

Endoscopic Linear Cutter-IFU

Instruction for Use



STERILE DISPOSABLE ENDOSCOPIC LINEAR CUTTER AND RELOAD

MIRUS™ Endoscopic Linear Cutter and Reload

Rev. 06 Rev. Dt.: 2020/08 Document No.: ME/IFU/STA/001

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CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

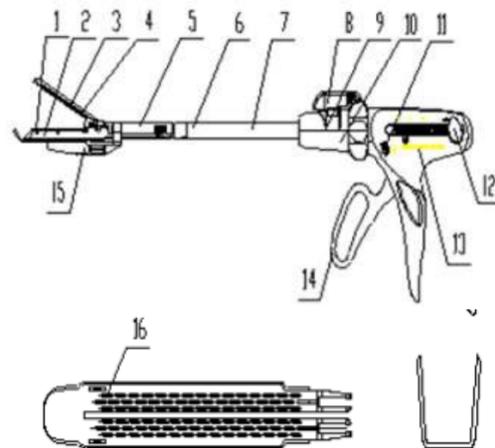
DESCRIPTION

Mirus™ Endoscopic Linear Cutter places two, double or triple-staggered rows of titanium staples and simultaneously divides the tissue between the two rows. The devices are available in 3 different shaft lengths and furnished without a cartridge. Cartridges for Endoscopic Linear Cutter are available in sizes that correspond to the thickness of tissue that is to be transected or resected. The cartridge/reload for Mirus™ Endoscopic Linear Cutter are supplied separately.

INDICATIONS

Mirus™ Endoscopic Linear Cutter and Reload is intended for Transection, resection, and/or creation of anastomosis. The instrument has application in multiple open or minimally invasive general, gynaecologic, urologic, thoracic, and paediatric surgical procedures. It can be used with tissue buttressing materials.

CONFIGURATION



- | | | |
|----------------------------|-----------------------|---------------------------|
| 1. Staple Cartridge, | 2. Cartridge Support, | 3. Anvil, |
| 4. Anvil Cover, | 5. Clamp Cover, | 6. Locking Lever, |
| 7. Shaft, | 8. Adjusting Knob, | 9. Above Rotation Collar, |
| 10. Under Rotation Collar, | 11. Green Button, | 12. Return Knob, |
| 13. Unmovable Handle, | 14. Firing Handle, | 15. Shipping Wedge, |
| 16. Staple | | |

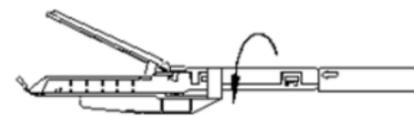
STEPS TO USE

(Note: This Operation Instructions may not be used as a technical guide for surgical anastomosing operations.)

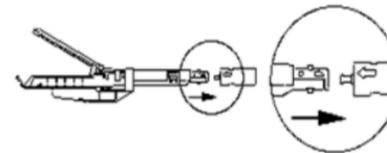
Always include the combined thickness of the tissue and of any staple line reinforcement material in use when choosing the proper staple cartridge.

LOADING

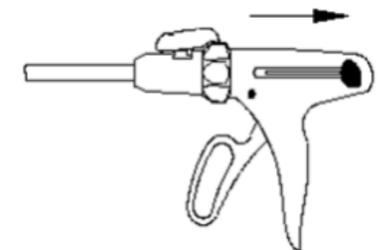
- To Load the Endoscopic Linear Cutter with the appropriate loading unit insert the pin located at the distal end of the instrument shaft into the loading unit. Ensure that the LOAD alignment indicator on the loading unit aligns with the load alignment indicator on the shaft. (Figure 1)
- Push the loading unit in and twist clockwise relative to the instrument, so that the loading unit will lock into place. The load alignment indicator on the instrument shaft will align with the load alignment indicator on the loading unit (Figure 2).
- To confirm proper loading, cycle the instrument after loading the loading unit. Squeeze the handle once to close the jaws of the loading unit. Pull back on the black return knobs and confirm that the loading unit jaws open fully (Figure 3)



(Figure 1)



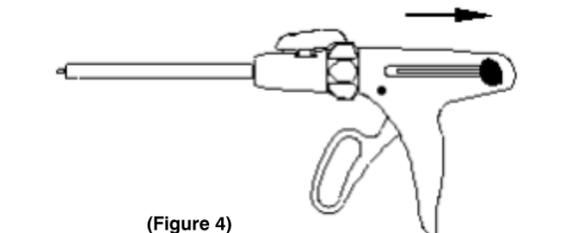
(Figure 2)



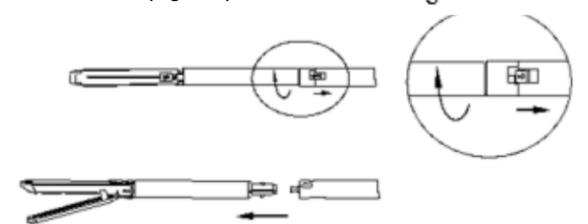
(Figure 3)

UNLOADING

- To unload a loading unit from the stapler, the articulating lever must be in the neutral position. Ensure that the jaws of the loading unit are open by pulling the black return knobs back completely. (Figure 4)
- Pull the UNLOAD/UNLOCK button (located on the underside of the shaft) back towards the instrument, twist the loading unit counterclockwise 45° and remove the loading unit from the shaft of the instrument. (Figure 5)



(Figure 4)



(Figure 5)

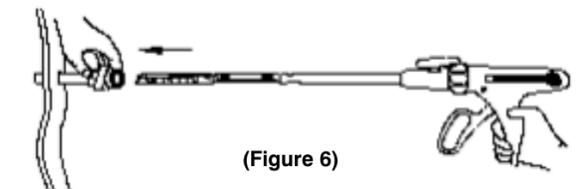
INSTRUCTIONS FOR USE

Insert the Endoscopic Linear Cutter into an appropriately sized trocar sleeve, or larger, with the use of a converter.

Note: The Endoscopic Linear Cutter white, Blue, Purple, Gold, loading unit is designed for introduction and use through a 12 mm trocar sleeve, or larger, with the use of a converter.

When using the Endoscopic Linear Cutter Green, Black loading unit, it must be inserted into a 15mm trocar sleeve. The instrument may be reloaded and fired up to 12 times in a single procedure.

- The jaws of the loading unit must be closed prior to introducing the instrument into the trocar sleeve. To do so, squeeze the handle (Figure 6). Pull the UNLOAD/UNLOCK button (located on the underside of the shaft) back towards the instrument, twist the loading unit counterclockwise 45° and remove the loading unit from the shaft of the instrument. (Figure 5)



(Figure 6)

- Once inside the body cavity, open the jaws of the instrument by pulling the black return knobs completely back. (Figure 7)

Prepared by	Verified by	Approved by	Approved by RA

ARTWORK No.	REV.
ME/IFU/STA/001	06
Revision History:	
- Change in CE Number	
- Add Disposable word in generic name	

Colour Shade	
	PANTONE 279 C
	PANTONE 1235 C
	BLACK

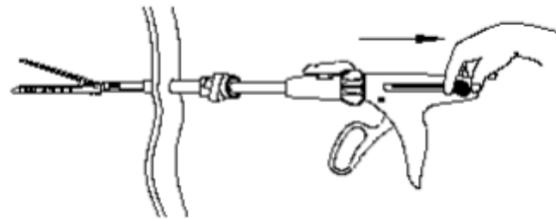
Meril Endo Surgery Private Limited

Artwork Approval

Endoscopic Linear Cutter-IFU

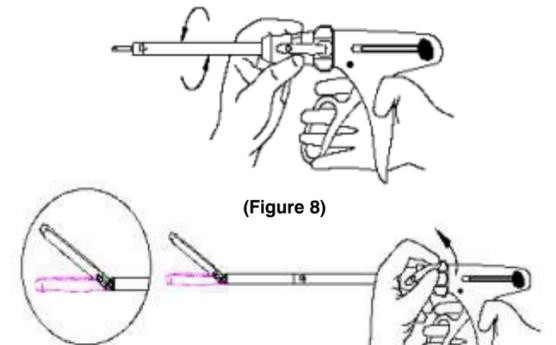
Caution:

1. Do not squeeze the instrument handle while pulling back the black knobs.
2. Apply the Endoscopic Linear Cutter across the tissue to be transected.
Caution: Ensure that no obstructions (such as clips) are incorporated in the instrument jaws. Firing over an obstruction may result in incomplete cutting action and/or improperly formed staples.



(Figure 7)

3. Adjust Rotation collar to make the instrument shaft rotates 360° (Figure 8) Turn around the adjusting knob to make the Rotary single use of units rotates 35° in both directions. (Figure 9)



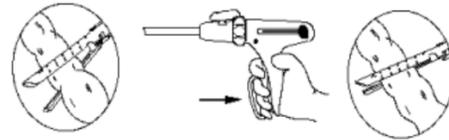
(Figure 8)

(Figure 9)

4. Close the jaws of the instrument across the tissue to be transected by squeezing the handle completely. The stapler is equipped with a safety interlock the instrument will not fire the stapler and cut tissue unless the green button is pushed. (Figure 10)

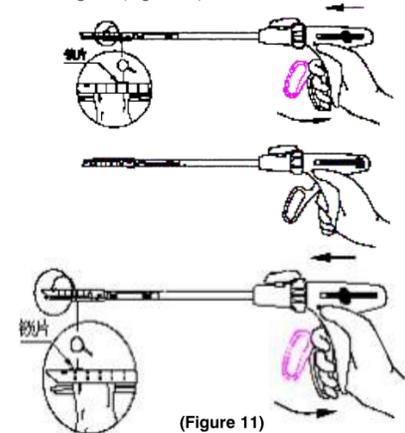
Caution:

1. A safety interlock is provided that prevents an empty single use loading unit from being fired a second time. Do not attempt to override the safety interlock.
2. The jaws of the instrument may be repositioned on the tissue prior to firing by pulling the black return knobs completely back, allowing the jaws to open.



(Figure 10)

3. In order to fire the instrument, push the green button. Squeeze the handle sequentially until the oval clamp cover reaches the distal end of the cartridge slot, and the handle locks. Sequential squeezes of the handle are required to fully fire the loading unit (Figure 11)

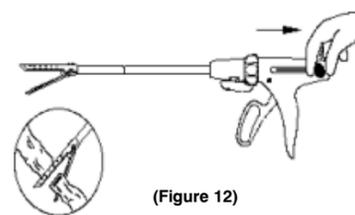


(Figure 11)

4. Once the instrument has been completely fired, open the jaws by pulling the black return knobs completely back. Gently remove the instrument from the tissue. The site should be checked for hemostasis following removal of the instrument. Minor bleeding may be controlled using electro cautery or manual sutures (Figure 12)

Note:

1. Do not attempt to insert or remove the instrument from the trocar sleeve if the instrument is in the articulated position.
2. This instrument can be reloaded and fired up to 12 times in a single surgery.



(Figure 12)

CONTRAINDICATIONS

1. Do not use 2.0, 2.5, 3.0 mm staple in endoscopic linear cutter on any tissues that compresses to less than 0.75 mm and 1.0 mm in thickness, or any tissues that cannot comfortably compresses to 1.0 and 1.5 mm on the aorta, respectively.
2. Do not use the Endoscopic Linear Cutter 3.0, 3.5, 4.0 mm staples on any tissue that compresses to less than 1.5 mm in thickness, on any tissue that cannot comfortably compress to 2.0 mm or on the aorta.
3. Do not use the Endoscopic Linear Cutter 4.0, 4.5, 4.8, 5.0 mm staples on any tissue that compresses to less than 2.0mm in thickness, on any tissue that cannot comfortably compress to 2.0 mm or on the aorta.
4. The Endoscopic Linear Cutter instrument should not be used on tissue such as liver or spleen where compressibility is such that closure of the instrument would be destructive.
5. Do not use the Endoscopic Linear Cutter where adequacy of hemostasis cannot be verified visually after applications.
6. These devices are provided STERILE and are intended for use in a single procedure only. Discard after use. Do not resterilize.

RISK OF REUSE

The product is intended to be used single time only. If used multiple time it may lead to cross contamination / infection, also it may not meet the intended use. Hence instruction for single use only is mentioned on label as well as IFU.

STERILIZATION

Mirus™ Endoscopic Linear Cutter Gun is sterilized by Gamma Radiation method and Reload is sterilized by Ethylene oxide sterilization method as indicated on package.

STORAGE

Recommended storage conditions: Between 15°C to 30°C, keep away from moisture and direct heat. Do not use after expiry date.

MIRUS™ ENDOSCOPIC LINEAR CUTTER

Code	Maximum Firings
MEC065	12
MEC160	12
MEC255	12

MIRUS™ ENDOSCOPIC LINEAR CUTTER RELOADS

Code	Color	Open Leg length (mm)	Close Leg length (mm)	Number of staple (EA)	Rows	Staple line Length (mm)	Cutting Length (mm)
MECR45-2.5	White	2.5 mm	1.0 mm	66	6	45	43.5
MECR45-3.5	Blue	3.5 mm	1.5 mm	66	6	45	43.5
MECR45-4.8	Green	4.8 mm	2.0 mm	66	6	45	43.5
MECR60-2.5	White	2.5 mm	1.0 mm	90	6	60	58.5
MECR60-3.5	Blue	3.5 mm	1.5 mm	90	6	60	58.5
MECR60-4.8	Green	4.8 mm	2.0 mm	90	6	60	58.5

MIRUS™ ENDOSCOPIC LINEAR CUTTER TRIO RELOADS

Code	Color	Staple line Length (mm)	Cutting line length (mm)	Number of staple (EA)	Open Staple Height (mm)
MECRW45	White	45	40	66	2.6, 2.6, 3.0
MECRP45	Purple				3.5, 3.5, 4.0
MECRW60	White	61	55	90	2.6, 2.6, 3.0
MECRP60	Purple				3.5, 3.5, 4.0
MECRB60	Black				4.5, 4.5, 4.8

SYMBOLS USED ON LABELING

= Caution
 = Do Not Reuse
 = Manufacturer
 = Keep Dry
 = Do Not Resterilize
 = Date of manufacture
 = Keep Away from Sunlight
 = Batch Code
 = Consult Instructions for use
 = Do not Use if Package is damaged
 = Content
 = CE mark and identification number of notified body
 = Use by (Use until Year & Month)
 = Temperature Limitation (Store between 15° - 30° C)
 = Sterilized using Irradiation
 = Authorized representative in the European Community
 = Sterilized using Ethylene Oxide