

Instructions for Use of Multiple Polymer Ligating Clips

【Product Name】

Multiple Polymer Ligating Clips

【Model Specifications】

NLC-CL-2、NLC-CL-3、NLC-CL-4、NLC-CL-5、NLC-CL-6、NLC-CM-2、NLC-CM-3、
NLC-CM-4、NLC-CM-5、NLC-CM-6、NLC-CS-2、NLC-CS-3、NLC-CS-4、NLC-CS-5、
NLC-CS-6

【Intended Use】

Multiple Polymer Ligating Clips used to ligate blood vessels or tissues during surgery.

【Intended User】

Used by physicians who have received relevant professional knowledge and technical training.

【Intended Patient Population】

Adults, children, the elderly etc.

【Intended environment】

It is mainly used in the operation room.

【Product Description】

1. Multiple Polymer Ligating Clips is a disposable, non-absorbable, non-active implantable device used for common surgical treatments that require vascular or tissue ligation. The ligation clip is made of POM (Acetal Homopolymer).
2. Multiple Clip Reusable Applier is a delivery device for single-use continuous ligation clips. Multiple Clip Reusable Applier is a reusable device that needs to be loaded manually, and each loading can achieve continuous delivery of 2-6 ligation clips. Applier is not compatible with other types of ligature clips.
3. For product dimensions and compatibility, please refer to Table 1 below:

Sunstone's Multiple Polymer Ligating Clips Models	Size	Color	Casing size	Diameter of Closed Blood Vessels and Tubular Tissues (mm)	Compatible Multiple Clip Reusable Applier Models (Sunstone)	Compatible Remover Models (Teleflex)
NLC-CL-2, NLC-CL-3, NLC-CL-4, NLC-CL-5, NLC-CL-6;	L	Yellow	12 mm	3-10	MCA-12CL	544130
NLC-CM-2, NLC-CM-3, NLC-CM-4, NLC-CM-5, NLC-CM-6;	M	Purple	10 mm	2-7	MCA-10CM	544130
NLC-CS-2, NLC-CS-3, NLC-CS-4, NLC-CS-5, NLC-CS-6;	S	Green	10 mm	1-3	MCA-10CS	544121

4. Materials and Composition

The Multiple Polymer Ligating Clips consists of ligation clips, a ligation clip cartridge, and a ligation clip cover. The ligation clips are made of POM (as shown in the figure).

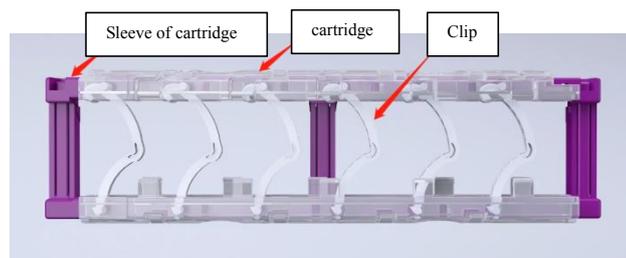


Figure 1 Multiple Polymer Ligating Clips Assembly

5. Material composition and patient exposure information

a. Qualitative and quantitative list of contact materials

No.	Composition	Content, Wt%
1	Polyoxymethylene (POM)	99
2	Fatty acid ester	1
3	Amide lubricants	
4	Hindered phenol antioxidants	

b. Residual components

Substance Name	Source	Maximum Residual Amount/Detection Limit	Safety Basis
Formaldehyde	Material degradation	≤ 0.1% (w/w)	CMR substances and EDCs test report

【Product Properties】

1. This is a single-use, sterile product.
2. The net weight of L size ligation clip is 0.124 g.

【Product Performance】

1. The ligating clip has good toughness.
2. The ligating clip does not bounce off itself after clamping.

【Contraindications】

1. It cannot be used as a blocking device for fallopian tubes for sterilization.
2. It cannot be used for ligation of the renal artery during laparoscopic donor nephrectomy.
3. It is not suitable for surgery with direct contact with the heart or central circulatory system or central nervous system.

【Indication】

For clamp vessels or tubular tissue during surgery.

【Side Effects】

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

【Intended Clinical Benefit】

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

【Precautions】

1. The shelf life of this product is 5 years. Please use it within the indicated shelf life.
2. This product is for single use and must not be sterilized or used repeatedly.
3. Please check the integrity of the packaging before use. If it is damaged, it should not be

used.

4. Avoid dropping, impacting, and forcible disassembly of the product.
5. This product should be used in conjunction with the Multiple Clip Reusable Applier produced by our company. It is recommended that a pair of Clip remover should be prepared in endoscopic surgeries involving the use of ligation clips. Please refer to Table 1 for details.
6. Ligation clips cannot be used for ligation of the renal artery in laparoscopic donor nephrectomy. For renal artery surgeries other than laparoscopic donor nephrectomy, it is recommended to use more than one ligation clip for closure. The application of the second ligation clip should be performed at the surgeon's discretion. If the blood vessel or tubular tissue is severed, do not use one side of the ligation clip as a guide for severance. The stump of the blood vessel or tubular tissue of no less than 3 mm should be retained to avoid incomplete closure after tissue contracture.
7. Before applying the ligation clip, verify the size and condition of the blood vessel or tissue structure, and then use the appropriate ligation clip model.
8. The ligature clip must be locked to ensure proper ligation of the blood vessel or tissue. Be sure to check the ligature site after the operation to ensure the correct closure of the ligation clip. After ligation, the safety of the closure must be confirmed.
9. Because the design and closure characteristics of the ligature clip are different from other nail clip systems. The user is responsible for the selection of the ligation clip and tissue structure, the confirmation of whether the ligation clip is safely clamped after application, and whether other surgical instruments should be applied to the area after the ligation clip is applied.

【Warning】

1. Multiple Polymer Ligating clips is sterile when supplied. Do not sterilize the ligation clip again. If the packaging is damaged, it is strictly prohibited to use it;
2. If damage or suspected damage is found during visual inspection, it should be abandoned.
3. Recycling of disposable products will lead to reduced performance or loss of function of the ligation clip. Reusing disposable products may cause infection with viral,

bacterial, fungal or prion pathogens. There are no validated cleaning and sterilization methods and operating procedures for ligation clip products, and they are reprocessed to reach the original specifications. This product must not be cleaned, disinfected or sterilized again.

4. Failure to perform standardized operations in accordance with the [Instructions for Use] in the instructions will directly affect the use effect of this product.
5. This product is used by physicians who have received relevant professional knowledge and technical training.
6. Ligation clips are used for permanent ligation of blood vessels or tubular tissues. If necessary, the ligation clip can be removed with a clip remover. If the ligation clip breaks during the removal process, the surgeon should remove the broken ligation clip from the surgical site.
7. After the operation, the remaining ligation clips in the ligation clip cartridge and the clip applier should be removed and discarded.
8. Do not try to use this product before reading this instruction for use in full. Any careless operation will bring risks to the success of the operation.

【Instructions for Use】

1. The clinician should select the appropriate hairpin specifications and models for clinical use according to the diameter and size of the blood vessel or tubular tissue, as compared with Table 1 above.
2. After removing the sterile packaging, press the ligation clip cartridge toward each other to make the upper and lower rails buckle (as shown in Figure 2), remove the ligation clip cover and take out the burst box; install the burst box into the burst clip applier in the direction of the clamp head as indicated by the arrow (as shown in Figure 3). Note: After the burst box is pressed and buckled, the ligation clips should be used within 4 hours. If they are not used within the time limit, the performance of the remaining ligation clips may be affected and they should be discarded and replaced.

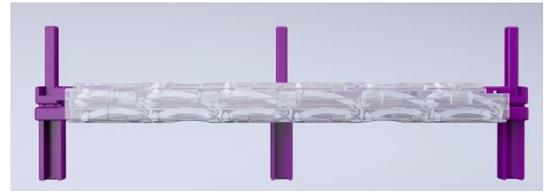
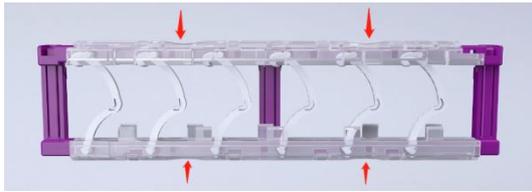


Figure 2



Figure 3

3. According to the instruction of use of the Multiple Clip Reusable Applier, push the ligation clip in the rapid-fire magazine to the clamp head position, and visually check to confirm that the ligation clip is stably fixed on the inner side of the clamp head of the clip applier (as shown in Figure 4).
4. Use the Multiple Clip Reusable Applier to deliver the ligation clip into the body. Visually check that the lock hook of the ligation clip should be exposed to the distal end of the target blood vessel or tubular tissue to confirm that the ligation clip can completely wrap the target blood vessel or tubular tissue. Note: Avoid damaging the hook lock structure of the ligation clip due to the blood vessel or tubular tissue covering it.

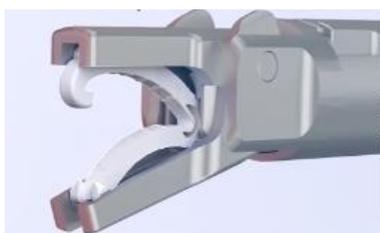


Figure 4



Figure 5

5. Position the ligation clip at the appropriate closable part of the target blood vessel or tubular tissue. After positioning, avoid lateral movement again. According to the instruction manual of the continuous clip applier, quickly trigger the clamping trigger of the continuous clip applier to close the ligation clip (as shown in Figure 5). When it is closed in place, a click can be heard. After visually confirming that the closure state is good, release the clamping trigger to detach the ligation clip from the clamp head and

leave it in the closure part of the target blood vessel or tubular tissue.

【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.

【Storage Conditions and Methods】

The product should be stored in a dry, non-corrosive gas and well-ventilated room.

【Transportation Requirements】

During transportation, the product should be protected from deformation due to heavy pressure, direct sunlight, scratches from hard objects, and immersion in rain, snow or liquid substances.

【Ligation Clip Product Compatibility】

Currently, there are many other types of ligation clips on the market besides the ligation clips provided by Hangzhou Sunstone Technology Co., Ltd. Sunstone Technology's clip applier are designed for use with Sunstone ligature clips. The ligation clip's case matches the color of the clip applier used with it, refer to table 1 for details. Sunstone Technology is not responsible for any adverse consequences caused by the use of any equipment or ligature clips not designated by Sunstone Technology as an integral part of a specific system.

【Disposal】

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

【Symbol】

You may see the following symbols on the product:

Symbol	Meaning	Symbol	Meaning
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	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
	Sterilized with ethylene oxide		No secondary use
	Do not use if package is damaged		Unique Identification Device
	Catalogue Number		Keep away from sunlight
	Humidity limitation		Temperature limit
	MR Safe		

【Production date】 See product package label

【Expiration date】 See product package label

【Shelf Live】 5 years

【Sterilization Method】 Ethylene oxide.



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Summary of safety and clinical performance is available on (SSCP):

<https://ec.europa.eu/tools/eudamed/eudamed>

Note: If the user is unable to access it directly, it is recommended to contact the manufacturer to obtain the offline version of SSCP.

【After-sales service organization】 Hangzhou Sunstone Technology Co., Ltd.

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