
**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*



Contents

	Page
1 Scope	1
2 Normative references	1
3 Definitions	1
4 Classification.....	2
5 Manufacturing requirements	2
6 Flow properties	2
7 Limits of contamination	2
8 Test method.....	3
9 Test certificate.....	4
10 Labelling	4

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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.

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.

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

This second edition cancels and replaces the first edition (ISO 5834-1:1985), 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 form*

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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 (PE-UHMW) for use in the manufacture of surgical implants.

It does not apply to finished products.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5834. At the time of publication, the editions indicated were valid. All the standards are subject to revision, and the parties to agreements based on this part of ISO 5834 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1628-3:1991, *Plastics — Determination of viscosity number and limiting viscosity number — Part 3: Polyethylenes and polypropylenes.*

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

ISO 11542-1:1994, *Plastics — Ultra-high molecular weight polyethylene (PE-UHMW) Thermoplastics — Part 1: Designation.*

ISO 11542-2:—¹⁾ *Plastics — Ultra-high molecular weight polyethylene (PE-UHMW) moulding and extrusion materials — Part 2: Preparation of test specimens and determination of properties.*

DIN 53474:1991, *Testing of plastics, rubbers and elastomers — Determination of the chlorine content.*

3 Definitions

For the purposes of this part of ISO 5834, the definitions given in ISO 11542-1 and ISO 11542-2 apply.

NOTE The PE-UHMW powder, semifinished and finished products for this application do not contain light stabilizers and should therefore be protected against the influence of ultraviolet radiation.

1) To be published.

4 Classification

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 elongational stress or viscosity number. When measured using the appropriate test method, as defined in table 1, the minimum value of either the elongational stress F (150/10) 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			Test method according to subclause
	mg/kg			
	Type 1	Type 2	Type 3	
Ash	150	150	300	8.3
Titanium	40	40	150	8.4
Calcium	50	50	50	8.4
Chlorine	20	75	90	8.4
Aluminium	40	40	100	8.4

7.2 Particulate matter

When measured using the test method given in 8.5, there shall be not more than five particles of contaminant in Type 1 or Type 2 materials and not more than 25 particles of contaminant in Type 3 materials, per (300 ± 20) g tested.

8 Test method

8.1 Elongational stress

The elongational stress F (150/10) 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 of the material in 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 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 — 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 1000 ml conical flasks. Shake each flask until the powder is thoroughly dispersed. Not less than 5 min after cessation of shaking, examine the flasks with normal or corrected vision 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 in conformance with the requirements of this part of ISO 5834. The test certificate shall include the following information:

- a) test values according to the appropriate clauses of this part of ISO 5834;
- 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 International Standard (ISO 5834-1).

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