Powered Articulating Endoscopic Stapler
Safety and Performance Information

Safety Signs and Definitions

The safety information contained in this manual helps users identify potential hazards and avoid danger. This manual uses three signs to highlight potential hazards:Warning, Caution, and Note.
This manual provides safety information regarding instrument use. Please read and understand all instructions completely before use. Failure to comply with warnings, cautions, and notes related to this instrument, may result in personal injury, instrument malfunction, and void warranty.

Symbol	Description
Warning	In terms of operation or maintenance procedures, failure to strictly adhere to relevant requirements may result in injury or death.
Caution	In terms of operation or maintenance procedures, failure to strictly adhere to relevant requirements may result in equipment damage or destruction.
Note	Operational tips or maintenance advice; failure to follow these may lead to errors.

Contraindications

Do not use the instruments on the aorta.
Do not use the instruments on ischemic or necrotic tissue.
Do not use any linear stapler on major vessels without making provision for proximal and distal control.
Tissue thickness should be carefully evaluated before firing any stapler. Refer to the Reload Product Codes Table below for tissue compression requirement (closed staple height) for each staple size. If tissue cannot comfortably compress to the closed staple height, or easily compresses to less than the closed staple height, the tissue is contraindicated as it may be too thick or too thin for the selected staple size.
These instruments are not intended for use when surgical stapling is contraindicated.
These instruments are not intended for the heart, central circulatory or central nervous system.

Side-effects

According to clinical and residual risk evaluations, poor stapling and other malfunctions can lead to potential complications, such as bleeding, blood transfusion requirements, leakage and infection, etc. Short-term readmission post-surgery may be required. These safety issues may occur under specific circumstances where the operation does not precisely align with the intended purpose, instructions for proper use, or warnings and cautions.

Warning

- Aseptic operational practices should be strictly implemented during use of this product.
- The user of the device must be a clinician with adequate training and familiarity with minimally invasive surgical techniques, and must be familiar with the procedures for operating this product.
- If other technical means (e.g., electrocautery) are to be used during the surgical procedure, follow the precautions described by the manufacturer of the original anastomotic stapler and cartridge in order to avoid associated hazardous conditions.
- Please refrain from using any batteries not provided by the company, as this may result in increased radiation from or decreased resistance to interference of the stapler.
- Avoid using the stapler in close proximity to or stacked on top of other equipment.If this is unavoidable, the position of the stapler in relation to the other equipment must be checked to ensure that they all work properly.
- The diameters of minimally invasive instruments from different manufacturers may vary. If minimally invasive instruments and accessories from different manufacturers must be used during a single procedure, check for compatibility before the procedure begins.
- No parts or components of our Powered Articulating Endoscopic Staplers may be replaced without the permission of Wuhan Mindray Scientific Co., Ltd.
- Check whether the cartridge model matches the stapler model to be used (for details, refer to the stapler and cartridge configuration table in the instruction manual).
- Once opened, the stapler and the cartridge must not be resterilized for use, regardless of whether it was used or not.
- If the firing trigger lock is not snapped, the firing trigger cannot be pulled and the instrument cannot be fired.
- Do not use any endoscopic linear stapler for major blood vessels if proximal or distal control is not provided.

Caution

- The product is intended for use in adults populations.
- Safety hazards and usage restrictions: Minimally invasive procedures should be performed by individuals with adequate training and familiarity with minimally invasive surgical techniques. The medical literature on the technique and its complications and hazards should be reviewed prior to performing any minimally invasive procedure.
- In the event of an accident during the correct use of the product, conventional manual suturing techniques should be employed promptly.
- Before firing the staple, the tissue thickness should be carefully assessed.
- Ensure that the tissue is appropriately positioned between the jaws. "Bunched" tissue along the cartridge, especially at the instrument jaw bifurcation, may result in an incomplete suture.
- The firing must be complete. Incomplete firing may result in malformed staples, incomplete cut lines, bleeding and leakage from the suture, or difficulty in removing the instrument.
- Closure and firing on excess or thickened tissue may result in suboptimal stapling outcomes, accompanied by incomplete sutures and consequent leakage, breakage, or suboptimal healing. Additionally, it may lead to damage to or malfunction of the instrument.
- Before closure, please ensure that all tissue residues in the jaws are removed.
- After removing the instrument, check the suture and ensure that hemostasis has been achieved and the anastomosis is correct. Minor bleeding can be controlled by using electrocautery, manual suturing, or other appropriate techniques.
- When placing the instrument at the surgical site, ensure that there are no obstructions (such as titanium staples, stents, and guidewires) in the jaws of the instrument, as firing onto an obstruction may result in incomplete cutting actions or improper staple formation.
- When tissue or suture support materials are used, the instructions provided by the manufacturer of the support materials should be followed. The combined use of the instrument and suture support material may increase the force required for firing, leading to a reduction in the number of times the instrument can be fired.
- The cartridge with an appropriate staple height should be selected based on the combined thickness of the tissue or suture support material, and careful consideration should be given to the pathological condition and the pre-procedure treatment received by the patient, such as radiation therapy. The pathological condition or pre-procedure treatment may have altered the tissue thickness, potentially causing it to exceed the range corresponding to the standard staple height selected.
- Instruments or materials that have been in contact with body fluids should undergo special handling to prevent biological contamination from occurring.
- The dimensions of minimally invasive devices may vary between manufacturers. Minimally invasive surgical instruments and their accessories made by different manufacturers may not be applied at the same time in a single procedure.
- This is a single-use, sterile surgery instrument that has been sterilized with ethylene oxide. Do not use if packaging is damaged.Before use, please check the sterilization date and the use-by date.
- Before use, please check the model and specifications of the stapler.
- If any defect is found in the staple within the cartridge, it must not be used.
- Any product that has been damaged due to improper storage, transportation, or handling must not be used.
- This is a single-use product, and after use, must be disposed of in accordance with local regulations.
- When patients with titanium staples from the cartridge of the instrument undergo an MRI scan, it is essential to strictly adhere to the contraindications, warnings, and precautions concerning the MRI equipment.
- This product is compatible with trocar of no less than φ12mm in size.
- Before each use, check the surface of the instrument for protrusions, rough surfaces, or sharp edges that could cause injury to the patient.
- Pre-surgical radiotherapy may result in tissue alterations. For example, these alterations may cause tissue thickening beyond that specified for the selected anastomotic staple. Careful consideration should be given to any pre-procedure treatment that the patient has received..
- According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, the side effects are concluded in the "Side-Effects" section. Appropriate knowledge of specific surgery-relevant side effects can be expected from the intended user. The residual risks associated with using the Powered Articulating Endoscopic Stapler have already been disclosed in the forms of warnings and cautions.
- After this product is used, the anastomotic staple stays in the body and a 1.5 T MRI and 3.0 T MRI can be performed.
- Before each use, check the surface of the instrument for protrusions, rough surfaces or sharp edges that could cause injury to the patient.
- Do not use this device on parenchymal organs that may be damaged under compression (e.g., organs such as the liver or spleen).

MRI Safety Information

Non-clinical testing of the worst-case implants has demonstrated that the implant matrix "Staples" is MR Conditional. A patient with staples can be safely scanned in an MR system meeting the following conditions. Failure to follow these conditions may result in injury to the patient.	
Item Name/Identification	Staples
Static Magnetic Field Strength[T]	1.5T or 3.0T
Maximum Spatial Field Gradient[T/m]	55T/m(5,500 gauss/cm)
RF Excitation	Circularly Polarized(CP)
RF Transmit Coil Type	Whole body transmit coil (short body coil), Head RF receive coil or Extremity RF receive coil
Maximum Whole Body SAR[W/kg]	whole body SAR <2.0W/kg at 1.5T And 3.0T
Maximum B_{1+RMS}[μT]	B_{1+RMS}<27.1μT at 1.5T Not reported for 3.0T
Scan Duration	for 15 minutes of continuous RF(a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 1.92mm.
If information about a specific parameter is not included,there are no conditions associated with that parameter.	
Note: All parameters are connected by AND logical conjunction and have to be within the limits always at the same time. For MR systems that use SAR only, SAR values shall be used. For MR systems that use B_{1+RMS} and SAR,B_{1+RMS} can be used.	

Note

- Before confirming that the staple is ready to fire, the firing trigger cannot be snapped, so as to avoid accidental firing of the staple.
- As the stapler and the cartridge of this instrument are packaged separately, the cartridge must be loaded before use.
- The cartridge of this instrument can be reloaded quickly, and the stapler can be fired a maximum of 12 times. The use of this device with suture reinforcement material may result in fewer firing times.

Warning

- Do not use hospital autoclaves to sterilize or disinfect the battery pack. After use, the stapler and batteries should be disposed of according to local regulations.
- If handled improperly, batteries may pose a fire hazard. Do not disassemble the battery pack, heat it above 100°C, or sterilize in an autoclave. Do not crush, puncture, short-circuit, or attempt to charge the battery.

Caution

- There is no need to disassemble the battery pack.

The stapler is powered by a DC 12V internal power source.
The stapler requires special precautions for electromagnetic compatibility (EMC) and should be installed and used as per the EMC information provided in this document.
Portable and mobile RF communication devices may have an impact on medical electronics.

Caution

- The stapler complies with the EMC requirements of the **EN/IEC 60601-1-2** standard.
- Users should install and operate the stapler based on the EMC information specified in the accompanying documentation.
- Portable and mobile RF communication devices may affect the performance of the stapler. When using the stapler, keep away from strong sources of electromagnetic interference, such as mobile phones and microwaves
- The stapler should not be used in close proximity to or stacked with other devices; if it is indeed necessary to do so, verify and ensure that it operates normally under the used configuration.
- Category A equipment is intended for use in industrial environments. Due to the radiation interference from the stapler, it may be difficult to ensure electromagnetic compatibility in other environments.
- When an endoscope with a CF model application portion is used together with this product, discontinue use of this product if the endoscope loses it function.
- If an endoscope with a CF model application portion is used, select the endoscope attachment with the minimum patient leakage current.
- The stapler should not be used simultaneously with high-frequency surgical devices.
- Avoid using the stapler in environments where there is a high concentration of explosive gases.
- When using the stapler together with other medical electronics, take precautions to avoid potential safety hazards that may arise.
- Except for attachments as internal component attachments, the use of unauthorized attachments may lead to an increase in emissions or a decrease in immunity for ME equipment or ME systems.

EMC

INTENDED ENVIRONMENT (EN/IEC 60601-1-2)

CAUTION: The Staplers is to be used by medical professionals qualified in the transportation, preparation, and use of surgical devices. The Staplers are intended for use in a sterile operating room environment in surgical procedures where surgical stapling is indicated.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Powered Articulating Endoscopic Stapler including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

ELECTROMAGNETIC COMPATIBILITY GUIDANCE (EN/IEC 60601-1-2)

Electromagnetic Emissions Guidance

Electromagnetic Emissions Guidance

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
The Staplers are intended for use in the electromagnetic environment specified below. The customer or the user of the Stapler should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1 Class A	The Staplers are suitable for use in all hospital establishments. Device is battery operated and requires no facility power.
Harmonic distortion emissions IEC 61000-3-2	Not applicable	The Staplers are not suitable for interconnection with other equipment.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Electromagnetic Immunity Guidance

For electromagnetic immunity, essential performance is: no knife movement without activation of the Firing Trigger.

Guidance and manufacturer's declaration—Electromagnetic Immunity		
The Staplers are intended for use in the electromagnetic environment specified below. The customer or the user of the Stapler should ensure that it is used in such an environment.		
Immunity test	Compliance level	Electromagnetic Environment - Guidance

Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM Fields IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	The Staplers are suitable for use in all hospital establishments. Device is battery operated and requires no facility power. The Staplers are not suitable for interconnection with other equipment.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Refer to next table	The Staplers are suitable for use in all hospital establishments. Device is battery operated and requires no facility power. The Staplers are not suitable for interconnection with other equipment.
Proximity magnetic fields IEC 61000-4-39	134.2 kHz, PM, 2.1 kHz, 65 A/m 13.56 MHz, PM, 50 kHz, 7.5 A/m	The sources of proximity magnetic fields should be used no closer than 0.15 m (Note 1) to any part of the product
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electrical fast transients / bursts IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	Not applicable
Surges IEC 61000-4-5	Line to line ±1 kV Line to ground ±2 kV	
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V, 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz, 80 % AM at 1 kHz	
Voltage dips and short interruption on power input line IEC 61000-4-11	0% UT, 0.5cycle (At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% UT, 1 cycle 70% UT, 25/30 cycles Single phase: at 0° 0% UT, 250/300 cycles	
Electrical transient conduction along supply lines ISO 7637-2	Not applicable	

Note 1: To established the proximity threshold 0.15 m for Proximity magnetic fields, the IEC Subcommittee (SC) 62A considered the types of proximity magnetic field disturbance sources expected:
– induction cooking appliances and ovens operating at frequencies up to 30 kHz;
– RFID readers operating at both 134.2 kHz and 13.56 MHz;
– electronic article surveillance (EAS) systems;
– sponge detection systems;
– equipment used for position detection (e.g. in catheter labs);
– wireless power transfer charging systems for electrical vehicles that operate in the frequency range of 80 kHz to 90 kHz.
These frequencies and applications are representative examples based on sources of magnetic field disturbance in use at the time of publication of the collateral standard IEC 60601-1-2:2014+A1:2020.

Recommended separation distance between portable and mobile RF communication equipment and Powered Articulating Endoscopic Stapler

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
710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9