TC150

International Standard ISO 5834/2

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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

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 5834/2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

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Implants for surgery — Ultra-high molecular weight polyethylene — Part 2 : Moulded forms

1 Scope and field of application

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

It does not apply to finished products.

2 References

ISO 179, *Plastics — Determination of Charpy impact strength of rigid materials.*

ISO 527, *Plastics — Determination of tensile properties.* [1]

ISO/R 1183, *Plastics — Methods for determining the density and relative density (specific gravity) of plastics excluding cellular plastics.*

ISO 3451/1, *Plastics — Determination of ash — Part 1 : General methods.*

ISO 5834/1, *Implants for surgery — Ultra-high molecular weight polyethylene — Part 1 : Powder form.* [2]

3 Classification

The material shall be classified as follows :

Type 1 — Compression moulded material.

Type 2 — Extruded material.

4 Material

The moulded forms shall be made from either Type A or Type B UHMWPE powder complying with the requirements of ISO 5834/1.

5 Manufacturing requirements

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

NOTE — "Batch" or "lot" refers to moulded forms for which testing has been carried out and for which discrete records are kept.

5.2 The material shall be subjected by the manufacturer to a stress-relief annealing process.

NOTE — Subsequent transit and storage may re-introduce stresses that should be relieved by the manufacturer of a finished implant.

6 Properties

6.1 Test requirements

The test requirements for moulded forms shall be as given in the table.

6.2 Particulate matter

In an area 400 mm × 800 mm of the moulded material not more than 10 particles shall be visible on the surface upon in-

1) At present at the stage of draft. (Revision of ISO/R 527-1966.)

2) At present at the stage of draft.

Table — Test requirements for moulded form UHMW polyethylene for surgical implants

Property	Unit	Requirement				Test method according to sub-clause
		Type 1		Type 2		
		from Type A powder	from Type B powder	from Type A powder	from Type B powder	
Density ϱ	kg/m^3	930 to 944	930 to 944	930 to 944	930 to 944	7.2
Ash content[1]	mg/kg (ppm)	150 max.	300 max.	150 max.	300 max.	7.3
Tensile stress σ_B at yield — at 23 °C / at 120 °C	MPa	21 min. / 3 min.		21 min.		7.4
Tensile stress σ_R at break — at 23 °C / at 120 °C	MPa	35 min. / 18 min.		27 min.		7.5
Elongation at break ε_R — at 23 °C / at 120 °C	%	350 min. / 600 min.		200 min.		7.6
Notched impact strength Izod or Charpy a_k	mJ/mm^2	140 min.		140 min.		7.7

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

spection by normal or corrected vision. The diameter of any particle shall not exceed 300 µm. If any particle is over 300 µm the material should be rejected.

7 Methods of test

7.1 Test conditions

Unless otherwise specified, the testing specified in 7.2 to 7.7 shall be conducted under standard conditions of 23 ± 2 °C and 50 ± 5 % relative humidity after storage of the test specimens for at least 16 h under these conditions.

7.2 Density

The density shall be measured by means of method A (buoyancy procedure) specified in ISO/R 1183 using at least three specimens.

7.3 Ash content

The ash content shall be determined in accordance with ISO 3451/1, performing duplicate tests on each of two test specimens.

7.4 Tensile stress at yield

The tensile stress at yield σ_B shall be determined by the tensile test specified in ISO 527 on at least five test specimens of thickness 1,5 mm at test temperatures of 23 °C and 120 °C using test speed F (100 mm/min ± 10 %) and D (25 mm/min ± 10 %) respectively.

7.5 Tensile stress at break

Tensile stress at break σ_R shall be measured during the test described in 7.4.

7.6 Elongation at break

Elongation at break shall be measured during the test described in 7.4.

7.7 Notched impact strength (Charpy)

The notched impact strength a_k shall be determined by the impact test specified in ISO 179 using at least five standard test specimens, type 3, a sharp notch at an angle of 15° and a depth of 3,4 mm.

8 Identification marking

Each item supplied shall be identified with an impressed batch or lot number and marked with the letter M.

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

9 Test certificate

The supplier shall furnish with each delivery a test certificate signed by a duly authorized representative of the supplier stating conformance with the requirements of this International Standard. In this certificate the results of the tests conducted

shall be stated. The test certificate shall include the following information :

a) purchase order number;

b) the number of this International Standard (ISO 5834/2);

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

d) number of items;

e) test values according to the relevant clauses of this International Standard;

f) date(s) of test.

10 Labelling

The external packaging of the supplied moulded forms shall be marked with the following information :

a) batch or lot number or serial number with reference to the batch or lot number;

b) mass of materials;

c) manufacturer's name or trademark;

d) purchase order number;

e) the number of this International Standard (ISO 5834/2).