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Instructions for Use

Endoscopic Clip Appliers

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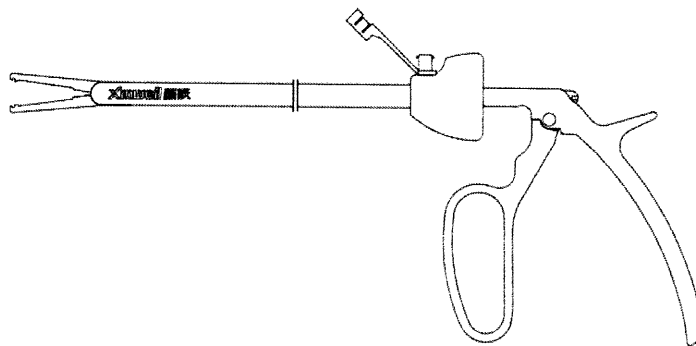
Xinwell

Endoscopic Clip Appliers

Device Description

Endoscopic Clip Appliers are a kind of laparoscopic surgical instruments used in combination with laparoscope, which are used as delivery devices for ligation clips to close and ligate vessels, bile ducts, pancreatic ducts and other tubular structures during surgery.

The Endoscopic Clip Applier consists of applier jaw, applier cannula, turn knob, applier handle and flush joint. It is a reusable device.



Model			Application
X-φ5×200ML	X-φ5×270ML	X-φ5×330ML	Xinwell ligating clips, size M, and Xinwell 05,10,12 specifications trocar
X-φ10×200L	X-φ10×270L	X-φ10×330L	Xinwell ligating clips, size L and Xinwell 10,12 specifications trocar
X-φ10×200XL	X-φ10×270XL	X-φ10×330XL	Xinwell ligating clips, size XL and Xinwell 12 specification trocar

Indications for Use

The Endoscopic Clip Appliers are indicated for uses as delivery devices for delivering ligation clips through a specified size cannula.

Performance characteristics

1. The Endoscopic Clip Appliers should be well matched with the ligation clips and have good clamping performance;
2. The Endoscopic Clip Appliers should have good elasticity and firmness;
3. The opening and closing of the Endoscopic Clip Appliers should be easy and flexible, and there should be no jamming and no shaking of the clamp rod during opening and closing;
4. The applier jaw and applier cannula of the Endoscopic Clip Appliers can turn freely

and position accurately within 360°. The clamp rod should be rotated without shaking of the disturbing.

Contraindications

The Clip Appliers not used in sterilizing operation.

Precautions

1. The Endoscopic Clip Appliers must be sterilized before use;
2. The Endoscopic Clip Appliers are passive surgical device and should not be used in the state of electrification;
3. The Endoscopic Clip Appliers is made of medical stainless steel, the clip appliers not used as tools for beating and crowbar, or used as toys. It's forbidden to be knocked, bent, squished, or put into fire. So as to avoid deformation or damage of the device and affect the normal function;
4. The Endoscopic Clip Appliers are precision instruments, and the applier jaw should not be deformed. Please use and keep them properly;
5. Before use, the Endoscopic Clip Appliers should be checked whether all parts are well assembled and clamped smoothly; otherwise, it shall be maintained and used after passing the inspection.

Note: Users are professionally trained, qualified professionals, and familiar with the product performance and the scope of application, can operate safely.

Directions for Use

Preparation

The clip appliers are provided non-sterile, please sterilize before use.

Operation procedure

1. Select appropriate clip appliers and ligation clips for the size of the cannulas and the vessel or tissue structure;
2. Hold the sterile clip appliers and keep the handle naturally open;
3. Carefully insert the applier jaws vertically into the cartridge slot, making sure the jaws are perpendicular to the base of cartridge (fig.2) ;
4. Remove the applier from the cartridge ensuring the clip is held securely in the applier jaws (fig3).
5. Check the attachment of the ligation clip to the applier jaw: all the four small plastic cylinders must fall into the hole of the applier jaw;
6. Place the lumen or tissue in the middle of the clamp and close the ligation clip with the applier handle closed, place the clamp head of the endoscope clamp applicator around the tissue to be ligated to provide a mechanism for closing the ligation clip, avoid excessive tissue (so as not to affect the safety of the ligation clip when closed).

Note: The ligation should be 2-3mm away from the end of the tissue (or at least

- 4-6mm between the two ligation clips) in order to leave a margin;(fig.4)
7. Align the ligation site and close the handle of the endoscopic clip applicator accurately and continuously until the ligation clip is completely closed(fig.5), loosen the applicator handle, move away the clip applicator (fig.6);

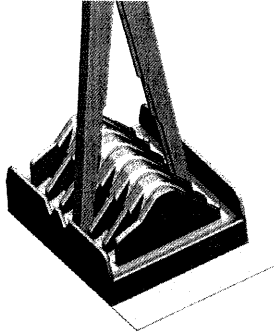


fig.2

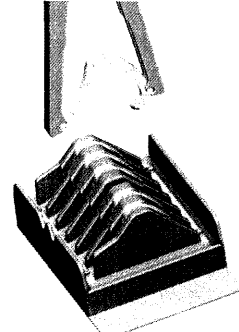
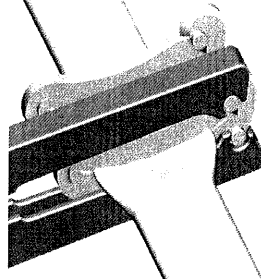


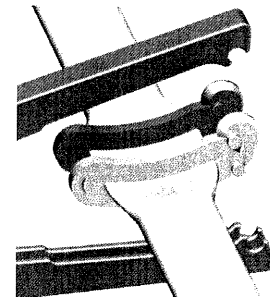
fig.3



fig.4



fig,5



fig,6

Cleaning, disinfecting and sterilization

The devices shall be cleaned, disinfected and sterilized in strict accordance with the operating Specifications of Endoscopic Cleaning and Disinfection Technology (2019 edition).

1. Wash thoroughly with running water immediately after use, remove blood, mucus and other residual substances, and dry them;
2. Thoroughly clean all parts of the device. The applicator jaws, applicator cannulas and the interior channels and cavities should be thoroughly washed with a high-pressure water gun and cleaned with an ultrasonic cleaner for 5-10 minutes;
3. The shaft section, bending part, applicator jaws, applicator cannulas and the interior channels and cavities should be thoroughly brushed with a soft brush;
4. Sterilization method: high temperature and high pressure sterilization (121 °C , 30 minutes);
5. After sterilization, the sterile clip applicators shall be stored according to the requirements for sterilization device;
6. The number times of repeat cleaning and sterilization is less than 200 times.

Maintenance

1. Carry out routine inspection of the instruments to check whether the screw is fastened and the parts are assembled well;
2. The instruments must be cleaned, lubricated, functionally checked and sterilized prior

to each use;

3. After every surgical operation, wipe the blood residue on the instruments with gauze, then rinse them with water (the removable part must be taken apart for cleaning), dry them with gauze, and smear a little silicone oil to prevent rust, and then store them in a dry, non-corrosive gas, clean room with a relative humidity of 15%~80%.

After-sales service commitment



















Under the conditions of following the storage and use rules, if the packaged Clip Appliers are unable to work normally within one year from the date of leaving the factory, the manufacturer shall repair or replace the parts and the products free of charge.


Storage and handling condition

Environmental temperature: -20℃~50℃

Relative humidity: 15%~80%

Packaging Marks

Symbol	Title of Symbol	Symbol	Title of Symbol
	Manufacturer		Authorized representative in the European Community
	Notified Body		Date of manufacture
	Catalogue number		Batch code
	Quantity		Use-by date
	Do not use if package is damaged		Non-sterile
	Caution		Consult instructions for use
	Do not roll		Fragile, handle with care
	Keep away from sunlight		Keep dry
	This way up		Temperature limits

	Humidity limitation	<div style="border: 1px solid black; padding: 2px; display: inline-block;">EN</div>	Language: English
<div style="border: 1px solid black; padding: 2px; display: inline-block;">NL</div>	Language: Nederlands		

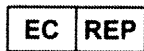


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