# Articulating Endoscopic Linear 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 Linear 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, leakage, and severe complications requiring surgical, endoscopic or radiological intervention, or life-threatening complications requiring intensive care management, 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 Linear Stapler and Reloads in order to avoid associated hazardous conditions.
- Avoid using the Linear Stapler in close proximity to or stacked on top of other equipment. If this is unavoidable, the position of the Linear Stapler in relation to the other equipment must be checked to ensure that they all work properly.
- Minimally invasive instruments made by different manufacturers may differ in diameter. If both minimally invasive instruments and accessories from different manufacturers must be used during a single procedure, check for compatibility before the procedure begins.
- Linear Staplers are packaged and sterilized prior to shipment from the factory. They are intended for single use only and may not be reused, reprocessed or resterilized. Reuse, reprocessing or resterilization may affect the structural integrity of the product and lead to product failure, which can result in injury or death. Reuse, reprocessing or resterilization of the Linear Stapler poses a risk of contamination, which can lead to cross-infection in different body parts in the same patient or between different patients, which can result in injury or death to the patient(s).
- No parts or components of our disposable endoscopic linear stapler Linear Staplers and assemblies for endoscopy may be replaced without the permission of Wuhan Mindray Scientific Co., Ltd.
- Check whether the Reloads model matches the Linear Stapler model to be used (for details, refer to the Linear Stapler and Reloads configuration table in the instruction manual).
- Once opened, the Linear Stapler must not be resterilized for use, regardless of whether it was used or not.
- Do not use any endoscopic linear stapler Linear Stapler for major blood vessels if proximal or distal control is not provided.

### Caution

- The product is intended for use in adults.
- Please check the packaging of this product carefully before use and discontinue using it if the packaging is damaged.
- This product is sterilized using ethylene oxide and is intended for clinical use as a sterile product.
- Before use, please check whether the product is within the use period.Sterilization is effective for 3 years. Using the product past its use period is strictly prohibited.
- 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.
- Always check that the staple Reloads holder is stable before firing.
- Always check for hemostasis at the suture site,  anastomosis integrity, and leakage after firing.
- Ensure that the tissue thickness is within the specified range and that the tissue is evenly distributed within the Linear Stapler device. Too much tissue on one side can cause a poor anastomosis, with the possibility of anastomotic leakage.
- Attempts to forcefully squeeze the closure handle in cases of excess or thick tissue may result in an incomplete suture, with the risk of anastomotic splitting or leakage. In addition, damage to the instrument and failure to fire may occur.
- Pre-surgical radiotherapy may result in tissue alterations. For example, these alterations may cause tissue thickening beyond that specified for the selected anastomotic staple. Any pre-surgical treatment of a patient should be carefully considered and a change in surgical technique or procedure may be required.
- Firing must be completed in one strike; never partially fire the instrument. Incomplete firing may result in improper staple molding, incomplete cut lines, bleeding and leakage from the suture, or difficulty in removing the instrument.
- Be sure to fire completely to ensure that the sutures are properly formed and the tissue is cut correctly.
- Squeezing the closing handle exposes the blade. Do not press the closure handle repeatedly, as this can lead to anastomotic site damage.
- When inserting the Reloads, ensure that the safety is in the closed position to avoid inadvertent activation of the closure handle, which could result in accidental exposure of the blade and premature partial or full deployment of the anastomotic staple.
- Instruments that have been in contact with body fluids should undergo special handling to prevent biological contamination from occurring.
- This product is sterilized and packaged for one use only. Use in multiple patients may jeopardize the integrity of the product, or there may be a risk of contamination, which in turn may lead to patient harm.
- The Linear Stapler can switch Reloadss and fire up to 12 times during the same procedure. The use of this device with suture reinforcement material may result in a lower number of strikes.
- This product is a single-use device. It must be destroyed after use so that its parts are no longer functional, and it must be sterilized and rendered harmless for disposal.
- 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

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| 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<br>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. | |

- 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 Articulating Endoscopic Linear Stapler have already been disclosed in the forms of Warnings and Cautions.