

Please read the instructions before using the product.



Linear Stapler

Instructions for use

Date of issue: Jan 6, 2017

I Application of the product

linear stapler (hereinafter referred to as stapler) is used for linear stapling of alimentary tract tissues.

II Indications

It is used for the closure of the tissue stump of stomach, duodenum, small intestine, colon and rectum. It cannot be used for the stapling of liver or spleen tissues.

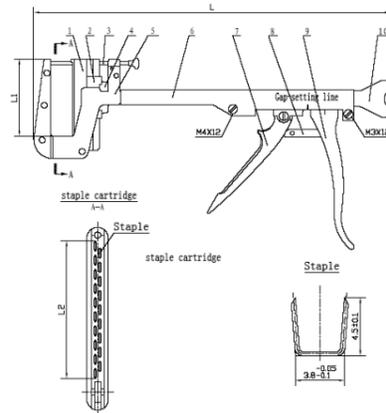
III Working principle

Place the instrument to the position to be stapled and fix the retaining shaft properly to prevent tissues from escaping. Adjust the shifting nut depending on the tissue thickness and preset a suitable thickness in the green zone of the pointer window. Press the front handle so that the staple pusher delivers the staples from the staple cartridge into tissues under the effect of the front handle cam. The staples are guided by the guiding slot in the anvil and bent into the shape of B to close two tissue layers securely by stapling just as a book stapler.

IV Product structure, performance, model and size

1 The product consists of a reusable stapler body and a staple cartridge. (Fig. 1).

In the product, the staples are made of Ta1, TA1 or 00Cr18Ni14M03 as raw materials specified by GB/T3463, GB/T3623, GB/T1220 and GB4234; the stapler body is made of 1Cr18Ni9, 3Cr13 and 2Cr13 as raw materials specified by GB/T1220 and GB3280.



1. Staple cartridge 2. Staple holder clipper 5. Retaining slide pin 4. Staple pusher 5. Anvil frame
6. Upper and lower casings 7. Front handle 8. Safety 9. Rear handle 10. Shifting nut

Fig. 1 Linear stapler

2 Marks on the product

2.1 Code or trademark of manufacturer: a code or trademark is provided on the upper and lower casings to indicate the manufacturer.

2.2 Mark for the green zone of the pointer window: a mark is provided on the upper and lower casings to indicate the green zone of the pointer window.

2.3 Mark for advance and retraction: arrow marks are provided on the B-direction end surface of the shifting nut to indicate "Advance" by clockwise rotation (closing the instrument) and "Retraction" by counterclockwise rotation (opening the instrument).

3 Product model and size, as shown in Table 1

Table 1 Product model and specification

Unit: mm

Stapler			Staple Cartridge (supplied component)		
Model & Size	Instrument Length (L)	Tip Width (L1)	Size	Stapling Length (L2)	Number of Staples
XF-30	275	40	L30	31.5	11
XF-60	275	60	L60	53.5	19
XF-90	280	100	L90	92.0	33

V. Instructions for use

1. Select a stapler with a proper size and a staple cartridge with a corresponding size depending on the requirement of stapling length. Close the stapler safety. Turn the shifting nut counterclockwise until the gap between the staple holder clipper and the anvil reaches the maximum. Pull to open the retaining slide pin and insert the staple cartridge into the staple holder clipper until it is pushed to its position. (Fig. 2)

2. Place the instrument to the position to be stapled. Push the retaining slide pin forward until it is correctly inserted into the retaining hole. Turn the shifting nut clockwise to advance the cartridge until the instrument jaws are closed to hold the tissues to be stapled. Make fine adjustment at the left or right of the gap-setting line depending on the tissue thickness. Be sure to avoid applying any excessive pressure so as to protect the tissues from injury by squeezing. The tissue thickness after compression shall be kept between 1.2~1.8mm. Beyond this range, the staples cannot be formed correctly. (Fig. 3)

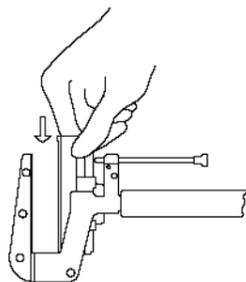


Fig. 2

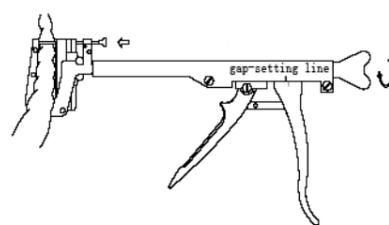


Fig. 3

3. Release the safety and squeeze the front handle firmly as far as it will go until stapling is completed. (Fig. 4)

4. After stapling, use an operating scalpel to remove the remaining parts that need resection. Then, open the instrument jaws by rotating the shifting nut counterclockwise to release the stapled tissue and withdraw the instrument. (Fig. 5)

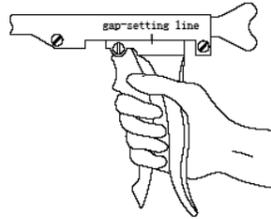


Fig. 4

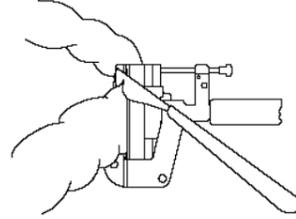


Fig. 5

5. When the instrument is withdrawn, turn the shifting nut counterclockwise until the gap between the anvil and the staple cartridge reaches the maximum. Pull out the retaining slide pin and remove the staple cartridge. (Fig. 6)

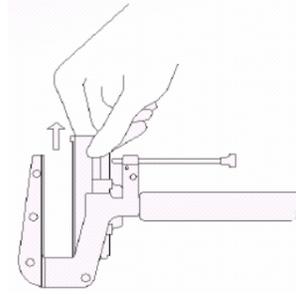


Fig. 6

VI. Cautions

1. The stapler body is a reusable product, which is subject to high-temperature sterilization prior to use.
2. The staple cartridge is a supplied component of the stapler that is separated packed by this company. "Instructions for Use of Staple Cartridge of Linear Stapler" is additionally provided.
3. When the staple cartridge is loaded, check the staples carefully to make sure no staples are missing.
4. Do not release the safety before stapling to avoid premature advance of staples.
5. Before stapling, make sure the retaining slide pin has been correctly inserted into the retaining hole. Incorrect positioning may cause malformation of the staples to affect the result of closure.
6. When stapling, please squeeze the front handle as far as it will go. Failure to fire in position may cause malformation of the staples to affect the result of closure.
7. Prior to removing the instrument, use the tip edge of the stapler as a guide to cut off along the edge the remaining parts that need resection. At this time, the remaining tissues beyond the stapling line are safe.
8. After removing the instrument, always inspect the whole staple line for hemostasis. Minor bleeding or missing stapling may be controlled by electrocautery or manual sutures.
9. After using the instrument, place the safety at the closed position immediately. When it is necessary to replace the cartridge, please make sure that the safety is kept at the closed position during the whole process.
10. The titanium staples in this device are nonmagnetic and have no effects on MRI or NMR procedures after implantation.

VII. Packing list

- | | |
|--|---------|
| 1. Linear stapler (excluding staple cartridge) | 1 piece |
| 2. Product instructions for use | 1 copy |
| 3. Product quality certificate | 1 copy |

VIII. Assembly, disassembly and maintenance

1. Disassemble the instrument in time after stapling. Clean the instrument carefully and first rinse off the contaminants on the outer surface of the stapler body;
2. Make disassembly as indicated by Fig. 1. Turn off the two screws of $M4 \times 12$ and $M3 \times 12$. Open the upper and lower casings. Remove the anvil frame. The removed parts and components should be placed in order of sequence to enable reassembly of the instrument.
3. Clean the disassembled parts in fresh water and wipe off contaminants from outside and inside of each part with gauze.
4. When the parts are dried by wiping or drying, coat them with liquid paraffin. Assemble them in sequence of "first assembling for late disassembled". Always ensure the flexibility and reliability of the movable positions of the stapler so as to make ready for reuse.

IX. Factors that may affect the instrument's stapling quality

1. The stapler as an instrument with high precision should be maintained by specially assigned person(s). Those who perform assembly, disassembly and maintenance should be familiar with the instrument's structural principle. Check the instrument strictly prior to use to avoid compromising the precision by errors in assembly.
2. The parts and components of the stapler should avoid collision or falling to the ground so as to prevent from bending and deformation that may compromise the instrument's performance.
3. When more than one staplers are cleaned at the same time, they must be placed separately and should not be interchanged so as to avoid malformation of staples.
4. When a stapler has been used for a certain time or several cases, a test of simulated stapling shall be conducted to check the formation of staples. Stop using the instrument and make replacement or repair in time in case of any problems or doubts.
5. The proposed service life of the instrument is 60 times of use.

Annex:

Instructions for Use of Staple Cartridge of Linear Stapler

Staple Cartridge for Linear Stapler

Instructions for use

Date of issue: Jan 6, 2017

I. Scope of application

1. This product is a supplied component of Linear Suturing Stapler.
2. This product is loaded on the linear stapler for linear stapling of alimentary tract tissues.
3. The staple cartridge is available in sizes L30, L60 and L90.

II. Major technical parameters

1. The staple cartridge is assembled with the components of staple, staple pusher and staple holder seat.
2. The staple is made of tantalum wire, titanium wire or stainless steel wire. The staple pusher is made of stainless steel. And the staple holder seat is made of ABS.
3. The product surface shall be neat, smooth and free of burrs. The cartridge after loading shall not have any self-dropping of elements without the effect of external force. The staple tip shall not be exposed out of the staple holder seat.
4. The anastomosis site after stapling shall be capable of withstanding a pressure not lower than $3.6 \times 103\text{Pa}$ without water leakage and tearing.
5. The product shall be sterile. The residual amount of ethylene oxide shall be less than $10 \mu\text{g/g}$.

III. Method of use and points for attention

1. This product is not intended for independent use. It shall only be used in combination after loading on a linear stapler. The method of loading and use is detailed in the instructions for use of linear stapler.
2. The product size must be validated prior to use to ensure that its size is corresponding to that of the linear stapler.
3. Check the product prior to use to ensure that the small package is intact and the shelf-life is valid. It is forbidden to use if the small package is damaged or the shelf-life has expired.
4. This product is intended for single use only. Destroy it after use. Reuse is forbidden.
5. The titanium staples in this cartridge are nonmagnetic and have no effects on MRI or NMR procedures after implantation.

IV. Method of disinfection

1. This product has been sterilized by ethylene oxide treatment.
2. Date of sterilization: detailed on the product package.
3. Effective period of sterilization: The shelf-life is two years starting from the date of sterilization, subject to the specified storage conditions.

V. Transportation and storage

1. The product shall be protected during transportation to avoid heavy pressure, direct sunlight and exposure to rain and snow.
2. This product is packaged sterile. It should be kept in a well-ventilated indoor environment that is free of corrosive gases and with a relative humidity not higher than 80%.

X Package Identification



Sterilized by
ethylene oxide



Sterile



Lot
number



Expiration
date



Do not use
if package
is damaged



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