mindray

Endoscopic Linear Cutter Reloads

Instruction Manual

046-030197-00(1.0)

Description

Product Name:	Articulating Endoscopic Linear Cutter
Specifications and Model:	See main text for details
Structural Composition:	See main text for details
Intended purpose:	The instruments are intended for transection, resection, and/or creation of anastomoses.
Registrant/ Manufacturer Name:	Hangzhou Mindray Medical Technology Co., Ltd.
Registrant/ Manufacturer Address:	2 Fengxiang Road, Tonglu Economic Development Zone, Tonglu County, Hangzhou City, Zhejiang Province
Production Address:	2 Fengxiang Road, Tonglu Economic Development Zone, Tonglu County, Hangzhou City, Zhejiang Province
Phone:	0571-58504222
Fax:	0571-58504300
URL:	www.mindray.com
Post Code:	311508
Date of Manufacture:	See label
Use-by Date:	See label
Issue Date of This User Manual:	2024-07
EC REP Address:	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Tel:	0049-40-2513175/2513174

Statement

Thank you for purchasing this product.
Before using the product, please read the contents of this user manual carefully to ensure the correct use of the product.
Please keep this user manual properly after reading, so that you can refer to it whenever necessary.
The intellectual property rights of this product and its instruction manual belong to Hangzhou Mindray Medical Technology Co., Ltd. (hereinafter referred to as Mindray). Mindray has right to final interpretation of this instruction manual. No individual or organization shall copy, modify or translate this instruction manual without the written permission of Mindray. This manual describes the use, function and operation of the product in detail. Before using this product, please read and understand the contents of this manual fully to ensure the correct use of this product and the safety of patients and operators.
The user manual is only for product usage instructions, and should not be considered as a reference for surgical techniques.
Mindray shall be responsible for the safety, reliability and performance of the product provided that the following conditions are met:

- This product is used in accordance with the Instruction Manual.
- Product damage is caused by non-human factors (human factors refer to accidental drops, deliberate damage, etc.).

If you really need to return the product to Mindray, please contact Mindray's after-sales service department and provide the product model, serial number, and a brief explanation of the reason for the return.
The product's "triple guarantee" and the after-sales service are defined by the service contract between the distributor and the manufacturer.

After-sales service provider: Hangzhou Mindray Medical Technology Co., Ltd.
After-sales provider's address: 2 Fengxiang Road, Tonglu Economic Development Zone, Tonglu County, Hangzhou City, Zhejiang Province
After-sales provider's telephone: 0571-58504222

To the Customer: Important 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.

Symbol Description

The following table contains all symbols used on this instrument and labels, along with their meanings:

Table 1 Symbol Description

(Blue)	Follow the instructions for use		Warning
UDI	Unique instrument identifier		Do not re-use
	Temperature limit		Atmospheric pressure limit
	Humidity limit		Refer to the instructions for use
	Single-layer sterile barrier system		Single-layer sterile barrier system, with protective packaging inside
	Manufacturer		Date of Manufacture:
	Use-by Date:		This side up
	Avoid sun exposure		Protect from rain
	Fragile, handle with care	50kg	Stacking weight limit 50 kg
STERILE EO	Sterilized using ethylene oxide		Do not resterilize
LOT	Lot Code	Rx Only	For use under medical supervision
	Do not use if packaging is damaged	2 HDPE	High-density polyethylene
	Compliant with EU Directive 2012/19/EU on Waste Electrical and Electronic Equipment		Packaging Recycling Label

	A change from red to blue indicates that sterilization is complete.	MR	MR (Magnetic Resonance) Safe Under Specific Conditions
MD	Medical Device	REF	Catalogue Number
CE 0197	The product is provided with a CE marketing in accordance with regulations stated in Regulation(EU)2017/745 concerning Medical Devices.	mindray	Hangzhou Mindray Medical Technology Co., Ltd. has been authorized the use of the registered trademark of Shenzhen Mindray Bio-medical Electronics Co., Ltd.

Note

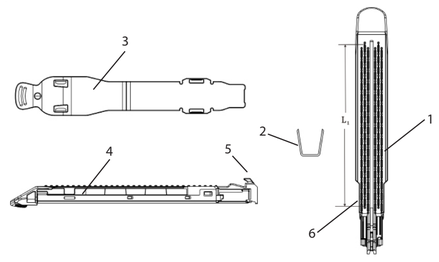
- Before operating this instrument, it is necessary to be familiar with and understand the meanings of the symbols mentioned above.

Product Overview

Structural Composition

Endoscopic Linear Cutter Reloads consists of a cartridge shell, staple, cartridge base plate, staple pusher, protective cover, and cutting blade.

Endoscopic Linear Cutter Reloads



1. Staple cartridge shell 2. Staples 3. Protective cover 4. Staple cartridge baseplate
5. Cutter 6. Pusher

Figure 1 Endoscopic Linear Cutter Reloads

Warning

- The cartridge can only be used in conjunction with the stapler.
- Before use, if rust is found on the product, its use should be strictly prohibited.
- Visually inspect the staple holder for deformation before firing. If deformation is observed, do not use it.
- The stapler cartridge is a single-use, sterile product.
- This product is intended for use in sterile operating rooms within medical facilities.

Note

- After each stapling and suturing, remove the empty staple cartridge from the staple cartridge holder.

Intended purpose

The instruments are intended for transection, resection, and/or creation of anastomoses.

Intended users

Persons having adequate training and familiarity with minimally invasive techniques.

Indications:

The product is intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general abdominal, gynecologic, thoracic, and pediatric surgical procedures.

Intended patient population

adult

Intended medical conditions

Medical Institution

Product Properties

- The endoscopic linear cutter reloads is a single-use, sterile product.
- The staples of the stapler are made of pure titanium.
- The connection between the stapler body and the assemblies should be firm and reliable, while being easy to replace.

Contraindications

- Do not use the instruments with Gray reload (2.0mm staple) on any tissue that compresses to less than 0.75mm in thickness, or on any tissue that cannot comfortably compress to 1.5mm.
- Do not use the instruments with White reload (2.5mm staple) on any tissue that compresses to less than 1.0mm in thickness, or on any tissue that cannot comfortably compress to 2.0mm.
- Do not use the instruments with Blue reload (3.5mm staple) on any tissue that compresses to less than 1.5mm in thickness or on any tissue that cannot comfortably compress to 2.4mm.
- Do not use the instruments with Golden reload (3.8mm staple) on any tissue that requires excessive force or compresses to less than 1.8mm in thickness, or on any tissue that cannot comfortably compress to 3.0mm.
- Do not use the instruments with Green reload (4.1mm staple) on any tissue that compresses to less than 2.0mm in thickness, or on any tissue that cannot comfortably compress to 3.3mm.
- Do not use the instruments with Dark reload (4.2mm staple) on any tissue that compresses to less than 2.3mm in thickness, or on any tissue that cannot comfortably compress to 4.0mm.
- The device should not be used to staple ischemic or edematous tissues.
- Do not use the instruments on the aorta.
- Do not reuse after surgery.
- Do not use curved tip staplers on tissues or strctures that can't fit completely within the jaws proximal to the transitional angle of the curved tip
- Staplers is not intended for use inside of the heart, central circulatory or central nervous system.

Side-effects

According to clinical and residual risk evaluations, Endoscopic Linear Cutter Reloads have no known side effects for the intended patients.

Intended Clinical Benefits

The use of cutter for vascular or tissue ligation provides the benefit of successful surgical outcomes.

User Manual

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.
- 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.
- 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.
- 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 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 cutter staplers and assemblies for endoscopy may be replaced without the permission of Hangzhou Mindray Medical Technology 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 must not be resterilized for use, regardless of whether it was used or not.
- Do not use any endoscopic linear cutter stapler for major blood vessels if proximal or distal control is not provided.
- summary of safety and clinical performance is available on https://ec.europa.eu/tools/eudamed.

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.
- The dimensions of minimally invasive devices may vary between manufacturers. If minimally invasive surgical instruments and their accessories made by different manufacturers are applied at the same time in a single procedure, it is important to verify their compatibility before the procedure.
- Always check that the staple cartridge 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 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 cartridge, 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 stapler can switch cartridges 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).
- The titanium implant staples are safe under specific conditions:
  Non-clinical trials have shown that endoscopic linear cutter staplers and titanium staples (pure titanium) in the cartridge are safe under MR-specific conditions. Patients with implanted staples can be safely scanned under the following conditions:
  The strength of the static magnetic field is less than or equal to 3.0 T;
  The highest spatial gradient of the magnetic field is 12.0 T/m;
  The maximum body-averaged specific absorption rate (SAR) reported by the MR system after 15 minutes of scanning (per pulse sequence) was 2.7 W/kg.
- MRI-related warming:
  In nonclinical testing, when sutures were subjected to 15-minute sequential MRI scans (per sequence) performed at 3.0 T using a transmit-receive body RF coil, anastomotic staples produced no more than 1.8°C of warming at a maximum body-averaged specific absorption rate of 2.7 watts/kg.
- Artifact information:
  Image quality may be affected if the area imaged by the MRI is completely identical to the area where the sutures fired by the endoscopic linear cutter stapler and cartridge are located, or if these areas are located in close proximity to each other. Therefore, it is necessary to optimize the settings of the MRI parameters to compensate for the effects caused by these staples. The size of the signal-free area of the suture (e.g., 60 mm) in a worst-case scenario.

Pulse sequence	SE	SE	GRE	GRE
Planar orientation	Horizontal	Vertical	Horizontal	Vertical
Signal void size (mm^2)	572	68	934	89

Instructions for Use

Inspection before use

1. Check that the size of the staple cartridge matches the instrument to be used.
2. Use your index finger to turn the rotary wheel and rotate the jaws of the instrument by 360°. Use your other hand to turn the articulating head knob, to familiarize yourself with the turning action of the instrument. The jaws can be turned to a maximum angle of 60°. The greater the bending angle, the greater the force that may be required to turn the articulating head knob. The jaws can be returned to a straight position by reversing the articulating head knob.
3. Check the compatibility of all instruments and accessories before use.

Installation and removal of cartridges

1. After removing the cartridge from its sterile packaging using aseptic handling procedures, check that the protective cover of the cartridge is intact. If there are any misalignments, defects or missing parts, please discontinue use of the cartridge, replace it with a new one and submit it to after-sales service for disposal after the procedure.
2. It is essential to ensure that the stapler jaws are open before installing the cartridge.
3. When installing the cartridge, slide it against the bottom of the cartridge holder until the cartridge aligns and snaps into the cartridge slot, securely install the cartridge in its designated location, then remove and discard the protective cover of the cartridge.
4. To unload the cartridge, push the cartridge in the direction of the staple cartridge holder to loosen it from the cartridge holder.
5. Install a new cartridge and repeat steps 1–4 above.

Warning

- Prior to reinstalling the cartridge, hold the instrument vertically while fully immersing the staple cartridge holder and the cartridge holder in saline solution. Shake vigorously, then wipe the inner and outer surfaces of the staple cartridge holder and cartridge holder to remove any remaining suturing staples from the jaws. Before proceeding with use of the instrument, the instrument must be visually inspected to confirm that there are no staples in the staple cartridge holder and cartridge holder.

Caution

- Tissue thickness should be carefully assessed before using the stapler (see Models and Specifications).
- After removing the protective cover of the cartridge, the surface of the cartridge must be re-examined. If any abnormality is seen (normally, the surface of the cartridge is smooth and no colored staple drivers are visible; however, if a colored staple driver can be seen, this indicates that the cartridge may not have an anastomotic staple), the cartridge must be removed and replaced with a new cartridge for use.
- The cartridges of our endoscopic linear cutter staplers are interchangeable among all of our endoscopic linear cutter staplers that are identified by each code number in all series. Do not use the cartridge series of the endoscopic linear cutter staplers for surgical instruments other than instruments in our endoscopic linear cutter series.
- The appropriate cartridge should be selected by combining two factors: tissue thickness and thickness of the suture support pad material.
- If suture support material is utilized when using this device, force may be required for closure. This has the potential to reduce the number of strikes by the firing instrument. The material manufacturer's instructions should be followed when utilizing suture support pad materials. Suture support material is not supplied by our company.
- Do not remove the protective cover of the cartridge until the cartridge is in place.
- When unloading the cartridge, do not place your thumbs against the head end of the cartridge holder at the same time.

Compatible Instruments

The Endoscopic Linear Cutting Reloads are intended to be used in combination with the devices as below:

- Trocar: User needs to operate the Articulating Endoscopic Linear Cutter as well as the Endoscopic Linear Cutting Reloads through trocar to perform surgery. The diameter of adaptive trocar should not smaller than φ12mm.
- Articulating Endoscopic Linear Cutter: User needs to insert the Endoscopic Linear Cutting Reloads into the Articulating Endoscopic Linear Cutter prior to use. The staple line length of the Endoscopic Linear Cutting Reloads should be compatible with the jaw length of the Articulating Endoscopic Linear Cutter. The Endoscopic Linear Cutting Reloads should only be used with the following Articulating Endoscopic Linear Cutter.

Table 2 Model and Specification of Articulating Endoscopic Linear Cutter

Style	Model Type	Specification	Rod Length L (mm)	Tolerance (mm)	Bending Angle W (°)	Tolerance (°)
MS30	MS30-C30A	280	192	± 5	60	± 10
	MS30-S30A	340	252			
	MS30-L30A	440	352			
	MS30-C45A	280	192			
	MS30-S45A	340	252			
	MS30-L45A	440	352			
	MS30-C60A	280	192			
	MS30-S60A	340	252			
	MS30-L60A	440	352			
MS31	MS31-C30A	280	192	± 5	60	± 10
	MS31-S30A	340	252			
	MS31-L30A	440	352			
	MS31-C45A	280	192			
	MS31-S45A	340	252			
	MS31-L45A	440	352			
	MS31-C60A	280	192			
	MS31-S60A	340	252			
	MS31-L60A	440	352			
MS32	MS32-C30A	280	192	± 5	60	± 10
	MS32-S30A	340	252			
	MS32-L30A	440	352			
	MS32-C45A	280	192			
	MS32-S45A	340	252			
	MS32-L45A	440	352			
	MS32-C60A	280	192			
	MS32-S60A	340	252			
	MS32-L60A	440	352			
MS37	MS37-L60A	440	352	± 5	60	± 10

Storage Conditions

Storage Conditions

- Temperature range: 0°C to 35°C
- Humidity range: 10% to 80%
- Atmospheric pressure range: 50 kPa to 106 kPa

Caution

- The instrument should be stored in a dark, cool, fireproof, rat-proof, insect-proof, non-corrosive gas, well-ventilated, dry and clean room, and should be protected from compression, wear and impact.

Transportation Conditions

- Temperature range: -10°C to 50°C
- Humidity range: 10% to 60%
- Atmospheric pressure range: 50 kPa to 106 kPa

Caution

- If the instrument needs to be transported, it should be carried out according to the requirements in the purchase contract, and it must be protected from severe impact during transportation, rain and exposure to sun. During transportation, severe vibration and damp environments should be avoided when handling the instrument.

Operational conditions:

- Temperature range: 5°C to 40°C
- Humidity range: 30% to 75%
- Atmospheric pressure range: 80 kPa to 106 kPa

Batch Number, Production Date, Use-by Date

- Batch Number: See label
- Date of Manufacture: See label
- Expiration Date: See label
- Use-by Date: 3 years.

Notification of Incident

As a health care provider, you may report the occurrence of certain events to Hangzhou Mindray Medical Technology Co., Ltd. and possibly to the competent authority of the member state in which the user and / or patient is established. These events include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, Hangzhou Mindray Medical Technology Co., Ltd. requests to be notified of device failures or malfunctions. This information is required to ensure that Hangzhou Mindray Medical Technology Co., Ltd.. provides only the highest quality products.

Disposal

The products must be decontaminated prior to disposal.
The products must be disposed of in compliance with the local regulations. If you have any questions concerning disposal of the equipment, please contact Mindray.

Model and Specification

Table 1 Model and Specification of Endoscopic Linear Cutter Reloads

Style	Model No.	Specification	Stapling length L1 (mm)	Tolerance (mm)	Staple height H (mm)	Tolerance (mm)
MR30	MR30-W30A	30-2.5	35.0	±2	2.5	±0.2
	MR30-B30A	30-3.5	35.0		3.5	
	MR30-M45A	45-2.0	48.0		2.0	
	MR30-W45A	45-2.5	48.0		2.5	
	MR30-B45A	45-3.5	48.0		3.5	
	MR30-D45A	45-3.8	48.0		3.8	
	MR30-G45A	45-4.1	48.0		4.1	
	MR30-T45A	45-4.2	48.0		4.2	
	MR30-M60A	60-2.0	60.0		2.0	
	MR30-W60A	60-2.5	60.0		2.5	
	MR30-B60A	60-3.5	60.0		3.5	
	MR30-D60A	60-3.8	60.0		3.8	
	MR30-G60A	60-4.1	60.0		4.1	
	MR30-T60A	60-4.2	60.0		4.2	
MR31	MR31-W30A	30-2.5	35.0	±2	2.5	±0.2
	MR31-B30A	30-3.5	35.0		3.5	
	MR31-M45A	45-2.0	48.0		2.0	
	MR31-W45A	45-2.5	48.0		2.5	
	MR31-B45A	45-3.5	48.0		3.5	
	MR31-D45A	45-3.8	48.0		3.8	
	MR31-G45A	45-4.1	48.0		4.1	
	MR31-T45A	45-4.2	48.0		4.2	
	MR31-M60A	60-2.0	60.0		2.0	
	MR31-W60A	60-2.5	60.0		2.5	
	MR31-B60A	60-3.5	60.0		3.5	
	MR31-D60A	60-3.8	60.0		3.8	
	MR31-G60A	60-4.1	60.0		4.1	
	MR31-T60A	60-4.2	60.0		4.2	
MR32	MR32-W30A	30-2.5	35.0	±2	2.5	±0.2
	MR32-B30A	30-3.5	35.0		3.5	
	MR32-M45A	45-2.0	48.0		2.0	
	MR32-W45A	45-2.5	48.0		2.5	
	MR32-B45A	45-3.5	48.0		3.5	
	MR32-D45A	45-3.8	48.0		3.8	
	MR32-G45A	45-4.1	48.0		4.1	
	MR32-T45A	45-4.2	48.0		4.2	
	MR32-M60A	60-2.0	60.0		2.0	
	MR32-W60A	60-2.5	60.0		2.5	
	MR32-B60A	60-3.5	60.0		3.5	
	MR32-D60A	60-3.8	60.0		3.8	
	MR32-G60A	60-4.1	60.0		4.1	
	MR32-T60A	60-4.2	60.0		4.2	
MR33	MR33-T60A	60-4.2	60.0	±2	4.2	±0.2