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

GB/T 19701.5-2024

**Implants for surgery - Ultra-high-molecular-weight polyethylene
- Part 5: Morphology assessment method**

外科植入物 超高分子量聚乙烯 第5部分：形态评价方法

(English Translation)

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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 part 5 of GB/T 19701 Ultra-high molecular weight polyethylene for surgical implants. GB/T 19701 has been published the following parts.

- Part 1: Powders;
- Part 2: Moulding materials;
- Part 3: Accelerated aging methods;
- Part 5: Morphological evaluation method.

This document is modified to adopt ISO 5834-5:2019 "Ultra-high molecular weight polyethylene for surgical implants - Part 5: Morphological evaluation methods".

The technical differences between this document and ISO 5834-5:2019 and their reasons are as follows.

- The normative reference GB/T 21461.1 replaces ISO 11542-1 (see Chapter 3) to adapt to my country's technical conditions and provide High operability;
- ISO 11542-2 (see Chapter 3) has been replaced by the normative reference GB/T 21461.2 to adapt to my country's technical conditions and provide High operability;
- Changed the observation method of microscope in the test method (see 4.2.2, 4.2.2 of ISO 5834-5:2019), and the terminology and definition the test conditions are consistent with those given in the specification.

Introduction

Ultra-high molecular weight polyethylene has good mechanical properties, wear resistance and biocompatibility, and is widely used in surgical implants such as artificial joints, Widely used in tissue stent products.

GB/T 19701 "Ultra-high molecular weight polyethylene for surgical implants" is planned to consist of 5 parts.

--- Part 1: Powders. The purpose is to standardize the requirements and corresponding tests of ultra-high molecular weight polyethylene powders for surgical implants method.

--- Part 2: Moulding materials. The purpose is to specify the requirements and related the method should be tested.

--- Part 3: Accelerated aging method. The purpose is to provide ultra-high molecular weight polyethylene (UHMWPE) materials for surgical implants Test method for oxidative stability during processing and sterilization.

--- Part 4: Oxidation index test method. The purpose is to provide a test method for the relative oxidation degree of ultra-high molecular weight polyethylene.

Evaluation of the relative degree of oxidation of ultra-high molecular weight polyethylene.

--- Part 5: Morphological evaluation method. The purpose is to provide a test method for the morphological quality of ultra-high molecular weight polyethylene molding compounds to evaluate Relative cured quality (morphology) of ultra-high molecular weight polyethylene molding compounds.

Ultra-high molecular weight polyethylene for surgical implants Part 5: Morphological evaluation methods

1 Scope

This document describes the morphological evaluation of ultra-high molecular weight polyethylene (PE-UHMW) molding compounds as defined in GB/T 19701.2.

Test method.

This document does not apply to ultra-high molecular weight polyethylene (PE-UHMW) powder described in GB/T 19701.1.

NOTE: Performance requirements for this test method have not yet been established.

2 Normative references

The contents of the following documents constitute 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 21461.1 Plastics Ultra-high molecular weight polyethylene (PE-UHMW) molding and extrusion materials Part 1: Nomenclature system and Classification basis (GB/T 21461.1-2023, ISO 21304-1:2019, MOD) GB/T 21461.2 Plastics Ultra-high molecular weight polyethylene (PE-UHMW) molding and extrusion materials Part 2: Sample preparation and Performance measurement (GB/T 21461.2-2023, ISO 21304-2:2021, MOD)

3 Terms and definitions

The terms and definitions defined in GB/T 21461.1, GB/T 21461.2 and the following apply to this document.

The terminology databases used for standardization maintained by ISO and IEC are located at.

A typeA non-fused flake Visible under the conditions described in 4.2.2, with a black, gap-like border with a substantially complete circumference and a white center.

Note: See Figure 1.