Endoscopic Linear Stapler Reloads
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

- When this product is used, aseptic operational practices should be strictly implemented.
- 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 interference resistance 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 both 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.