Meril Endo Surgery Private Limited

ARTWORK APPROVAL

Date : 16/06/2025

IFU - LIGATING CLIP

INSTRUCTION FOR USE

Meril
Endo-Surgery

MIRUS™

LIGATING CLIP & CLIP APPLIER

Rev. 00 Rev. Dt. : 2025/06 Document No. ME/IFU/STA/060

Manufactured by :
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DESCRIPTION

Mirus™ Ligating clip are sterile, medical grade pure titanium nonabsorbable, implantable device intended for general surgical procedures that require vessel or tissue ligation.
Mirus™ ligating clip are made of pure titanium grade 1 (ASTM F 67/ ISO 5832-2). The clips are available in various sizes and six clips are packed in a single plastic cartridge. They are available in different color cartridge to distinguish sizes. Mirus™ Ligating clips are supplied with multiuse non sterile Mirus™ Ligating Clip applier as an accessory, allowing the end user to ligate a wide range of vessels and tissue structures, using the Mirus™ Ligating clips.

INDICATION

The Mirus™ Ligating clip is indicated for use in open & endoscopic general surgical procedures of head, neck and abdominal region for tubular structures and vessel ligation.

INTENDED PURPOSE

The Mirus™ Ligating clip is intended to be used for ligation of tubular structures or vessels during various surgical procedure in an operation theatre. The tissue being ligated should be consistent with the size of the clip.

INTENDED USER GROUP

The Mirus™ Ligating clip and Mirus™ Ligating clip applier are intended to be used by surgeons who perform tubular structures and vessel ligation.

TARGET PATIENT POPULATION

The Mirus™ Ligating clip and Mirus™ Ligating clip applier are intended to be used in both male and female including adults and elderly.

CONTRAINDICATIONS

- Mirus™ ligating clips are contraindicated for use in central circulatory system (in the aorta, truncus, brachiocephalicus, carotid artery, coronary arteries and veins, pulmonary arteries and veins, vena cava)
- Mirus™ ligating clips are contraindicated for use in central nervous system.
- Mirus™ ligating clips are contraindicated for use in the case of foreign-body sensitivity for Titanium.
- Mirus™ ligating clips are contraindicated for use in contraceptive procedures such as tubal ligation, vasectomy.
- Mirus™ ligating clips are contraindicated for use in medical and/or surgical conditions that could prevent the safe use of the product, e.g. disorders of the connective tissue.

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-sterilize.
- Always ensure that the correct clip applier is selected for respective clip size prior to initiation of the procedure.
- Do not use damaged Clip, damaged pack or damaged applier.
- The device must be used by professional healthcare person only.
- The patient can be safely scanned during a MR procedure up to 1.5T. Mirus™ ligating clip have not been evaluated above 1.5T and the patient should not be scanned above 1.5T.
- The safety and performance of ligating clip is not evaluated in paediatrics, pregnant or breastfeeding women or the immunocompromised patients.

PRECAUTIONS

- The reusable clip applier is provided non sterile and must be cleaned and sterilized prior to each use
- 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 applier by both shanks when loading the clip.
  - Do not squeeze the applier handles before jaws are placed around vessel or tissue.
  - Ensure appliers 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 applier jaws
  - Avoid introducing applier tips at an angle into the cartridge rack, this may misalign jaws
  - Use Mirus™ Ligating clips with recommended Mirus™ Ligating clip appliers
- Closure of empty jaws on a vessel or anatomic structure may result in a patient injury.
- In case of Malfunction of the device
  - Do not use the malformed clips as it may lead to compromised device safety and performance.
  - Remove the malformed clips if any.
  - Do not use applier again if it is malfunctioning. Replace the applier in that case.

INSTRUCTION

- Inspect the integrity of the individual packaging before using.

ARTWORK No.	REV.
ME/IFU/STA/060	00

Colour Shade	
	PANTONE 636 C
	PANTONE 279 C
	PANTONE 1235 C
	BLACK

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- Select the appropriate applier as per clip size and vessel size.
- The recommended vessel size to be ligated ranged from 2.5 mm to 12 mm.
- Grasp the applier so that the handles are fully open and jaws will not compress as the applier is inserted into the cartridge
- Align applier's jaw vertically and laterally over a clip in the cartridge and push the applier firmly onto the clip without compressing the handle
- Remove the applier (with clip) from the cartridge
- Verify that the clip is fully inserted into the applier's jaws and clip legs do not protrude beyond the end of the jaws
- Handle the applier carefully. The jaws should not close prematurely
- Proceed carefully through the cannula, ensuring the applier jaws remain open and the ligating clip is not pre-compressed
- At the ligation site, surgeon should close the applier firm, press until the clip is fully closed. If handle is not fully decompressed, clip may remain on applier resulting in improper ligation, injury or other serious surgical complications
- Releasing the pressure on the handle will cause the applier jaws to spring open
- Remove the applier from the surgical site.

ADVERSE REACTION

Adverse reactions related to the use of Ligating Clip include cross infection or infection, thrombosis, haemorrhage, swelling, fever, vomiting, seroma formation and inflammation at the wound site.

DEVICE LIFETIME

Mirus™ Ligating clip is long term permanent implant.

STERILITY

Mirus™ Ligating clip is sterilized by Gamma Irradiation as indicated on package. Do not resterilize. Do not use if package is open or damaged.
Discard opened remaining unused clips as per the local area discard procedure.

STORAGE

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

MR SAFETY INFORMATION

Mirus™ Ligating clip is made up of medical grade 1 pure titanium (ASTM F 67/ISO 5832-2) non ferromagnetic material. A patient with such a device can be safely scanned during a MR procedure under MRI with the field up to 1.5 Tesla. No risk or hazards caused by magnetic field but it may produce possible artifacts.

RISK OF REUSE

Mirus™ Ligating clip is instructed to be used single time only. If used multiple times it may lead to cross contamination / infection.

DISPOSAL OF PRODUCT

Disposal of unused / used product and packaging should be carried out in accordance with hospital, administrative and / or local government policy.

SSCP SUMMARY

Refer below link for SSCP Summary as long as EUDAMED is not operational.
https://drive.google.com/drive/folders/1V-L1VRxF0p7-uKi0vBbKPUC4AmtkjB0V?usp=sharing

"Contact Meril Endo Surgery Pvt. Ltd. and Competent authority of the member state in case of any serious incident occur with the device"

SIZE SELECTION

CLIP SIZE	SHAPE	CODE	COLOUR	CORRESPONDING APPLIER (APPLIER SIZES & CODES)
Small	U	MLT100	Blue	OPEN APPLIER 100- 15CM- FTOA-10015 OPEN APPLIER 100- 20CM- FTOA-10020 OPEN APPLIER 100- 28CM- FTOA-10028
Medium	U	MLT200	White	OPEN APPLIER 200- 15CM- FTOA-20015 OPEN APPLIER 200- 20CM- FTOA-20020 OPEN APPLIER 200- 28CM- FTOA-20028
Medium - Large	U	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	U	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
Micro	V	VMLT-060	White	OPEN APPLIER 060-20CM-VTOA-6020
Small	V	VMLT-080	Red	OPEN APPLIER 080-20CM-VTOA-8020
Small-Medium	V	VMLT-100	Yellow	OPEN APPLIER 100-20CM-VTOA-10020
Medium	V	VMLT-200	Blue	OPEN APPLIER 200-20CM-VTOA-20020
Medium-Large	V	VMLT-300	Green	OPEN APPLIER 300-20CM-VTOA-30020
Large	V	VMLT-400	Orange	OPEN APPLIER 400-20CM-VTOA-40020

CLEANING, DISINFECTION AND DRYING INSTRUCTION FOR CLIP APPLIER

Mirus™ Clip Appliers should be cleaned and sterilized prior to each use. Appropriate handling, care, cleaning and maintenance are important to avoid damage and ensure proper function. The user must ensure that cleaning and sterilization are conducted in accordance with the appropriate guidelines, standards or national Health Authorities' requirements. The Mirus™ Ligating Clip applier has a limited life and may be used up to 300 times.

Clip Applier should be cleaned independently according to the instruction listed below. The instruments are 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
- Sonicate 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 date (Use until Year & Month)
= Do Not Reuse
= Do not re-sterile
= Keep Dry
= Keep away from sunlight
= MR Conditional
= Temperature Limitation (Store between 15°C - 30°C)
= European authorized representative
= Single sterile barrier system with protective packaging outside
= Manufacturer
= Date of manufacture
= Batch Code
= Do not Use If Package is damaged
= Consult Instructions for use
= Medical device
= Sterilised using Irradiation
= Unique device identifier
= CE mark and identification number of notified body

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