International Standard

ISO 5834-5

Third edition
2025-07

Implants for surgery — Ultra-high-molecular-weight polyethylene —

Part 5: Morphology assessment method

Implants chirurgicaux — Polyéthylène à très haute masse moléculaire —

Partie 5: Méthode d'évaluation de la morphologie

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This third edition cancels and replaces the second edition (ISO 5834-5:2019), which has been technically revised.

The main changes are as follows:

— the normative references have been updated;

— updates have been made to harmonize this document with ASTM F648-21

— Figures 1 and Figure 2 have been moved to Annex A.

A list of all parts in the ISO 5834 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

While no known surgical implant material has ever been shown to cause absolutely no adverse reactions in the human body, long-term clinical experience with the material referred to in this document has shown that an acceptable level of biological response can be expected when the material is used in appropriate applications. However, this document covers the raw material and unfinished medical devices, where the design and fabrication of the device can impact biological response.

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Implants for surgery — Ultra-high-molecular-weight polyethylene —

Part 5: Morphology assessment method

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1 Scope

This document specifies the test method for assessing the morphology of ultra-high-molecular-weight polyethylene (UHMWPE) moulded forms as defined in ISO 5834-2.

The assessment of morphology of UHMWPE moulded forms is not required in routine monitoring of validated moulding process because alternative test methods defined in ISO 5834-2, such as density and mechanical properties, already provide reasonable, redundant assurance of successful consolidation.

This document is not applicable to UHMWPE powder forms, which are described in ISO 5834-1.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 21304-1, *Plastics — Ultra-high-molecular-weight polyethylene (PE-UHMW) moulding and extrusion materials — Part 1: Designation system and basis for specifications*

ISO 21304-2, *Plastics — Ultra-high-molecular-weight polyethylene (PE-UHMW) moulding and extrusion materials — Part 2: Preparation of test specimens and determination of properties*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 21304-1, ISO 21304-2 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
type A non-fused flake
indication that has an essentially complete circumferential black boundary and a white centre

Note 1 to entry: Conditions described in 4.2.2 apply to type A non-fused flakes.

Note 2 to entry: See Figure A.1 for example images of type A non-fused flakes.

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