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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0640-2016

Replacing YY/T 0640-2008

Non-active surgical implants - General requirements

无源外科植入物 通用要求

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Table of Contents

Foreword 3
Introduction 6
1 Scope 7
2 Normative references 7
3 Terms and definitions 8
4 Intended performance 10
5 Design attributes 10
6 Materials 12
7 Design evaluation 13
8 Manufacture 15
9 Sterilization 15
10 Packaging 16
11 Information supplied by the manufacturer 17
Bibliography 23

Foreword

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

This Standard replaces YY/T 0640-2008 Non-active surgical implants - General requirements. Compared with YY/T 0640-2008, the main differences in this Standard are as follows:

apply to the implants from active animal tissues;

added the terms and definitions for “magnetic resonance environment” (see 3.4) and “magnetic resonance imaging” (see 3.5);

added some requirements for design attributes [see Clause 5 f], s), t), u), v)];

made more detailed provisions on “pre-clinical evaluation” (see 7.2) and “post-market surveillance” (see 7.4);

made more detailed provisions on “instructions for use” [see 11.3 a], t), u)];

of basic principles outlined in ISO/TR 14283”.

This Standard uses translation method to identically adopt ISO 14630:2012 Non-active surgical implants -- General requirements.

The Chinese documents which have consistency with the international normative reference in this Standard are as follows:

- YY 0970-2013, Sterilization of single-use medical devices incorporating materials of animal origin - Validation and routine control of sterilization by liquid sterilants (ISO 14160:1998, IDT)

- YY/T 0802-2010, Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664:2004, IDT)

Attention is 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 State Food and Drug Administration.

This Standard shall be under the jurisdiction of National Technical Committee on Surgical Implants and Orthopedic Instruments of Standardization Administration of China (SAC/TC 110).

The drafting organizations of this Standard: Tianjin Medical Device Quality Supervision and Inspection Center, State Food and Drug Administration Medical Device Technical Review Center.

Main drafters of this Standard: Ma Chunbao, Li Jia, Li Libin, Qi Baofen, Liu Bin, Min Yue, Sun Jiayi.

Version of standard substituted by this Standard is:

Introduction

This Standard provides a method of addressing the fundamental principles outlined in ISO/TR 14283 as they apply to non-active surgical implants. It also provides a method for demonstrating compliance with the relevant essential requirements as outlined in the general terms in Annex 1 of the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as they apply to non-active surgical implants, hereafter referred to as implants. It might also help manufacturers comply with the requirements of other regulatory bodies.

There are three levels of standards dealing with non-active surgical implants and related instrumentation. For the implants themselves, they are as follows, with level 1 being the highest.

- Level 1: General requirements for non-active surgical implants.

- Level 3: Specific requirements for types of non-active surgical implants.

Level 1 standards, such as this Standard and Reference [4], contain requirements that apply to all non-active surgical implants. They also anticipate that there are additional requirements in the level 2 and level 3 standards.

Level 2 standards (see References [5], [6], [7], [8] and [9]) apply to a more restricted set or family of non-active surgical implants, such as those designed for use in neurosurgery, cardiovascular surgery, or joint replacement.

Level 3 standards (see References [10], [11], [12] and [13]) apply to specific types of implants within a family of non-active surgical implants, such as hip joints or arterial stents.

To address all requirements for a specific implant, it is advisable that the standard of the lowest available level be consulted first.

or national standards or regulatory bodies can prescribe other requirements.

1 Scope

This Standard specifies general requirements for non-active surgical implants, hereafter referred to as implants. This Standard is not applicable to dental implants, dental restorative materials, trans-endodontic and trans-radicular implants, intra-ocular lenses and implants utilizing viable animal tissue.

With regard to safety, this Standard specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests to demonstrate compliance with these requirements.

Additional tests are given or referred to in level 2 and level 3 standards.

NOTE: This Standard does not require that the manufacturer have a quality management system in place. However, the application of a quality management system, such as that described in ISO 13485, might be appropriate to help ensure that the implant achieves its intended performance.

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.

ISO 14160, Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization process for medical devices ISO 14937, Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices ISO 14971, Medical devices - Application of risk management to medical devices ISO 17664, Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices ISO 17665-1, Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices ISO 22442-1, Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management ISO 22442-2, Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling ISO 22442-3, Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents

3 Terms and definitions

3.1 coating

3.2 implantable state

condition of an implant prepared for implantation into a human subject

3.3 leakage

unintended movement of fluid, including body fluids, into or out of an implant Note: An unintended diffusion phenomenon is an example of leakage for the purposes of this Standard.