
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. 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 fifth edition cancels and replaces the fourth edition (ISO 5834-2:2011), which has been technically revised.

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

- requirement and test for maximum ash content removed;
- limit values and test methods harmonized with respective ASTM standards;
- 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 2: Moulded forms

1 Scope

This document specifies the requirements and corresponding test methods for moulded forms, e.g. sheets and rods, made from ultra-high-molecular-weight polyethylene (UHMWPE) for use in the manufacture of surgical implants.

This document is not applicable to direct-moulded (near net shape), irradiated or finished products or products manufactured from polyethylene blended with additives or by blending different forms of polyethylene.

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 1183-1:2012, *Plastics — Methods for determining the density of non-cellular plastics — Part 1: Immersion method, liquid pycnometer method and titration method*

ISO 5834-1, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 1: Powder form*

ASTM F648, *Standard specification for ultra-high-molecular-weight polyethylene powder and fabricated form for surgical implants*

3 Terms and definitions

No terms and definitions are listed in this document.

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

The material moulded from Type 1, Type 2 or Type 3 powder as defined in ISO 5834-1 shall be classified as Type 1, Type 2 or Type 3 respectively.

5 Material

The moulded material shall be made from UHMWPE powder in accordance with the requirements of ISO 5834-1.

6 Manufacturing requirements

The moulded material supplied for each order shall be traceable back to the manufacturing process, i. e. by batch number or lot number.

If required by the implant manufacturer, the supplied material may be subjected to a stress-relief annealing process. In the moulding process, no liquid or powdery release agents shall be used (such as silicon or talc-based release agent) in order to avoid contamination, migration and moulding defects.

7 Requirements

7.1 Physical properties

When measured using the appropriate test method, as defined in [Table 1](#), the physical properties of the moulded material shall conform to the relevant values given in [Table 1](#) for each type of material.

The physical properties shall be measured on material in the consolidated and annealed state before further processing. Subsequent manufacturing processes can influence the comparison of test results.

Table 1 — Physical properties

Property	Unit	Requirement Type 1	Requirement Type 2	Requirement Type 3	Test method according to subclause
Density	kg/m ³	927 to 944	927 to 944	927 to 944	8.2
Tensile stress, σ_y , at yield, minimum	MPa	21	19	19	8.3.2
Tensile stress, σ_R , at break, minimum	MPa	40	40	27	8.3.3
Elongation at break, ϵ_R , minimum	%	380	340	250	8.3.4
Double-notched Izod impact strength, a_{cN} , minimum	kJ/m ²	126	73	25	8.4
NOTE The minimum values given in this table are for the mean of the results for the specimens tested. Individual test specimen results might be below this minimum.					

7.2 Particulate matter

Not more than ten particles shall be visible on the surface of a sample area when prepared and inspected in accordance with [8.5](#).

8 Test methods

CAUTION — The UHMWPE powder and the 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 Test conditions

Unless otherwise specified, the testing specified in [8.2](#) to [8.5](#) shall be conducted under standard conditions of $(23 \pm 2)^\circ\text{C}$ after storage of the test specimen for at least 16 h under these conditions.

8.2 Density

The density shall be measured by means of method A (immersion method) specified in ISO 1183-1, using at least three specimens. The mean of the results on the three test specimens shall be within the limits given in [Table 1](#).

8.3 Tensile testing

8.3.1 General

The tensile test shall be conducted as specified in ASTM F648. At least five test specimens shall be tested.

8.3.2 Tensile stress at yield

The tensile stress at yield, σ_y , shall be determined in accordance with [8.3.1](#). The mean of the results on the five test specimens shall not be less than the values given in [Table 1](#).

8.3.3 Tensile stress at break

The tensile stress at break, σ_R , shall be determined in accordance with [8.3.1](#). The mean of the results on the five test specimens shall not be less than the values given in [Table 1](#).

8.3.4 Elongation at break

The elongation at break, ε_R , shall be determined in accordance with [8.3.1](#). The mean of the results on the five test specimens shall not be less than the values given in [Table 1](#).

8.4 Notched impact strength

The double-notched impact strength, a_{cN} , shall be determined by the impact test specified in ASTM F648. The number of test specimens is specified in ASTM F648.

8.5 Sample area for particulate matter

A total machined surface area of $(0,500 \pm 0,005) \text{ m}^2$ shall be taken from locations within the fabricated form. The area examined shall include both transverse and longitudinal samples, or it may be produced by repeated sectioning through the thickness of the fabricated form. The sample area shall be visually inspected for particulate matter using normal or corrected vision with no magnification.

9 Identification marking

Each item supplied shall be identified with at least a lot identification. A marking, which can also be a serial identification, with reference to the lot identification, may be repeated at intervals along the length of the item.

10 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 5834-2:2019;
- b) statement of material type, i.e. Type 1 or Type 2 or Type 3;
- c) lot number or serial number with reference to the lot number;

- d) number of moulded forms tested;
- e) test values in accordance with the appropriate clauses of this document;
- f) description of the UHMWPE annealing treatment.

11 Labelling

The moulded material shall be clearly identifiable.

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