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

**GB/T 25440.3-2010**

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**Retrieval and analysis of surgical implants -- Part 3: Analysis of  
retrieved polymeric surgical implants**

外科植入物的取出与分析 第3部分：取出聚合物外科植入物的分析

**(English Translation)**

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## Foreword

GB/T 25440 "removal and analysis of surgical implants" is divided into four parts.

--- Part 1. Remove and processing;

--- Part 2. Remove the metal analysis of surgical implants;

--- Part 3. Remove the analysis of polymer surgical implants;

--- Part 4. Remove Analysis ceramic surgical implants.

This section GB/T Part of 325,440.

This part identical with ISO 12891-3:2000 "surgical implant removal and analysis - Part 3. Remove the polymer surgical implants Analysis "(in English).

Appendix A of this section and Appendix B is an informative annex.

This part is proposed by the State Food and Drug Administration.

This part of the National Surgical implants and orthopedic instruments Standardization Technical Committee (SAC/TC110) centralized.

This section is drafted. Tianjin State Food and Drug Administration Medical Device Quality Supervision and Inspection Center.

## Introduction

Study removed surgical implants and adjacent tissues of diagnostic value of clinical complications can deepen clinical implant performance and plant Into the matter with the understanding of the human interaction, providing an implant performance and security of information, so as to promote the development of a biocompatible implant material and Improve life.

GB/T 25440 for each part of surgical implants and related samples taken, processed and analyzed to provide guidance, implants and related Routine samples taken from the patient, surgical repair or autopsy. This standard is intended to remove the implant and analysis provided A guidance, in order to avoid damage to the sample affect the findings and to provide guidance for the collection of data at the right time and the environment.

GB/T 25440 specifies the different parts of the analytical methods specific implant material, including the collection of data used for reporting program. for Special research projects, the need for additional more detailed plan. If you use special analytical techniques, it is desirable to identify appropriate procedures.

GB/T 25440 Part of the analysis taken into polymer surgical implants provide guidance aimed at reducing the damage to the implant, Determine the typical research methods, findings from different sources were compared. This section also provides guidance for clinical research literature. Headquarters Points can also be used for animals removed and analyzed. Other parts of the GB/T 25440 describes polymer material than other materials the detailed procedure of implant removal and processing and analytical methods.

GB/T 25440.1 provides removal and processing of general guidance, and applied to this section and other parts, which relate to different materials Analysis of materials. GB/T 25440.1 of Information Appendix B and Appendix C includes examples of clinical and removing data collection. These data Other parts of the GB/T 25440 will not be repeated; based on fetched surgical implants, may be attached to or associated with the removal and analysis of biological materials and the purpose, they can be cut and increased.

Surgical implants removed and Analysis Part 3. Remove Analysis polymer surgical implants

## 1 Scope

GB/T 25440 Part of the analysis taken into polymer surgical implants provide guidance. Based on the increasing level of damage research Study can be divided into three stages. Research stage and type of selection depends on the type of implant material and research purposes.

**NOTE:** Use this section relates to the removal of the implant, tissue processing and analysis and related biological material shall comply with national laws and regulations.

## 2 Normative references

The following documents contain provisions which, through reference GB/T 25440 in this section constitute provisions of this section. For dated reference documents Member, all subsequent amendments (not including errata content) or revisions do not apply to this section, however, encouraged to reach under this section Parties to research agreement to use the latest versions of these documents. For undated reference documents, the latest versions apply to this section.

GB/T 25440.1-2010 surgical implant removal and analysis - Part 1. Remove and handling (ISO 12891-1:1998, IDT) ASTM D883 standard terminology related to plastic (Standard Terminology Relating to Plastics)

## 3 Terms and Definitions

The following terms and definitions apply to this part of the GB/T 25440 of.

Polymer surgical implants polymeric surgical implant in surgical technique to implant the polymer material of medical devices.

**Note 1:** hereinafter referred to as "implant."

**Note 2:** The polymer implant may be a member or component of a multi-part implant.

## 4 Out, handling and packaging procedures

Remove, handling, packaging and related personnel protection program should be consistent with the provisions of GB/T 25440.1 of.

**NOTE:** As a precaution, remove the implant suitably appropriate method for sterilization, this method should not adversely impact on the implants and prospective study. Corresponding fine See section GB/T 25440.1-2010 Appendix A.

### 5.1 Implant/tissue interface

Removal of the implant of important information is usually located in the implant/tissue interface. It should pay attention to the surrounding tissue implants particles the study. If possible, consideration should be given to study implant degradation byproducts of chemical analysis and cellular response of the implant.

With the implant surface from the different organizations, and its appearance are very different, so the combination of the implant tissue analysis is particularly important (see GB/T 25440.1-2010, such as 4.5).

## **5.2 Implant/implant interface**

Due to the nature of the polymer, the implant made of a polymer may be relatively soft. Therefore, you should check the parts and other components of the polymer are there wear debris in and around the room.