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

GB/T 25440.2-2021

**Retrieval and analysis of surgical implants - Part 2: Analysis of
retrieved surgical implants**

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Table of Contents

1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Take-out, handling and packaging procedures	1
5 Implant interface analysis	2
6 Implant analysis	2
7 Implant performance	5
Appendix A (Normative Appendix) Standard format for the analysis of removal of surgical implants	6
Appendix B (informative appendix) International standards applicable to material evaluation	14
Reference	18

Foreword

GB/T 25440 "Removal and Analysis of Surgical Implants" is divided into two parts.

---Part 1.Take out and handle;

---Part 2.Analysis of the removal of surgical implants.

This part is Part 2 of GB/T 25440.

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

This part replaces GB/T 25440.2-2010 "Removal and Analysis of Surgical Implants Part 2.Removal of Metal Surgical Implants"

Analysis", GB/T 25440.3-2010 "Removal and Analysis of Surgical Implants Part 3.Analysis of Removal of Polymer Surgical Implants" and

GB/T 25440.4-2010 "Removal and Analysis of Surgical Implants Part 4.Analysis of Removal of Ceramic Surgical Implants", and GB/T

Compared with 25440.2-2010, in addition to editorial changes, the main technical changes are as follows.

---Added the performance test about taking out polymer and ceramic implants (see 6.5.2.3, 6.5.2.4, A.3 and A.4);

--- Modified the scope of application, adding "This section also applies to other materials,

such as animal-derived implants" (see Chapter 1).

This part uses the redrafting method to modify and adopt ISO 12891-2:2020 "Removal and Analysis of Surgical Implants Part 2: Removal

Analysis of Surgical Implants.

This section has made the following editorial changes.

---Delete the references to laws and regulations in the scope (see Chapter 1 in ISO 12891-2:2020) to comply with the compilation of Chinese standards

Write rules;

--- Modify the scope of "Analysis is divided into three stages based on the increase in the degree of damage to the removal of surgical implants" to the form of "Note";

---Adjust the content of 6.1 Note 1 in ISO 12891-2:2020 to the main text.

Introduction

The study of removing surgical implants and adjacent tissues has diagnostic value for clinical complications, and can deepen the performance and safety of clinical implants.

A comprehensive understanding to improve the understanding of the interaction between implants and the human body, thereby promoting the development of implants with better biocompatibility.

High service life.

This section stipulates that surgical implants and related samples taken from the patient's body should be taken during revision surgery or autopsy.

Methods of output, processing and analysis. The purpose is to provide a guideline to avoid unclear research results due to sample damage, and

Provide guidance on collecting data at the right time and environment. GB/T 25440.1-2021 involves taking out and handling. This section deals with specific materials

Analysis of implants, and report programs including data collection. For special research projects, more detailed plans need to be attached. If make

With special analysis techniques, it is important to specify the steps.

This section specifies the analytical methods for removing surgical implants to ensure that the implants are not damaged, and to determine typical research methods.

The source of the research results are compared. These methods may be suitable for removal and analysis of animals.

This section provides comprehensive inspection items for all aspects of surgical implants.

But in most cases only a small part of these inspection items

The points are applicable to the research of specific surgical implants.

GB/T 25440.1-2021 specifies the method of removal and disposal, and is applied to this section. Appendix to GB/T 25440.1-2021

A and Appendix C include sample reports of data related to the retrieval process. These examples are not repeated in this section. According to the removed surgical implant

Entry, attachment and accompanying biological materials, as well as the purpose of removal and analysis, can be deleted and added.

Removal and analysis of surgical implants

Part 2. Analysis of removal of surgical implants

1 Scope

This part of GB/T 25440 specifies the analytical method for removing surgical implants.

This section applies to the analysis of metal, polymer and ceramic implants taken out.

Note. The analysis is divided into three stages based on the increase in the degree of damage to the removal of surgical implants.

This section also applies to other materials, such as animal-derived implants.

2 Normative references

The following documents are indispensable for the application of this document. For dated reference documents, only the dated version applies to this article

Pieces. For undated reference documents, the latest version (including all amendments) is applicable to this document.

GB/T 25440.1-2021 Removal and analysis of surgical implants Part 1. Removal and handling (ISO 12891-1.2015,

IDT)

3 Terms and definitions

The following terms and definitions apply to this document.

ISO and IEC provide a database of terminology used in the standard at the following websites.

3.1

Surgical implant

Implant

Medical devices that are expected to be implanted into the human body with surgical techniques.

Note 1. Hereinafter referred to as "implant".

Note 2. The implant can be a single component or multiple components.

4 Unloading, handling and packaging procedures

The procedures for removal, handling, packaging and related personnel protection shall be in accordance with GB/T 25440.1-2021.

As a preventive measure, the removed implant should be sterilized by an appropriate method, which should not adversely affect the implant and the anticipated research.

ring. For appropriate measures, see 3.8 in GB/T 25440.1-2021.

During the removal process of the implant, any difficulties and the description of the damage caused during the removal process should be included in the report.

In the report.

The cleaning solution (see Table 1 in GB/T 25440.1-2021) may react with the material, such as corrosion or dissolution, the choice of solution should be

Minimize this risk.

If possible, take pictures of the surgical area before removing the implant.