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Panther® Healthcare

CE 0197

Motorized Circular Stapler for Single-use

Instruction Manual

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EN

 Please read through these Manual carefully!

All information contained in this Manual has been confirmed to be correct. The Company shall not be liable for any accidental injuries or life-threatening incidents directly or indirectly arising from the use or improper operation of the product. All information contained in this Manual is protected by law.
This Manual only provides instructions for the use of the stapler and contains no information on surgical techniques.

Chapter 1 Overview

1.1 Product name

Motorized Circular Stapler for Single-use

1.2 Product model & specifications

1.2.1 Product characteristic parameters

Mode	Anastomotic Diameter	Number of Anastomotic Staples	Number of staple rows	Open Staple Leg Length	Adjustable Closed Staple Height
PCAA-21R	21±5mm	18	2	4.5mm	1.8±0.2mm
PCAA-24R	24±5mm	18	2	4.5mm	1.8±0.2mm
PCAA-26R	26±5mm	20	2	4.8mm	2.0±0.2mm
PCAA-29R	29±5mm	24	2	4.8mm	2.0±0.2mm
PCAA-32R	32±5mm	30	2	5.0mm	2.2±0.2mm
PCAA-34R	34±5mm	32	2	5.0mm	2.2±0.2mm

1.2.2 Basic Safety Features

a. Type of electric shock protection: internally powered equipment

b. Electric shock protection classification: Type BF

c. Liquid ingress protection grade: IPX0

d. Operating mode: Continuous operation

e. Equipment category: Not suitable for use in presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide

f. Rated supply voltage: DC 9 V

g. Input power: Not applicable

h. Defibrillation-proof applied parts: None

i. Signal input/output interface: None

j. Installation type: Non-permanently installed equipment

k. Overall dimensions: 479 mm (Length) × 160 mm (Width) × 40 mm (Height)

l. Weight: Approx. 650 g

m.Material of anastomotic staples: TA2 .

1.3 Indications

The product has application throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomoses.

1.4 Intended purpose

The product consists of four assemblies: anvil assembly, bent instrument shaft assembly, handle assembly and auxiliary accessories. It is intended to be used for the creation of anastomoses and has application throughout the alimentary tract for end-to-end, end-to-side and side-to-side anastomoses. It is suitable for open general surgery.

1.5 Patient selection criteria:

Adult patients aged 18 years and above undergoing reconstruction surgery for digestive tract lesions in the esophagus, stomach, and intestines

1.6 Intended users

Medical institutions have qualified doctors

1.7 Use times

Motorized Circular Stapler for Single-use is only for single use.

1.8 Complications and adverse reactions

1). Anastomotic fistula represents a common serious complication, and especially chest fistula is a worldwide challenge for treatment. In China, clinicians currently treat anastomotic fistulas by using a membrane-covered stent to block the leak.

2). Anastomotic stenosis: It is also a common complication after anastomosis. Treatment with interventional dilation stents may also achieve satisfactory results.

3). Bleeding or infection at the anastomosis: Treatment shall be administered according to the symptoms. .

1.9 Contraindications

1）This product shall not be used when the total thickness of compressed tissue is less than 1.0 mm or greater than 2.5 mm, or the tissue inner diameter is less than 21 mm. Use on tissue outside this thickness range will lead to unsatisfactory anastomosis, possibly causing

anastomotic leakage, insufficient hemostasis or unsatisfactory therapeutic outcomes.

2）Do not use the device on ischemic or necrotic tissues.

3）Do not use for vascular anastomosis, inflamed areas, edematous mucosa, tumor sites, or resection margins with suspected residual cancerous tissue.

1.10 Operating Environment

a) Temperature: +10℃ to +40℃;

b) Relative humidity: 30% to 75%;

c) Atmospheric pressure range: 800 hPa to 1060 hPa;

1.11 Sterilization method

The 100% ethylene oxide (EO) gas sterilization technology for EO sterilization. Provided that the primary packaging remains undamaged and unopened, the sterilization status of the product remains assured, rendering re-sterilization unnecessary prior to use.

1.12 Period of sterilization validity

The sterilization is valid for five years.

1.13 Principles of operation of the device

The stapler has a battery pack, which drives the transmission device through a motor to drive the staples that are pre-placed in two or several rows in parallel and misaligned in the component into the tissues that have been aligned and need to be stapled together. After passing through the tissue, the staples are blocked by the front anvil and bend inward, forming a "B" shape with misaligned arrangement, which staples the tissues together. Since small blood vessels can pass through the gaps in the "B" shape staples, it does not affect the blood supply at the stapling site and its distal end.

1.14Intended Clinical Benefits

Intended for end-to-end, end-to-side and side-to-side anastomoses in open alimentary tract surgery. It helps improve the anastomotic success rate, reduce the risks of anastomotic bleeding and anastomotic leakage, decrease mild-to-moderate postoperative complications, and facilitate achievement of intended surgical treatment outcomes.

Chapter 2 Device Overview

2.1 Product Structure Diagram

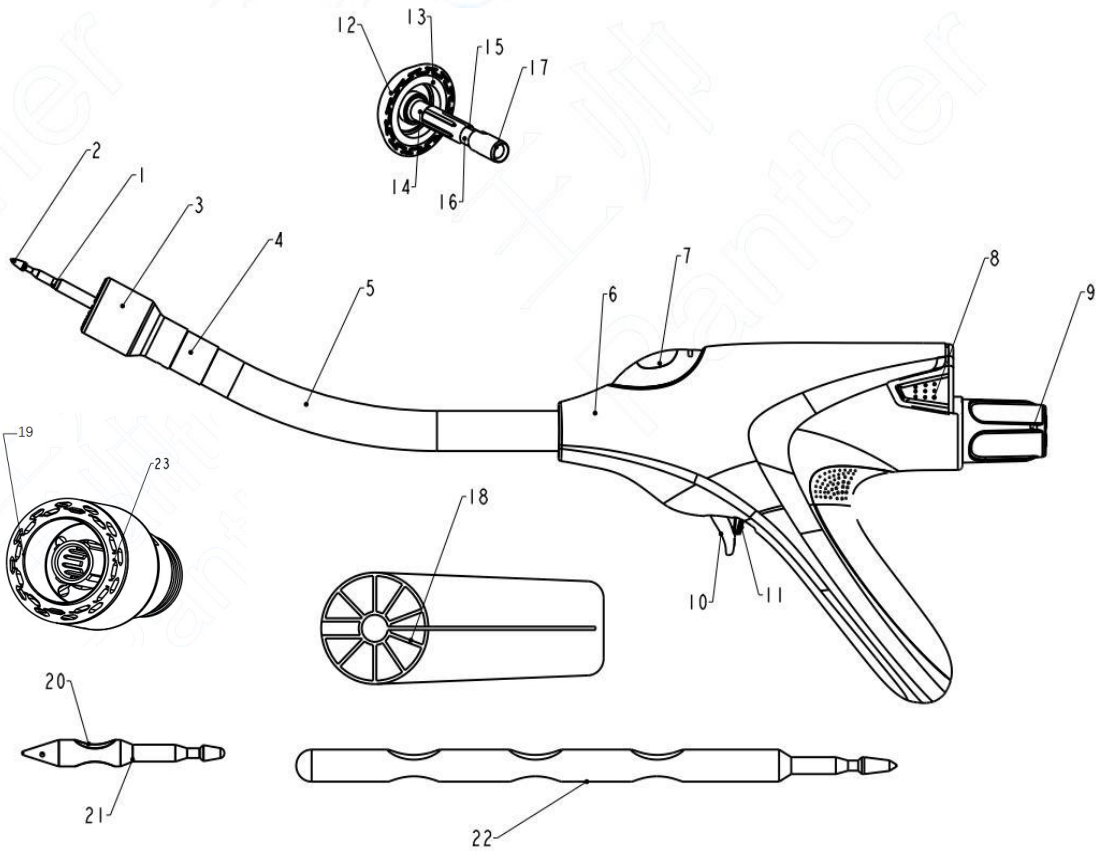
The product consists of four assemblies: anvil assembly, bent instrument shaft assembly, handle assembly and auxiliary accessories.

1. Anvil assembly (Items 12 – 17): Anvil Cap, Breakaway Washer, Locking Spring, Anvil Shaft

2. Bent instrument shaft assembly (Items 2 – 5, 18 – 19, 23): Device Trocar, Stapling housing, Front tightening ring, Instrument Shaft, Staple retaining cap, Cutter, Staple. The Cutter and Staple are installed inside the Stapling housing.

3. Handle assembly (Items 6 – 11): Outer casing, Visible Window, Battery Pack, Adjusting Knob, Firing Trigger, Red Safety

4. Auxiliary accessories (Items 21 – 22): Ancillary Trocar, Extension shaft



2.2Illustration and Nomenclature

1	Red ring	13	Breakaway Washer
2	Device Trocar	14	Suture Tying Area
3	Stapling housing	15	Locking Spring
4	Front tightening ring	16	Anvil grasping area
5	Instrument Shaft	17	Anvil Shaft
6	Outer casing	18	Staple retaining cap

7	Visible Window	19	Cutter
8	Battery pack	20	Finger Notch
9	Adjusting Knob	21	Ancillary Trocar
10	Firing Trigger	22	Extension shaft
11	Red Safety	23	Staple
12	Anvil Cap		

Chapter 3 Warnings, Cautions

3.1Warning and Prompt Description

1).If the green indicator light fails to illuminate or is significantly dim after power-on, it indicates insufficient battery power. Replace the entire device assembly.

2).If the white light illuminates after power-on, it means the battery compartment is reversely connected with positive and negative poles, rendering the device inoperable. Replace the entire device assembly.

3).If the indicator light is on but firing fails when the trigger is pulled, this indicates device malfunction or voltage lower than 5 V. Do not use the device under this circumstance and replace it immediately.

4).If the safety lock can be unlocked even when the red indicator pin is outside the viewing window, the device is faulty and shall be replaced.

5).If the white light does not turn on and firing cannot stop after completion of firing actuation, pull out the battery compartment immediately.

6).If the white light illuminates after firing, and secondary firing can still be triggered by squeezing the firing handle, the device is defective.

7).Surgical operation shall be performed promptly after battery insertion; prolonged standby storage is prohibited.

8).Unauthorized modification of the product may cause product functional failure.

9).Battery replacement by untrained personnel may result in overheating, fire or explosion hazards.

3.2Precautions

1) The use of this product shall follow the general operating principles of circular gastrointestinal staplers. Surgical procedures shall only be performed by personnel who

have been adequately trained and are familiar with relevant surgical techniques. Prior to any surgical procedure, consult professional medical literature regarding operative techniques, complications and clinical risks. This manual only provides general operation guidance for this motorized stapler and shall not substitute professional surgical guidelines. Operating surgeons shall refer to authoritative medical literature intraoperatively.

2) This is a single-use device. The entire device shall be discarded immediately after operation and must not be reused.

3) Inspect core stapling components including the Anvil assembly, stapling housing, blade ring and ring cutter before operation to prevent component displacement, detachment or loss during handling and intraoperative assembly.

4) After completing anastomosis, inspect residual tissue at the cutting margin. A continuous complete circular cutting edge confirms qualified anastomosis. If tissue defect or anastomotic leakage is found, perform supplementary hand suturing at the defective site to guarantee anastomotic sealing quality.

5) Contraindicate use for patients with confirmed hypersensitivity to any device materials that come into contact with human tissue.

6) Handle the stapler gently; do not drop, impact or collide the device. Forbidden destructive operations include filing, grinding, scraping, scratching and striking the device with hard metal objects. Do not use damaged devices. Securely fix the device during transportation and avoid consigning together with sharp hard objects.

7) After clinical use, perform full decontamination on the device first and detach the battery compartment assembly before disposal. The device and separated battery pack must be submitted to designated professional WEEE electronic waste recycling collection points. Do not discard the device together with unsorted municipal household waste, and random dumping is prohibited to prevent environmental pollution and leakage of restricted hazardous substances.

8) Prevent liquid and foreign substances from penetrating the internal electronic structure of the device, including the battery compartment assembly and internal wiring.

9) Battery pack disposal shall comply with the requirements specified in the dedicated section *Disposal of Battery Pack*.

10) Select the appropriate specification of stapler according to the thickness and diameter of target digestive tract tissue before deployment.

11) Verify the safety and functional reliability of matched auxiliary accessories including the ancillary trocar and extension rod prior to operation.

12) Visually inspect the surface of the stapling housing preoperatively. If staples, blade ring or ring cutter protrude above the plane of the stapling housing, replace the whole device with a new sterile unit.

13) Before locking the Anvil assembly onto the guide shaft, confirm that target tissue is fully positioned between the Anvil assembly and stapling housing. Misplaced tissue will cause docking failure of the Anvil assembly, accidental separation during tissue tightening, and malformation of staples after firing.

14) Thoroughly check hemostasis status, anastomotic continuity and leakage risk after stapling. Pre-existing metal clips, sutures or foreign implants within the anastomotic area will compromise anastomotic integrity. Implement remedial measures such as supplementary suturing or electrocoagulation when necessary.

15) Unauthorized structural modification of the main device, stapling housing and staple assembly is strictly prohibited, which will directly lead to functional failure of the stapler.

16) This disposable motorized circular stapler is factory sealed and ethylene oxide sterilized, intended for single use on one patient only. Once the sterile packaging is opened, reuse, reprocessing, resterilization and repackaging are totally forbidden. Reprocessing disposable devices will damage structural stability of the stapling housing, Anvil

assembly and cutting components, triggering device malfunction, patient trauma, severe infection, cross-contamination, infectious disease transmission and even life-threatening adverse outcomes.

17) Hospitals shall complete mandatory manufacturer-provided operational training before initial clinical use of the product. The manufacturer provides training PPT and physical device demonstration covering assembly of the battery compartment assembly, guide shaft, adjusting knob and full firing workflow.

Chapter 4 Operating Instructions

Prior to Using Device

Verify compatibility of all devices and accessories prior to using the device.

Preparing the Device for Use

1. Using sterile technique, remove the device and battery from the package. To avoid damage, do not flip or drop the device or battery into the sterile field.

2. Install the Battery Pack. The Battery Pack must be installed prior to use. Insert the Battery Pack by lining up the release tabs on the Battery Pack with the slots on the rear of the device. Ensure Battery Pack is fully inserted into the device. An audible click will be heard and the Tissue Compression Scale backlight will be illuminated when the Battery Pack is fully inserted.

CAUTION: The device must be used within 12 hours of inserting the Battery Pack Failure to use within this time frame may cause the battery to be depleted. **Refer to Battery Pack Disposal** for Battery Pack disposal instructions.

3. After the Battery Pack is installed, adjust the adjusting knob counterclockwise, remove the protective cover and anvil. The blister box contains an ancillary Trocar and an extension shaft. Do not discard the ancillary Trocar if you expect to use it. Keep the ancillary Trocar and extension shaft in a sterile area for following use. Refer to the section on Using ancillary Trocar.

CAUTION: Before preparing the firing device, avoid accidentally releasing the red safety. Premature release of the red safety will remove the firing protection prematurely, which will affect the process of adjusting the height of the staple.

Using the Device

CAUTION: Do not inadvertently release the Red Safety or Firing Trigger until ready to fire the device. Releasing the Red Safety removes protection from premature firing which will compromise the ability to select the desired staple height.

1. The device can be used with either of the following two techniques: A) the Open Lumen Purse String Technique, or B) the Closed Lumen Stapling Technique (double or triple stapling technique).
2. Open the device by tuning the Adjusting Knob counter clockwise until the Anvil Shaft is fully exposed. Remove the anvil to expose the Device Trocar. Retract the Device Trocar by rotating the Adjusting Knob clockwise until a stop is reached. Check the Device Trocar to verify that it is fully retracted before proceeding.

   The device may also be inserted without removing the anvil if the preferred application is a sutured purse-string technique. In this case, however, prior to insertion, ensure the anvil is properly attached and the device is fully closed by rotating the Adjusting Knob clockwise.
3. Insert the anvil into the lumen using either technique ensuring the tissue is located at the Suture Tying Area.
4. With the Anvil assembly (Items 12-17) removed, and the Device Trocar (Item 2) fully retracted by turning the Adjusting Knob clockwise until it stops, insert the device into the targeted anastomosis area.

   NOTE: Component numbers in this IFU correspond to those listed in Chapter 2.
5. Fully extend the Device Trocar and pierce tissue by holding the device while gently rotating

   the Adjusting Knob counter-clockwise. Continue to push the tissue down until the Red ring is visible.

CAUTION: Keep the Device Trocar visible at all times to prevent injury or inadvertent trauma to adjacent structures. DO NOT use the Anvil Shaft to assist in piercing the tissue by placing it over the unexposed Device Trocar to avoid inclusion of tissue within the Anvil Shaft. DO NOT use it for piercing.

6. Grasp the Anvil Grasping Area and reattach the anvil by sliding the Anvil Shaft over the Device Trocar and pushing until the anvil snaps into its fully seated position. The Red

ring on the Device Trocar will be covered when the anvil is fully attached. If necessary, hold the adjusting knob to prevent the Device Trocar from retracting during laparoscopic anvil attachment.

CAUTION: DO NOT clamp across or grip on the Locking Springs when attempting to reattach the anvil as this will prevent anvil attachment.

CAUTION: Ensure the Anvil is attached by verifying the Red ring is covered and the anvil is secure. The device will not fire with an unsecure anvil

7. While closing the device, keep the organ segments in proper orientation. Inspect to ensure extraneous tissue is excluded. To close the device, turn the Adjusting Knob clockwise.

CAUTION: Ensure tissue thickness lays flat and is evenly distributed within the device. Excess tissue on one side may result in unacceptable staple formation and can result in staple line leakage.

8. As the final adjusting revolution is approached, visible window moves into the green range of the Tissue Compression Scale. Adjust the device until appropriate tissue resistance is felt for a secure anastomosis. Wait 15 seconds to allow for adequate tissue compression, and adjust if needed to maintain appropriate tissue resistance. Providing visible window falls fully within the green range of the Tissue Compression Scale upon firing, the device will form staples at the height indicated for the selected tissue compression.

   Markings are provided in the Tissue Compression Scale to serve as reference points only. Refer to the Product Codes Table for adjustable closed staple height range.

Product Model	CLOSED STAPLE HEIGHT
PCAA-21R	1.8 mm
PCAA-24R	2.0 mm
PCAA-26R	2.0 mm
PCAA-29R	2.0 mm
PCAA-32R	2.2 mm
PCAA-34R	2.2 mm

9. Pre-fire checklist:

Red staple height indicator is fully within green range. Anvil is properly attached.

CAUTION: The device will not fire if the anvil is not properly attached or if visible window is not fully within the green range of the Tissue Compression Scale.

10. To fire the device, draw the Red Safety back toward the handle. To ensure the device remains in the safe firing range, once the Red Safety has been released, do not turn the Adjusting Knob. Activate the firing sequence by completely depressing the Firing Trigger

    Remain still until the full firing sequence is completed which will be indicated by the illuminated white check light on the indicator window. It is not necessary to hold the trigger once the firing sequence has initiated. The user may notice audible feedback during the firing sequence when cutting through the breakaway washer. Once fired, the device cannot be fired again.

CAUTION: Do not attempt to manipulate the Adjusting Knob during the firing sequence. Doing so may result in malformed staples, incomplete cut line, bleeding, and leakage from the staple line and/or difficulty removing the device.

CAUTION: If excessive force is required to close the device, this may indicate there is too much tissue or thickened tissue in the device. Attempting to fire the device in this condition may result in malformed staples, incomplete cut line, bleeding, and leakage from the staple line and/or difficulty removing the device.

WARNING: If the firing cycle is not complete as indicated by the illuminated. To fire the device, draw the Red Safety back toward the handle. To ensure the device remains in the safe firing range, once the Red Safety has been released, do not turn the Adjusting Knob. Activate the firing sequence by completely depressing the Firing Trigger. Remain still until the full firing sequence is completed which will be indicated by the illuminated white check light on the indicator window. It is not necessary to hold the trigger once the firing sequence has initiated. The user may notice audible feedback during the firing sequence when cutting through the breakaway washer. The cutter may remain exposed and staples may not be fully formed. Use caution when removing a device with an exposed cutter. Since staples may not be fully formed, consider further reinforcement of staple lines.

WARNING: The device is designed to stop automatically at the completion of the firing. If device fails to automatically stop, remove the battery. Use caution when removing the device.

Failure to automatically stop may compromise the integrity of the anastomosis. Use caution when inspecting the anastomosis and consider further reinforcements of staple lines.

To safely release the device from the newly formed anastomosis, turn the Adjusting Knob counterclockwise for two complete revolutions or four half turns.

To withdraw the open device, rotate it 90° in both directions taking care to minimize movement of the distal tip. This ensures the tissue is released. Gently pull out the device while simultaneously rotating.

CAUTION: If the device does not freely release from the anastomosis or withdraw easily after rotation, turn the adjusting knob counterclockwise one additional complete revolution (360°) and attempt removal again by rotating the device 90° in both directions, taking care to minimize movement of the distal tip. Gently pull out the device while simultaneously rotating.

11. To inspect the donuts, remove the anvil, breakaway washer (if present), and donuts from within the cutter. Examine the integrity of the donuts and white breakaway washer. Donuts should be intact and include all tissue layers. Ensure that donuts are complete, and the white breakaway washer is completely transected into inner and outer concentric rings. If donuts or breakaway washer are not complete, the anastomosis should be carefully checked for leakage and appropriate repairs made.

12. Dispose of all opened devices whether used or unused. This device is packaged and sterilized for single use only.

13. Dispose of the Battery Pack. **See Battery Pack Disposal.**

Using the Ancillary Trocar

The radiopaque Ancillary Trocar is designed to facilitate controlled penetration through tissue selected by the surgeon. For example, a surgeon may elect to use the Ancillary Trocar to perform a triple stapling technique or end-to-side anastomosis.

CAUTION: Injury hazard. Keep the Ancillary Trocar visible at all times to prevent personal injury or inadvertent trauma to adjacent structures.

Attaching the Ancillary Trocar to the Anvil

1. The ancillary Trocar is placed in a blister box packaged with a Motorized Circular stapler.

2. To remove the ancillary Trocar from the blister box, hold the finger slot and pull it directly out perpendicular to the blister box.

3. Place the blunt end of the ancillary Trocar in the Anvil Shaft. Turn the auxiliary Ancillary Trocar about 45 degrees against the Anvil Shaft to ensure a firm connection.

CAUTION: If Ancillary Trocar is not properly seated in the Anvil Shaft, the Ancillary Trocar could detach from the anvil during manipulation

Detaching the Ancillary Trocar from the Anvil

1. Using the Finger Notches, rotate the Ancillary Trocar approximately 45 degrees in the Anvil Shaft and pull the Ancillary Trocar out of the Anvil Shaft.
2. Discard the Ancillary Trocar in a sharp's disposal.

Chapter 5

Storage, Disposal and Supplementary Regulatory Provisions

5.1 Storage Requirements & Shelf Life

Storage Precautions

Prohibited storage environments: direct sunlight, high-temperature & high-humidity areas, radiation/X-ray exposure areas, and strong electromagnetic field surroundings (near MRI, microwave/short-wave therapeutic devices, radio transmitters), to prevent device damage and infection risks.

Avoid heavy impact during storage to prevent structural damage.

Handle the product gently during loading, unloading and transit; stack strictly per outer packaging graphic symbols with proper protection.

Environmental Parameters for Storage & Transportation

Temperature: −22 ℃ ～+30 ℃;

Relative humidity: 10% ~ 65%;

Storage site: clean, dry and well-ventilated area; general transportation allowed with rainproof and shockproof protection.

Shelf Life

The product shelf life is 5 years.

5.2 Waste Disposal Rules

5.2.1 General Disposal Principle

Discard the product and all components in compliance with national and local legal requirements for medical waste management.

5.2.2**Battery Pack Disposal**

The Battery Pack has a built-in automatic discharge function and must be inserted into the device to activate this feature. The pack does not need to stay inside the device; it will continue discharging after being removed. Once the Battery Pack has completed its discharge cycle, it may be placed directly into waste bins designated in compliance with local WEEE (Waste Electrical and Electronic Equipment) regulations, subject to applicable regional waste management rules.

If the Battery Pack requires disposal before being fitted into the device (for example, if the product has exceeded the Use by Date printed on its packaging or the Battery Pack has been dropped), insert the Battery Pack into the device and then remove it to activate its built-in automatic discharge function. Once fully discharged, place the Battery Pack into dedicated waste bins that comply with WEEE (Waste Electrical and Electronic Equipment) regulations.

5.3 Serious Adverse Incident Reporting

The definition of serious adverse incident complies with MDR (EU) 2017/745. In case any serious adverse incident occurs: Within the European Union: The user has a legal obligation to report the serious adverse incident to the competent authority of the EU Member State where the user and/or patient is situated. Simultaneously, immediately inform the manufacturer, distributor and EU authorized representative. Outside the European Union: Perform adverse event reporting obligations in accordance with local medical device regulatory requirements and notify the manufacturer promptly.

Chapter 6 Electromagnetic Compatibility

1. This chapter is a reminder of electromagnetic compatibility. The Motorized Circular Stapler for Single-use shall be installed and used according to the electromagnetic compatibility information in this chapter.

2. A portable or mobile radio frequency communication device may affect the use of the Motorized Circular Stapler for Single-use. it is recommended to stay away from portable or mobile radio frequency communication devices or keep them in an off state when using the Motorized Circular Stapler for Single-use in a normal way,.

3. Warning: The use of any accessory other than the accessories provided by this company may lead to the increase of emission or to the decrease of immunity of the Motorized Circular Stapler for Single-use.

4. See Table 1.

5. The Motorized Circular Stapler for Single-use should not be close to or be superimposed with other equipment with the same or similar frequency. If the stapler is required to do so, it should be observed and verified to be able to operate normally under its used configuration.

6. See Table 2

7. See Tables 3,4,5.

8. Please choose the connection cables and their related accessories provided by this company in order to ensure that the normal use of the Motorized Circular Stapler for Single-use and that no increase of its emission or no decrease of its immunity

9、The use of non-specified accessories, transducers or cables in conjunction with the Motorized Circular Stapler for Single-use may result in increased emission or reduced immunity of the equipment or the system.

Table 1

Guidelines and Manufacturer's Statement-Electromagnetic Emission-Electromagnetic radiation guidelines		
Motorized Circular Stapler for Single-use is expected to be used in the following specific electromagnetic environments. Users and buyers of the Motorized Circular Stapler for Single-use the must ensure that this product is used in such an environment.		
Radiation Test	**Conformity**	**Electromagnetic environment-guidelines**
CISPR 11 Radio-frequency emission	Group 1	The product uses radio-frequency (RF) energy only for its internal functions. Therefore, it emits very little RF and causes minimal interference with nearby electronic devices.
CISPR 11 Radio-frequency emission	Class A	The product applies to all facilities that are not for domestic use and are not directly connected to the public low-voltage power supply network of the

		domestic residence
IEC 61000-3-2 Harmonic emission	inapplicable	
IEC 61000-3-3 Voltage fluctuation/Flicker emission	inapplicable	
CISPR 14-1 Radio-frequency radiation	Conformable	Motorized Circular Stapler for Single-use is not suitable for interconnecting with other equipment.

Table 2

Guidelines and manufacturer's statement-electromagnetic immunity guidelines			
Motorized Circular Stapler for Single-use is expected to be used in the following specific electromagnetic environments. Users and buyers of the Motorized Circular Stapler for Single-use must ensure that this product is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Coincidence Detection Level	Electromagnetic Environment-Guidelines
Electrostatic Discharge(ESD) IEC 61000-4-2	±4kV, ±8kV Contact discharge ±2kV, ±4kV, ±8kV, ±15kV Air discharge	±4kV, ±8kV Contact discharge ±2kV, ±4kV, ±8kV, ±15kV Air discharge	The floor should be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic materials, the relative humidity should be at least 30%.
Electrical Fast Transient Burst IEC 61000-4-4	2kV for AC main sport 1kV for signal port	Inapplicable	The grid power supply shall be of a quality typically applied in commerc or hospital environments.
Surge IEC 61000-4-5 Line to line	±2kV (Line to ground) ±1kV (Line to line) for AC mains port	Inapplicable	The grid power supply shall be of a quality typically applied in commercial or hospital environments.
Voltage Sag on Power Input Line, short interruption and voltage change IEC 61000-4-11	<5% UT, lasting for 0.5 weeks (On the UT, >95% temporary drop) 40% UT, lasting for 5 weeks (On the UT, 60% temporary drop) 70% UT, lasting for 25 weeks (On the UT, 30% temporary drop) <5% UT, lasting for 5 s (On the UT, >95% temporary drop)	Inapplicable	The grid power supply shall be of a quality typically applied in commercial or hospital environments. If the user [of the device or system] is required to operate without interruption during a power failure, it is recommended that [the device or system] be powered by an uninterruptible power supply or battery.
Power frequency magnetic field IEC 61000-4-8	30A/mg） （50/60Hz）	30A/m （50/60Hz）	The power frequency magnetic field should have the horizontal characteristics of power frequency magnetic field in typical places in a typical commercial or hospital environment.
Note: UT refers to the AC network voltage before voltage is applied.			

Table 3

Guidelines and manufacturer's statement - electromagnetic immunity guidelines			
Motorized Circular Stapler for Single-use is expected to be used in the following specific electromagnetic environments. Users and buyers of the Motorized Circular Stapler for Single-use must ensure that this product is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Coincidence Detection Level	Electromagnetic Environment-Guidelines
Radio-frequency Conduction IEC 61000-4-6 Radio-frequency Radiation IEC 61000-4-3	3V h) 150kHz~80MHz 3V/mf) 80MHz-2.7GHz 80%AM,1kHz c)	Inapplicable 3V/m	A portable or mobile radio frequency communication device shall be at a distance from any part of the Motorized Circular Stapler for Single-use (cables included) no shorter than the recommended isolation distance for the device. The specific distance shall be calculated by a formula corresponding to the transmitter frequency **Recommended isolation distance** $d=1.2\sqrt{\mathbf{P}}$ 80MHz~800MHz $d=1.2\sqrt{\mathbf{P}}$ 800MHz~2.5GHz where, P is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts(W); and d is the recommended isolation distance, in meters(m). [b] The field strength of the fixed RF transmitter is determined by the electromagnetic field site surveys[C] , and should be lower in each frequency range [b] than the Coincidence Detection Level. Interference may occur near devices marked with the following symbol. 
Note 1: The formula for the higher frequency range is adopted at frequencies 80MHz and 800MHz. Note 2: These guidelines may not be appropriate for all situations, as electromagnetic wave transmission is affected by absorption and emission from buildings, objects and human bodies.			
"a" field strengths of fixed transmitters, such as: wireless (cellular/cordless) telephones and base stations for ground mobile radios, amateur radio, AM (amplitude modulation) and FM (frequency modulation) radio broadcasting and television broadcasting, etc., These field strengths above cannot be predicted accurately in theory. In order to evaluate the electromagnetic environment of a fixed RF transmitter, the survey of electromagnetic field site should be considered. If the field strength in the place where the Motorized Circular Stapler for Single-use is located is measured to be higher than the RF Coincidence Detection Level for the above application, the device shall be observed and verified to be able to operate normally. If any abnormal performance is observed, supplementary measures, such as redirection or repositioning of the device, may be necessary. "b" In the whole frequency range of 150kHz-80kHz, the field strength should be less than 3V/m.			

Table 4

Recommended isolation distance between a portable or mobile radio frequency communication device and the [equipment or System]			
Motorized Circular Stapler for Single-use is expected to be used in an electromagnetic environment where RF harassment is controlled. According to the maximum output power of the communication device, buyers and users of the Motorized Circular Stapler for Single-use can prevent electromagnetic interference by maintaining the minimum distance recommended below between a portable or mobile radio frequency communication device (transmitter) and the Motorized Circular Stapler for Single-use.			
Rated maximum Output power of the transmitter W	Isolation distances for different frequencies of the transmitter (m)		
	150kHz~80MHz ISM Frequency Band $d=1.2\sqrt{P}$	80MHz~800MHz $d=1.2\sqrt{P}$	800MHz~2.5GHz $d=1.2\sqrt{P}$
0.01	Inapplicable	0.12	0.23
0.1	Inapplicable	0.37	0.74
1	Inapplicable	1.17	2.33
10	Inapplicable	3.69	7.38
100	Inapplicable	11.67	23.33
For any rated maximum output power of the transmitter not listed in the table above, the recommended isolation distance d, in meters(m), can be determined by the formula in the corresponding transmitter frequency column, where p is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (w). Note 1:The formula for the higher frequency range is adopted at frequencies 80MHz and 800MHz. Note 2: These guidelines may not be appropriate for all situations, as electromagnetic wave transmission is affected by absorption and emission from buildings, objects and human bodies.			

Table 5

Test Specifications for Immunity of Surgical Ports to RF Wireless Communication Devices						
Test Frequency (MHz)	Frequency Range a）（MHz）	Service a）	Modulation b）	Max Max Power(W)	Separation Distance(m)	Immunity Test Level （V/m）
385	380-390	TETRA	Pulse Modulation b） 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM c） **Deviation** ±5 kHz Sine 1 kHz	2	0.3	28
710 745 780	704-787	LTE Frequency Band 13,17	Pulse Modulation b） 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Frequency Band 5	Pulse Modulation b） 18Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Frequency Band 1,3,4,25, UMTS	Pulse Modulation b） 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth， WLAN, 802.11 b/g/n, RFID 2450, LTE Frequency Band 7	Pulse Modulation b） 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse Modulation b） 217 Hz	0.2	0.3	9
Note: The distance between the transmitting antenna and the device or the system can be reduced to 1 meter if the immunity test level requires to be reached. IEC 61000-4-3 allows a test distance of 1 meter.						
a） For some services, only uplink frequencies are included. b） The carrier shall be modulated using a square wave signal with a 50% duty cycle c) As an alternative to FM modulation, 50% pulse modulation at 18Hz can be used. Because while it does not represent actual modulation, this would be the worst case scenario.						

Chapter 7 MR Information

MRI Safety Information

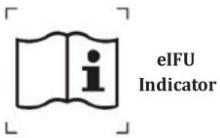
A person implanted with the Disposable Motorized Circular Stapler staple may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	Motorized Circular Stapler for single-use
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	720 gauss/cm
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	NA
Scan Duration	Staple rises maximum 1.5°C for 15 min of scanning as defined above
MR Image Artifact	Under T1 SE and GRE pulse sequence, Staple extended maximum 4.46mm artifact size compared to its original shape

The Implantable Staples are MR Conditional when the above conditions are met. The motorized Circular Stapler and cartridges is MR Unsafe

Chapter 8 Symbols and Meanings

No.	Symbols	Description
1		Caution
2		**Reference number**
3		Date of Manufacture
4		Manufacturer
5		Authorized representative in the European Union
6		Batch code
7		Use-by date
8		Sterilized using ethylene oxide
9		Sterile Barrier System
10		Consult instruction for use
11		Do not re-use
12		Do not re-sterilize
13		Do not use if package is damaged and consult instruction for use
14		Temperature limit
15		Humidity limitation
16		Medical device

17		CE label
18		Logo of manufacturer
19		Tear here
20		Fragile, handle with care
21		Keep dry
22		Keep away from sunlight
23		Separate collection for electrical and electronic equipment
24	IPX0	Anti-liquid inlet device
25		electronic Instructions for Use
26		Instructions for Use
27		Unique Device Identification
28		MR Conditional – See instructions for MR scan limitations.
29		Country of manufacture (China)

EU REP

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