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Medical endoscopes - Endotherapy device - Separating forceps

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Contents

Foreword

Codeofchina.com is in charge of this English translation. In case of any doubt about the English translation, the Chinese original shall be considered authoritative.

This standard is developed in accordance with the rules given in GB/T 1.1-2009.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing body of this document shall not be held responsible for identifying any or all such patent rights.

This standard was proposed by the China Food and Drug Administration.

This standard is under the jurisdiction of SAC/TC 103/SC 1 Subcommittee on Medical Optics and Optic Instruments of National Technical Committee on Optics & Optic Instruments of Standardization Administration of China.

Medical endoscopes - Endotherapy device - Separating forceps

1 Scope

This standard specifies the scope, terms and definitions, requirements, and test methods of separating forceps.

This standard is applicable to separating forceps used in endoscopic surgery.

2 Normative references

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

GB/T 1962 (All parts)	*Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment*
GB/T 4340.1-2009	*Metallic materials - Vickers hardness test - Part 1: Test method*
GB 9706.4	*Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment*
GB 9706.19	*Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment*
GB/T 14233.1-2008	*Test methods for infusion, transfusion, injection equipment for medical use - Part 1: Chemical analysis methods*
GB/T 14233.2-2005	*Test methods for infusion, transfusion, injection equipment for medical use - Part 2: Biological test methods*
GB/T 16886 (All parts)	*Biological evaluation of medical devices - Part 1: Evaluation and testing*
YY/T 0149-2006	*Medical instruments of stainless steel - Test methods of corrosion resistance*
YY 0167-2005	*Non-absorbable surgical suture*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
separating forceps
a type of endotherapy device intended to be used in conjunction with specified endoscopes, primarily consisting of a handle, forceps shaft, and forceps jaws, utilized for separating tissues at surgical parts of the human body

3.2
insertion portion
component of the separating forceps that can be inserted into a natural body orifice, a surgical incision, a device channel of endoscope, a device channel of endoscope accessory, or a device channel of endotherapy device

3.3
maximum insertion portion width
maximum external width of the insertion portion

3.4
working length
the maximum length of the insertion portion of the separating forceps

3.5
endotherapy device
medical device used in endoscopic surgery for inspection, diagnosis, or treatment, entering natural body orifices or surgical incisions through channels identical or different from those of the endoscope

Note: Endotherapy devices include devices guiding the insertion of endotherapy devices. Devices used when observing with an endoscope, entering the human body from orifices different from those of the endoscope for safety purposes, also fall under the category of endotherapy devices.

4 Requirements

4.1 Materials used in the patient-contacting parts

4.1.1 Requirements for chemical composition

The materials used in the patient-contacting parts shall be explicitly specified by the manufacturer in any possible form. For metallic materials, the grade and/or code, as well as the chemical composition of the materials, shall be indicated, and the chemical composition of metallic materials shall be verified through test.

4.1.2 Biocompatibility

Materials in contact with patients shall be evaluated for biosafety following the principles and requirements specified in GB/T 16886.1 to demonstrate their good biocompatibility.

For biological evaluation, the results of biological tests may be taken into account, and the test items shall be selected according to the guidelines given in GB/T 16886.1. All tests shall give priority to the relevant standards of GB/T 16886 as reference standards.

For materials previously proven to be applicable, if it can be demonstrated that subsequent manufacturing processes do not pose a biosafety hazard, repeated biological tests may be omitted.

Note 1: Materials in devices with a demonstrable history of use in specific applications or for which information regarding materials and/or devices is available from other sources may be considered previously proven.

Note 2: If medical metallic materials in align with the application scope outlined in national or professional standards are used, repeated biological tests may be omitted.

4.1.3 Dissolved precipitate from polymer materials in contact with patients

4.1.3.1 Appearance (turbidity, color): Colorless and transparent, and no visible foreign matter to the human eye.

4.1.3.2 pH: Compared with the blank control solution of the same batch, the pH difference between them shall be less than 2.0.

4.1.3.3 Total content of soluble heavy metals: The total content of soluble heavy metals in the leachate shall not exceed 5.0μg/mL.

4.1.3.4 Potassium permanganate-reducing substances: The difference in consumption shall be less than 2.0mL when compared to the blank control solution of equal volume from the same batch.

4.1.3.5 Evaporation residue: The total residue after drying of the leachate shall be less than 2.0mg.

4.1.4 Hardness

The hardness of the forceps jaws shall meet the requirements of the manufacturer.

4.1.5 Consistency between surface and internal materials

For components claimed by the manufacturer to be made of metallic materials, the surface material shall be consistent with the internal material. If surface coating is deemed necessary, the manufacturer shall provide corresponding coating requirements and test methods.

4.2 Appearance

4.2.1 In the visual field of the endoscope, the visible distal end of the surgical instrument shall be treated to eliminate potential orienting reflex.

4.2.2 Except for specific purposes, the outer surface shall be free from defects such as burrs that could cause injury.

4.3 Dimensions

4.3.1 Maximum insertion portion width

The manufacturer shall provide the nominal value of the maximum insertion portion width in the manual.

The measured value shall not exceed the nominal value.

4.3.2 Working length

The manufacturer shall provide the nominal value of the working length in the manual, accompanied by illustrative diagrams.

The tolerance for nominal value of working length shall be ±3%.

4.3.3 Maximum opening range of forceps jaws

The manufacturer shall provide the nominal value of the maximum opening range of forceps jaws in the manual, accompanied by illustrative diagrams.

The tolerance for nominal value of opening range of forceps jaws shall be ±20%.

4.4 Service performance

4.4.1 Opening and closing performance

The forceps jaws shall operate smoothly during both opening and closing, and the forceps shaft shall remain stable without any undesirable wobbling that might interfere with the user's operation.

4.4.2 Locking engagement force (applicable to separating forceps with a locking device)

The manufacturer shall give the engagement force of the forceps jaws in the locked state, and the actual engagement force shall not exceed 20% of the value claimed by the manufacturer.

4.4.3 Transmission coefficient of opening force

The force transmission coefficient between the force applied to the handle and the opening force of the forceps jaws shall meet the requirements of the manufacturer.

4.4.4 Transmission coefficient of closing force

The force transmission coefficient between the force applied to the handle and the closing force of the forceps jaws shall meet the requirements of the manufacturer.

4.4.5 Elasticity and robustness

After being tested using the method specified in 5.4.3, the separating forceps shall be free from distortion, cracking, or any other permanent deformation.

4.4.6 Rotation performance (applicable to separating forceps with rotation function)

The separating forceps shall rotate smoothly, and during rotation, the forceps shaft shall remain stable without any undesirable wobbling that might interfere with the user's operation.

4.4.7 Teeth profile of forceps jaws

In terms of arrangement, the teeth on the forceps jaws of the separating forceps shall meet the design requirements, and the teeth shall be regular in profile, accurately aligned, and properly engaged.

4.5 Durability (applicable to non-disposable products)

4.5.1 High-temperature and high-pressure resistance

Separating forceps labeled as capable of withstanding high temperature and high pressure shall still meet the requirements of 4.4 after 20 cycles of high-temperature and high-pressure test.

4.5.2 Corrosion resistance

Parts made of martensitic or austenitic stainless steel shall be tested using the boiling water test method specified in YY/T 0149-2006, and after the test, these portions shall be up to criteria Class b. For other materials, a single round of disinfection and sterilization shall be conducted following the instructions specified by the manufacturer in the manual, using the most unfavorable method. After this process, the materials shall be free from corrosion.

4.5.3 Capability to withstand repeated operations

The separating forceps shall be able to withstand 20 cycles of repeated operations without damage or breakage.

4.6 Sterilization requirements (applicable to disposable products)

4.6.1 The separating forceps shall be sterile.

4.6.2 Ethylene oxide residue (applicable to products sterilized with ethylene oxide): The residue concentration of ethylene oxide shall be below 10μg/g.

4.7 Luer taper (applicable to separating forceps with an injection port)

The Luer fitting shall meet the relevant requirement of GB/T 1962.

4.8 Product manual

4.8.1 The product manual shall include a clear explanation of the endoscope and its accessories that can be used in conjunction with the separating forceps. This information is intended to guide users in selecting the appropriate endoscope and accessories based on the provided instructions.

4.8.2 The product manual shall include an illustrative diagram depicting the separating forceps with the forceps jaws opened to their maximum, along with the names and functions of all the components. If necessary, accompanying diagrams shall be provided to facilitate understanding.

4.8.3 The product manual shall include instructions for product specification.

4.8.4 The product manual shall include a description of the intended design purposes of the product.

4.8.5 It shall include instructions for preparation, inspection, and operation when using the product.

4.8.6 Instructions for environmental protection shall be included:

——Indicate any risks related to wastes, residues and their disposal at the end of the service life of the product;

——Provide recommendations to minimize these risks.

4.8.7 If the separating forceps are not disposable, the instructions for use shall include details on acceptable cleaning, disinfection, or sterilization methods. Specify appropriate disinfectants if necessary and list temperature, pressure, humidity, and time limits that the device components can withstand.

4.8.8 Environmental restrictions for operation, transportation and storage: Permissible environmental conditions for operation, transportation and storage shall be specified.

4.9 Marking and labeling

There shall be clear, easily recognizable, and securely affixed permanent markings on the product, including the name and/or trademark of the manufacturer or supplier.

Note: For disposable products, the above information may be marked on the sterile packaging.

4.10 Requirements for electrical safety

If the separating forceps are high-frequency surgical instruments, they shall meet the requirements of GB 9706.4 and GB 9706.19.

4.11 Water/air permeability performance (applicable to separating forceps with an injection port)

The manufacturer shall specify requirements for the water or air injected into the injection channel and provide details on the test method.

5 Test methods

5.1 Material tests

5.1.1 Chemical composition test

The chemical composition of metallic materials shall be analyzed using currently recognized methods with accuracy reaching or superior to 1/3 of the tolerance or limit.

5.1.2 Biocompatibility

All tests shall give priority to the relevant standards of GB/T 16886 as reference standards and be conducted following their specified methods.

5.1.3 Test method for dissolved precipitates

Preparation of test solution: Prepare the test solution following the method given under S.N. 6 of Table 1 in GB/T 14233.1-2008.

5.1.3.1 Appearance: Check the appearance following the method specified in 5.1 of GB/T 14233.1-2008.

5.1.3.2 pH: Test the pH following the method specified in 5.4.1 of GB/T 14233.1-2008.

5.1.3.3 Heavy metals: Test the heavy metals following the method specified in 5.6 of GB/T 14233.1-2008.

5.1.3.4 Potassium permanganate-reducing substances: Test the substances following the method specified in 5.2 of GB/T 14233.1-2008.

5.1.3.5 Evaporation residue: Test the residue following the method specified in 5.5 of GB/T 14233.1-2008.

5.1.4 Hardness test

The test shall be carried out with the method specified in GB/T 4340.1-2009, measuring at 3 points on each piece of forceps jaws, and taking the arithmetic mean of every 3 points.

5.1.5 Inspection for consistency between the surface and the internal materials

Inspect them visually. For products with coating on the surface, the inspection shall be performed following the corresponding test method provided by the manufacturer.

5.2 Appearance

5.2.1 Imitate the practical operation and inspect the appearance visually.

5.2.2 Defects such as burrs: Feel them with hand and inspect them visually.

5.3 Dimensions

5.3.1 Inspection of maximum insertion portion width

Inspect it using a universal measuring tool.

5.3.2 Inspection of working length

Inspect it using a universal measuring tool.

5.3.3 Inspection of maximum opening range of forceps jaws

Inspect it using a universal measuring tool.

5.4 Service performance tests

5.4.1 Opening and closing test

Imitate the practical operation and inspect it visually.

5.4.2 Locking engagement force

The locking engagement force shall be tested under simulated application conditions, with the forceps jaws slightly open to the degree specified by the manufacturer, indicated by the opening height at 1/3 of the front ends of the jaws. With the handle of the separating forceps in the locked state, measure the engagement force at 1/3 of the front end of the jaw in this state, that is, the locking engagement force.

5.4.3 Transmission coefficient of opening force

When the forceps jaws open at an angle of 30° (or 70% of the maximum opening angle if 70% is less than 30°), apply a force (f_i) of 5N~15N to the handle, with intervals not exceeding 3N. Record the opening force (f_o) generated at the front ends of the jaws, perpendicular to the bisector of the opening angle of the forceps jaws. Then, fit the collected data using the least squares method to obtain the value of f_o/f_i, which is the transmission coefficient of opening force.

The direction of f_i is shown in Figure 1, and the application point of f_i is determined by simulating clinical application, it is the point where the handle is subject to force in a free state.

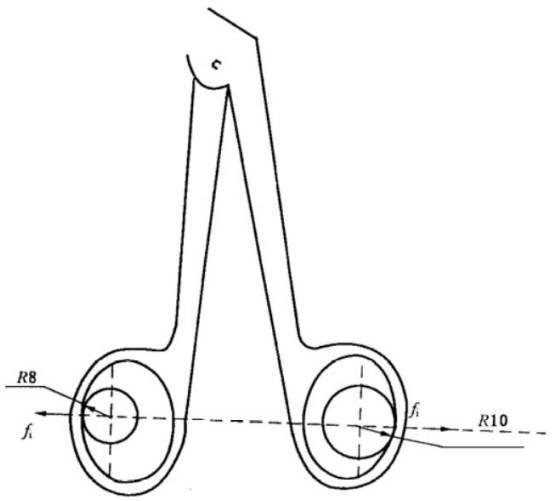

Figure 1

For handles with a structure different from that shown in Figure 1, the manufacturer shall specify the application point of f_i. The deviation in actual application point of f_i shall be within 1mm.

If the placement of device in the test affects the test result, the manufacturer shall specify the placement of device.

5.4.4 Transmission coefficient of closing force

The closing force shall be tested under simulated application conditions, with the forceps jaws slightly open to the degree specified by the manufacturer, indicated by the opening height at 1/3 of the front ends of the jaws. Then, apply a force (f_i) of 5N~20N to the handle, with intervals not exceeding 3N. Record the closing force (f_o) generated at 1/3 of the front ends of the jaws, perpendicular to the bisector of the opening angle of the forceps jaws. Then, fit the collected data using the least squares method to obtain the value of f_o/f_i, which is the transmission coefficient of closing force.

The direction of f_i is shown in Figure 1, and the application point of f_i is determined by simulating clinical application, it is the point where the handle is subject to force in a free state.

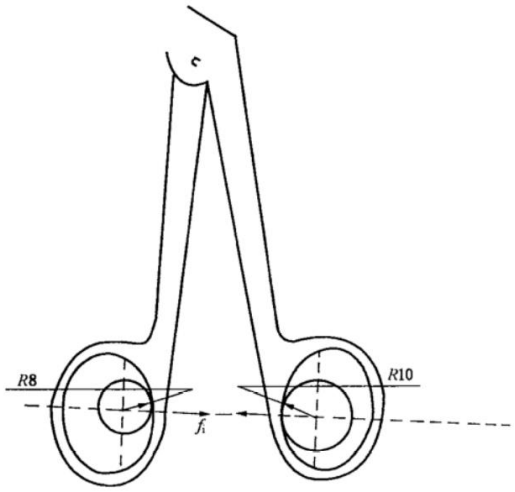

Figure 2

For handles with a structure different from that shown in Figure 2, the manufacturer shall specify the application point of f_i. The deviation in actual application point of f_i shall be within 1mm.

If the placement of device in the test affects the test result, the manufacturer shall specify the placement of device.

5.4.5 Elasticity and robustness test

Put a stainless steel wire with a diameter equal to 10% of the length from the front ends of the forceps jaws to the center of the box joint shaft at the front ends of the separating forceps. Close the separating forceps completely and maintain this state for 3h at room temperature. Then, inspect the separating forceps for cracks or permanent deformation.

5.4.6 Rotation test

Imitate the practical operation and inspect it visually.

5.4.7 Teeth profile test of forceps jaws

Observe and compare them using a 10X magnifying glass.

5.5 Durability tests

5.5.1 High-temperature and high-pressure resistance test

Repeat the high-temperature and high-pressure resistance test for 20 cycles using the method specified in 5.4, following the instructions specified by the manufacturer.

5.5.2 Corrosion resistance test

For parts made of martensitic or austenitic stainless steel, conduct the test using the boiling water test method specified in YY/T 0149-2006. For parts made of other materials, disinfect and sterilize them once following the method specified by the manufacturer in the manual.

5.5.3 Test for capability to withstand repeated operations

Imitate the practical operation.

5.6 Sterilization requirement tests

5.6.1 Sterility test

Conduct the test following the method specified in GB/T 14233.2, if the method for preparing the test solution is not applicable, it can be specified by the manufacturer.

5.6.2 Ethylene oxide residue test

Conduct the test using the gas chromatographic method specified in Clause 9 of GB/T 14233.1-2008.

5.7 Luer taper test

Conduct the test according to the relevant requirements of GB/T 1962.

5.8 Product manual inspection

Inspect the product manual provided by the manufacturer.

5.9 Marking and labeling inspection

Visually inspect the markings and labels on the product.

5.10 Electrical safety test method

Conduct the test following the methods specified in GB 9706.4 and GB 9706.19.

5.11 Water/air permeability performance

Conduct the test following the method specified by the manufacturer.

6 Inspection rules

Inspection rules shall be determined by the manufacturer based on the characteristics of the product.