

## Statement

Hangzhou Mindray Medical Technology Co., Ltd. (Hereinafter called Mindray) owns the intellectual property rights to this product and this manual. Disclosure of the information in this manual in any manner whatsoever without the written permission of Mindray is strictly forbidden. This manual provides the instructions necessary to operate the product in accordance with its function and intended use. Observance of this manual is a prerequisite for proper performance and correct operation, and ensures patient and operator safety. Mindray is responsible for safety, reliability and performance of this product only in the condition that:

- This product is operated under strict observance of this manual.
- This product is not damaged by human factors. Human factors refer to unintentional falling, intentional damaging, etc.

In the event that it becomes necessary to return a unit to Mindray, please contact the Mindray Service Department. Please provide the model number, batch code, and a brief description of the reason for return. The customer is responsible for freight charges when this product is shipped to Mindray for service (including any relevant customs fees or other freight related charges).

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# Polymer Ligation Clip Instructions For Use

## Intended purpose

Polymer Ligation Clips are intended for use in procedures involving the ligation of blood vessels or tissue structures.

## Intended user

Instrument nurse: Be responsible for the collection, unpacking, installation, and delivery of the ligation clips to the doctor, the cleaning of the clip applicators after use, as well as the counting of the clip cartridges, disposal and other operations.

Surgeon: Use the clip applicator with the ligation clip to ligate the target tissue, and then safely take out the clip applicator.

## Indications

Polymer Ligation Clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure.

## Intended environment

It is mainly used in the operation room.

## Intended Patient population

Adult and Pediatric.

## Product Models and Specifications

Serial No.	Model No.	Specification
1	191-01136	ML,1PCS
2	191-01236	ML,2PCS
3	191-01436	ML,4PCS
4	191-01636	ML,6PCS
5	191-01146	L,1PCS
6	191-01246	L,2PCS
7	191-01446	L,4PCS
8	191-01646	L,6PCS
9	191-01156	XL,1PCS
10	191-01256	XL,2PCS
11	191-01456	XL,4PCS
12	191-01656	XL,6PCS

## Structural Composition of Product

This product comprises ligation clips, a ligation clip cartridge, and a ligation clip cover.

Polymer Ligation Clip are made of polyoxymethylene (POM). Polymer Ligation Clip cartridge is made of acrylonitrile butadiene styrene (ABS) and the cover is made of polypropylene (PP). The product has been sterilized by ethylene oxide and is intended for single use only.

Each ligation clip comprises five components: the lock, hinge, bow-shaped legs, anti-slip teeth, and bosses. The structural diagram and dimensions of Polymer Ligation Clip must meet the requirements in Figure 1, 2 and Table 2.

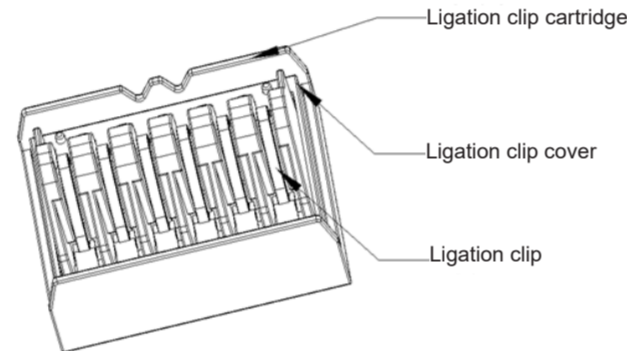


Figure 1 Product Composition

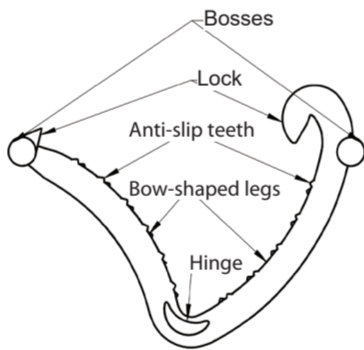


Figure 2 Polymer Ligation Clip

Table 2 Product Specifications and Dimensions (mm)

Serial	Model No.	Specification	Tissue bundle	Vessel bundle
1	191-01136	ML,1PCS	3-10	1-4
2	191-01236	ML,2PCS		
3	191-01436	ML,4PCS		
4	191-01636	ML,6PCS		
5	191-01146	L,1PCS	5-13	2-6
6	191-01246	L,2PCS		
7	191-01446	L,4PCS		
8	191-01646	L,6PCS		
9	191-01156	XL,1PCS	7-16	3-8
10	191-01256	XL,2PCS		
11	191-01456	XL,4PCS		
12	191-01656	XL,6PCS		

## Product Properties

1. This is a single-use, sterile product.
2. The net weight of XL ligation clip is 0.12 g.

## Sterilization Method

Ethylene oxide.

## Instructions for Use

### Pre-operative preparation

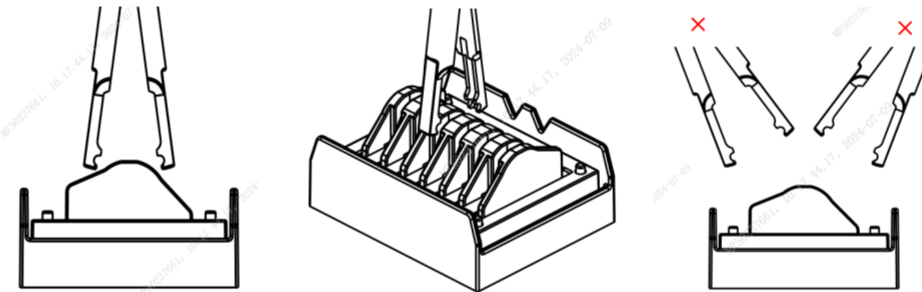
1. Check that the product packaging is intact before use.
2. Check the appearance, model, and specification of the product.
3. Remove the product from its packaging using an aseptic technique.
4. Check the jaws of the applicator for any bends, damage, cracks, abrasion, and other defects. The jaws must be fully aligned. They must allow proper ligation and open normally.

### Operation

1. Insert the jaws of the applicator perpendicularly into Polymer Ligation Clip cartridge of a compatible model. A click should be heard when Polymer Ligation Clip is properly loaded onto the applicator. Hold the cartridge and slowly withdraw the applicator perpendicularly from the cartridge. Make sure Polymer Ligation Clip is lodged securely within the tip of the applicator. The bosses of Polymer Ligation Clip should be located in the notches of the tip. Keep the applicator perpendicular during the above two steps. It should enter and withdraw from Polymer Ligation Clip cartridge easily. Do not use force and do not insert or withdraw the applicator at an angle.
2. Slightly squeeze the applicator handles, and insert the tip and shaft into the trocar. After the tip has fully passed through the trocar cannula, release the pressure on the handles.
3. Position the applicator such that the jaws encapsulate the target tubular structure or tissue that has been suitably isolated. The operator must ensure the locking mechanism is clearly visible. Squeeze the applicator handles to lock the clip.
4. Release the pressure on the applicator handles to allow the jaws to fully open again. Slowly move the jaws away from the ligated target tissue to avoid pulling and tearing the target tissue. Once the ligation is complete, check that Polymer Ligation Clip is securely closed.
5. When severing a ligated blood vessel, do not cut along Polymer Ligation Clip. Cut 2 to 3 mm from the distal side of Polymer Ligation Clip.

### Precautions

- The applicator must be inserted forward into the Ligation clip cartridge.



- The clip must be latched to ensure proper ligation of the vessel or tissue. The distance between the clip and the incision is at least 2-3 mm.
- Inspect the ligation site after application to ensure proper closure of the clip. Security of the closure should be confirmed after ligation.

## Contraindications

Polymer ligation clips are not intended for use as a fallopian contraceptive tubal occlusion device. Polymer ligation clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

## Side effects

According to clinical and residual risk evaluations, polymer ligation clips have no known side effects for the intended patients.

## Intended clinical benefit

The use of polymer ligation clips for vascular or tissue ligation provides the benefit of successful surgical outcomes, and facilitates smooth postoperative recovery for patients.

## Production Date

See label.

## Shelf Life

5 years.

## Warnings

1. Do not use if the primary package is damaged or if the product has expired.
2. This product is sterile and intended for single use only. Do not reuse the product or resterilize it for reuse.
3. Once opened, the product must be used for the current surgical operation. Do not keep the opened product until the next surgery.
4. The product must only be used by licensed physicians and medical professionals trained in its operation. Non-compliance will cause harm to the patient.

## Precautions

- Please read this instruction manual carefully before using the product.
- Before use, check the compatibility of other equipment or accessories to be used with the product.
- To maintain sterility of the product, do not open the sterile packaging before surgery.
- The product must not be used if the packaging is damaged or no longer within the sterile period.
- The Polymer Ligation Clip should be used once the primary package is opened. Discard all unused clips.
- Applicators manufactured by Hangzhou Mindray Medical Technology are recommended. Always check that the applicator is compatible with Polymer Ligation Clip.
- The Polymer Ligation Clips are not intended for ligation of renal arteries during laparoscopic donor nephrectomy. For ligation of renal arteries in surgeries other than laparoscopic donor nephrectomy, the use of more than 1 ligation clip is recommended. The vessels' distal cuff must be at least 2 to 3 mm from Polymer Ligation Clip.
- Always ensure Polymer Ligation Clip is positioned correctly before use. Incorrect positioning can cause the clip to close abnormally or break due to shearing by the rigid tip or incorrect pressurization of the tip.
- Polymer Ligation Clip must be locked shut to ensure proper ligation of the vessel or tissue. After the procedure, always check the ligation site to make sure Polymer Ligation Clip has been closed correctly. Check that the closure is secure after the ligation.
- Except for the renal arteries, a second ligation clip should only be applied to vessels when deemed necessary by the surgeon.
- Do not use Polymer Ligation Clip as tissue markers. Do not use Polymer Ligation Clip and applicator as dissection tools.
- It is recommended to have a Teleflex clip remover ready during endoscopic surgeries using the Polymer Ligation Clip.
- Before applying Polymer Ligation Clip, verify the dimensions and conditions of the vessel or tissue structure and use the appropriate ligation clip model. The closure of this ligation clip system does not share the same features as that of other stapling systems due to differences in design and other aspects of Polymer Ligation Clip. The user is responsible for selecting Polymer Ligation Clip and tissue structure, and for checking that Polymer Ligation Clip has been securely locked upon release. It is also the user's responsibility to determine whether the use of other surgical instruments and devices is necessary where Polymer Ligation Clips have been placed.
- Ligation clips that have been removed must not be reused.
- According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations. Thus, no residual risk associated with using the medical device should be disclosed.
- Polymer Ligation Clips are constructed of a nonabsorbable polymer material and are considered MR safe according to the current criteria and labeling terminology.
- summary of safety and clinical performance is available on <https://ec.europa.eu/tools/eudamed>.
- Use of a matching applicator is recommended. Always check that the applicator to be used is compatible with Polymer Ligation Clip. Incompatibility can cause the ligation to fail or damage the vessel or tissue.
- It is recommended to lock Polymer Ligation Clip shut to ensure proper ligation of the vessel or tissue. After the procedure, always check the ligation site to make sure Polymer Ligation Clip has been closed correctly. Check that the closure is secure after the ligation. Otherwise, bleeding could potentially occur during or after the surgery.

## Compatible Instruments

Table 3

Mindray Ligation clip Specification	Ligation clip Model	Compatible Applier Models (Hangzhou Mindray Medical Technology)	Compatible Remover Models (Teleflex)
ML,1PCS/ ML,2PCS/ ML,4PCS/ ML,6PCS	191-01136/ 191-01236/ 191-01436/ 191-01636	221-55636	544121
L,1PCS/ L,2PCS/ L,4PCS/ L,6PCS	191-01146/ 191-01246/ 191-01446/ 191-01646	221-05646	544130
XL,1PCS/ XL,2PCS/ XL,4PCS/ XL,6PCS	191-01156/ 191-01256/ 191-01456/ 191-01656	221-05656	544130

## Storage Conditions

1. Store the product indoors in a clean and well-ventilated area. Keep the product cool and dry. Protect from light, fire, pests, and corrosive gases.

## Transportation Conditions

1. Temperature range: -20°C to 50°C; relative humidity range: 10% to 80%; air pressure: 500hpa-1060hpa.

## Notification of Incident

As a health care provider, you may report the occurrence of certain events to Hangzhou Mindray Medical Technology Co., Ltd. and possibly to the competent authority of the member state in which the user and / or patient is established.

These events include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, Hangzhou Mindray Medical Technology Co., Ltd. requests to be notified of device failures or malfunctions. This information is required to ensure that Hangzhou Mindray Medical Technology Co., Ltd. provides only the highest quality products.



















## Disposal







Dispose of discarded product according to the practice for hospital medical waste.

## Symbol

You may see the following symbols on the product:

Table 4 Symbol definition

Symbol	Meaning	Symbol	Meaning
	Consult instructions for use or consult electronic instructions for use		Sterilized using ethylene oxide
	Batch No.		Date of manufacture
	Do not re-use		Use-by date
	Do not use if packaging is damaged		Atmospheric pressure limitation
	Do not resterilize		Temperature limit
	Single sterile barrier system		Humidity limitation
	Single sterile barrier system with protective packaging inside		Unique Identification Device
	The product is provided with a CE marketing in accordance with regulations stated in Regulation(EU)2017/745 concerning Medical Devices.		Catalogue Number
	Stacking limit by mass		Keep away from sunlight

	Fragile,handle with care		This way up
	Authorized representative in the European Community		MR Safe
	Medical Device		Trademark of manufacture, authorized by Shenzhen Mindray Bio-Medical Electronics Co., Ltd.