INTERNATIONAL STANDARD

ISO 5834-2

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

Part 2: Moulded forms

Implants chirurgicaux — Polyéthylène à très haute masse moléculaire — Partie 2: Produits sous forme moulée

Reference number
ISO 5834-2:2011(E)

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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.

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 5834-2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This fourth edition cancels and replaces the third edition, which has been technically revised.

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 2: Moulded forms

1 Scope

This part of ISO 5834 specifies the requirements and corresponding test methods for moulded forms, e.g. sheets and rods, made from ultra-high-molecular-weight polyethylene (UHMWPE) for use in the manufacture of surgical implants.

This part of ISO 5834 is not applicable to direct-moulded (near net shape), irradiated or finished products or products manufactured from polyethylene blended with additives or by blending different forms of polyethylene.

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 527-1, *Plastics — Determination of tensile properties — Part 1: General principles*

ISO 1183-1:—[1)], *Plastics — Methods for determining the density of non-cellular plastics — Part 1: Immersion method, liquid pyknometer method and titration method*

ISO 3451-1:2008, *Plastics — Determination of ash — Part 1: General methods*

ISO 5834-1, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 1: Powder form*

ISO 11542-2:1998, *Plastics — Ultra-high-molecular-weight polyethylene (PE-UHMW) moulding and extrusion materials — Part 2: Preparation of test specimens and determination of properties*

3 Classification

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

4 Material

The moulded material shall be made from UHMWPE powder in accordance with the requirements of ISO 5834-1.

5 Manufacturing requirements

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

NOTE “Lot” refers to the material for which testing has been carried out and for which discrete records are kept.

The material shall be subjected to a stress-relief annealing process as agreed by the purchaser and the vendor.

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1) To be published (revision of ISO 1183-1:2004).

In the moulding process, no liquid or powdery release agents shall be used (such as silicon or talc-based release agent) in order to avoid contamination, migration and moulding defects.

6 Requirements

6.1 Physical properties

When measured using the appropriate test method, as defined in Table 1, the physical properties of the moulded material shall conform to the relevant values given in Table 1 for each type of material.

The physical properties shall be measured on material in the consolidated and annealed state before further processing. Subsequent manufacturing processes can influence the comparison of test results.

6.2 Particulate matter

When visually inspected using normal or corrected vision with no magnification, not more than ten particles shall be visible on the surface of a sample or samples prepared in accordance with 7.8.

Table 1 — Physical properties

Property	Unit	Requirement Type 1	Requirement Type 2	Requirement Type 3	Test method according to subclause
Density	kg/m^3	927 to 944	927 to 944	927 to 944	7.2
Ash, maximum	mg/kg	150	150	300	7.3
Tensile stress, σ_y, at yield, minimum	MPa	21	19	19	7.4
Tensile stress, σ_R, at break, minimum	MPa	35	27	27	7.5
Elongation at break, ε_R, minimum	%	300	300	250	7.6
Double-notched impact strength, Charpy [a], a_{cN}, minimum	kJ/m^2	180 (126) [b]	90 (73)	30 (25)	7.7

NOTE The minimum values given in this table are for the mean of the results for the specimens tested. Individual test specimen results might be below this minimum.

[a] Either the Charpy or Izod impact test specified in 7.7 may be performed. In cases of doubt or dispute, the test method specified in ISO 11542-2 (Charpy) shall be used as the reference method.

[b] The values in parentheses are determined in accordance with ASTM F648:2007 (Izod).

7 Test methods

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

7.1 Test conditions

Unless otherwise specified, the testing specified in 7.2 and 7.4 to 7.7 shall be conducted under standard conditions of (23 ± 2) °C after storage of the test specimen for at least 16 h under these conditions.

7.2 Density

The density shall be measured by means of method A (immersion method) specified in ISO 1183-1, using at least three specimens. The mean of the results on the three test specimens shall not exceed the value given in Table 1.

7.3 Ash

The ash shall be measured in accordance with ISO 3451-1:2008, method A, performing duplicate tests on each of two test specimens at (700 ± 50) °C. The mean of the results on the two test specimens shall be less than the value given in Table 1.

7.4 Tensile stress at yield

The tensile stress at yield, σ_y, shall be determined by the tensile test specified in ISO 527-1, using an extensometer to measure the strain and applying a test speed of (100 ± 10) mm/min. At least five test specimens of thickness (1,5 ± 0,5) mm shall be tested. The mean of the results on the five test specimens shall not be less than the values given in Table 1.

7.5 Tensile stress at break

The tensile stress at break, σ_R, shall be measured during the test described in 7.4. The mean of the results on the five test specimens shall not be less than the values given in Table 1.

7.6 Elongation at break

The elongation at break, ε_R, shall be measured during the test described in 7.4. The mean of the results on the five test specimens shall not be less than the values given in Table 1.

7.7 Notched impact strength

The double-notched impact strength, a_{cN}, shall be determined by the impact test specified in either ISO 11542-2:1998, Annex B (Charpy) or ASTM F648:2007 (Izod).

In case of doubt or dispute, the test method specified in ISO 11542-2 shall be used as the reference method.

7.8 Sample area for extraneous matter

A total machined surface area of (500×10^3) mm^2 shall be taken from locations within the fabricated form. The area examined shall include both transverse and longitudinal samples, or it may be produced by repeated sectioning through the thickness of the fabricated form.

8 Identification marking

Each item supplied shall be identified with at least a lot identification. A marking, which can also be a serial identification, with reference to the lot identification, may be repeated at intervals along the length of the item.

9 Test certificate

Each lot shall be supplied with a test certificate stating the results of the tests conducted and conformance with the requirements of this part of ISO 5834. The test certificate shall include the following information:

a) reference to this part of ISO 5834, i.e. ISO 5834-2:2011;

b) statement of material type, i.e. Type 1 or Type 2 or Type 3;

c) lot number or serial number with reference to the lot number;

d) number of items;

e) test values in accordance with the appropriate clauses of this part of ISO 5834;

f) description of the UHMWPE annealing treatment as agreed by the purchaser and the vendor.

10 Labelling

Each package of moulded material shall be clearly marked as agreed between the purchaser and vendor.

Bibliography

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

[2] ASTM F648:2007, *Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants*

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