BRITISH STANDARD

BS ISO
5834-2:1998

Implants for surgery — Ultra-high molecular weight polyethylene —

Part 2: Moulded forms

ICS 11.040.40

National foreword

This British Standard reproduces verbatim ISO 5834-2:1998 and implements it as the UK national standard. It supersedes BS 7253-5:1990 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee Surgical implant materials, to Subcommittee CH/18/1, Non-metallic materials, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

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Summary of pages

This document comprises a front cover, an inside front cover, the ISO title page, pages ii and iii, a blank page, pages 1 to 4, an inside back cover and a back cover.

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BS ISO 5834-2:1998

INTERNATIONAL STANDARD

ISO 5834-2

Second edition
1998-08-01

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

Reference number
ISO 5834-2:1998(E)

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Descriptors: surgical implants, polyethylene, specifications, properties, tests, marking, labelling, medical equipment, castings.

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 5834-2 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 5834-2:1985), 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 forms*

Implants for surgery — Ultra-high molecular weight polyethylene —

Part 2:
Moulded forms

1 Scope

This part of ISO 5834 specifies the requirements and corresponding test methods for moulded forms made from ultra-high molecular weight polyethylene (PE-UHMW) for use in the manufacture of surgical implants.

It does not apply to direct-moulded or 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 Standard.

ISO 527:1976, *Plastics — Determination of tensile properties.*

ISO 1183:1987, *Plastics — Methods for determining the density and relative density of non-cellular plastics.*

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

ISO 5834-1:1998, *Implants for surgery — Ultra-high molecular weight polyethylene — Part 1: Powder form.*

ISO 11542-1:1994, *Plastics — Ultra-high-molecular-weight polyethylene (PE-UHMW) moulding and extrusion materials — Part 1: Designation systems and basis for specifications.*

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.*

ASTM F 648, *Standard specification for ultra-high molecular weight polyethylene powder and fabricated form for surgical implants.*

1) To be published.

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, semi-finished and finished products for this application do not contain light stabilizers and should therefore be protected against the influence of ultraviolet radiation.

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 material shall be moulded from PE-UHMW powder complying with the requirements of ISO 5834-1.

6 Manufacturing requirements

The moulded material supplied for each order shall be identified by lot numbers.

NOTE 1 "Lot" refers to the material for which testing has been carried out and for which discrete records are kept.

NOTE 2 The material may be subjected to a stress-relief annealing process by agreement between vendor and purchaser. Subsequent transit and storage may re-introduce stresses.

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 be as per the relevant values given in table 1 for each type of material.

7.2 Particulate matter

When inspected using normal or corrected vision, not more than 10 particles shall be visible on the surface of a sample(s) prepared in accordance with 8.8.

8 Test methods

8.1 Test conditions

Unless otherwise specified, the testing specified in 8.2 and 8.4 to 8.7 shall be conducted under standard conditions of (23 ± 2) °C and (50 ± 5) % relative humidity 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 (buoyancy procedure) specified in ISO 1183:1987 using at least three specimens. The average of the results on the three test specimens shall not exceed the value given in table 1.

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
Ash content [1]	mg/kg	150 max.	150 max.	300 max.	8.3
Tensile stress δ_B at yield [2]	MPa	21 min.	19 min.	19 min.	8.4
Tensile stress δ_R at break [2]	MPa	35 min.	27 min.	27 min.	8.5
Elongation at break ϵ_R [2]	%	300 min.	300 min.	250 min.	8.6
Double-notched impact strength Charpy a_{CN}	kJ/m^2	180 min.	90 min.	30 min.	8.7
Double-notched impact strength Izod	kJ/m^2	140 min.	73 min.	25 min.	8.7

1) When determining ash content, it should be noted that in certain cases mould-release agents based on silicone are used in the production of the moulded forms. The residual mould-release agent on and in the moulded form will therefore be included in the determination of the ash. [The upper limit of silica content (SiO_2) from ashing is considered to be 20 mg/kg.]

2) The minimum values given in this table apply to the average of the results for the specimens tested. Individual test specimen results may be below this minimum.

8.3 Ash content

The ash content shall be measured 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 1.

8.4 Tensile stress at yield

The tensile stress at yield δ_B shall be determined by the tensile test specified in ISO 527 on at least five test specimens of thickness (1,5 ± 0,5) mm using a test speed of (100 ± 10) mm/min. The average of the results on the five test specimens shall not be less than the values quoted in table 1.

8.5 Tensile stress at break

The tensile stress at break δ_R shall be measured during the test described in 8.4. The average of the results on the five test specimens shall not be less than the values quoted in table 1.

8.6 Elongation at break

The elongation at break ϵ_R shall be measured during the test described in 8.4. The average of the results on the five test specimens shall not be less than the values quoted in table 1.

8.7 Notched impact strength

The notched impact strength a_{CN} shall be determined by the impact test specified in either annex B of ISO 11542-2:— (Charpy) or ASTM F 648 (Izod).

In case of doubt or dispute, the test method specified in ISO 11542-2 shall be used as the reference method.

8.8 Sample area for particulate matter

A total machined surface area of (320×10^3) mm^2 shall be taken from locations within the fabricated form. The area examined shall include both transverse and longitudinal samples or may be produced by repeated sectioning through the thickness of the fabricated form.

9 Identification marking

Each item supplied shall be identified with an impressed identification number.

NOTE The marking, which may also be a serial number, with reference to the lot number, 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 in conformance with the requirements of this part of ISO 5834. The test certificate shall include the following information:

a) the number of this International Standard (ISO 5834-2);

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

c) lot number or serial number with reference to the lot number;

d) number of items;

e) test values according to the appropriate clauses of this part of ISO 5834;

f) date(s) of test.

11 Labelling

Each package of moulded 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 5834-2).

BS ISO 5834-2:1998

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