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Single-use Huber needles used for implantable drug-supplying devices

一次性使用植入式给药装置专用针

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Foreword

This Standard is drafted in accordance with the rules given in GB/T 1.1.

This Standard is proposed by State Food and Drug Administration.

This Standard is under the jurisdiction of National Technical Committee on Infusion Equipment for Medical Use of Standardization Administration of China (SAC/TC 106).

Drafting of organizations this Standard: State Food and Drug Administration Jinan Medical Device Quality Supervision and Inspection Center, Zhejiang Kindly Medical Devices Co., Ltd.

Main drafters of this Standard: Wan Min, Yu Xin, Mou Pengtao, Zhang Honghui.

Introduction

After the implantable drug-supplying device as specified in YY 0332 implants subcutaneously, it needs to use a Huber needle to puncture and inject into its injection seat, through which the drug will be infused into the body's fluid circulation system or specific parts. Experiments show that using traditional intravenous infusion needle or hypodermic needle to puncture the injection seat of the drug-supplying device will easily produce debris, which will bring not only harm to the human body when falling into the human body, but also bad effects on the device life and performance. The configuration of the Huber needle specified in this Standard can significantly reduce the amount of debris produced during the puncture process.

The implantable drug-supplying device is divided into two types, i.e. hypodermic needle and infusion needle, according to the use. At present, the structural feature of all Huber needles for subcutaneous puncture is that there is a bending angle between the needle tip and the needle tubing axis, so that the first bevel of the needle tip is parallel to the needle tubing axis, and the edge becomes a "side hole", to reduce debris produced during the puncture process.

There is a kind of Huber needle on the market, its composition is as same as the composition of the hypodermic needle; this kind of needle not only has a bending angle on the needle tip, but also the needle tubing is bent into 90° to make it became the infusion needle. Considering that the needle is clinically difficult to puncture, the committee does not advocate such a design, so that this type of Huber needle is not included in the schematic diagram given in this Standard. In addition to the examples given by the standard, there are many types of Huber infusion needles seen on the market, such as that with anti-acupuncture protection device, injection seat and other components. The product with these components may refer to the relevant infusion, injection device standards. This Standard does not repeat the requirements for these components.

Not easy to produce falling debris during the puncture process is a widely-concerned requirement. However, due to the absence of reference material for puncture debris test, it is not possible to develop a test method for evaluating the puncture debris performance of the needle tip. Nonetheless, C.2 of this Standard recommends a reference method for evaluating puncture debris. The standardized test method in the future, if any, will be added to this Standard.

Single-use Huber needles used for implantable drug-supplying devices

1 Scope

This Standard specifies the requirements for single-use Huber needles used for implantable drug-supplying devices (including infusion needles and hypodermic needles) to ensure the compatibility of implantable drug-supplying devices and infusion and injection devices.

This Standard provides guidance on the performance and quality specifications of materials used for Huber needles.

This Standard does not involve the anti-acupuncture safety requirements for Huber needles.

2 Normative references

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

GB/T 1962.1 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirement

GB/T 1962.2 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings

GB 8368 Infusion sets for single use - gravity feed

GB 15811 Sterile hypodermic needles for single use

GB 18457 Stainless steel needle tubing for the manufacture of medical devices

GB 18671 Intravenous needles for single use

YY 0286.4-2006 Special infusion sets - Part 4: Single-use infusion equipment for use with pressure infusion apparatus

YY/T 0296 Hypodermic needles for single use - Color coding for identification

6.7 Needle tip

6.7.1 The needle tip of the Huber needle shall have a bending angle facing the direction of the cutting edge (which is approximately equal to the first bevel angle *α* of the needle tip), so that the first bevel is parallel to the needle tubing axis.

NOTE: This configuration allows the needle tip to become a “side hole” needle, to effectively reduce puncture debris. C.2 gives the information on the evaluation of puncture debris. See also the introduction.

6.7.2 The needle tip of the Huber needle shall be sharp; in the 2.5 times magnification condition, with normal or corrected visual acuity, the needle tip shall be no burrs, hooks and other defects.

NOTE 1: In order to reduce the bending angle of the needle tubing, the first bevel angle of the needle tip is usually a “long bevel angle” of (12 ± 2) °. C.1 gives the geometry and naming illustrations of the needle tip. When describing the configuration of the needle tip, it is not necessary to use all the illustrations shown.

NOTE 2: C.3 gives a method for evaluating the puncture performance of the needle tip.

6.7.3 The first bevel angle of the needle tip shall be facing the direction of the needle handle (as shown in Figure 1).

6.8 Lubricant

If the needle tubing is coated with lubricants, observe with normal or corrected visual acuity, the outer surface of the needle tubing shall not have visible lubricant buildup.

NOTE 1: The suitable lubricant is polydimethylsiloxane.

NOTE 2: The amount of lubricant per square centimeter on the needle tubing shall not exceed 0.25 mg.

6.9 Connecting seat

The conical joint of the connecting seat shall meet the requirements of GB/T 1962.1 or GB/T 1962.2.

The connecting seat of the Huber needle used in conjunction with the infusion set for pressure infusion apparatus shall use lock fittings.

6.10 Needle handle

The needle handle of the Huber infusion needle shall be complete, and the mark shall be clear.

NOTE: The graphic symbols given in YY/T 0466 can be used to meet the above requirements.

9.2 Mediate packaging

There shall be at least the following information in the mediate packaging:

a) product name and the specification mark in accordance with Clause 4;

b) quantity;

c) words of “sterile”, “pyrogen free” or “no bacterial endotoxin”;

d) batch number, started with the word “Batch”;

e) failure date;

f) words of “single-use” or equivalent words;

g) letter “P” that represents the pressure, its height shall be higher than the surrounding words, if applicable;

h) requirements for handling, storage and transportation (if required);

i) name and address of manufacturer and/or distributor;

j) recommended storage conditions (if any).

NOTE: The graphic symbols given in YY/T 0466 can be used to meet the above requirements.

9.3 Transportation packaging

There shall be at least the following marks on the transportation packaging:

a) product name and the specification mark in accordance with Clause 4;

b) quantity;

c) words of “sterile”, “pyrogen free” or “no bacterial endotoxin”;

d) batch number, started with the word “Batch”;

e) failure date;

f) words of “single-use” or equivalent words;

g) requirements for handling, storage and transportation;

h) name and address of manufacturer and/or distributor.

2 - test needle;
3 - polymer film;
4 - polymer film clamping device;
5 - signal amplifier;
6 - data processing device;
7 - plotter;
8 - cartridge storage device.

Figure C.2 Basic structure of test apparatus for needle tip's puncture force

C.3.2 Material of polymer films

The polymer film suitable for the puncture test is the polyurethane film with elasticity, a thickness of 0.35 mm ± 0.05 mm and a Shore (A) hardness of 85 ± 10.

C.3.3 Procedure of puncture force evaluation test

C.3.3.1 The polymer film is allowed to be placed at 22 °C ± 2 °C for at least 24 h, and tested at the same temperature.

C.3.3.2 Vertically clamp a part of the continuous-length polymer film 3 in the clamping device 4, and the polymer film shall be prevented from being tensioned. If the polymer film has a finishing surface, this surface shall be facing the needle tip.

C.3.3.3 MOUNT the test needle on a fixture, of which the axis is perpendicular to the surface of the polymeric film, and the needle tip towards the center of the circular area for puncture.

C.3.3.4 The moving speed is set to 100 mm/min.

C.3.3.5 START the test apparatus.

C.3.3.6 PUNCTURE the polymer film, while record the curve of forces corresponding to the displacement.

C.3.3.7 DETERMINE the corresponding peak forces F_0, F_1, F_2 and F_4.

C.3.3.8 Each time when the polymeric film is punctured, a region that has not been used and punctured shall be selected.

C.3.4 Record the peak force in the coordinate figure

When the needle is puncturing, the force values can be identified by observing several typical peak values when puncturing through the polymer film.

F_0: peak force when the needle is puncturing through the polymer film

Bibliography

[1] GB 15593-1995 Plasticized polyvinyl chloride (PVC) compounds for transfusion (infusion) equipment

[2] GB 15811-2000 Sterile hypodermic needles for single use

[3] GB/T 16886 (all parts) Biological evaluation of medical devices

[4] GB 18279 Medical devices - Validation and routine control of ethylene oxide sterilization

[5] GB 18280 Sterilization of health care products - Requirement for validation and routine control - Radiation sterilization

[6] YY 0332 Implantable drug-supplying device

[7] YY 0466 Medical devices - Symbols to be used with medical device labels labelling and information to be supplied

[8] YY/T 0618 Bacterial endotoxins - Test methodologies routine monitoring and alternatives to batch testing

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