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Fourth edition
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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

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This fourth edition cancels and replaces the third edition (ISO 5834-1:2005), which has been technically revised. It also incorporates the Technical Corrigendum ISO 5834-1:2005/Cor.1:2007.

The main changes compared to the previous edition are as follows:

— editorial updates in line with all other parts of the ISO 5834 series.

A list of all parts in the ISO 5834 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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

Part 1: Powder form

1 Scope

This document 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 documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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 limit of contaminations given in Clause 7.

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 traceable back to the manufacturing process, i. e. by batch number or lot number.

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 Conformity to 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 document 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 the 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 ± 2) °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 document. The test certificate shall include the following information:

a) reference to this document, i.e. ISO 5834-1:2019;

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

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

d) 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 document, i.e. ISO 5834-1:2019.