YY

PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.70

C 40

YY/T 0283-2007

Replacing YY/T 0283-1995

Large intestine fiber endoscope

纤维大肠内窥镜

Issued on: July 02, 2007 **Implemented on: March 01, 2008**

Issued by: China Food and Drug Administration

Table of Contents

Foreword

This Standard is the revision of YY/T Q283-1995 “Large Intestine Fiber Endoscope”. Compared with YY/T 0283-1995, main differences in this Standard are as follows:

— Specify the name of standard;

— Add the classification of waterproof ability of product;

— Increase the quantity index of broken-fiber number;

— Add the coincidence requirements between illumination source and observation view-field;

— Modify the requirements on product marking;

— Add the requirements on waterproof product;

— Add the requirements on biocompatibility;

— Modify the test method of view-field angle;

— Delete the requirements on sealing property in previous standard;

— Add Annex A (Normative).

For electrical connection part, it shall comply with GB 9706.1-1995 “Medical Electrical Equipment - Part 1: General Requirements for Safety”, GB 9706.4-1999 “Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment”, and GB 9706.19-2000 “Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Endoscopic Equipment”. The details are given in Annex A (Normative).

Annex A and B of this Standard are normative; Annex C is informative.

This Standard replaces YY/T 0283-1995, since the date of issuance.

This Standard was approved by State Food and Drug Administration.

This Standard shall be under jurisdiction of National Technical Committee on Medical Optical Instruments of Standardization Administration of China.

Drafting organization of this Standard: Medical Optical Equipment Factory of Shanghai Medical Instruments Co., Ltd.

Main drafters of this Standard: Li Yafen, Sun Qi, and Shen Tianming.

This Standard was first-time published in November 1995.

Large Intestine Fiber Endoscope

1 Scope

This Standard specifies the classification, marking, requirements, test methods, inspection rules, identification, operation instructions, packaging, transportation, and storage of large intestine fiber endoscope.

This Standard is applicable to large intestine fiber endoscope (hereinafter referred as fiber endoscope). This product is used to the examination and diagnosis of large intestine cavity and can also be used in the relevant surgical operation.

2 Normative references

The provisions in following documents become the provisions of this Standard through reference in this Standard. For dated references, the subsequent amendments (excluding corrections) or revisions do not apply to this Standard, however, parties who reach an agreement based on this Standard are encouraged to study if the latest versions of these documents are applicable. For undated references, the latest edition of the referenced document applies.

GB/T 191-2008 Packaging - Pictorial marking for handling of goods

GB/T 2829-2002 Sampling procedures and tables for periodic inspection by attributes (Apply to inspection of process stability)

GB 9706.1-1995 Medical electrical equipment - Part 1: General requirements for safety

GB 9706.4-1999 Medical electrical equipment - Part 2: Particular requirements for the safety of high frequency surgical equipment

GB 9706.19-2000 Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment

GB 11244-2005 General requirements for the medical endoscope and endoscope accessories

GB/T 14710-1993 The environmental requirements and test methods for medical electrical equipment

GB/T 16886.1-2001 Biological evaluation of medical devices - Part 1: Evaluation and testing

GB/T 16886.5-2003 Biological evaluation of medical devices - Part 5: Test for in vitro cytotoxicity

GB/T 16886.10-2005 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity (ISO 10993-10: 2002, IDT)

YY 0466-2003 Medical devices - Symbols to be used with medical device labels labelling and information to be supplied (ISO 15223: 2000, IDT)

4.3.5 Light spot at working distance shall fill-cover the whole view-field, without obvious dark-light boundary.

Clear observation range: 5 mm~100 mm.

4.4 Water supply and suction system

4.4.1 Supplied water can wash the surface of lens. The flow of supplied water shall not be lower than 45 mL/min.

4.4.2 Suction shall be smooth. There is no liquid ejected backward at the places of button and forceps channel socket. The suction flow must not be lower than 400 mL/min.

4.4.3 Suction tube shall be able to be washed by mild brush (only applicable to waterproof type).

4.5 Bend-angle operation system

4.5.1 Bend-angle locking structure shall be able to tightly lock the hand-wheel. The bend-angle part shall be able to do bend action under locking state. After locking is released, it shall not affect the operating function of bend-angle hand-wheel. There is no too-tight, too loose or stuck-up phenomenon during operation.

4.5.2 For upward and downward directions, the bend-angle of fiber endoscope shall be ≥ 180°; for left-ward and right-ward directions, it shall be ≥ 160°. When it is bent at any angle, the entry and exit of matching tools shall be smooth.

4.6 Sealing

4.6.1 Fiber endoscope shall be soaked in water as a whole. Its internal cavity can withstand pressure of 22 kPa for 3 min; without air leakage (applicable to waterproof type).

4.6.2 The head-end part shall be used within 20°C ~ 40°C. The surface of optical parts shall not generate mist due to temperature variation that affect observation.

4.7 Marking

4.7.1 The inserted flexible tube shall be marked with length marking. The marked line and words shall be legible.

4.7.2 There shall be direction-mark on top of filed.

4.7.3 Hand-wheel must have operation direction mark. The front bend direction shall be consistent with the marked sign.

4.8 Dimension

The mechanical dimensions of fiber endoscope shall conform to Table 1.

Where:

B -- View-field angle, unit: degree (°);

D -- Diameter of annulus, unit: mm;

L -- Distance BETWEEN the end-face of the centre of head-end window AND the centre of measuring target, unit: mm.

5.2.5 Coincidence of illumination source and observation view-field

Visual inspection shall be conducted under the maximum illumination of the provided lamp in accordance with Article 4.3.5.

5.2.6 Clear observation range

Fix the endoscope; adjust the distance between objective lens and the observed object. When it is at 5mm and 100mm positions, observe through the eyepiece of endoscope; it shall be able to clearly see 1.0mm-wide strip; it shall conform to Article 4.3.6.

5.3 Water supply and suction performance test

5.3.1 Water supply performance

Turn on the air pump according to the usage requirements (pressure is not greater than 50kPa; flow rate is not greater than 500 L/h) to conduct water supper operation. Use the measuring glass of which the minimum scale value is not greater 5mL and stopwatch to measure the volume of the supplied water within 1min in accordance with Article 4.4.1.

GB/T 16886.5-2003. Cytotoxicity shall conform to the requirements in Article 4.9.1.

5.8.2 Sensitization shall be tested in accordance with the method specified in Chapter 6 of GB/T 16886.10-2005. It shall conform to the requirements in Article 4.9.2.

5.8.3 Stimulus response shall be tested in accordance with the method specified in Chapter 5 of GB/T 16886.10-2005. It shall conform to the requirements in Article 4.9.3.

5.9 Dissolved precipitate

For the test methods of dissolved precipitate, adopt the method specified in Annex C (Informative) or the equivalent method. It shall conform to the requirements in Article 4.10.

5.10 Environmental test

Environmental test shall be conducted in accordance with the relevant requirements in GB/T 14710-1993 and Article 4.11 of this Standard.

5.11 Safety test

Safety test shall be conducted in accordance with the methods specified in GB 9706.1-1995, GB 9706.4-1999, and GB 9706.19-2000. It shall conform to the requirements in Article 4.12.

6 Inspection rules

6.1 Classification of inspection

The inspections of fiber endoscope are divided into exit-factory inspection and type inspection.

6.2 Exit-factory inspection

6.2.1 Product can be delivered out of factory after being confirmed as qualified through exit-factory inspection.

6.2.2 Exit-factory inspection items for each product are specified in Article 4.2 to Article 4.8, and annex A. Product shall pass all the inspection items.

6.2.3 The products produced from same-batch of raw materials are classified into one batch products. Randomly select the samples according to the test needs; conduct the test as specified in Article 4.10. The product samples shall be qualified.

6.3 Type inspection

6.3.1 In case of the following circumstances, type inspection shall be conducted:

a) When the product is being registered;

b) Before the mass production of new product (including old product transferred to other production);

c) The production is launched at interval of more than one year;

7.1.1 Fiber endoscope shall have the following marks:

a) Name of producer or brand;

b) Name and model of product;

c) Production serial number.

7.1.2 Product qualification certificate shall have the following marks:

a) Name of producer;

b) Name and model of product;

c) Inspection date;

d) Code of inspector.

7.1.3 Outer package shall have the following marks:

a) Name and address of manufacturer;

b) Name and model of product;

c) Delivery date;

d) Product standard number;

e) Product registration number;

f) Volume (L x W x H);

g) Net weight and gross weight;

h) “Handle with care”, “Up”, “Keep dry” and other words and marks. Marks shall conform to relevant provisions of GB/T 191-2008 and YY 0466-2003. Words and signs on packing case shall not be obscured because of time lasting.

The words and markings on the package shall be legible for time lasting.

7.2 Operation instruction

It shall conform to the requirements specified in No. 10 “Management Regulations on Manual, Labelling, and Packaging Logo of Medical Instruments” issued by China Food and Drug Administration, and the relevant requirements in GB 9706.1-1995 and GB 9706.19-2000.

8 Package, transportation and storage

8.1 Package

8.1.1 For each set of fiber endoscope, it shall be accompanied with operation instructions, qualification certificate, packing list and warranty card. Pack it within damp-proof paper bag or plastic bag; then put it in the carton box.

Annex A

(Normative)

Safety Requirements of the Inter-Connected Medical Electric Devices

A.1 Product characteristics

Fiber endoscope belongs to application part of BF-type endoscopic electrical equipment.

A.2 External marking

A.2.1 Requirements

It shall have the following “permanent fixed” and “clear legible” marks:

a) Enterprise mark;

d) Product model or code;

c) Classification mark: BF.

A.2.2 Test method

Test shall be conducted in accordance with Article 6.1 of GB 9706.1-1995.

A.3 Completeness of accompanying documents

A.3.1 Requirements

Conform to Article 6.8.1 of GB 9706.1-1995.

A.3.2 Test method

Inspect and read the accompanied documents.

A.4 Operation instructions

A.4.1 Requirements

The following requirements shall be satisfied:

a) Conform to the requirements specified in Article 6.8.2 of GB 9706.1-1995.

b)[1]* Conform to Article 6.8.2 aa), bb), and dd) of GB 9706.4-1999, and 6.8.2 aa) and bb) of GB 9706.19-2000.

A.4.2 Test method

[1]* This article does not apply to those fiber endoscopes that do not work together with surgery system.

A.8[2]* Isolation of application part

A.8.1 Requirements

Conform to Article 17. c) of GB 9706.1-1995. It must not be electrically connected to the touchable metal parts that are not unprotected from grounding.

A.8.2 Test method

Test shall be conducted in accordance with the method specified in Article 17. c) of GB 9706.1-1995 to check whether it conforms to the requirements.

A.9[3]* Continuous leak current under normal working temperature

A.9.1 Requirements

The following requirements shall be satisfied:

Ground-leak current: Normal status ≤0.5 mA; Single fault status: ≤1 mA

Shell-leak current: Normal status ≤0.1 mA; single fault status: ≤0.5 mA

Patient-leak current: Normal status ≤0.1 mA; Single fault status: ≤0. 5 mA

A.9.2 Test method

Use leak-current measuring instrument to conduct the test in accordance with Chapter 19 of GB 9706.1-1995. It is required to connect to the matched electrical devices of endoscope (cold light source, high frequency generator, etc.).

A.10[4]* High frequency leak current

A.10.1 Requirements

Conform to the requirements specified in Article 19.101 of GB 9706.4-1999.

A.10.2 Test method

After it is connected to the matched high frequency generator, it shall be tested in accordance with the method specified in Article 19.10.1 of GB 9706. 4-1999 to check whether it conforms to the requirements.

A.11[5]* Dielectric strength under normal working temperature

A.11.1 Requirements

---

[2]* This article does not apply to those fiber endoscopes that do not work together with surgery system.

[3]* This article does not apply to those fiber endoscopes that do not work together with surgery system.

[4]* This article does not apply to those fiber endoscopes that do not work together with surgery system.

[5]* This article does not apply to those fiber endoscopes that do not work together with surgery system.

conforms to the requirements.

A.14[8]* Dielectric strength after moisture pre-treatment

A.14.1 Requirements

Between the parts specified in Table A.1, it shall be able to withstand 50 Hz, sinusoidal wave and specified test voltage for 1 min; there will be no breakdown or flashover phenomenon.

A.14.2 Test method

Moisture pre-treatment shall be conducted in accordance with Article 4.10 of GB 9706.1-1995. After moisture pre-treatment, dielectric strength test shall be conducted in accordance with Article 20.4 of GB 9706.1-1995. Use medical electrical device shock protection parameter tester to conduct the est.

A.15 Safety of surface, corner, and edge

A.15.1 Requirements

Conform to the requirements in Chapter 23 of GB 9706.1-1995.

A.15.2 Test method

Adopt visual inspection and hand-touch inspection.

A.16 Prevention of overheat operation

A.16.1 Requirements

The following requirements shall be satisfied:

a) The parts and surrounding temperature shall conform to Article 42.1 of GB 9706.1-1995 under specific conditions.

b) The parts and surrounding temperature shall conform to Article 42.2 of GB 9706.1-1995 under normal conditions.

c) Replacement requirements:

The temperature of the inserted part, except the part of light exit, shall not exceed 41°C. However, if it is used together with other endoscope accessories, the surface temperature shall not exceed 41°C within short time with the maximum temperature of 50°C. Under such condition, warnings and suggestions shall be specified in accessory's operation instructions to protect patient.

Light exit window can exceed 41°C. However, warnings, suggestions and the description on the potential clinical consequence due to surface temperature shall be specified in operation instructions to protect patient and operator from harm.

---

[8]* This article does not apply to those fiber endoscopes that do not work together with surgery system.

Annex C

(Informative)

Test Method of Dissolved Precipitate

C.1 Preparation of test liquid

Take 15g of synthetic resin; cut into thin slices. Put them into 150mL of boiling water for 30 min. Properly add water to 150mL to prepare test liquid. Take 1.5 g of rubber; use the same method to prepare 150mL of test liquid.

C.2 Test items and analysis method

C.2.1 Appearance and pH

Adopt visual inspection to check the status of test liquid. Add 1mL of potassium chloride solution (1 →1000) in 20mL of test liquid and in 20mL of standard test liquid respectively. The pH value is tested in accordance with the method specified in “Chinese Pharmacopoeia 2005”.

C.2.2 Heavy metals (Pb)

10mL of test liquid + 30mL of water + acetic acid (1+15) 2mL + water (→50mL) + 1 drop of sodium sulfide…compare colour…, acetic acid (1+15) 2mL + 10mL of standard test liquid + standard lead liquid (0.01 mgPb/mL) 2 mL + water (→ 50 mL) + 1 drop of sodium sulphide solution to check whether the displayed colour approaches to deep colour.

C.2.3 Reducing substance of potassium permanganate

Put 10 mL of test liquid in conical flask→ + 20mL of 0.002 mol/L potassium permanganate (0.01) + 1.0mL of sulfuric acid (10%) → boil for 3 min → cool + 0.1g of potassium iodide + 5 drops of starch solution → use 0.01 mol/L sodium thiosulfate to titrate. 10 mL of standard test liquid → follow the same operation steps and titration; measure the difference of the consumption of potassium permanganate solutions.

C.2.4 Evaporated residue

Evaporate 20mL of test liquid by water-bath method, and then solidify. Dry the residue under 105°C for 1h, and weigh its mass.

C.3 Symbol in test method

The symbols used in test method are shown as follows:

a) + “add”;

b) → "operate” (heat, wait, stir or vibrate);

d) … “compare or result”;

e) + water (→ a mL) "the total volume a mL, after adding water”.

This is an excerpt of the PDF (Some pages are marked off intentionally)

------ The End ------