

Instructions for Use of the Single Clip Reusable Applier

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

Sunstone's Single Clip Reusable Applier are designed for use with Sunstone's Single Polymer Ligating Clips. The ligature clips match the color of the clip appliers they are used with. Hangzhou 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】

Single Clip Reusable Applier

【Model specification】

ECA-10L、ECA-10M、ECA-5S、TECA-10L、TECA-10M、TECA-5S、KFQ-10L、KFQ-10M、KFQ-5S

【Intended Purpose】

This product is used as a delivery and clamping device to deliver and clamp Single Polymer Ligating Clip. ECA and TECA models require through a trocar of a specific size.

【Intended User】

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

【Product Description】

1.The single clip reusable applier serves as the delivery device for the ligation clip. The single clip reusable applier is a reusable instrument that requires manual loading and delivers one ligation clip each time. The clip applier is not compatible with other types of ligation clips.

2.The single ligation clip is a disposable, non-absorbable, and non-active implantable device, which is used for general surgical treatments that require the ligation of blood vessels or tissues. The ligation clip is made of medical-grade POM.

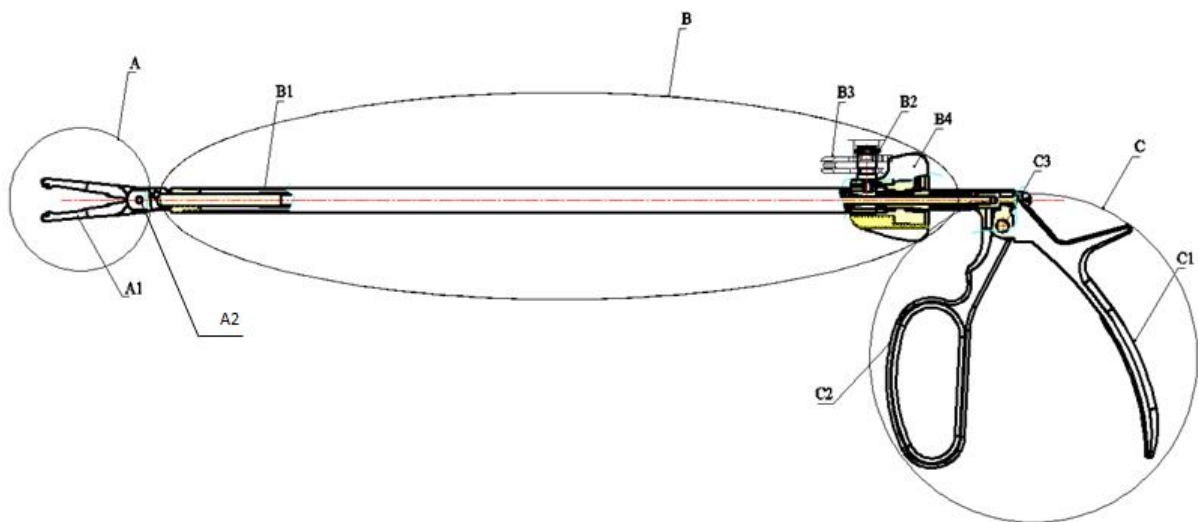
3.For product dimensions and compatibility, please refer to Table 1 below:

Product Model No.	Size	Reel Color	Compatible Single Polymer Ligating Clip Models (Hangzhou Sunstone)	Casing Size (mm)	Diameter of Closed Blood Vessels and Tubular Tissues (mm)
ECA—10L	L	Yellow	NLC-OL-2, NLC-OL-3, NLC-OL-4, NLC-OL-5, NLC-OL-6;	10	3-10
TECA-10L				10	
KFQ-10L				/	
ECA—10M	M	Purple	NLC-OM-2,	10	2-7

TECA-10M			NLC-OM-3, NLC-OM-4,	10mm	
KFQ-10M			NLC-OM-5, NLC-OM-6;	/	
ECA—5S	S	Green	NLC-OS-2, NLC-OS-3,	5	1-3
TECA-5S			NLC-OS-4, NLC-OS-5,	5	
KFQ-5S			NLC-OS-6;	/	

4. Materials and composition

The product is composed of three parts: the head, the shaft, and the handle. The head is made up of the forceps head and the gill axis. The shaft consists of the forceps tube, the flushing valve, the sealing cap, and the rotating wheel. The handle comprises the fixed handle, the firing handle, and the rivet.



A Head (A1 Forceps head、 A2 Gill axis)

B Shaft (B1 Forceps tube、 B2 Flushing valve、 B3 Sealing cap、 B4 Rotating wheel)

C Handle (C1 Fixed handle、 C2 Firing handle、 C3 Rivet)

【Contraindications】

No

【Adverse Reactions】

No

【Precautions, Warnings and Tips】



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



The applier must be cleaned and sterilized in time after use, and there is no need to disassemble it during the cleaning and sterilization process;



Avoid dropping, impacting, and forcible disassembly of the product.



Pay attention not to forcefully insert the single-fire clip applier into the base of the single-use ligation clip.



The Single Clip 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.



Single Polymer Ligating Clip 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.



The Single Clip 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 between 6.0 and 8.0.



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



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

【Instructions for Use】

1. Pre-use inspection

1.1 Single clip reusable applier should be cleaned, sterilized and packaged intact.

1.2 When the Single 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, the appropriate ligating clip specification and model should be selected first, and then the suitable applier specification and model should be selected.

2.2 Hold the single clip reusable applier by hand and keep the forceps head in a naturally open state. Carefully insert the forceps head into the slot of the base of the single ligation clip. Make sure the head is perpendicular to the base. Gently press down the forceps head of the single clip reusable applier above the single ligation clip to install the single ligation clip onto the forceps head. You'll hear a "click" sound, indicating that the single ligation clip is properly seated. Then pull out the single clip reusable applier, and the installation and removal of the single ligation clip are completed.

2.3 Check the attachment of the single ligation clip to the forceps head. All four small cylinders of the single ligation clip must fall into the clamping holes of the forceps head.

2.4 Place the blood vessel or tubular tissue in the middle or at the end of the single ligation clip, and close the handle to clamp the single ligation clip.

3. Release the handle and move the single clip reusable applier away.

【Cleaning and Sterilization】

1. Cleaning

1.1 Manual Cleaning

Flushing: After use, flush the Single Clip 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 Single Clip 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 Single Clip 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

- Packaging:** After cleaning and drying, the instruments are wrapped with sterile non-woven fabric.
- 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	Recommended

		parameters 2	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】

The product should be stored in a dry, well-ventilated room without corrosive gases.

【Maintenance】

Before daily use, check the fire handle of the Single clip reusable applier to ensure that the fire handle 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. 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】

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