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Intra-uterine suction curettes for single use

一次性使用流产吸引管

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Foreword

This Standard was drafted in accordance with the rules given in GB/T 1.1-2009.

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

This Standard was proposed by the State Food and Drug Administration of the People's Republic of China

This Standard shall be under the jurisdiction of the National standardization technical committee for family planning devices. (SAC/TC 169).

The drafting organizations of this standard: Tianjin Medical device Factory, China Food and Drug Administration, Shanghai Medical Device Quality Supervision and Inspection Center, Beijing Yuanhao Huaxin Science and Technology Co., Ltd.

The main drafters of this standard: Jian Dehong, Yao Tianping, Jia Fuhua, Huang Shuze, Wang Shiyuan.

Intra-uterine suction curettes for single use

1 Scope

This standard specifies the structural type and material, requirements, test methods, inspection rules, marking and instructions for use, packaging, transportation and storage of intra-uterine suction curettes.

This standard is applicable to single-use intra-uterine suction curettes (hereinafter referred to as suction curette) which is connected to a suction device for performing negative pressure suction operation on early pregnant women.

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 2828.1 Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

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

GB/T 9969 General principles for preparation of instructions for use of industrial products

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

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

GB/T 16886.10 Biological evaluation of medical devices - Part 10: Tests for irritation and sensitization

YY/T 0466.1 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

5.5 Negative pressure resistance

Connect one end of the suction curette to a vacuum device and seal the other end. Under (25±2)°C, apply negative pressure according to Table 2 for 30s. Shall conform to the requirements in 4.5.

5.6 Cavity smoothness

5.6.1 Single/ double cavity suction curette

Take a syringe no less than 30mL and take sufficient amount of water. Connect the joint end of the suction curette (or the main tube of a double cavity suction curette) with the cone head of the syringe, push the core rod, so that the water in the syringe is discharged from the suction end of the suction curette. There shall be no obvious resistance. Shall conform to the requirements of 4.6.

5.6.2 Accessory tube of double cavity suction curette

Take one syringe filled with water. Inject water from either side of the accessory tube with the syringe needle. There shall be water discharged from the other side. Shall conform to the requirements of 4.6.

5.7 Sterile

Inspect according to 1101 sterility test method in the "Pharmacopoeia of the People's Republic of China Fourth Part" (2015 edition). Shall conform to the requirements of 4.7.

5.8 Ethylene oxide residue

Test according to the test method of ethylene oxide residue in GB/T 14233.1-2008. Shall conform to the requirements of 4.8.

5.9 Biological evaluation

5.9.1 Cytotoxicity

Test according to the test method of leaching solution in GB/T 16886.5. Shall conform to the requirements of 4.9.1.

5.9.2 Delayed type hypersensitivity

Test according to the test method in GB/T 16886.10. Shall conform to the requirements of 4.9.2.

5.9.3 Intradermal stimulation test

The markings of the suction curette shall comply with the specifications of Appendix A.

7.2 Instructions for use

7.2.1 There shall be instructions for use in the package.

7.2.2 The instructions shall be compiled in accordance with the requirements of GB/T 9969.

7.2.3 The instruction for use shall contain the following:

a) Name and address of the manufacturer;

b) Product approval number and product standard number;

c) Scope of use and precautions of the product;

d) Product performance, manufacturing materials and possible side effects;

e) Requirements to ensure the correct and safe use of the suction curette, as well as the requirements and precautions when used with other devices;

f) The measures and the precautions to be taken in case of accident occurred during the use of the products;

g) Required contents and descriptions specified in the product standard.

8 Packaging, transportation and storage

8.1 Packaging

The packaging of the suction curette shall comply with the provisions of Appendix A.

8.2 Transportation

Transportation requirements shall conform to the order contract.

8.3 Storage

The packaged suction curette shall be stored in a clean and well-ventilated room at room temperature with relative humidity no more than 80% and no corrosive gas.

8.4 Period of sterilization expiry

The suction curette sealed in the package shall be indicated with the period of

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