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**Biopsy needles for single use -**

**Part 3: Mechanical assembly type**

一次性使用活组织检查针 第3部分：机动装配式

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## 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 3 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 Syringes (Needles) 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.

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## Introduction

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 assembly 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 assembly type biopsy needle produced by each of the manufacturers.

# Biopsy needles for single use - Part 3: Mechanical assembly type

## 1 Scope

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

This Part applies to mechanical assembly type biopsy needles for single use, which consist of needles for single use and reusable mechanical power devices for automatic or semi-automatic cutting operations to collect biopsy samples.

This Part does not apply to reusable biopsy needles and mechanical power devices connected with the biopsy needle by means of assembly before use.

## 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 outer needle seat, an inner needle bar, an inner needle seat, a fixed part and a protective cover.

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

## 7 Instructions for use

The instructions for use shall have at least the following information:

- a) product name;
- b) product model description;
- c) product performance, main structure;
- d) use methods and precautions;
- e) storage conditions;
- f) prompt information that it can be equipped with mechanical power device;
- 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.