

Інструкція по використанню Лігатор гемороїдальних вузлів одноразового використання з аноскопом



Будь ласка, уважно прочитайте всю інформацію.

Невиконання інструкцій може призвести до серйозних наслідків хірургічного втручання.

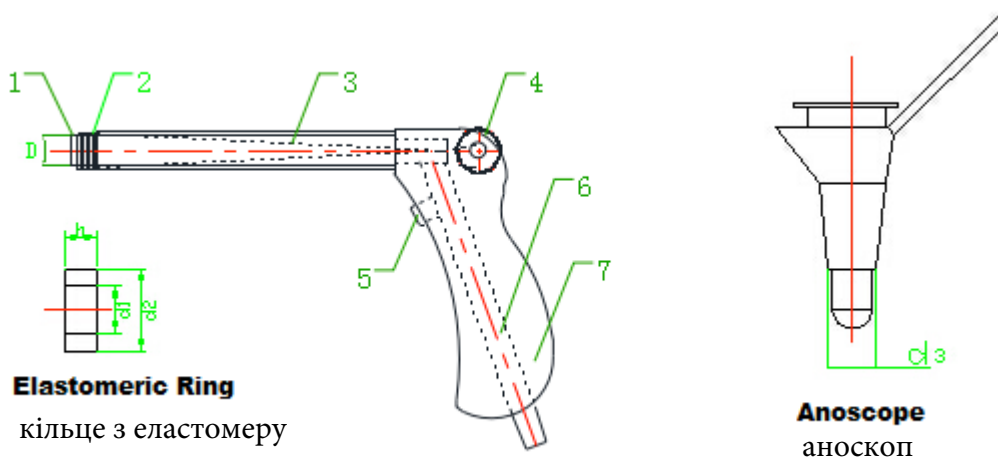
【Показання/Призначення】

Лігатор гемороїдальних вузлів одноразового використання з аноскопом використовується для лікування геморою за допомогою аноскопа ,лише для дорослих.

【Опис пристрою】

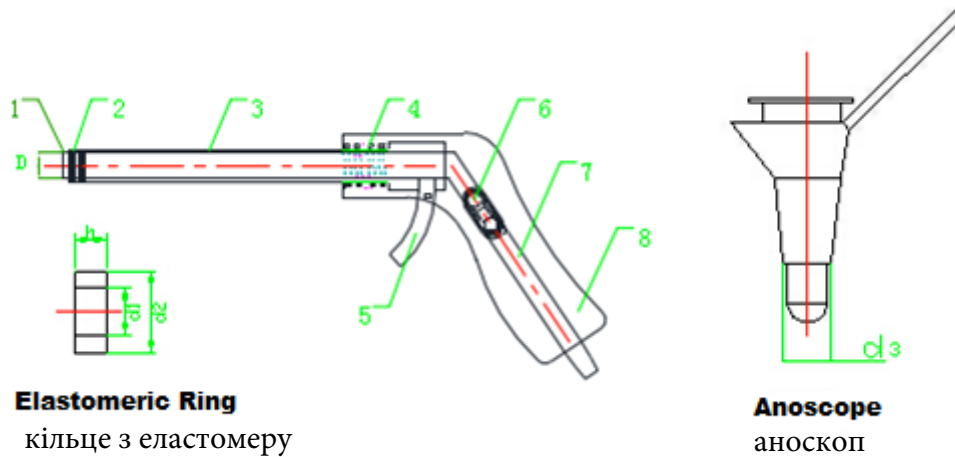
Лігатор гемороїдальних вузлів одноразового використання з аноскопом має два типи, тобто тип А і тип В відповідно до різної форми, і кожен тип має 7 специфікацій, тобто 1 мм, 2 мм, 3 мм, 4 мм, 5 мм, 6 мм і 7 мм.

Детальний схематичний ескіз лігатора гемороїдальних вузлів з аноскопом виглядає наступним чином:



1. Абсорбційна трубка; 2. Кільце з Еластомеру; 3. Спусковий дрiт; 4. Натяжне колесо; 5. Повiтряний клапан; 6. Всмоктувальна трубка негативного тиску; 7. Ручка

Малюнок. 1 Тип А Лігатор гемороїдальних вузлів з аноскопом



1. Абсорбційна трубка; 2. Кільце з Еластомеру; 3. Спусковий дріт; 4. Регулювальна пружина; 5. Спускова кнопка; 6. Повітряний клапан; 7. Всмоктувальна трубка негативного тиску; 8. Ручка

Малюнок. 2 Тип А Лігатор гемороїдальних вузлів з аноскопом

Disposable Hemorrhoid Multi-band Ligature with Anoscopes specifications:

Type	Spec.	Anoscope Type	D		Diameter of Elastomeric Ring				d3		Height of Elastomeric Ring (h)	
					d1		d2					
			Size	Tol.	Size	Tol.	Size	Tol.	Size	Tol.	Size	Tol.
RYTZ	1	A/B	12	±0.5	2.0	±0.5	5.0	±0.5	20	±0.5	1.8	±0.5
	2											
	3											
	4											
	5											
	6											
	7											

【Product Appearance】

- ✓ The elastometric rings should be smooth and without burr; the inner tube and head of anoscope should be smooth and without burr.
- ✓ The surface of elastometric rings should be smooth and bright without focal spot, stain, bubble, crack defects, etc.
- ✓ The trigger pull wire is complete without broken.

【Product Performance】

- ✓ The elastometric rings should have good elasticity and good resilience. When the elastometric rings are taken off from the hemorrhoids absorption tube, its inner diameter is no more than 3.0mm when in nature state for 30min.
- ✓ Operation performance: the ligator should be agile and effective.
- ✓ Sealing: when the negative pressure suction joint connected to the negative pressure aspirator for suction, the inner cavity of hemorrhoids adsorption tube shall not leak.

【Instructions for Use】

- 1) Take Hemorrhoidal Multi-Band Ligator from the package and check its quality, especially the joint, crack, knot or damage, etc. If you find some abnormal situation that may affect the use, do not use. When you find some abnormal situation, inform our company to get permission to return.
- 2) The barrel of the Ligator should be operated freely in the tube of anoscope.

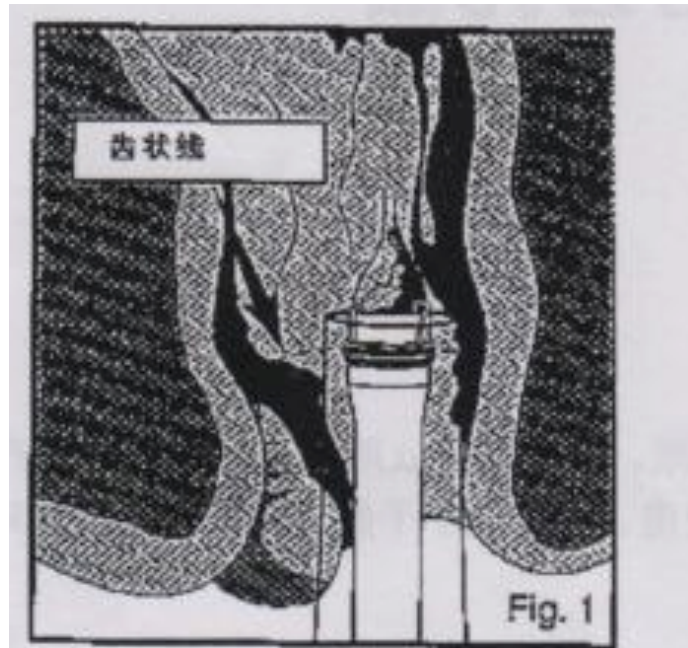
Note: before the operation, check the barrel of the Ligator should be operated freely in the tube of anoscope.

- 3) Connect the negative pressure suction tube and the negative pressure suction joint on the bottom of the ligator handle. Close the vent switch, check whether the negative pressure is produced in the barrel mouth. So far we have prepared the ligator surgery ready.

Note: Before using the Hemorrhoidal Multi-Band Ligator, inspect and screening the hemorrhoidals with anoscope.

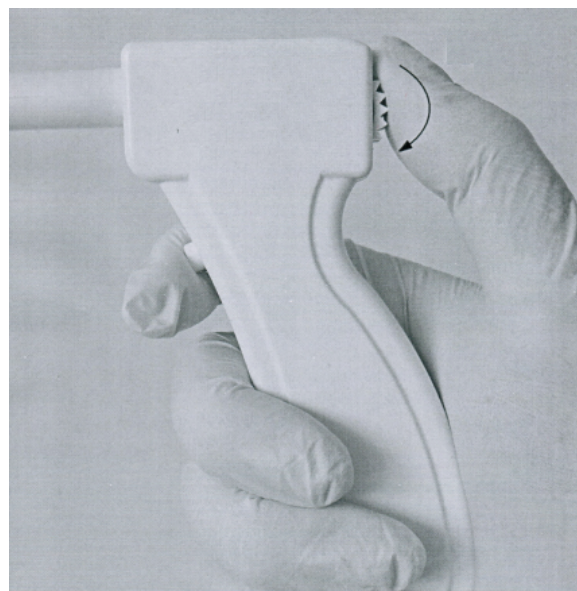
Caution: This can only treat the hemorrhoidals above the dentate line; this can not treat the hemorrhoids below the dentate line, because this will cause pain.

- 4) Insert the anoscope with lubricant.
- 5) Fix the anoscope in order to observe the hemorrhoids that need to be ligature. Insert the Hemorrhoidal Multi-Band Ligator through the anoscope. (Picture 1)



Caution: Before fixing the position to ligature, open the vent switch.

- 6) When the barrel of ligator contacts the hemorrhoids completely, close the vent switch, absorb the hemorrhoids in the suction mouth.
- 7) Keep the negative pressure, rotate the gear at the back of the barrel until the tension is released, then elastometric ring will be placed in designated position. (Picture 2)



Note: Keep the vent switch close, then the negative pressure can be kept.

- 8) Open the vent switch, release the negative pressure, then leave the trapped hemorrhoids slowly.
- 9) If need, repeat the operation above. If you need to place more elastometric rings, connect the

negative pressure suction tube to the ligator.

- 10) After ligation, take out the Hemorrhoidal Multi-Band Ligator and Anoscope.
- 11) Dispose the used products according to the management standards of medical waste with biological risk in the organization.

【Notes】

- ✓ Before use, it is necessary to fully understand the technical principle, clinical application and the risk caused by the Hemorrhoidal Multi-Band Ligator and Anoscope surgery. The product must be used by the physician who have trained the use of anoscope and ligation surgery or under the supervision of trained physician.
- ✓ Do not use this product for unexpected purchase.
- ✓ In this set, the inner diameter of anoscope matches the Hemorrhoidal Multi-Band Ligator, then during the surgery, this set functions best. In order to keep enough room for ligation to pass through the anoscope and prevent the elastometric rings to shifting, do not change the anoscope randomly.
- ✓ This product is sterile, it is manufactured in ISO-Class 8 certified manufacturing area. Because for single use only. Reuse will cause the risk of cross-contamination.
- ✓ If the package has been opened or damaged, forbid to use.
- ✓ After use, dispose as medical waste. Please pay attention to the expiration. The expiration of this product is one year. Please check the expiration on the labels before use. If it is not in validation, please do not use.

【Warnings】

- ✓ Ligation from the proximal end of anal sphincter to the distal end, because the elastometric ring may shift when the anoscope get through.
- ✓ Before use Hemorrhoidal Multi-Band Ligator, normal anoscope inspection is suggested, in order to confirm the need of RPH.

【Contraindication】

- ✓ The contraindication of ligation.
- ✓ The contraindication of hemorrhoids ligation include (but not be limited): Coagulation disorders, anal stenosis and rectum terminal mobility inflammation.
- ✓ This product is forbid to use for rubber allergy patients.

【Potential Complication】

Jiangsu Ripe Medical Instruments Technology Co., Ltd.
No. 12 of Group, Qianjing Cun, Jingcheng Town, Jingjiang City, 214500 Jiangsu, China

- ✓ Those associated with anoscope include (but not be limited): hemorrhage, aspiration.
- ✓ Those associated with sedative drugs include (but not be limited): allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.
- ✓ Those associated with the treatment of hemorrhoids ligature include (but not be limited): aspiration, fever, infection, nausea, urinary retention, stricture formation and obstruction.
- ✓ Hemorrhoidal banding may result in severe pain if the procedure is performed below the dentate line.

【Package】

The instruments are sealed and packaged with blister box and dialysis paper, and supplied sterile for single patient use. Discard after use.

【Sterilization】

Ethylene oxide sterilization.

【Shelf-Life】

Three years after the date of sterilization.

【Transportation and Storage】

- Prevent the overweight pressure, direct sunlight and rain leaching during transportation.
- Products should be stored in no corrosive gas and well ventilated room with relative humidity of not more than 80% and the temperature not more than 54 °C.

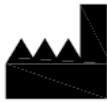

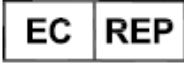














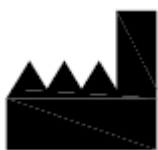
【Product Disposal】

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

【Symbol Explanation】

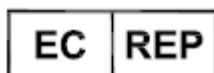
Symbol	Explanation	Symbol	Explanation
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	Manufacturer		Keep away from sunlight
	Authorized representative in the European Community		Keep dry
	Date of manufacture		Temperature limit
	Use-by date		Do not re-use
	Batch code		Consult instructions for use
	Sterilized using ethylene oxide		Caution
	Do not use if package is damaged		Catalogue number
	Notified Body, and product meet the basic requirements of MDD93/42/EEC		



Jiangsu Ripe Medical Instruments Technology Co., Ltd.

No. 12 of Group, Qianjing Cun, Jingcheng Town, Jingjiang City, 214500 Jiangsu, China



Landlink GmbH

Jiangsu Ripe Medical Instruments Technology Co., Ltd.
 No. 12 of Group, Qianjing Cun, Jingcheng Town, Jingjiang City, 214500 Jiangsu, China

Dorfstrasse 2/4, Emmendingen, Germany

Tel.: 0049 7641 9626855

Fax: 0049 7641 9262855

DIMDI Code: DE/0000047525

E-mail: info@landlink-med.com

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