

Instructions for Use of Single Polymer Ligating Clips

【Product Name】

Single Polymer Ligating Clips

【Model Specification】

NLC-OL-2、NLC-OL-3、NLC-OL-4、NLC-OL-5、NLC-OL-6、NLC-OM-2、NLC-OM-3、
NLC-OM-4、NLC-OM-5、NLC-OM-6、NLC-OS-2、NLC-OS-3、NLC-OS-4、NLC-OS-5、
NLC-OS-6

【Intended Use】

For ligating blood vessels and tubular tissues during surgery.

【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】

Single Polymer Ligating 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.

【Product Structure Composition】

1. Comparison table of product model specifications and related parameters:

Table 1:

Model	Closed vessel and tubular tissue area diameter (mm)
NLC-OL-2, NLC-OL-3, NLC-OL-4,	3-10

NLC-OL-5, NLC-OL-6;	
NLC-OM-2, NLC-OM-3, NLC-OM-4, NLC-OM-5, NLC-OM-6;	2-7
NLC-OS-2, NLC-OS-3, NLC-OS-4, NLC-OS-5, NLC-OS-6;	1-3

2. Materials and composition

Single Polymer Ligating Clips consist of ligating clips, a cover plate and a base (as shown in Figure 1); the closing clip is made of Acetal Homopolymer (POM) material and is non-absorbable.

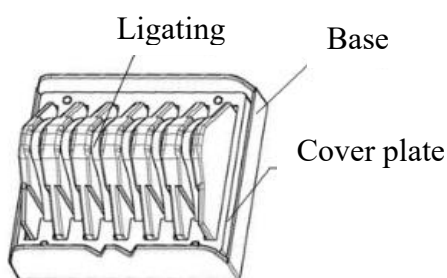


Figure 1 Single Polymer Ligating Clips

3. Material composition and patient exposure information

a. Qualitative and quantitative list of contact materials

SN	Material Name	CAS No.	Contact Method	Content	Exposure Duration	Biocompatibility Standards
1	Acetal Homopolymer (POM)	66455-31-0	Tissue contact at the implant site	≥94%	Permanent	ISO 10993-1

b. Residual components

Substance Name	Source	Maximum Residual Amount/Detection Limit	Safety Basis

Formaldehyde	Material degradation	$\leq 0.1\%$ (w/w)	CMR substances and EDCs test report
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【Product Performance】

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

【Sterilization Method】

Ethylene oxide.

【Contraindications】

1. It can not be used as a fallopian tube blocking device during IUD;
2. It can not be used for renal artery ligation in laparoscopic donor nephrectomy.
3. It is not suitable for large arteries and veins.

【Note】

1. This product is valid for 5 years. please use it within the indicated validity period.
2. This product is for one-time use. can not be repeated sterilization. use.
3. Please check the integrity of the package before use. if found damaged should not be used.
4. Should avoid falling, impact and forced dismantling product use.
5. This product is recommended to be used in conjunction with the Single Clip Reusable Applier (hereinafter referred to as the applier) produced by our company.

【Side Effects】

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

【Intended Clinical Benefit】

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

【Warnings and Instructions】

1. When the product is delivered. ethylene oxide has been sterilized. If the package is damaged.it is strictly prohibited to use;
2. If there is damage or suspected damage found by visual inspection. it should be

abandoned and contacted with the company.

3. The product is disposable and shall not be used after repeated treatment or repeated sterilization.

4. Factors such as storage beyond the [storage conditions and methods] marked in this manual and failure to follow the [instructions for use] in the manual will directly affect the use effect of the product.

5. This product is used by physicians who have received relevant professional knowledge and technical training.

6. Please do not try to use this product without reading this instruction manual completely, any careless operation will bring risks to the success of the operation.

7. It is recommended that the product be used in conjunction with the "Single Clip Reusable Applier" produced by our company for clipping. It is recommended to use model ECA-5S for small ligating clips, ECA-10M for medium ligating clips, and ECA-10L for large ligating clips.

8. When the product fails to be clamped and needs to be removed, it is recommended to use the "Clamp removal (Registration No.)" produced by Zhejiang Shendashiao Medical Devices Co., Ltd. for clamp removal. It is recommended to use model number SD-301.231 for small ligating clips, and SD-301.232-1 for medium and large sizes.

【Instructions for use】

1. The clinician should select the appropriate ligating clip specification and model and the matching model of applier for clinical use according to the diameter and size of the blood vessel or tubular tissue and the above Table 1.

2. Align the applier vertically with the ligating clip in the base, and gently push the head of the applier into the slot of the base. The head of the applier should be fully open when pushed in (see Figure 3) until the clicking sound is heard. Be careful not to force the applier into the base, and the ligating clip should easily enter and exit the base. Remove the applier from the base and visually check that the ligating clip is securely attached to the inside of the applier's head (see Figure 4).



Figure 3



Figure 4



Figure 5

3. Deliver the ligating clip into the body through the applicator. Visually observe that the locking hook of the ligating clip should be exposed to the distal end of the target blood vessel or tubular tissue. Confirm that the ligating clip can completely wrap the target blood vessel or tubular tissue. Note: When applying the ligating clip, avoid damage may caused by the hook-lock structure of the ligating clip on the blood vessels or tubular tissue.

4. Position the ligating clip on the target blood vessel or tubular tissue to avoid lateral movement; the applicator is quickly excited to close the ligating clip, and the clicking sound can be heard. After visual inspection, the applicator is released and the ligating clip is removed from the head of the applicator and placed in the target blood vessel or tubular tissue (see Figure 5).

5. Note: If the blood vessel or tubular tissue is severed, do not use the side of the ligating clip as a guide for the disconnection, and keep no less than 3mm of the blood vessel or tubular tissue stump.

【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.

【Shipping Requirements】




















The product transportation process should prevent heavy pressure deformation, direct sunlight, scratching by hard objects and immersion in rain, snow or liquid substances.

【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
	Warning		Do not resterilize
	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		Non-pyrogenic

【Production date】 See product package label

【Expiration date】 See product package label



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