

Front Side:-

IFU of Endoscopic Ligation Clips
Manufactured by Mais India Medical Devices Pvt. Ltd.

General Device Description:
 The Endoscopic Ligation Clip is a single-use, sterile, mechanical implantable accessory intended for use in endoscopic procedures to achieve mechanical ligation and hemostasis by clamping targeted blood vessels or tissue structures.

Product Name: Endoscopic Ligation Clips

Variants:
 1. Titanium
 2. Polymer

Sizes:
 Small (LT-100), Medium (LT-200), Medium Large (LT-300) & Large (LT-400)

Intended Use:
 The Endoscopic Ligation Clip is intended for mechanical hemostasis, ligation, and tissue approximation during gastrointestinal endoscopic procedures, by clamping soft tissue such as bleeding sites or vessels using a flexible endoscope.

Material of construction:

Sr. No.	Components	Material
1.	Endoscopic Ligation Clips	Polymer/Titanium

Indications for use:

- Ligation of blood vessels.
- Closure of mucosal or submucosal defects.
- Approximation of tissue edges following endoscopic intervention.

Contra-Indications:
 The device should not be used:

- Where the target tissue cannot be adequately visualized or accessed endoscopically
- In friable, necrotic, severely inflamed, fibrotic, or calcified tissue where effective clip closure cannot be achieved.
- In patients with known hypersensitivity to the device materials.
- Where clip placement may cause perforation, obstruction, ischemia, or unintended tissue injury.
- In anatomical locations unsuitable for mechanical clipping due to size, angulation, or excessive tension.

Intended Patient Population:
 Adult, pediatric, and neonatal patients requiring mechanical hemostasis, ligation, tissue approximation, or lesion marking during gastrointestinal endoscopic procedures.

Intended User:
 Healthcare Professionals.

Use environment:
 Hospital and Clinical environment.

Instruction for use:

- Inspect the sterile package for integrity. Do not use if the package is damaged or expired.
- Open the package using aseptic technique.
- Select a compatible Endoscopic Clip Applier according to the clip size (color coding, if applicable).
- Secure the clip cartridge on a stable surface as per manufacturer instructions.
- Hold the clip applier at the box lock and insert the jaws vertically into the cartridge housing.
- Advance the jaws fully into the cartridge to ensure proper clip loading.
- Introduce the loaded applier through the working channel of the flexible endoscope.
- Under direct endoscopic visualization, position the clip over the target vessel or tissue.
- Firmly squeeze the applier handles to deploy the clip.
- The clip closes tip-to-tip first to prevent tissue or vessel slippage, followed by full closure.
- Release the handle and withdraw the applier from the endoscope.
- Confirm secure clip placement endoscopically.

Intended Clinical Benefits to the patients:

- Enables precise mechanical ligation and hemostasis at targeted gastrointestinal sites.
- Provides secure and consistent tissue compression to control bleeding and approximate tissue.
- Controlled deployment mechanism allows accurate placement through the endoscope working channel.
- Compact metallic clip design permits clear endoscopic visualization during positioning and release.
- Single-use, sterile configuration minimizes cross-contamination and reduces infection risk compared to reusable devices.

Clinical Safety:

- Device Design and Material Safety.
- Biocompatible products.
- Our device is a single use device.
- Our product is non-toxic, sterile & non-pyrogenic.

Performance characteristics:

- Accurate and controlled placement of the clip at the target gastrointestinal site under direct endoscopic visualization.
- Reliable mechanical compression achieved through the clip's pre-formed jaw design to support effective hemostasis and tissue approximation.
- Secure clip closure and retention at the deployment site, minimizing unintended release or migration.
- Sterile, single-use design reduces the risk of cross-contamination and supports patient safety during endoscopic procedures.

Accessories which can be used with the device:
 The device is itself an accessory of Endoscopic Clip Appliers.

Warnings:

- The product should not be reprocessed.
- Improper transport and handling may cause structural and/or functional damage to device or packaging.
- Do not clean or resterilize.
- Do not expose to heat or direct sunlight.
- The product should be used immediately after opening the packaging.

MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.

Cautions:

- Do not use if package is damaged.
- Discard after single use.

Limitations:

- Not suitable for large, thick, fibrotic, or calcified tissue where adequate closure cannot be achieved.
- Provides mechanical hemostasis only and may be insufficient for severe, diffuse, or arterial bleeding requiring adjunctive therapies.
- Effectiveness is dependent on adequate visualization, access, and positioning of the target tissue.
- Once applied, the clip cannot be repositioned or reused.

Potential Side Effects:

- Irritation or Inflammation at application site.
- Pain & Discomfort.
- Mucosal Injury.

Back Side:-

Disposable instructions:
 Used Devices may be contaminated with infectious and/or other hazardous materials. Unused expired devices should be disposed of as per local regulations.

Duration of use:
 Short-term duration (temporary implant).

Storage Conditions:
 Store in Cool & Dry Place. Keep away from direct sunlight.

Shelf life:
 5 Years.

Type of Sterilization:
 This device is sterilized by ethylene oxide gas. Do not re-sterilize, and do not reuse. Do not use it if the package is opened or damaged. Discard opened unused devices.

Notice to Users and/ or Patients:
 Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Explanation of symbols used:

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)		Latex free (Indicates a medical device that is Latex free)
	Caution (To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.)		Date of manufacture (Indicates the date when the medical device was manufactured)
	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)		Use-by date (Indicates the date after which the medical device is not to be used)
	Single sterile barrier system (Indicates a single sterile barrier system)		Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)		Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)
	Do not re-use (Indicates a medical device that is intended for one single use only)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	Non-pyrogenic (Indicates a medical device that is non-pyrogenic)		Keep dry (Indicates a medical device that needs to be protected from moisture)
	Do not use if packaging is damaged and consult instructions for use. (Indicates a medical device that should not be used if its packaging has been damaged or opened, and that the user should consult the instructions for use for additional information)		Manufacturer (Indicates the medical device manufacturer) Manufacturing Unit: 525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India. Contact Details: +91 8527589990 Fax No.: 0124 404 7533 Email ID: info@maisindia.com Website:www.maisindia.com
	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)		Medical device (Indicates the item is a medical device)
	Country of manufacture (To identify the country of manufacture of products)		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)
	This way up		

ISO & CE Certified Company

Manufactured by:
Mais India Medical Devices Pvt. Ltd.
 525-P, Sector-37, Pace City-II,
 Gurgaon, Haryana-122001 (INDIA)
 Mfg. Lic. No.: MFG/MD/2019/000037

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