

INSTRUCTION FOR USE



STERILE DISPOSABLE LINEAR STAPLER AND RELOAD

MIRUS™ LINEAR STAPLER AND RELOAD

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Manufactured By :

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CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

DESCRIPTION

Mirus™ Linear Stapler places a double staggered row of titanium Staples. They are available in 30mm, 45mm, 60mm and 90mm staple line length. The cartridge/ reload for Mirus™ Linear stapler are supplied separately.

INDICATIONS

Mirus™ Linear Stapler and Reload has applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection or transection of tissue and creation of anastomosis, including occlusion of the left atrial appendage in open procedures. They may be used for transection and resection of pancreas.

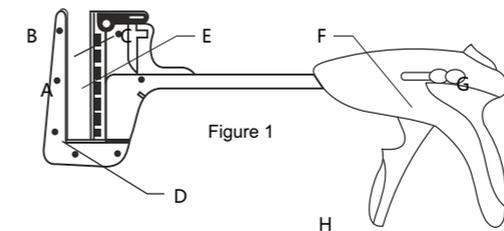
PERFORMANCE/ MECHANISM OF ACTION

The stapler holds the staples in double staggered row within the staple cartridge. The linear stapler, on firing (squeezing the handle), staple tissue to create an anastomosis.

CONTRAINDICATIONS

1. The Mirus™ Linear Stapler should not be used if surgeon determines the tissue would not be able to tolerate conventional suture materials or closure techniques.
2. Tissue thickness should be carefully considered before firing any stapler. The Mirus™ Linear Stapler 30, 45, 60, and 90 mm should not be used on tissue that will not be easily compressed, or compressed to less than, the specified compression requirements. Otherwise, closure failure, tissue trauma, dehiscence tissue tearing and displacement may occur, and/or hemostasis may not be obtained.
3. The Mirus™ Linear Stapler should not be used on tissues such as liver and spleen, or similar tissue as compressing these tissues may be destructive.
4. The Mirus™ Linear Stapler should not be used when there are suspicions of remaining cancerous tissue at the cutting edge or severely damages at the cutting edge.
5. The Mirus™ Linear Stapler should not be used on patients with alimentary tract edema, excessive thickness of the muscle layer, or healing deficiency.
6. Mirus™ Linear Stapler should not be used to staple tissues that are necrotic, friable, or have altered integrity, e.g., ischemic or edematous tissues.

SCHEMATIC VIEW



- | | |
|----------------------------|--------------------------------|
| A) Jaws | E) Cartridge Housing |
| B) Anvil | F) Retaining Pin Thumb Buttons |
| C) Retaining Pin | G) Release Button |
| D) Single Use Loading Unit | H) Handle |

DIRECTIONS FOR USE

1. Ensure to select a Reload with the appropriate staple size for the tissue thickness.
Note: The stapler may be used for vascular, regular, thick or thin tissues.
2. Slip the instrument jaws around the tissue to be transected or resected.
3. The retaining pin should be advanced and properly seated before closing, or firing, of the instrument. The pin can be manually advanced by pushing the white thumb buttons forward or automatically seat as the instrument jaws are closed.
Caution: Proper seating of the retaining pin in the anvil hole should be visually confirmed and by feeling each side of the anvil. Pressing the retaining pin firmly into place will insure proper placement of the retaining pin. Firing an instrument with a misplaced retaining pin may improperly form staples, which may lead to leakage or disruption of the staple line.
Note: If the retaining pin is manually seated and the release button is activated prior to a complete handle squeeze, the pin can only be retracted manually. In all other situations the pin will retract automatically.
4. Squeeze the handle to approximate the tissue. In pre-clamp position the handle can be released without returning to its original position to allow for final positioning of the tissue within the jaws. After the tissue positioning, continue to squeeze the handle until the instrument is clamped. The handle will return to the original position.
Caution: Do not squeeze the handle twice unless the tissue is properly positioned (a second squeeze will fire the staples). The release button (G) may be used to open the instrument at any point during approximation.
5. To fire the instrument, squeeze the handle a second time until it reaches a solid stop and locks in the back position. When fully fired, the handle will remain in the locked position.

Caution: The stapler performs only single firing. If the instrument handle is partially squeezed during firing then released, bleeding may occur as the instrument was not fully fired and staples may not properly form. The release button can be used to option the instrument at any point during approximation. After firing, always inspect the staple line for hemostasis & integrity by visual inspection for oozing or bleeder.

6. Prior to opening the fully fired instrument and in the fired position, the cartridge edge can be used as the cutting guide during the resection of tissue.
7. Press the release button to open the jaws and unlock the handle. The alignment pin will automatically retract.

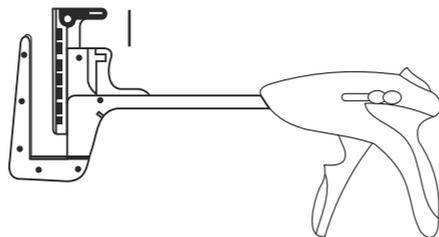
Note: Always inspect the staple line for hemostasis & integrity by visual inspection for oozing or bleeder, after removing the instrument. Manual sutures or electrocautery may be used to control minor bleeding.

RELOADING

- Ensure that the instrument jaws are in the fully open position, and the alignment pin is fully retracted before removing the Reload.
- To remove the fired Reload, grasp the finger pads at the top of the Reload and pull straight up from the jaws to remove the Reload.
- Prior to reloading the instrument, the Anvil surface should be cleaned and has no tissue or staples to ensure proper staple formation in subsequent firings.
- To reload the instrument, grasp the new Reload at the finger pads, with staple holes facing the instrument anvil. Insert the Reload into the metal cartridge housing and push firmly downward until Reload clicks into position.

Note: The instrument jaws will not close if a fired or partially fired Reload is loaded into the jaws, or the Reload is not fully loaded into the jaws. A proper Reload should be used for the tissue of different thickness. An fired Reload has yellow pushers presented in the front of the staple slots.
- Repeat the loading procedure as needed.

Note: Each Mirus™ Linear Stapler and Reload should only be reloaded no more than 10 times.



WARNING AND PRECAUTION

1. This instrument is intended for use by medical professional only.
2. Preoperative radiotherapy may result in tissue changes that may cause the tissue thickness to exceed the indicated range for the selected staple size. Careful consideration should be given to any pre-surgical treatment that the patient may have undergone and in corresponding selection of staple size. Selection of staple size may vary depending on patients' pre-surgical treatment.
3. Each component in the package must be used in the manner indicated.
4. Visually inspect that there is no inclusion of unintended anatomic structures within the staple line.
5. Make sure that no metal clips or other obstructions are incorporated into the instrument jaw when positioning the stapler on the application site, otherwise the stapling may not form properly.
6. Verify the compatibility of cartridge (Reload) ,instruments and accessories prior to using the instrument.
7. Mirus™ linear Staplers are provided STERILE and are intended for multiple use during a single surgical procedure for one patient. DISCARD AS MEDICAL WASTE AFTER USE. DO NOT RESTERILIZE.
8. The Reload is provided STERILE and is intended for use in a SINGLE procedure only. DISCARD AS MEDICAL WASTE AFTER USE. DO NOT RESTERILIZE.
9. Each Reload will fit and operate properly in only the staplers designed for use with the Reload. Attempting to use a Reload in any instrument other than for which it has been designed will result in stapler malfunction.
10. Mirus™ Linear Stapler and Reload should not be used on the tissue that was considered not to be suitable for suturing by a doctor according to experience.
11. Avoid use of the stapler on large blood vessels, such as the aorta.
12. Establish and maintain adequate proximal control of blood vessels prior to stapling.
13. Clamping and unclamping of delicate structures such as venous structures and bile ducts may result in damage to tissue irrespective of stapler firing.
14. If a stapler malfunction occurs while applying staples across a blood vessel, then the user should clamp or ligate the vessel before releasing the stapler, while the stapler is still closed on the tissue.

15. Do not reuse, reprocess or re-sterilize Mirus™ Linear stapler. Reuse, reprocessing or re-sterilization of the instrument may result in functional failure, contamination, patient injury or infection.

16. Do not use if package is damaged or open.

STERILIZATION

Mirus™ Linear Stapler 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™ LINEAR STAPLER AND RELOAD

Tissue type & thickness	Type: Vascular and Standard Min. tissue thickness: 1.5mm Max. tissue thickness: 2.0mm										
	Stapler Code	Cartridge Size / Jaw length (mm)	Stapling Line Length (mm)	Shaft Thickness (mm)	Compatible Reload code	Open Staple Height (mm)	Close Staple Height (mm)	Color	Tissue Type	Max no. of reloads	Pre-firing Compression time (Sec)
	MALS30	30	30	13	MLSR30-3.5	3.5	1.5	Blue	Vascular and standard	10	20-30
					MLSR30-4.8	4.8	2.0	Green	Thick		
MALS45	45	45	MLSR45-3.5		3.5	1.5	Blue	Vascular and standard	10		
			MLSR45-4.8		4.8	2.0	Green	Thick			
MALS60	60	60	MLSR60-3.5		3.5	1.5	Blue	Vascular and standard	10		
			MLSR60-4.8		4.8	2.0	Green	Thick			
MALS90	90	90	MLSR90-3.5		3.5	1.5	Blue	Vascular and standard	10		
			MLSR90-4.8		4.8	2.0	Green	Thick			

SYMBOLS USED ON LABELING

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