INTERNATIONAL STANDARD

ISO 5834-5

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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

Reference number
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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 5834-5 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

ISO 5834 consists of the following parts, under the general title *Implants for surgery — Ultra-high-molecular-weight polyethylene*:

— *Part 1: Powder form*

— *Part 2: Moulded forms*

— *Part 3: Accelerated ageing methods*

— *Part 4: Oxidation index measurement method*

— *Part 5: Morphology assessment method*

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

Part 5: Morphology assessment method

1 Scope

This part of ISO 5834 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.

2 Normative references

The following referenced documents are indispensable for the application 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 5834-1, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 1: Powder form*

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.

3.1
Type A non-fused flake
indication visible under the conditions described in 8.3.2 that has an essentially complete circumferential black boundary and a white centre

See Figure 1.

3.2
Type B non-fused flake
indication visible under the conditions described in 8.3.2 that has a partially circumferential black boundary that appears to trace out 50 % to 99 % of a flake's perimeter

See Figure 2.

3.3
morphology index
MI
material morphology quality determined as the ratio of the total number of Type A and Type B indications to the total surface area examined in cm^2, as shown in the following equation

$$MI = \frac{\text{Type A + Type B}}{\text{Area}}$$

3.4
lot
material for which testing has been carried out and for which discrete records are kept

4 Classification, designation and coding

The moulded material from Type 1, Type 2 or Type 3[1)] powder as defined in ISO 5834-1 shall be classified as Type 1, Type 2 or Type 3, respectively.

5 Material

The moulded material which is the subject of the test shall be made from UHMWPE powder complying with the requirements of ISO 5834-1.

6 Manufacturing requirements

The moulded material supplied for each order shall be identified by lot numbers.

The material may be subjected to a stress-relief annealing process by agreement between vendor and purchaser. Subsequent transit and storage may re-introduce stresses.

7 Requirements

Performance requirements for this test method have not been established.

8 Test method

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

8.1 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.

1) Type 3 polymer is no longer manufactured. However, in order to cover existing supplies held in stockpile, this Type 3 material is retained in this part of ISO 5834 until the next revision.

8.2 Test specimens

Test specimens are approximately (100 ± 50) µm thick slices of the material. 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 agreement between vender and purchaser. If multiple film samples are taken from the same piece they shall be taken from regions no closer than 0,5 mm apart. At least 2 cm^2 of each test specimen shall be examined according to 8.3.2.

8.3 Preparing thin film specimens

A minimum of five translucent film specimens approximately (100 ± 50) µm thick shall be prepared. Films should be relatively uniform in thickness and essentially free of skives, tears, etc., commonly resulting from the use of dull cutting equipment. The thin films may be placed flat between two clean glass microscope slides for convenient microscopic examination.

8.3.1 Material sampling

Test specimens shall be collected as agreed upon between the purchaser and vendor.

8.3.2 Procedure

Test specimens are evaluated by dark field optical microscopy at 40 × magnification. Documentation shall be made of the number of Type A indications observed, the number of Type B indications observed, and the total surface area examined for each test specimen.

A maximum score of 100 shall be reported for the number of Type A or Type B indications in a single sample.

The maximum morphology index of 100 reflects a practical limit to the number of defects an operator is willing to count. The maximum value of 100 for morphology index should not be construed as a performance requirement for the morphology of UHMWPE.

8.4 Test certificate

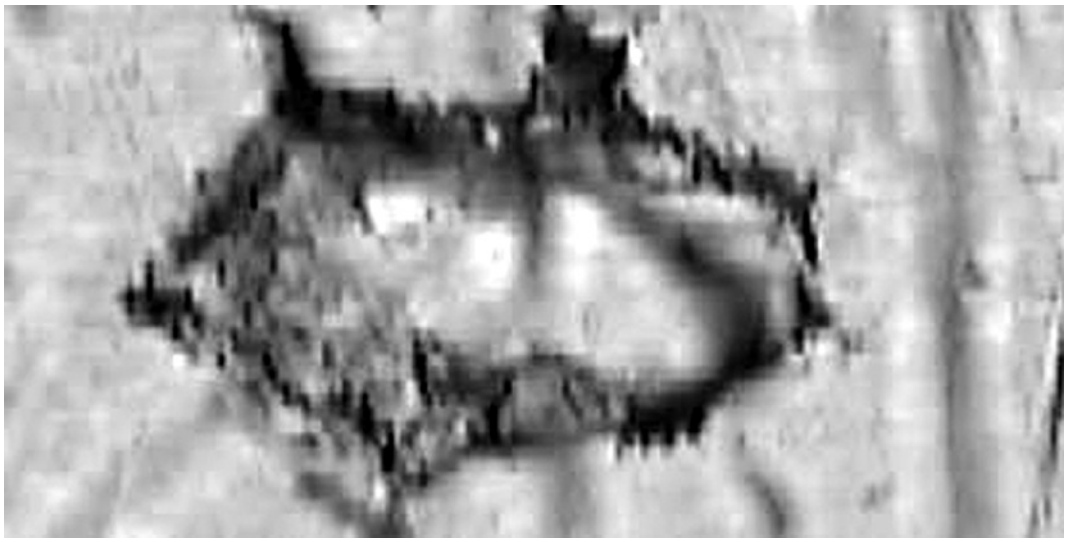
The certificate shall include the following for each material tested.

a) The arithmetic average of the number Type A indications observed for the five specimens.

b) The arithmetic average of the number Type B indications observed for the five specimens.

c) Total surface area examined in cm^2.

d) The arithmetic average of the morphology index (3.3) for the five specimens.



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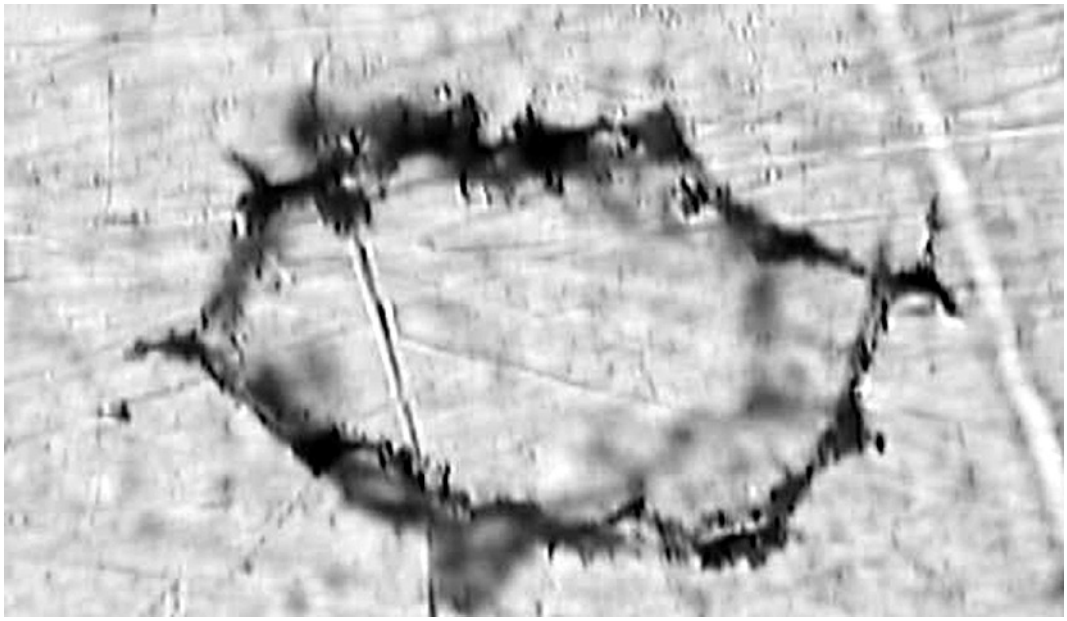
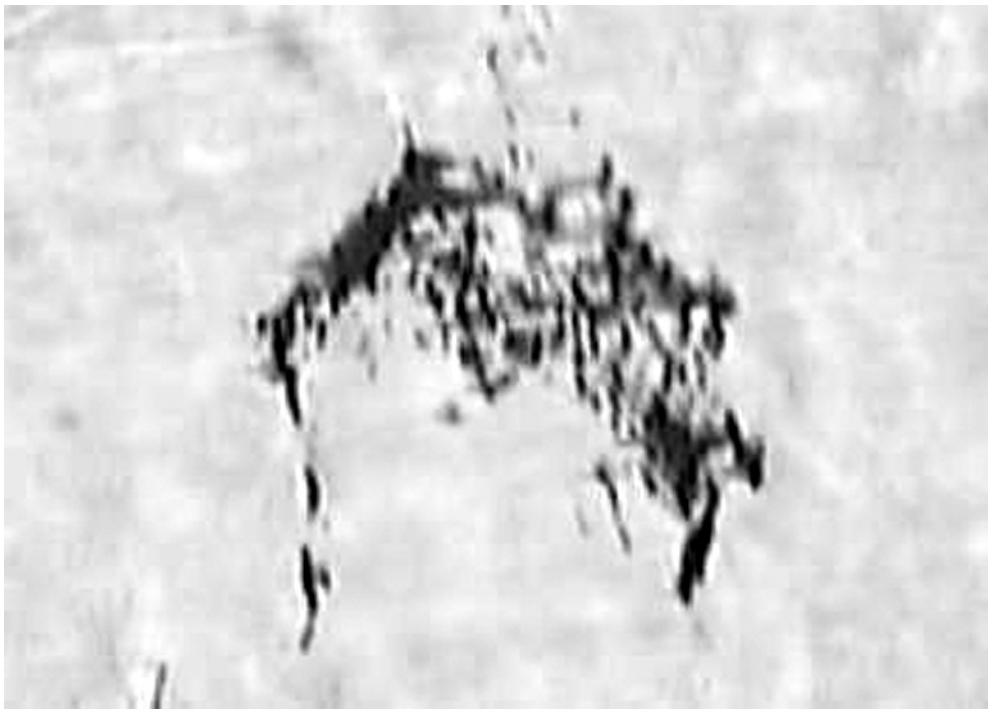


b)

Figure 1 — Representative Type A indications



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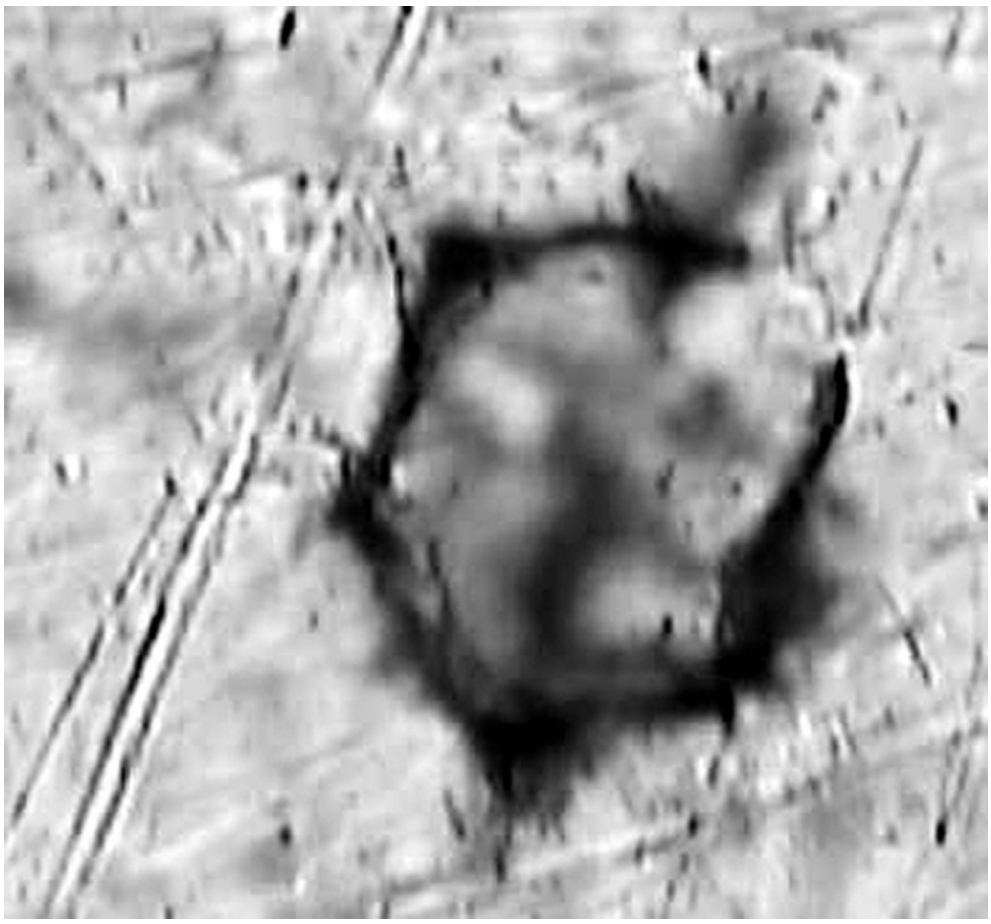

b)

Figure 2 — Representative Type B indications

Bibliography

[1] ISO 5834-2, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 2: Moulded forms*

[2] ASTM F648, *Standard specification for ultra-high-molecular-weight polyethylene powder and fabricated form for surgical implants*

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