INTERNATIONAL STANDARD

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Second edition
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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

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 second edition cancels and replaces the first edition (ISO 5834-5:2005) which has been technically revised.

The main changes compared to the previous edition are as follows:

— limit values and test methods harmonized with respective ASTM standards;

— editorial updates in line with all other parts of the ISO 5834 series.

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.

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

Part 5: Morphology assessment method

1 Scope

This document specifies the test method for assessing the morphology of UHMWPE moulded forms, which are described in ISO 5834-2.

It 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 11542-1, *Plastics — Ultra-high-molecular-weight polyethylene (PE-UHMW) moulding and extrusion materials — Part 1: Designation system and basis for specifications*

ISO 11542-2, *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 11542-1 and ISO 11542-2 and the following apply.

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

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

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

3.1
Type A non-fused flake
indication visible under the conditions described in 4.2.2 that has an essentially complete circumferential black boundary and a white centre

Note 1 to entry: See Figure 1.

3.2
Type B non-fused flake
indication visible under the conditions described in 4.2.2 that has a partially circumferential black boundary that appears to trace out 50 % to 99 % of a flake's perimeter

Note 1 to entry: See Figure 2.

3.3
morphology index
MI
material morphology quality determined as the ratio of the total number of Type A non-fused flakes plus Type B non-fused flakes to the total surface area examined in cm^2, as shown in the following formula:

$$MI = \frac{N_A + N_B}{a}$$

where

N_A is the total number of Type A non-fused flakes;

N_B is the total number of Type B non-fused flakes;

a is the total surface area examined, in cm^2.

4 Test method

CAUTION — The UHMWPE semi-finished and finished products for this application are not equipped with light stabilizers and should therefore be protected against UV influence.

4.1 General description

This test method covers the determination of the morphology quality of moulded forms of ultra-high-molecular-weight polyethylene (UHMWPE). Well-consolidated UHMWPE has few or no regions of incompletely fused UHMWPE flake particles. This procedure is designed to evaluate the relative consolidation quality (morphology) of moulded forms of UHMWPE by measuring the number of incompletely fused UHMWPE particles.

4.2 Sampling and test specimens

4.2.1 General

A minimum of five specimens shall be evaluated for each representative sample (or lot) of material.

Test specimens shall be collected from locations known to be most prone to consolidation difficulties; otherwise, at the approximate centre of the sample or as required by the implant manufacturer.

If multiple film samples are taken from the same piece they shall be taken from regions no closer than 0,5 mm apart.

Test specimens shall be approximately (100 ± 50) µm thick slices of the material.

NOTE The use of dull cutting equipment can result in non-uniform thickness and defects.

At least 2 cm^2 of each test specimen shall be examined according to 4.2.2.

4.2.2 Procedure

The thin films may be placed flat between two clean glass microscope slides for convenient microscopic examination.

Test specimens shall be evaluated by dark field optical microscopy at 40 × magnification for the number of incompletely fused UHMWPE particles, characterized as Type A or Type B non-fused flakes.

Documentation shall be made of the number of Type A non-fused flakes observed, the number of Type B non-fused flakes observed, and the total surface area examined for each test specimen.