

Translated English of Chinese Standard: YYT0980.3-2016

www.ChineseStandard.net

Sales@ChineseStandard.net

YY

PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.20

C 31

YY/T 0980.4-2016

Biopsy needles for single use -

Part 4: Mechanical complete type

一次性使用活组织检查针 第 4 部分：机动一体式

YY/T 0980.4-2016 How to BUY & immediately GET a full-copy of this standard?

1. www.ChineseStandard.net;
2. Search --> Add to Cart --> Checkout (3-steps);
3. No action is required - Full-copy of this standard will be automatically & immediately delivered to your EMAIL address in 0~60 minutes.
4. Support: Sales@ChineseStandard.net. Wayne, Sales manager

Issued on: July 29, 2016

Implemented on: June 1, 2017

Issued by: China Food and Drug Administration

Table of Contents

Foreword.....	3
Introduction	4
1 Scope.....	5
2 Normative references.....	5
3 Structure type.....	5
4 Material	7
6 Packaging and marking	9
7 Instructions for use.....	9
8 Transportation and storage	10
9 Type inspection rules	10
Annex A (informative) Type inspection rules	11
Bibliography	12

Foreword

YY/T 0980 “Biopsy needles for single use” series of standards consist of the following parts:

- Part 1: General requirements;
- Part 2: Manual biopsy needle;
- Part 3: Mechanical assembly type
- Part 4: Mechanical complete type.

This Part is Part 4 of YY/T 0980 “Biopsy needles for single use”.

This Part is drafted 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. Issuing organizations of this document shall not be held responsible for identifying any or all such patent rights.

This Part is proposed by China Food and Drug Administration.

This Part is under the jurisdiction of National Technical Committee on Medical Syringe (Needle) of Standardization Administration of China (SAC/TC 95).

Main drafting organizations of this Part: Zhejiang Fert Medical Device Co., Ltd., Shanghai Testing & Inspection Institute for Medical Devices, Shanghai SA Medical & Plastic Instruments Co., Ltd.

Main drafters of this Part: Su Weidong, Wang Zewei, Cao Xianming.

Introduction

This Part of YY/T 0980 specifies the requirements for mechanical complete type biopsy needles for single use.

This Part does not provide requirements and methods for sampling performance and ultrasonic development, because currently there is no suitable test methods and simulation test materials.

In view of the fact that the structure type of mechanical complete type biopsy needles and the location, depth, state, texture and method of the puncture are different, this Part does not specify the puncture force. However, manufacturers are encouraged to determine appropriate puncture force by verifying, combining the specific structure and use of the mechanical complete type biopsy needle produced by each of the manufacturers.

In view of the fact that the trigger device of mechanical complete type biopsy needles may be mistakenly triggered in the course of clinical use, and there is no suitable test method for trigger devices, this Part does not specify the trigger device. However, manufacturers are encouraged to determine appropriate trigger device data and test method by verifying.

Biopsy needles for single use - Part 4: Mechanical complete type

1 Scope

This Part of YY/T 0980 specifies the requirements for biopsy needles for single use - mechanical complete type (hereinafter referred to as “biopsy needles”).

This Part applies to mechanical complete type biopsy needles for single use, of which the needle for single use and the mechanical power device are assembled together at the time of manufacture; the mechanical power device is for automatic or semi-automatic cutting operations to collect biopsy samples.

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 1220 Stainless steel bar

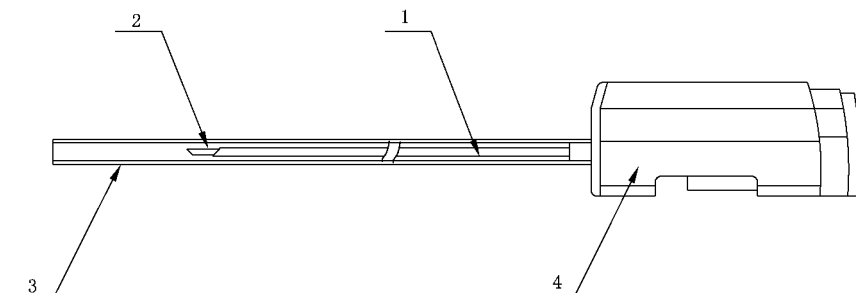
GB/T 2965 Titanium and titanium alloy bar

YY/T 0980.1-2016 Biopsy needles for single use - Part 1: General requirements

3 Structure type

3.1 A biopsy needle consists of an outer needle tube, an inner needle bar, a protective cover and a mechanical power device.

NOTE: Biopsy needles can be used with guide needles, cursors, etc. when necessary.



- a) product name;
- b) product model description;
- c) product performance, main structure;
- d) scope;
- e) use methods and precautions;
- f) storage conditions;
- g) other instructions and necessary warnings.

8 Transportation and storage

8.1 During transportation and storage process, biopsy needles shall be prevented from stress, sun and rain and snow.

8.2 Biopsy needles shall be stored in a non-corrosive-gas, well ventilated and clean environment.

9 Type inspection rules

See Annex A for type inspection rules.

Bibliography

- [1] GB 15811-2001 Sterile hypodermic needles for single use
- [2] YY 0321.2-2009 Single-use needle for anaesthesia
- [3] YY/T 0313-2014 Medical polymer products - Requirement for package and information supplied by manufacturer
- [4] YY/T 0466.1-2009 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

————— **END** —————