that the knife is at the origin position. The position of the knife can be confirmed by observing the knife blade indicator on the bottom surface of the cartridge jaw (Figure 3-12). If the knife blade indicator is not at the origin position or the position of the knife cannot be confirmed, slide the knife reverse switch and start the motor to reset the knife to the origin position (Figure 3-7). Using the reset button, try to open the jaws again. If the jaw cannot be opened at this time, gently pull the closing trigger upward away from the handle until the both firing trigger and closing trigger return to their original position.
- After removing the device, check the anastomotic line， to see whether the hemostasis / air sealing effect and whether the Ti staple are properly formed. Minor bleeding can be treated by electrocautery, manual suture or other appropriate methods.
- Before reloading the cartridge for the device, flush and wipe the surface of the anvil and cartridge jaw with sterile solution to eliminate all unused Ti staples from the device. The device shall not be used until there is no Ti staple on the surface of the anvil and cartridge jaw through visual inspection.
- Before removing the device, make sure there is no tissue in the device jaw, and then close the device jaw.
- When selecting the cartridge, carefully consider the existing pathological conditions and all preoperative treatments that the patient may have undergone, such as radiotherapy. Some conditions or preoperative treatment may change the tissue thickness such that the range of appropriate tissue thickness for the standard selection of the cartridge assembly is exceeded.
- Do not use autoclave, ethylene oxide or radiation to sterilize or disinfect the primary lithium battery pack.
- If not handled properly, the battery may cause a fire. Do not disassemble, heat to above 100 ℃, sterilize with the autoclave, squeeze, puncture, external short-circuit contact or charge.
- Using any type of battery other than the battery equipped with the device may cause the Powered Endoscopic Linear Cutting Stapler to increase emissions or reduce immunity.
- Portable radio and mobile radio frequency communication equipment can affect medical devices. Please follow the instructions in the table below when using the Powered Endoscopic Linear Cutting Stapler.
- Avoid use of the Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, monitor the Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit and the other

equipment to ensure normal operation.

- Do not modify this device without the authorization of the manufacturer.
- Instruments or device in contact with body fluids may require special treatment to prevent biological contamination.
- This product is only for one-time use and shall be disposed of according to the regulations on the administration of medical waste.
- It is forbidden for people who are allergic to product materials.
- This product is a disposable surgical device, which has been sterilized with ethylene oxide. It is a sterile product and cannot be used if the package is damaged.
- Please pay attention to the sterilization date and expiration date before use.
- MRI compatibility

Non clinical tests have confirmed that titanium nails in the cartridge assembly can be safe under MR specific conditions. It can be safely scanned under the following conditions: the magnetic flux density of the stable magnetic field is equal to 3 Tesla; The spatial gradient magnetic field is 720 Gauss / cm; After 15 minutes of scanning, the maximum human average absorption ratio (SAR) was 2.7 W / KG.

- When performing magnetic resonance imaging (MRI) for patients with titanium nails in the cartridge, strictly refer to the contraindications, warnings and precautions of MRI equipment.

5. Contraindications

- Do not use this product on the aorta;
- Do not use this product for ischemic or necrotic tissue;
- Do not use the product for major vessels;
- Tissue thickness should be carefully evaluated before firing any staples. For the tissue compression requirements of each staple size (Ti staple closure height), please refer to the **Model and size of cartridge** (Table 2-2). If tissue cannot comfortably compress to the closed staple height,or easily compresses to less than the closed staple height, it is prohibited to use on the tissue because the tissue may be too thick or too thin for the selected Ti staple size.
- Other situations where Ti staples are prohibited.

6. Specifications

The rated voltage of Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit is 12V.

The Powered Endoscopic Linear Cutting Stapler can be waterproof and classified as IPX0 according to EN IEC 60601-1.

The Powered Endoscopic Linear Cutting Stapler needs to take special precautions in terms of electromagnetic compatibility (EMC), and needs to be installed and put into use in accordance with the electromagnetic compatibility (EMC) provided in this document. Portable radio and

mobile radio frequency communication equipment can affect medical electronic device.

- The stapler meets the relevant requirements of EN IEC 60601-1-2standard electromagnetic compatibility.
- The user shall install and use according to the electromagnetic compatibility information provided in the accompanying documents.
- Portable and mobile RF communication equipment may affect the performance of stapler. Avoid strong electromagnetic interference when using, such as close to mobile phone, microwave oven, etc.

Warning: Using any type of battery other than the battery equipped with the device may cause the Powered Endoscopic Linear Cutting Stapler to increase emissions or reduce immunity.

Warning: Portable radio and mobile radio frequency communication equipment may affect medical devices. Please follow the instructions in the table below when using the Powered Endoscopic Linear Cutting Stapler.

Warning: Avoid use of the Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, monitor the Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit and the other equipment to ensure normal operation.

7. Electromagnetic compatibility safety instructions

7.1. Electromagnetic compatibility safety instructions

The Powered Endoscopic Linear Cutting Stapler shall be operated according to the special prompt to meet the requirements of electromagnetic compatibility, and the installation and operation instructions shall be carried out according to the electromagnetic compatibility information provided in the accompanying documents.

Description of portable radio and mobile radio frequency communication devices that can affect medical electronic devices.

Except for the transducers and cables sold by the manufacturer of the equipment or system as spare parts of internal components, the use of accessories, transducers and cables other than those specified may increase the emission of the equipment or system or reduce the immunity.

Guidelines and manufacturer's statements - electromagnetic emissions

Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in

		nearby electronic equipment
RF emissions CISPR 11	Class B	Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidelines and manufacturer's statements-Electromagnetic Immunity (1)

The stapler is expected to be used in the electromagnetic environment specified below. The purchaser or user of Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit shall ensure that it is used in this electromagnetic environment:			
Anti-interference measurement	**IEC6060 Test level**	**Compliance level**	**Electromagnetic environment - Guidelines**
Electrostatic discharge IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	The floor shall be wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity shall be reduced by 30%.
Electrical fast transient pulse train IEC 61000-4-4	± 2kV pair power line ±1kV pair I / O lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±1kV line to line ±2kV line to ground	Not applicable	
Voltage dips, short interruptions and voltage changes on the power input line IEC 61000-4-11	0% UT: 0.5 cycle at 0°, 45°,90°,135°,180°,225°, 270°and 315° 0 % UT: 1 cycle and 70 % UT: 25/30 cycles Single phase: at 0° 0 % UT：250/300 cycle	Not applicable	

Power frequency magnetic field （50Hz/60Hz） IEC 61000-4-8	30A/m	Not applicable	The power frequency magnetic field shall have the horizontal characteristics of power frequency magnetic field in typical places in typical commercial or hospital environment.
Note: UT refers to the AC grid voltage before the test voltage is applied.			

Guidelines and manufacturer's statements-Electromagnetic Immunity (2)

The stapler is expected to be used in the electromagnetic environment specified below. The purchaser or user of Powered Endoscopic Linear Cutting Stapler and Single Use Loading Unit shall ensure that it is used in this electromagnetic environment.			
RF conduction IEC61000-4-6 RF radiation IEC61000-4-3	3V(effective value) 150kHz~80MHz 3V/m(effective value) 80MHz ~2.5GHz	Not applicable 3V/m	Portable and mobile RF communication equipment shall not be used closer to any part of the stapler than the recommended isolation distance, including cables. The distance shall be calculated by the formula corresponding to the transmitter frequency. Recommended isolation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz ～ 800 MHz $d = 2.3\sqrt{P}$ 800 MHz ～ 2.5 GHz
Electromagnetic environment - Guidelines			
Where: *P*——The maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (W); *d*——Recommended isolation distance, in meters (m). The field intensity of a stationary RF transmitter is determined by surveying the electromagnetic field c, and should be lower than the coincidence level in each frequency range d. Interference may exist around equipment marked with the following symbols.  The stapler is suitable for use in all facilities not for domestic use and not directly			

connected to the residential public low-voltage power grid for domestic use.
Note 1: At 80 MHz and 800 MHz, the formula of higher frequency band shall be used. **Note 2:** These guidelines may not apply in all cases. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human body.
[a] The field strength of fixed transmitters, such as base stations of wireless (cellular / cordless) telephones and ground mobile radios, amateur radios, am and FM radio broadcasting and television broadcasting, cannot be predicted accurately in theory. In order to evaluate the electromagnetic environment of fixed RF transmitter, the survey of electromagnetic site should be considered. If the field strength of the stapler is higher than the above applicable RF compliance level, the stapler shall be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as reorienting or repositioning the stapler. [b] The field strength should be less than 3 V / m over the entire frequency range of 150 kHz to 80 MHz.

Recommended distance between portable and mobile RF communication equipment and Powered Endoscopic Linear Cutting Stapler

The Powered Endoscopic Linear Cutting Stapler is expected to be used in the electromagnetic environment with controlled RF radiation disturbance. According to the maximum rated output power of communication equipment, the purchaser or user of the Powered Endoscopic Linear Cutting Stapler can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile RF communication equipment (transmitter) recommended below and the Powered Endoscopic Linear Cutting Stapler.

Maximum rated output power of transmitter W	Interval distance corresponding to different frequencies of transmitter/m		
	150kHz-80Mhz $d=1.2\sqrt{P}$	80MHz-800Mhz $d=1.2\sqrt{P}$	800MHz-2.5Ghz $d=2.3\sqrt{P}$
0.01	Not applicable	0.12	0.23
0.1		0.38	0.73
1		1.2	2.3
10		3.8	7.3
100		12	23

For the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column. Here P is the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W).

At 80MHz and 800MHz point frequencies, the formula of higher frequency band is adopted.

These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human body.

Recommended minimum separation distances

Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. This handpiece has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and this handpiece as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

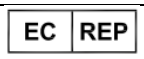
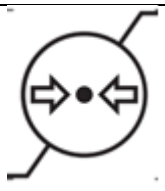
7.2. Product features

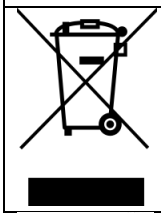
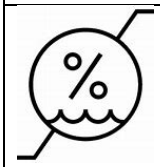
1) Category of device: internal power supply device;

2) Type of applied part(Jaw): CF type;
3) Power supply type of device: internal power supply; DC voltage 12V;
4) The device has application part: the closing trigger;
5) The device has no protection against the discharge effect of defibrillator;
6) The device does not have signal input and signal output parts;
7) Liquid inflow prevention degree: IPX0;
8) The device does not belong to AP type or APG type;
9) Device operation mode: continuous operation;
10) The device is a handheld device.

8. Symbols

8.1. Explanation of Figure, symbols and abbreviations used in packaging and labels

	Manufacturer		Authorized representative in the European Community
	Caution		EC notified body identification number
	Use-by date		Date of manufacture
	Batch code		Do not use if package is damaged
	Do not re-use		Sterilized using ethylene oxide
	Non-pyrogenic		Do not resterilize
	Medical Device		Unique device identifier
	Type CF applied part		Consult instructions for use or consult electronic instructions for use
	Temperature limit		Atmospheric pressure limitation
	This way up		Refer to instruction manual/ booklet

	Keep dry		Keep away from sunlight
	Waste disposal		Fragile, handle with care
	Humidity limitation		Made from 100% recycled fibres
	Serial number		Catalogue number
	MR Conditional		

9. Transportation and storage

9.1. Product transportation and storage conditions

Ambient temperature: -22℃-60℃

Relative humidity: 10%-80%

Atmospheric pressure: 80-106kPa

9.2. Product working conditions

Ambient temperature: 10℃-40℃

Relative humidity: 30%-75%

Atmospheric pressure: 80-106kPa

9.3. Sterilization method

After sterilization with ethylene oxide, the production date and sterilization period of the product are marked on each layer of packaging. Overdue products should not be used in clinical practice.

9.4. Production date and expiration date

See product label

9.5. Sterilization date

See product label

9.6. Shelf-Life

3 Years

9.7. Batch number

See product label

Manufacturer: MICONVEY TECHNOLOGIES CO., LTD.
Manufacturer Address: No.16, Fangzheng Avenue, Beibei District, 400714 Chongqing, P.R. China
Tel: + 86-23 6317 1596
Fax: + 86-23 6317 1516

After-sales service unit: MICONVEY TECHNOLOGIES CO., LTD.
www.miconvey.com

EC REP 【Authorized representative in the European Community】
Name: SUNGO Europe B.V.

Address:

Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands

Troubleshooting：If there is a dispute, the two parties will negotiate first, and if the negotiation cannot be resolved, the dispute will be dealt with by the court.