INTERNATIONAL STANDARD

ISO 5834-1

Third edition
2005-06-01

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

Part 1: **Powder form**

Implants chirurgicaux — Polyéthylène à très haute masse moléculaire —

Partie 1: Produits sous forme de poudre

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 5834-1 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 5834-1:1998), 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 1: Powder form

1 Scope

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

It is not applicable to 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 1628-3, *Plastics — Determination of the viscosity of polymers in dilute solution using capillary viscometers — Part 3: Polyethylenes and polypropylenes*

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

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*

DIN 53474, *Testing of plastics, rubber and elastomers — Determination of the chlorine content (Wickbold-combustion)*

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, designation and coding

The material shall be classified as Type 1, Type 2 or Type 3 as defined by the flow properties given in Clause 6 and the ash/trace element contents given in 7.1.

5 Manufacturing requirements

The material shall consist of a homopolymer prepared by the polymerization of ethylene.

The powdered 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.

6 Flow properties

Flow properties shall be determined by measuring either elongation stress or viscosity number. When measured using the appropriate test method, as defined in Table 1, the minimum value of either the elongational stress or the viscosity number shall exceed the relevant value given in Table 1 for each type of material.

Table 1 — Flow properties — Minimum values

Property	Units	Type 1	Types 2 and 3	Test method according to subclause
Elongational stress	MPa	0,2	0,42	8.1
Viscosity number	ml/g	2,000	3,200	8.2
NOTE Compliance with either of the above test requirements indicates satisfactory polymer molecular mass.				

7 Limits of contamination

7.1 Ash and trace elements

When measured using the appropriate test method, as defined in Table 2, the amounts of ash, titanium, aluminium, calcium and chlorine shall not exceed the relevant value given in Table 2 for each type of material.

Table 2 — Maximum ash and trace element content

Element	Maximum quantity permitted mg/kg			Test method according to subclause
	Type 1	Type 2	Type 3[a]	
Ash	125	125	300	8.3
Titanium	40	40	150	8.4
Calcium	5	5	50	8.4
Chlorine	30	30	90	8.4
Aluminium	20	20	100	8.4

[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 the next revision.

7.2 Particulate matter

When measured using the test method given in 8.5, there shall be no more than three particles of contaminant in Type 1 or Type 2 materials and not more than 25 particles of contaminant in Type 3 materials (see Footnote to Table 2), per (300 ± 20) g tested.

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 Elongational stress

The elongational stress shall be determined in accordance with ISO 11542-2.

8.2 Viscosity number

The viscosity number shall be determined in accordance with ISO 1628-3 using a 0,02 % solution by mass of the material in decahydronaphthalene (decalin) at 135 °C.

8.3 Ash content

The ash content shall be determined in accordance with ISO 3451-1 performing duplicate tests on each of two test specimens at (700 ± 50) °C. The average of the results on the two test specimens shall not exceed the value given in Table 2.

8.4 Trace elements

The amounts of the trace elements shall be determined using the methods given in Table 3.

Table 3 — Methods of test for trace elements

Element	Method of test
Titanium	Atomic absorption or emission spectroscopy
Aluminium	Atomic absorption or emission spectroscopy
Calcium	Atomic absorption or emission spectroscopy
Chlorine	Ion chromatography in accordance with DIN 53474 or equivalent

8.5 Particulate matter

Mix each of four test portions of (75 ± 5) g of the moulding material with (400 ± 10) ml of propan-2-ol, in four 1 000 ml conical flasks. Shake each flask until the powder is thoroughly dispersed. Examine the flasks with normal or corrected vision no less than 5 min after cessation of shaking and count the number of particles that settle to the bottom of each flask.

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) test values obtained in Clauses 7 and 8 as appropriate;

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

c) lot number;

d) date(s) of test.

10 Labelling

Each package of moulding material shall be clearly marked with at least the following information:

a) manufacturer's name or trademark;

b) description of contents;

c) lot number;

d) mass of the contents;

e) the number of this part of ISO 5834, i.e. ISO 5834-1:2005.

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