

Instruction for Use



MIRUS™

LIGATING CLIP | Titanium

Rev. 05 Rev. Dt.: 2022/07 Document No. ME/IFU/STA/013

Manufactured By :

Meril Endo Surgery Pvt. Ltd.

Third Floor, E1-E3, Meril Park, Survey No.135/2/B & 174/2,
Muktanand Marg, Chala, Vapi - 396 191, Gujarat, India.

Customer Care No. for India : 18004194433,

Customer Care No. for other than India : + 91-260-2408005

E: enquiry.endosurgery@merilife.com, W: www.merilife.com

DESCRIPTION:

Mirus™ Ligating clip are sterile, medical grade titanium, non-absorbable, implantable device intended for general surgical procedures that require vessel or tissue ligation.

Mirus™ Ligating clips are supplied with multiuse non sterile Mirus™ Ligating Clip applicator, allowing the end user to ligate a wide range of vessels and tissue structures.

INDICATION:

The Mirus™ Ligating clip is intended to securely grip the vessel or tissue to provide complete occlusion atraumatically.

Mirus™ Ligating Clip applicator allows the end user to ligate a wide range of vessels and tissue structures

CONTRAINDICATIONS:

- Mirus™ ligating clips are not intended for use for fallopian tube ligation Mirus™ ligating clips are contraindicated for use in ligation of renal artery

WARNINGS:

- This clip is intended for single use only. Multiple use may result in degradation or loss of performance / functionality and may result in cross contamination / bacterial infection.
- Do not re-sterilise.
- Do not use damaged applicator

PRECAUTIONS:

- Before applying the clip, verify the structure size and condition of the vessel or structure and select the appropriate size.
- To prevent the premature closure or release of the clip
- Never grasp the applicator by both shanks when loading the clip.
- Do not squeeze the applicator handles before jaws are placed around vessel or tissue.
- Ensure applicators are fully close to handle stop point when applying clip.
- Inspect the ligation site to ensure secure application and hemostasis.
- To prevent the damage to applicator jaws

- Avoid introducing applicator tips at an angle into the cartridge rack, this may misalign tips
- Use recommended applicators
- Closure of empty jaws on a vessel or anatomic structure may result in a patient injury

INSTRUCTION:

- Inspect the integrity of the individual packaging before using.
- Select the appropriate applicator.
- Grasp the applicator so that the handles are fully open and jaws will not compress as the applicator is inserted into the cartridge
- Align applicator's jaw vertically and laterally over a clip in the cartridge and push the applicator firmly onto the clip without compressing the handle
- Remove the applicator from the cartridge
- Verify that the clip is fully inserted into the applicator's jaws and clip legs do not protrude beyond the end of the jaws
- Handle the applicator carefully. The jaws should not close prematurely
- Proceed carefully through the cannula, ensuring the applicator jaws remain open and the ligating clip is not pre-compressed
- At the ligation site, surgeon should close the applicator firm, press until the clip is fully closed.
- Releasing the pressure on the handle will cause the applicator jaws to spring open
- Remove the applicator from the surgical site.

STERILITY:

Mirus Ligating clip is sterilized by Gamma Irradiation as indicated on package. Do not re-sterilize. Do not use if package is open or damaged.

STORAGE:

Store the sterile package in a cool dry area, with good ventilation away from areas of extreme temperature and humidity.

SIZE SELECTION:

CLIP SIZE	CODE	COLOUR	CORRESPONDING APPLIER (APPLIER SIZES & CODES)
Small	MLT100	BLUE	OPEN APPLIER 100- 15CM- FTOA-10015 OPEN APPLIER 100- 20CM- FTOA-10020 OPEN APPLIER 100- 28CM- FTOA-10028

Medium	MLT200	WHITE	OPEN APPLIER 200-15CM- FTOA-20015 OPEN APPLIER 200-20CM-FTOA-20020 OPEN APPLIER 200-28CM-FTOA-20028
Medium- Large	MLT300	GREEN	OPEN APPLIER 300-15CM- FTOA-30015 OPEN APPLIER 300-20CM-FTOA-30020 OPEN APPLIER 300-28CM-FTOA-30028 LAPROSCOPIC APPLIER 300-FTEA-00300
Large	MLT400	YELLOW	OPEN APPLIER 400-15CM- FTOA-40015 OPEN APPLIER 400-20CM- FTOA-40020 OPEN APPLIER 400-28CM- FTOA-40028 LAPROSCOPIC APPLIER 400-FTEA-00400

CLEANING, DISINFECTION AND DRYING INSTRUCTION FOR CLIP APPLIER

Clip Applier should be cleaned independently according to the instruction listed below. The instruments are validated to be cleaned according to the following

- Pre-Cleaning
- Soak the instrument in tap water for minimum time of 5 minutes.
- Brush under tap water until no residues are visible
- Flush the distal and proximal joints with a syringe until the rinsed water is clear
- Cleaning
- Place the instrument in an ultrasonic bath at 104 F (40°C) with a 0.8 % enzymatic detergent
- Sonicating for 10 minutes.
- Remove the instrument and flush with deionised water for 15 - 20 Sec.
- Drying
- Dry the instrument with clean and sterile lint free cloth
- Sterilisation
- Instrument should be sterilised in the disassembled/ open position
- The instruments are validated to be sterilised according to following parameters.

Sterilisation method	Instrument Configuration	Temperature	Exposure Time (minimum)	Drying time (minimum)
Pre vacuum	Wrapped	270 F (132°C) / 275 F (135°C)	4 min / 3 min	10 min
Gravity	Wrapped	250 F (121°C)	30 min	10 min

SYMBOLS USED ON LABELING

 = Caution  = Use By (Use until Year & Month)

 = Keep Dry  = Batch Code

 = Do Not Use If Package is damaged  = Manufacturer

 = Do Not Reuse  = Date of manufacture

 = Do Not Resterilize  = Consult Instructions for use

 = Sterilised using Irradiation

 = Temperature Limitation (Store between 15°C - 30°C)