YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0944-2014

Medical endoscopes - Endotherapy devices - Separating forceps

医用内窥镜 内窥镜器械 分离钳

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1 Scope

YY/T 0944 is the product standard for endoscopic separating forceps, the dissecting instrument passed down a working channel or a trocar to separate tissue planes. It belongs to the Chinese series on endoscopic therapeutic instruments alongside YY/T 0941 on punch forceps, issued the same day. An endotherapy instrument is a long, thin mechanism that has to transmit a surgeon's hand movement faithfully over half a metre, hold its grip, survive repeated sterilisation and never shed a component inside the patient, so jaw geometry, actuation force, durability and joint integrity are the requirements that matter. For a manufacturer or an importer of laparoscopic and endoscopic forceps for the Chinese market, this is the governing product standard.

This Standard specifies the scope, terms and definitions, requirements, and test methods of separating forceps. This Standard applies to separation 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 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

4.1 Materials used in parts in contact with patients

4.1.1 Chemical composition requirements For materials used in parts that are in contact with patients, the manufacturer shall indicate this clearly in any possible form. Among them, the metal material shall be marked with the designation and (or) code and the chemical composition requirements of the material. The chemical composition of the metal material shall be verified through tests.

4.1.2 Biocompatibility Materials in contact with patients shall undergo biosafety evaluation in accordance with the principles and requirements of GB/T 16886.1 to prove good biocompatibility. Biological evaluation may consider biological test results, and the selection of test items shall be carried out in accordance with the guidelines of GB/T 16886.1. All tests are preferably based on the relevant standards of GB/T 16886. For materials that have been previously proven to be suitable, if it can be proven that the subsequent manufacturing process is not sufficient to cause biosafety hazards, biological tests may be exempted. NOTE 1: If the material of a device under design has a demonstrable history of

use in specific applications, or if information about the material and (or) the device is available from other sources, the material can be considered to have been previously proven suitable. NOTE 2: If the metal material is a medical metal material suitable for the application range in the national or industry standards, biological tests may be exempted.

4.1.3 Leachables of polymer materials used in parts in contact with patients

4.1.3.1 Appearance (turbidity, color): colorless and transparent, no foreign matter can be seen visually.

4.1.3.2 pH: when compared with the blank control solution of the same batch, the pH difference 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 dissolution solution shall not exceed 5.0 μg/mL.

4.1.3.4 Potassium permanganate reducing substance: the consumption difference with the same volume of blank control solution from the same batch shall be less than

4.1.3.5 Evaporation residue: the total amount of dry residue in the dissolution solution shall be less than

4.1.4 Hardness The forceps head shall meet the hardness requirements specified by the manufacturer.

4.1.5 Consistency of surface and interior in material The manufacturer claims that the surface of the device part made of metal materials shall be consistent with the interior in material. If it is indeed necessary to coat the surface of the device, the manufacturer shall provide the corresponding coating requirements and test methods.

4.2 Appearance

4.2.1 Under the field of view of the endoscope, the visible head end of the surgical instrument shall be processed to eliminate possible directional reflections.

4.2.2 Except for special purposes, there shall be no burrs or other defects that may cause injury on the outer surface.

4.3 Dimensions

4.3.1 Maximum insertion portion width The manufacturer shall give the nominal value of the maximum insertion portion width in the instructions. The actual measured value must not be greater than the nominal value.

4.3.2 Working length The manufacturer shall give the nominal value of the working length in the instructions and provide a diagram to clearly indicate it. The tolerance of nominal value of the working length: ±3 %.

4.3.3 Maximum opening range of forceps head The manufacturer shall give the nominal value of the maximum opening range of forceps head in the instructions and provide a diagram to clearly indicate it. The tolerance of nominal value of the opening range of forceps head: ±20 %.

4.4 Usage performance

4.4.1 Opening and closing performance requirements of Class b; the remaining materials are sterilized once in accordance with the most unfavorable sterilization method for the device specified by the manufacturer in the instructions, and there shall be no corrosion.

4.5.3 Performance of withstanding repeated operations It can withstand repeated operations for 20 times without damage or breakage.

4.6 Sterilization requirements (applicable to single-use products)

4.6.1 The separating forceps shall be sterile.

4.6.2 Residual amount of ethylene oxide (applicable to products that use ethylene oxide sterilization method): the residual concentration of ethylene oxide is less than 10 μg/g.

4.7 Luer connector (applicable to separating forceps with injection ports) It shall comply with the relevant requirements of GB/T 1962.

4.8 Product instructions

4.8.1 It shall include clear instructions on the endoscopes and their accessories that can be used in conjunction with the separating forceps, so that users can select the appropriate endoscope and its accessories according to this guidance.

4.8.2 It shall include a schematic diagram of the shape of the separating forceps in the maximum opened state of the forceps head; it shall include an introduction to the names and functions of each component of the separating forceps, and provide a schematic diagram if necessary.

4.8.3 It shall include the product specifications.

4.8.4 It shall include a description of the product's intended use.

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

4.8.6 It shall include the environmental protection content: - indicate any risks related to waste, residues, etc. and their disposal at the end of their useful life; - provide suggestions for minimizing these risks.

4.8.7 If the separating forceps are not single-use products, their instructions shall include details about the cleaning, disinfection or sterilization methods that can be used, specify