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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 44138-2024

Cardiovascular implants - Cardiovascular absorbable implants

心血管植入物 可吸收植入物

(English Translation)

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Reference

Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document is modified to adopt ISO/T S17137.2021 Cardiovascular implants and absorbable implants for extracorporeal systems. The document type is ISO 's technical specifications are adjusted to our country's national standards.

The technical differences between this document and ISO/T S17137.2021 and their reasons are as follows.

--- ISO 17665-1 (see Chapter 4) has been replaced by the normative reference GB 18278.1 to adapt to my country's technical conditions and improve the reliability of the product.

Operability;

--- ISO 11135-1 (see Chapter 4) has been replaced by the normative reference GB 18279.1 to adapt to my country's technical conditions and improve the reliability of the product.

Operability;

--- ISO 11137-1 (see Chapter 4) has been replaced by the normative reference GB 18280.1 to adapt to my country's technical conditions and improve the reliability of the product.

Operability;

--- ISO 11137-2 (see Chapter 4) has been replaced by the normative reference GB 18280.2 to adapt to my country's technical conditions and improve the reliability of the product.

Operability;

--- ISO 11137-3 (see Chapter 4) has been replaced by the normative reference GB 18280.3 to adapt to my country's technical conditions and improve the reliability of the product.

Operability;

--- ISO 11607-1 (see Chapter 4) has been replaced by the normative reference GB/T 19633.1 to adapt to my country's technical conditions and provide High operability;

--- ISO 14937 (see Chapter 4) has been replaced by the normative reference GB/T 19974 to adapt to my country's technical conditions and improve the reliability of the product.

Operability;

--- ISO 14971 (see Chapter 4) has been replaced by the normative reference YY/T 0316 to adapt to my country's technical conditions and improve the reliability of the product.

Operability;

--- Replaced ISO 10993 (all parts) (see Chapters 4 and 5) with normative references GB/T 16886 (all parts) to adapt to my country's technical conditions to improve operability;

--- ISO 12417-1 (see Chapters 4 and 5) has been replaced by the normative reference GB/T 39381.1 to adapt to my country's technical conditions.

Improve operability;

--- Replaced ISO 25539 (all parts) (see Chapters 4 and 5) with the normative reference YY/T 0663 (all parts) to adapt to my country's technical conditions to improve operability;

--- Replaced ISO/T S37137 (see Chapters 4 and 5) with the normative reference YY/T 1775.1 to adapt to my country's technical conditions.

Improve operability;

--- ISO 5840-1 (see Chapter 5) has been replaced by the normative reference GB/T 12279.1 to adapt to my country's technical conditions and improve Operability;

--- ISO 5840-2 (see Chapter 5) has been replaced by the normative reference GB/T 12279.2 to adapt to my country's technical conditions and improve Operability;

--- ISO 5840-3 (see Chapter 5) was replaced by the normative reference YY/T 1449.3 to adapt to my country's technical conditions and improve Operability;

--- Deleted "5.7 Clinical Evaluation, 5.8 Post-marketing Follow-up, 5.9 Clinical Trial Selection of Absorbable Cardiovascular Implants" and Relevant normative reference documents and references should be used to avoid inconsistencies with relevant regulations of our country.

The following editorial changes were made to this document.

- This document does not include the relevant content of the extracorporeal circulation system, and the name of the standard is changed to "Cardiovascular Implants Absorbable Implants";
- Deleted the introduction to ISO and IEC terminology databases in Chapter 3;
- The informative reference YY/T 0681.1 replaces ASTM F1980, and YY/T 1474 replaces IEC 62366 (see Chapter 4); replace ISO 10555-1 with informative reference YY0285.1, replace ISO 10555-4 with YY0285.4, YY/T 0474 replaced ISO 13781, YY/T 0586 replaced ASTM F640, and YY/T 0695 replaced ASTM F2129, YY/T 0807 replaced ASTM F2394, YY/T 0858 replaced ASTM F2606, YY/T 0987.1 replaced ASTM F2503 was replaced, ASTM F2052 was replaced by YY/T 0987.2, ASTM F2119 was replaced by YY/T 0987.3, YY/T 0987.4 replaced ASTM F2182, YY/T 0987.5 replaced ASTM F2213, and the People's Republic of China the Pharmacopoeia replaced the United States Pharmacopoeia (USP) (see Chapter 5);
- Modified the notes in Appendix A;
- Added Appendix B (informative) "Conformity between GB/T 16886 (all parts) and ISO 10993 (all parts) degree of sexuality".

Introduction

Cardiovascular absorbable implants are implants in the cardiovascular system with a variety of clinical indications.

Parts of the implant are degraded over time, and the degradation products are absorbed, assimilated, and/or excreted (eliminated) through metabolism.

Surgical or interventional procedures are used to reach the treatment site.

This document outlines the expected performance requirements, design attributes, materials and design, manufacturing, sterilization, packaging, and information provided by the manufacturer.

This document should be used as a supplement to YY/T 0640-2016, which specifies the general requirements for passive surgical implants.

For example, YY/T 0663 (all parts) specifies the special requirements for endovascular prostheses, but does not include absorbable implants and coatings.

Degradation and time-related requirements.

This document is not a complete evaluation of the pharmaceutical aspects of absorbable cardiovascular implants. Detailed pharmacological safety and performance requirements are given in GB/T 39381.1.

This document covers only those aspects related to the degradation and resorption of cardiovascular implants. Due to the differences in implant designs covered by this document, as some implants (such as absorbable stents) were developed relatively late, acceptable standardized in vitro tests and clinical results are not always available.

Valid. With the development of science and accumulation of clinical data, it is necessary to revise this document appropriately.

NOTE For issues related to mechanical properties common to cardiovascular implants, reference may be made to other standards (see References).

Cardiovascular Implants Absorbable Implants

1 Scope

This document specifies absorbable cardiac blood products for use in the treatment of blood vessels and/or vascular areas of the circulatory system (including the heart and all circulatory system) this document is intended to supplement standards for specific devices.

This document applies to implants that come into direct contact with the cardiovascular system and are intended to act on the circulatory system.

Note 1: Certain aspects of the absorbable components of cardiovascular drug-device combination products (such as coatings) related to drugs are described in GB/T 39381.1.

Note 2: For explanations of absorbable, degradable and related terms, see Appendix A.

Note 3: This document does not specifically address issues related to implants containing living tissue, living cells and/or non-living biological material and their derivatives.

In addition, the use of procedures and devices before and after the implantation of absorbable cardiovascular implants (such as balloon angioplasty devices) should not affect the implant.

Absorbable cardiovascular implants may contain substances that would be considered medicinal products (drugs) when used alone.

The drug's action is to assist the implant and support the implant's primary mode of action.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to this document.

GB/T 12279.1 Cardiovascular implantable devices - Artificial heart valves - Part 1: General