INTERNATIONAL STANDARD

ISO 5834-2

Third edition
2006-04-01

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
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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 third edition cancels and replaces the second edition (ISO 5834-2:1998), Table 1 of which has been technically revised. Further, type 3 polymer is no longer manufactured.

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 (sheets, rods) made from ultra-high-molecular-weight polyethylene (UHMWPE) for use in the manufacture of surgical implants.

It does not apply to direct moulded (near net shape) or finished products.

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 1183-1:2004, *Plastics — Methods for determining the density of non-cellular plastics — Part 1: Immersion method, liquid pyknometer method and titration method*

ISO 3451-1:1997, *Plastics — Determination of ash — Part 1: General methods*

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

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

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*

ASTM F648, *Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11542-1 and ISO 11542-2 apply.

4 Classification

The material moulded 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 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.

NOTE 1 "Lot" refers to the material for which testing has been carried out and for which discrete records are kept.

NOTE 2 The material can be subjected to a stress-relief annealing process by agreement between vendor and purchaser. Subsequent transit and storage might re-introduce stresses.

7 Requirements

7.1 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 should be measured before the annealing process because different annealing processes can influence the comparison of test results.

7.2 Particulate matter

When inspected using normal or corrected vision, not more than ten particles shall be visible on the surface of (a) sample(s) prepared in accordance with 8.8.

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 next revision.

Table 1 — Physical properties

Property	Unit	Requirement Type 1	Requirement Type 2	Requirement Type 3 [a]	Test method according to subclause
Density	kg/m^3	927 to 944	927 to 944	927 to 944	8.2
Ash [b]	mg/kg	$\leqslant$ 150	$\leqslant$ 150	$\leqslant$ 300	8.3
Tensile stress, σ_y, at yield [c]	MPa	$\geqslant$ 21	$\geqslant$ 19	$\geqslant$ 19	8.4
Tensile stress, σ_R, at break [c]	MPa	$\geqslant$ 35	$\geqslant$ 27	$\geqslant$ 27	8.5
Elongation at break, ε_R [c]	%	$\geqslant$ 300	$\geqslant$ 300	$\geqslant$ 250	8.6
Double-notched impact strength, Charpy, a_{CN}	kJ/m^2	$\geqslant$ 180	$\geqslant$ 90	$\geqslant$ 30	8.7
Double-notched impact strength, Izod	kJ/m^2	$\geqslant$ 126	$\geqslant$ 73	$\geqslant$ 25	8.7

[a] 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 next revision.

[b] When determining the ash, it should be noted that in certain cases mould-release agents based on silicone are used in the production of the moulded forms. The residual mould-release agent on and in the moulded form will therefore be included in the determination of the ash. The upper limit of silica content (SiO_2) from the ashing is considered to be 20 mg/kg.

[c] 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.

8 Test methods

CAUTION — The UHMWPE powder, 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.

8.1 Test conditions

Unless otherwise specified, the testing specified in 8.2 and 8.4 to 8.7 shall be conducted under standard conditions of (23 ± 2) °C and (50 ± 5) % relative humidity after storage of the test specimen for at least 16 h under these conditions.

8.2 Density

The density shall be measured by means of method A (buoyancy procedure) specified in ISO 1183-1:2004 using at least three specimens. The mean of the results on the three test specimens shall not exceed the value given in Table 1.

8.3 Ash

The ash shall be measured in accordance with ISO 3451-1:1997 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 not exceed the value given in Table 1.

8.4 Tensile stress at yield

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

8.5 Tensile stress at break

The tensile stress at break, σ_R, shall be measured during the test described in 8.4. The mean of the results on the five test specimens shall not be less than the values quoted in Table 1.

8.6 Elongation at break

The elongation at break, ε_R, shall be measured during the test described in 8.4. The mean of the results on the five test specimens shall not be less than the values quoted in Table 1.

8.7 Notched impact strength

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

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

8.8 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 may be produced by repeated sectioning through the thickness of fabricated form.

9 Identification marking

Each item supplied shall be identified with an impressed identification number.

NOTE The marking, which may also be a serial number, with reference to the lot number, may be repeated at intervals along the length of the item.

10 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) the number of this International Standard, i.e. ISO 5834-2:2006;

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

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

d) number of items;

e) test values according to the appropriate clauses of this part of ISO 5834;

f) date(s) of test.