
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



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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Contents

	Page
Foreword.....	iv
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Classification, designation and coding.....	1
5 Manufacturing requirements.....	1
6 Flow properties.....	2
7 Limits of contamination.....	2
7.1 Ash and trace elements.....	2
7.2 Particulate matter.....	2
8 Test methods.....	2
8.1 Elongational stress.....	3
8.2 Viscosity number.....	3
8.3 Ash content.....	3
8.4 Trace elements.....	3
8.5 Particulate matter.....	3
9 Test certificate.....	3
10 Labelling.....	3

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.