

Instructions for Use of the Multiple Clips Reusable Applier

CAUTION: This IFU contains information necessary for the safe operation of the Multiple Clips Reusable Applier. Please read and understand all instructions in this IFU before attempting to use the Multiple Clips reusable Applier. Any disregard of the safety information will be considered abnormal use.

Sunstone's Multiple Clips Reusable Applier are designed for use with Sunstone's Multiple Polymer Ligating Clips. The magazines of the repeating ligature clips match the color of the clip applicators they are used with. Sunstone assumes no liability for any adverse consequences resulting from the use of any equipment or ligature clips not designated by Sunstone as an integral part of a particular system.

【Product Name】

Multiple Clips reusable Applier

【Model Specifications】

MCA-12CL、MCA-10CM、MCA-10CS

【Intended Purpose】

This product is used as a delivery device to deliver the ligation clip through a puncture cannula of a specific size to clamp the non-absorbable polymer ligation clip. It is used in conjunction with the Multiple Polymer Ligating Clips produced by our company.

【Intended User】

This product should only be operated by doctors/physicians who have received training and are proficient in Multiple Clips Reusable Applier.

【Product Description】

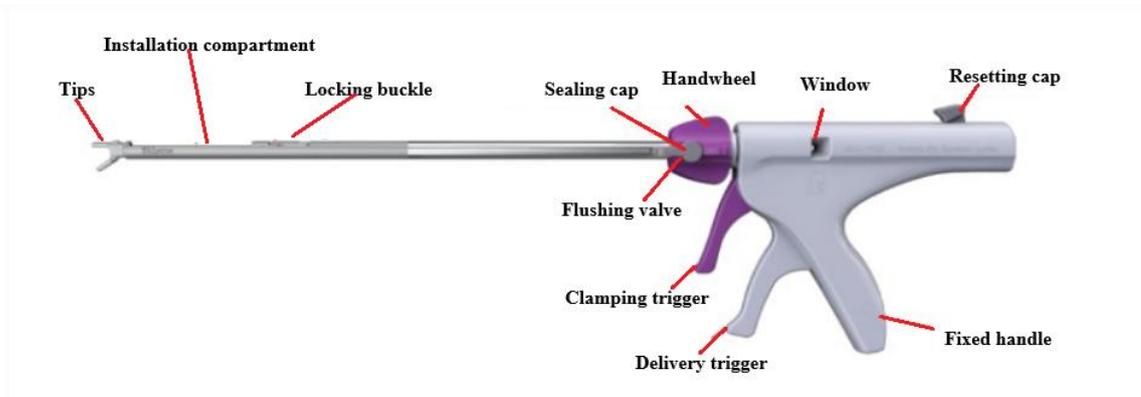
1. The Multiple Clips Applier is a delivery device for single-use multiple ligation clips. It is a reusable device that requires manual loading. Each loading allows for the continuous delivery of 2 - 6 ligation clips. This applier is only compatible with the types of ligation clips listed in Table 1 and is incompatible with other types of ligation clips.
2. The multiple ligation clips are disposable, non-absorbable, and non-active implantable devices, which are used for general surgical treatments requiring the ligation of blood vessels or tissues. The ligation clips are made of polyoxymethylene (POM).
3. For product dimensions and compatibility, please refer to table 1 below:

Product Model No.	Size	Reel Color	Compatible Multiple Polymer Ligating Clips Models (Hangzhou Sunstone)	Casing Size (mm)	Diameter of Closed Blood Vessels and Tubular Tissues (mm)
MCA-12CL	L	Yellow	NLC-CL-2, NLC-CL-3, NLC-CL-4, NLC-CL-5, NLC-CL-6;	12	3-10
MCA-10CM	M	Purple	NLC-CM-2, NLC-CM-3, NLC-CM-4, NLC-CM-5,	10	2-7

			NLC-CM-6;		
MCA-10CS	S	Green	NLC-CS-2, NLC-CS-3, NLC-CS-4, NLC-CS-5, NLC-CS-6;	10	1-3

4. Materials and composition

The product consists of a pliers beak, a joint, and a handle, wherein the pliers beak consists of a tip, a locking buckle, and a push rod; the joint consists of a flushing valve, a sealing cap, and a handwheel; the handle consists of a resetting cap, a fixed handle, a clamping trigger, and a Delivery trigger.



【Contraindications】

No

【Adverse Reactions】

No

【Precautions, Warnings and Tips】



The product should be used in conjunction with the Multiple Polymer Ligating Clips produced by our company. Please confirm the model of the Multiple Polymer Ligating Clips before use and choose the appropriate model of multiple clips reusable applier.



The Multiple Clips Reusable Applier are supplied non-sterile and must be cleaned and sterilized before use.



The Multiple Clips Reusable Applier must be carefully inspected before and after use, as any damage will affect the safety of the device. For instruments with moving parts, please check whether they can work properly before use.



Multiple Polymer Ligating Clips is a safe ligation solution. Please check all tissues inside the ligation clip before closing to ensure that the tissue to be ligated is correct. Because the ligation clip that is safely closed needs to be removed, a ligation clip remover is required.



Endoscopic procedures should only be performed by physicians who have been trained and skilled in endoscopic techniques. To avoid possible risk of injury to the user and/or patient, please be sure to fully understand the principles of operation, risks and benefits, as well as the specific dangers of using an endoscope.



Multiple Clips reusable Applier must be cleaned and sterilized promptly after use. The cleaning and sterilization process does not require disassembly of the device.



The pH value of the cleaning agent shall be between 6.0 and 8.0.



Sterilization temperature should not exceed 135°C (275°F).



Avoid using corrosive solvents when cleaning and sterilizing the Multiple Clips Reusable Applier forceps; avoid heavy pressure or impact on the instrument components.

【Instructions for Use】

1. Pre-use inspection
 - 1.1 Multiple clips reusable applier should be cleaned, sterilized and packaged intact.
 - 1.2 When the Multiple Clips reusable Applier is closed, the two pieces of the clamp head should be aligned without misalignment or shaking.
2. Medical devices must be operated by personnel who hold relevant qualifications and have received training on the use of the device (read the instructions for use in detail in conjunction with the illustrations).
 - 2.1 According to the size of blood vessels or tubular tissues, you should first select the appropriate specifications and models of Multiple Polymer Ligating Clips, and then select the appropriate specifications and models of Multiple Clips reusable Applier.
 - 2.2 Check the resetting cap, it should be at the end of the handle.
 - 2.3 Pull the clamping trigger to close the clamp head (tip), and check that the two pieces of the tip should fit together without misalignment or shaking.
 - 2.4 Release the clamping trigger to reset the clamp head, pull the delivery trigger, and it can be pushed forward normally without obstruction; Pull the resetting cap to return it to its original position.

- 2.5 Pull the safety lock back, install the fastened and removed magazine (with clip) into the installation compartment, and close the lock to press the fastener. Note: The arrow mark on the fastener should point to the clamp head;
- 2.6 After the rapid-fire magazine is installed, the following procedures should be followed depending on the amount of bullets (clips) loaded in the rapid-fire magazine: when the rapid-fire magazine is loaded with 6 bullets, the delivery trigger is pulled once, and the window digital display is 6; when the rapid-fire magazine is loaded with 5 bullets, the delivery trigger is pulled twice, and the window digital display is 5; when the rapid-fire magazine is loaded with 4 bullets, the delivery trigger is pulled 3 times, and the window digital display is 4; when the rapid-fire magazine is loaded with 3 bullets, the delivery trigger is pulled 4 times, and the window digital display is 3; when the rapid-fire magazine is loaded with 2 bullets, the delivery trigger is pulled 5 times, and the window digital display is 2. At this time, Multiple clips reusable applier has entered the standby state.
- 2.7 When in use, pull the clamping trigger to close the jaws, pass the trocar into the abdominal cavity, and release the clamping trigger after entering the abdominal cavity.
- 2.8 Pull the delivery trigger once to make the continuous ligation clip enter the clamp head, adjust the clamping angle of the multiple polymer ligating clips by rotating the wheel, place the blood vessel or tubular tissue in the middle or end position of the ligation clip, and pull the clamping trigger to close the ligation clip.
- 2.9 After confirming that the multiple polymer ligating clips is in a normal clamping state in the human luminal tissue by toggling or visually checking, Multiple clips reusable applier is moved away from the human luminal tissue.
- 2.10 Repeat the steps shown in "2.7, 2.8" to complete the delivery and clamping of the remaining ligature clips.
3. After using the multiple clips reusable applier, pull the reset cap to return it to its original position; click the lock to remove the used rapid-fire cartridge from the multiple clips reusable applier (the rapid-fire cartridge should be disposed of in accordance with relevant regulations on medical waste).

【Cleaning and Sterilization】

1. Cleaning

1.1 Manual Cleaning

Flushing: After use, flush the Multiple Clips Reusable Applier with running water to remove contaminants on the outer surface of the instrument; then connect the device flushing valve to preliminarily remove contaminants from the inner cavity of the device. During flushing, the clamping trigger should be pulled more than 5 times, and the flushing time should be no less than 120 seconds.

Washing: After rinsing Multiple Clips Reusable Applier, soak the device in a suitable cleaning agent for 12 to 15 minutes, then manually scrub or ultrasonically clean for 5 to 10 minutes. The sealing cap should be opened during washing.

Re-rinsing: After washing the Multiple Clips Reusable Applier, rinse it with running water according to the method in Section 1 of Cleaning and Sterilization until there is no blood stain, stain, residue or rust.

Final rinse: Rinse the clamp with purified water for 5 minutes.

1.2 Automatic cleaning

Prepare enzyme solution: Use enzyme cleaning agent. Recommended cleaning agent and cleaning solution pH value is between 6.0 and 8.0. (Neodisher® MediZym is recommended, concentration: 2~10 mL/L (0.2~1.0 %). Use the following automation parameters for automatic cleaning.

Step	Minimum time (minutes)	Temperature
Enzyme washing	5~10	40~45°C
Rinse 1	8	/
Rinse 2	8	/
Drying	30	90°C

2. **Packaging:** After cleaning and drying, the instruments are wrapped with sterile non-woven fabric.
3. **Sterilization:** It is recommended to use pressure steam sterilization (pre-vacuum type) or gravity cycle sterilization for sterilization. The specific sterilization parameters are as follows:

3.1 Pressure steam sterilization (Pre-vacuum type)

Parameter	Recommended parameters 1	Recommended parameters 2	Recommended parameters 3
Sterilization temperature	132°C (270°F)	134°C (273.2°F)	134°C (273.2°F)
Sterilization time	4 minutes	4 minutes	5 minutes
Drying time	30 minutes	30 minutes	30 minutes

3.2 Gravity cycle sterilization

Condition	Sterilization temperature	Minimum sterilization time	Reference pressure range
Parameter	121°C	20 minutes	102.8 kPa~122.9 kPa

【Storage conditions and methods】

Store in a clean room with relative humidity not exceeding 80%, no corrosive gas, normal temperature.

【Maintenance】

Before daily use, check the delivery/closing trigger of the Multiple clips reusable applier to ensure that the delivery trigger moves smoothly and the clamp head has no obvious deformation/defect; if damage is found, please contact your local sales representative for

replacement.

【Notification of Incident】

As a health care provider, you may report the occurrence of certain events to Hangzhou Sunstone 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 Sunstone Technology co.,Ltd. requests to be notified of device failures or malfunctions. This information is required to ensure that Hangzhou Sunstone Technology co.,Ltd. provides only the highest quality products.

【Production Date】

See product packaging label.

【Period of Validity】

The validity period is 2 years from the date of production. The number of times a single product can be reused shall not exceed 750 times, whichever comes first.



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【Symbol】

Symbol	Meaning	Symbol	Meaning
	Warning		Supplied non-sterile
	Manufacturer		Date of manufacture
	Use-by date	LOT	Batch number
	Consult instructions for use		Authorized Representative in the European Community
	Medical device		The product is provided with a CE marketing in accordance with regulations stated in Regulation(EU)2017/745 concerning Medical Devices

【After-sales service organization】

Hangzhou Sunstone Technology Co.,ltd.

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