

IFU of Single Clip Reusable Applier

【Product name】 Single Clip Reusable Applier

【Model specification】 ECA—10L、ECA—10M、ECA—5S

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【After-sales service organization】 After-sales service organization

【Production enterprise license number】 浙药监械生产许 20120117 号

【Registration number】 浙械注准 20232021017

【Product technical requirement number】 浙械注准 20232021017

【Product technical requirement number】 The Single Clip Reusable Applier(hereinafter referred to as the applier) consists of three parts: a head, a rod and a handle.The head is composed of a jaw head and a gill shaft, and the rod is composed of a tube, a flushing valve, a sealing cap and a hand wheel, and the handle consists of a fixed handle, a firing handle and a rivet.

【Product performance】 The head of applier and the front end of the rod are matte, and the rest is bright; the surface should be smooth and rounded, without sharp edges, cracks, or burrs, and the rod should be straight.In the rotation of the rod should be smooth, the rod can be 360 ° free rotation, and in the rotation should not interfere with the use of shaking.

【Scope of application】 This product is used as a delivery and clamping device for the delivery and clamping of single polymer ligating clips through specific sizes of trocar.

【Compatible model】

Specifications of applier	Specifications of single polymer ligating clips.	Trocar size
ECA—10L	NLC-OL-2 , NLC-OL-3 , NLC-OL-4 , NLC-OL-5, NLC-OL-6;	φ10mm
ECA—10M	NLC-OM-2, NLC-OM-3, NLC-OM-4, NLC-OM-5, NLC-OM-6;	φ10mm
ECA—5S	NLC-OS-2 , NLC-OS-3 , NLC-OS-4 , NLC-OS-5, NLC-OS-6;	φ5mm

【Contraindication】 None

【Precautions, Warnings and Instructions】

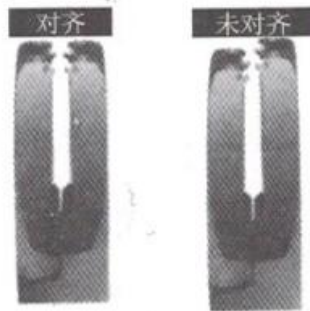
1. The product is recommended to be used in conjunction with the "Single Polymer Ligating Clips(Registration number:国械注准 20223021477)" (hereinafter referred to as the ligating clip) produced by our company. Please confirm the model of the ligating clip before use, and choose the suitable type of applier for use.

2. 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;
3. When cleaning and sterilizing the applier, avoid the use of corrosive solvents, avoid heavy pressure or impact on various parts of the product;
4. Be careful not to violently insert the applier into the base of single polymer ligating clips.

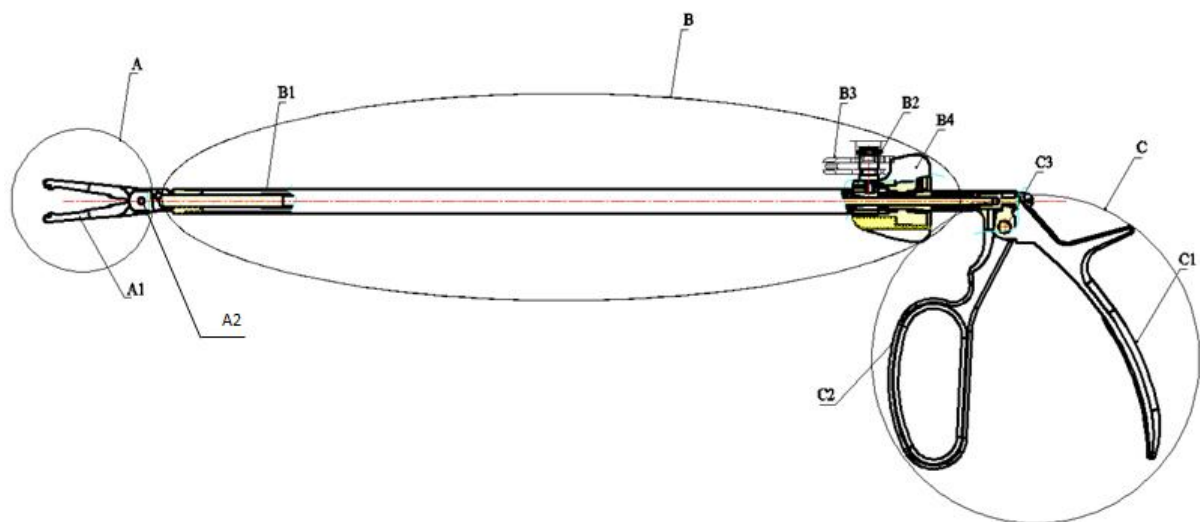
【Instructions for use】

1. Check before use:

- 1.1 The applier should be cleaned and sterilized and packaged in good condition.
- 1.2 When the applier is closed, the two pieces of the jaw should be aligned, and there should be no misalignment or shaking.



2. The following operations must be performed by trained medical personnel (read the instructions for use in detail with the illustration):
 - 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 applier, keep the jaw open naturally, carefully insert the jaw into the groove of the single polymer ligating clips base, confirm that the jaw is perpendicular to the base, and gently press the applier above the ligating clip. Use the applier to install the ligating clip on the jaw until you hear a "click" sound, indicating that the ligating clip has been confirmed to be in place. Pull out the applier to complete the installation of the single-shot ligation clip.
 - 2.3 Check the attachment of the ligating clip to the jaw. All four small cylinders of the ligating clip must fall into the clamping holes of the jaw;
 - 2.4 Place the blood vessel or tubular tissue in the middle or end position of the ligating clip, and press the handle to close the ligating clip.
3. Release the handle and remove the applier.



A Head (A1 jaw, A2 gill shaft)

B Rod (B1 tube, B2 flushing valve, B3 sealing map, B4 hand wheel)




C Handle (C1 fixed handle, C2 firing handle, C3 rivet)

【Cleaning and Sterilization】

1. Rinse: Immediately rinse the device with running water after use to remove contaminants on the outer surface of the device; open the sealing cap, connect the device flushing valve, and initially remove contaminants in the inner cavity of the device. During flushing, the firing handle should be pulled more than 5 times, and the flushing time should be not less than 30 seconds;
2. Washing: After rinsing, the device should be soaked in a neutral multi-enzyme cleaning agent for 12 to 15 minutes, and then manually brushed or ultrasonic cleaned for 5 to 10 minutes. The sealing cap should be opened during washing;
3. Rinse: After the applicator is washed, rinse with running water according to the washing method in Article 1 of 【Cleaning and Sterilization】 until there is no residue such as blood stains, stains and rust spots;
4. Final rinsing: Rinsing with purified water, rinsing time 5min.
5. Drying: Put the applicator into the blast drying oven, set temperature/time: 85°C/30min;
6. Sterilization: It is recommended to use high pressure steam sterilization for sterilization. The specific sterilization parameters are as follows: the type of sterilization equipment is internal circulation exhaust type (lower exhaust type), the reference pressure range is 102.8kPa ~ 122.9kPa, the sterilization temperature is 121°C, and the shortest sterilization time is 15min.
7. Storage after sterilization: (1) When the temperature and humidity of the environment in the storage area for sterile items meet the requirements of WS 310.1-2016, the validity period of sterile items packaged in ordinary cotton materials should be 14days. (2) When environmental standards are not met, the validity period of sterile items packaged in ordinary cotton materials should not exceed 7 days. (3) Sterile items packed in disposable medical paper bags should have a validity period of 30 days; sterile items packed in disposable medical crepe paper or medical non-woven fabrics should have a validity period of 180 days; sterile items packed in disposable paper-plastic bags should have a validity period of It should be 180 days. Sterile items packaged in rigid containers

should have a validity period of 180 days.

【Samples of labels and packaging marks】

	Read the instructions carefully before use
	Avoid the sun
	Avoid rain

【Storage conditions and methods】 Store in a clean room with a relative humidity not greater than 80%, no corrosive gas, normal temperature.

【Maintenance】 Before use, check that the firing handle moves smoothly and that the jaw has no obvious deformation/defect;

【Production date】 See product label

【Expiration date】 The use period is 2 years from the production date, and a single product cannot be reused more than 750 times. The validity period is based on which indicator is met first.

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