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OF THE PEOPLE'S REPUBLIC OF CHINA

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Endoscopic surgical instruments - Endoscopic cutter stapler and reload

内窥镜手术器械 腔镜切割吻合器及组件

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Endoscopic surgical instruments - Endoscopic cutter stapler and reload

1 Scope

This Standard specifies the structure and materials, requirements, test methods, type inspection, labels, instruction manuals and packaging of endoscopic cutter stapler and reload (hereinafter referred to as stapler) used in endoscopic surgery.

This Standard applies to disposable endoscopic cutter stapler and reload used in endoscopic surgery.

Note: This stapler applies to anastomotic establishment and stump or incision closure in digestive tract reconstruction and organ resection.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies to this document. For undated references, the latest edition (including any amendment) applies to this document.

GB/T 228.1, Metallic materials - Tensile testing - Part 1: Method of test at room temperature

GB/T 1220, Stainless steel bars

GB/T 3280, Cold rolled stainless steel plate, sheet and strip

GB/T 4237, Hot rolled stainless steel plate, sheet and strip

GB/T 4340.1, Metallic materials - Vickers hardness test. Part 1: Test method

GB/T 6682-2008, Water for analytical laboratory use - Specification and test methods

GB/T 10610, Geometrical product specifications (GPS) - Surface texture: Profile method - Rules and procedures for the assessment of surface texture

GB/T 13810, Wrought titanium and titanium alloy for surgical implants

GB/T 14233.1-2008, Test methods for infusion, transfusion, injection equipment for medical use - Part 1: Chemical analysis methods

GB/T 16886, Biological evaluation of medical devices

YY/T 0149-2006, Medical instruments of stainless steel - Test methods of corrosion resistance

YY 0167-2005, Non-absorbable surgical suture

Pharmacopoeia of the People's Republic of China

3 Structure and materials

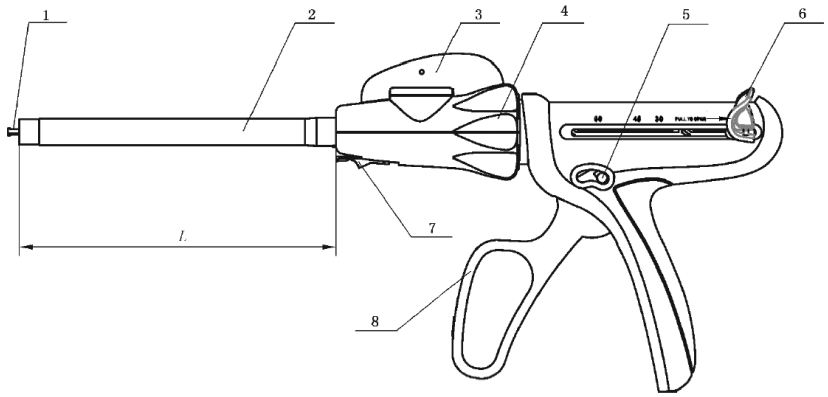
3.1 The stapler consists of a stapler body and some assemblies. According to the design of the cutter knife, the stapler can be divided into a type where the cutter knife is assembled to the assembly and a type where the cutter knife is assembled to the stapler body; according to the joint structure, it can be divided into the bending type and the non-bending type.

For the endoscopic cutter stapler whose cutter knife is assembled to the assembly, the stapler body is generally composed of a firing rod, a rod, a joint head knob, a rotating collar, a firing button, a recovery button, an unloading button, a handle, etc.; the assemblies consist of an anvil, a cartridge, a cartridge holder, a cutter and staples.

For the endoscopic cutter stapler whose cutter knife is assembled to the stapler body, the stapler body is generally composed of an anvil, a joint head, a rod, a rotary knob, an adjusting paddle, a blade direction switch button, a firing indicator window, a blade direction indicator window, a release button, a handle, a closing handle, a firing handle, a cutter knife, a cartridge holder, etc.; the assemblies are generally consist of a cartridge and staples.

3.2 See Figure 1, Figure 2, Figure 3, Figure 4 and Table 1 for the structure and basic dimensions of the stapler.

Note: The structure of the stapler shown is not the only type.



4.2.2 The shape and structure of the stapler head end shall be blunt, without sharp edges or corners.

4.2.3 The surface of the stapler (assemblies and stapler rod parts) shall be matt.

4.2.4 The handwriting and marking on the outer surface of the stapler shall be clear and free of defects such as dislocation and skew.

4.2.5 The tip of the staple shall be sharp, and the surface shall be free of defects such as burrs and dents.

4.3 Corrosion resistance

The corrosion resistance of the metal parts on the outer surface of the stapler head end shall not be lower than that specified in 5.4b) of YY/T 0149-2006.

4.4 Surface roughness

The roughness Ra of the metal outer surface of the stapler assemblies and the stapler rod parts shall not be greater than 1.6 μm.

4.5 Dimensions

The basic dimensions of the stapler shall meet the requirements of Table 1.

4.6 Hardness

The hardness of the cutter knife shall not be less than 377HV0.2.

4.7 Assembly

4.7.1 The stapler shall be positioned accurately; the replacement of assemblies shall be convenient, firm, and non-blocking; there shall be a sound or other prompts when the assemblies are installed in place.

4.7.2 The staples shall be stably loaded into the assembly, and the staples shall not be exposed on the surface of the staple cartridge after being shaken.

4.8 Flexibility

4.8.1 The opening and closing of the stapler jaws shall be flexible, and there shall be no blocking phenomenon.

4.8.2 The joint structure and rotational structure of the stapler shall be flexible and free of obstacles.

4.9 Performance

4.9.1 The connection between the stapler body and the assemblies shall be firm and reliable.

4.9.2 The bending stapler, after swinging to the maximum angle, shall be able to successfully complete the firing and reset.

4.9.3 The jaws of the stapler, after being closed, shall have a certain clamping force, which shall comply with the regulations of the enterprise.

4.9.4 The jaws of the stapler, after being closed, shall have a certain closing force, which shall comply with the regulations of the enterprise.

4.9.5 The stapler shall be available for one-hand operability.

4.9.6 The stapler shall be provided with good stapling and cutting performance. When the assemblies are replaced, the cutting edge after each anastomosis shall be neat and free of burrs, and the distal-end length of the staple line shall be at least 1.5 times longer than the cutting line. The staples after each anastomosis shall be shaped like "B".

4.9.7 The staple line after anastomosis shall have certain staple line suture strength, and the staple line suture strength shall comply with the regulations of the enterprise.

4.9.8 The stapler shall be provided with a firing process feedback indicating device that can indicate the firing process or state.

4.10 Cutter knife sharpness

The cutting edge of the cutter knife shall be sharp, and there shall be no curling or chipping; the cutting force shall not be greater than 0.80 N.

4.11 Pressure resistance

The stapled anastomosis or suture shall be able to withstand a pressure of not less than 3.6×10^3 Pa, and the leakage of water shall not exceed 10 drops within 15 s.

4.12 Protective device

4.12.1 The stapler shall have an empty staple cartridge protective device, so that it cannot be fired when the empty staple cartridge is installed by mistake.

Note: Empty cartridge refers to fired assemblies.

4.12.2 The stapler shall be provided with a protective device to avoid the movement of the cutter knife and staples when the assemblies are loaded after the firing rod is fired due to misoperation; alternatively, the stapler shall have a protective device, and the firing rod cannot be fired when the stapler body is not loaded with assemblies.

4.13 Matching performance with trocar

4.19 Instruction manual

4.19.1 A detailed table of the original height parameters of the staples, the height of the staples after forming, or the applicable tissue thickness shall be included in the product manual.

4.19.2 The specifications of the matched trocar shall be specified in the product manual.

4.19.3 The number of times the device is fired and used shall be clarified in the product manual.

5 Test methods

5.1 Staple materials

5.1.1 The chemical composition inspection of pure titanium and titanium alloy materials used for making staples shall be carried out according to the method specified in GB/T 13810, which shall meet the requirements of 4.1.1.

5.1.2 The tensile strength of staple material shall be tested according to the method specified in GB/T 228.1, which shall meet the requirements of 4.1.2.

5.2 Appearance

Under the illumination of 300 lx ~ 750 lx, observe by normal or corrected visual acuity, and rub with hands, which shall meet the requirements of 4.2.

5.3 Corrosion resistance

Carry out the test according to the boiling water test method in YY/T 0149-2006, which shall meet the requirements of 4.3.

5.4 Surface roughness

The surface roughness shall be tested by the sample block comparison method or the profile method specified in GB/T 10610, which shall meet the requirements of 4.4.

Use the profile method during arbitration.

5.5 Dimensions

Use a general or special measuring tool for measurement, which shall comply with the provisions of 4.5.

5.6 Hardness

According to the method specified in GB/T 4340.1, measure three points on the surface of the test piece, and take the arithmetic mean of the three points, which shall meet the requirements of 4.6.

5.7 Assembly

5.7.1 Imitate the use action to load and replace assemblies, which shall comply with the provisions of 4.7.1.

5.7.2 Shake the assemblies 5 times, and use hands to touch the surface of the cartridge, which shall meet the requirements of 4.7.2.

5.8 Flexibility

After correctly loading the assemblies, imitate the use action to check the flexibility, which shall meet the provisions of 4.8.

5.9 Performance

5.9.1 Imitate the use action to match the ethylene-vinyl acetate copolymer (hereinafter referred to as EVA) low-foamed plate sample (see Appendix A) whose total thickness is not less than 1.5 times the original height of the staple, after which all parts of the stapler shall be complete, which shall comply with the provisions of 4.9.1.

5.9.2 Imitate the use action to swing the stapler cartridge joints to the left extreme and right extreme positions respectively, to match the EVA low-foamed plate sample whose total thickness is 1/2 ~ 2/3 the original height of the staples, which shall comply with the provisions of 4.9.2.

5.9.3 Use the instrument to clamp the EVA low-foamed plate sample whose total thickness is 1/2 ~ 2/3 the original height of the staples; fix the stapler body on the fixture; apply a push-pull device to clamp the EVA low-foamed plate sample; then, measure the clamping force in axial direction, which shall comply with the provisions of 4.9.3.

5.9.4 After closing the stapler jaws, fix the side (which is installed with the staple cartridge) of the staple cartridge jaws on the fixture; to the distal end (12±2 mm) of the other side (installed with the anvil) of the staple cartridge jaws, apply a radial pulling force that meets the requirements of the enterprise in 4.9.4, and keep it for 15 s; then, imitate the use action to match the EVA low-foamed plate sample whose total thickness is 1/2 ~ 2/3 the original height of the staples. The cutting edge after anastomosis shall be neat, without burrs, and the staples after anastomosis shall be shaped like a "B".

5.9.5 Imitate the use action to match the EVA low-foamed plate sample whose total thickness is 1/2 ~ 2/3 the original height of the staples; except for the rotation of the instrument, the bending of the staple cartridge joint and the retraction of the cutter knife, it shall meet the requirements of 4.9.5.

5.12.1 Install an empty staple cartridge to the stapler, and adjust the stapler for firing, which shall comply with the provisions of 4.12.1.

5.12.2 Check whether there is a protective device, and actually verify it; alternatively, do not load the assemblies, and imitate the use action to fire the stapler, which shall comply with the provisions of 4.12.2.

5.13 Matching performance with trocar

Imitate the use action to close the stapler cartridge jaws; insert the matched trocar cannula and then pull it out, which shall comply with the provisions of 4.13.

5.14 Sterility

Carry out the test according to the "sterility inspection method" specified in the Pharmacopoeia of China, which shall meet the requirements of 4.14.

5.15 Bacterial endotoxin

Take the part in contact with the patient and conduct the test according to the "Bacterial endotoxin examination method" in Pharmacopoeia of the People's Republic of China, which shall meet the requirements of 4.15.

5.16 Residue of ethylene oxide

Perform the test according to Chapter 9 "Gas chromatography" of GB/T 14233.1-2008, which shall meet the requirements of 4.16.

5.17 Chemical properties (polymer material of the part in contact with the patient)

5.17.1 Test liquid preparation

Take the sample; put it in a glass container according to the ratio of 0.2 g of sample to 1 mL of test water (grade-2 water in accordance with GB/T 6682-2008); leach at the constant temperature of 37 ℃ ± 1 ℃ for 24 h; separate the sample from the liquid; cool to room temperature; use it as a test solution.

Take the same volume of test water and place it in a glass container; prepare a blank control solution in the same way.

5.17.2 Appearance

Take the test solution and observe the solution visually, which shall meet the requirements of 4.17.1.

5.17.3 pH value

Carry out the test according to the method specified in 5.4.1 of GB/T 14233.1-2008, which shall meet the requirements of 4.17.2.

5.17.4 Heavy metal

Carry out the test according to the method specified in 5.6 of GB/T 14233.1-2008, which shall meet the requirements of 4.17.3.

5.17.5 Reducing substances

Carry out the test according to the method specified in 5.2.2 of GB/T 14233.1-2008, which shall meet the requirements of 4.17.4.

5.17.6 Evaporation residue

Carry out the test according to the method specified in 5.5 of GB/T 14233.1-2008, which shall meet the requirements of 4.17.5.

5.18 Biological evaluation

The stapler shall be biologically evaluated in accordance with the provisions of the GB/T 16886 series standards, which shall comply with the provisions of 4.18.

5.19 Instruction manual

Observe visually, which shall meet the provisions of 4.19.

6 Type inspection

Type inspection items of the stapler are those specified in 4.1 ~ 4.17 and 4.19.

If there are no special regulations, the inspection items shall be randomly sampled for 3 sets, all of which are qualified.

7 Label, instruction manual

7.1 Label

The label of the stapler shall have at least the following contents or symbols:

a) product name, model and specification;

b) name and domicile, production address, contact information and production license number of the production enterprise;

c) number of the medical device registration certificate and name, address and contact information of the medical device registrant;

d) production date and service life or expiry date;

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