INTERNATIONAL STANDARD

ISO 5834-3

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

Part 3: Accelerated ageing methods

Implants chirurgicaux — Polyéthylène à très haute masse moléculaire —

Partie 3: Méthodes de vieillissement accéléré

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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.

ISO 5834-3 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

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*

— *Part 3: Accelerated ageing methods*

— *Part 4: Oxidation index measurement method*

— *Part 5: Morphology assessment method*

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

Part 3: Accelerated ageing methods

1 Scope

This part of ISO 5834 specifies a test method for investigating the oxidative stability of ultra-high-molecular-weight polyethylene (UHMWPE) materials as a function of processing and sterilization method. This part of ISO 5834 describes a laboratory method for accelerated ageing of UHMWPE specimens and components for total joint prostheses. The UHMWPE is aged at elevated temperature and at elevated oxygen pressure, to accelerate oxidation of the material and thereby allow for the evaluation of its potential long-term chemical and mechanical stability.

2 Normative references

The following referenced documents are indispensable for the application 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 5834-2, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 2: Moulded forms*

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*

ASTM F2003:2002, *Standard practice for accelerated aging of ultra-high molecular weight polyethylene after gamma irradiation in air*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11542-1, ISO 11542-2 and the following apply.

3.1
oxidation
incorporation of oxygen into another molecule (e.g. UHMWPE) by means of a chemical covalent bond

4 Classification, designation and coding

The test articles for accelerated ageing shall be made from moulded UHMWPE and classified as Type 1, Type 2 or Type 3[1)] in accordance with ISO 5834-2.

5 Material

CAUTION — The UHMWPE finished products for this application are not equipped with light stabilizers and should therefore be protected against UV influence.

The test articles for accelerated ageing shall be made from UHMWPE moulded forms complying with the requirements of ISO 5834-2.

6 Apparatus and materials

The apparatus and specimens shall be prepared in accordance with Sections 5 and 6, respectively, from ASTM F2003:2002.

7 Validation of apparatus

Validation of the apparatus shall be conducted in accordance with Section 7 of ASTM F2003:2002.

8 Conditioning

Conditioning of the test specimens shall be conducted in accordance with Section 8 of ASTM F2003:2002.

9 Significance and use

The method described in this part of ISO 5834 may be used to accelerate the oxidation of UHMWPE components using elevated temperature and elevated oxygen pressure. Under real-time conditions, such as shelf-ageing and implantation, oxidative changes to UHMWPE after sterilization using high energy radiation may take months or years to produce changes that may result in deleterious mechanical performance. The method outlined in this part of ISO 5834 permits the evaluation of oxidative stability in a relatively short period of time (e.g. weeks).

The standard methods may also be used to oxidize UHMWPE test specimens and joint replacement components prior to characterization of their physical, chemical, and mechanical properties. In particular, these methods may be used for accelerated ageing of UHMWPE components prior to evaluation in a hip or knee joint wear simulator as outlined in ASTM F1714 (hip wear), ASTM F1715 (knee wear), ISO 14242 (hip wear), and/or ISO 14243 (knee wear).

Although the accelerated ageing method described by this part of ISO 5834 will permit an investigator to compare the oxidative stability of UHMWPE, it is recognized that it may not precisely simulate the degradative mechanisms for an implant during real-time shelf ageing and implantation. However, this accelerated oxidation method has been successfully used to rank UHMWPE materials for their long-term oxidative stability.

The accelerated ageing method specified herein has been validated based on oxidation levels exhibited by shelf-aged UHMWPE components packaged in air and sterilized with gamma radiation. The method has not

1) 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 part of ISO 5834 until the next revision.

been shown to be representative of shelf ageing when the UHMWPE is packaged in an environment other than air. For example, this method has not been directly correlated with the shelf life of components that have been sealed in a low oxygen package, such as nitrogen.

Post-irradiation ageing in an oxygen-containing environment results in degradative changes to the physical, chemical, and mechanical properties of UHMWPE. Even under ambient conditions, oxidation of irradiated UHMWPE evolves at a slow pace, with a degradation rate measured in years. As a result, accelerated ageing methods have been developed to accelerate the oxidation process in UHMWPE and provide a means to assess oxidative stability during a comparatively short time period.

Oxidation of UHMWPE proceeds in a complex cascade of chemical reactions which may be accelerated by increasing the temperature and/or by increasing the concentration of available oxygen. Consequently, in several studies, post-irradiation ageing has been simulated using a combination of thermal oxidation and elevated oxygen pressure. Despite the variation in test conditions reported by these studies, accelerated oxidation protocols have been increasingly employed not only to characterize the effects of gamma sterilization in air, but also to evaluate the oxidation resistance of UHMWPE sterilized by alternative methods.

Accelerated oxidation methods for UHMWPE are not without their limitations. Even though the protocol outlined in this part of ISO 5834 is now widely used for accelerated ageing UHMWPE specimens prior to mechanical testing, the question remains as to whether or not the thermal techniques precisely recreate the morphology and mechanical properties of shelf-aged UHMWPE. Although research is still needed to elucidate the differences between thermal oxidation and long-term shelf ageing, this part of ISO 5834 is intended to provide information about an established method for evaluating the oxidative stability of UHMWPE specimens.

10 Accelerated ageing procedure

Accelerated ageing shall be conducted in accordance with Section 9 of ASTM F2003:2002.

11 Reporting

Details about the preparation of the test samples, the chronology of the accelerated ageing, the storage conditions for the test samples, and the method used shall be recorded in a report.

11.1 Test sample preparation

The investigator shall list the size, shape, and method of manufacture of the test samples. The report shall also contain the type of resin used, the manufacturer/supplier of the UHMWPE, and any subsequent processes that were performed on the test articles after manufacture, such as sterilization or high-energy irradiation.

11.2 Chronology

The report shall list the time at which the test specimens were manufactured, subsequently sterilized, and later aged. The report will also report the time that any subsequent analysis or testing was performed on the aged items.

11.3 Test sample storage conditions

The report shall indicate the environmental conditions (i.e. storage in air versus nitrogen) and temperature under which the specimens were stored before and after accelerated ageing.

11.4 Ageing method

The report shall indicate the ageing temperature, heating rate and the duration of the ageing period.

Bibliography

[1] ISO 527 (all parts), *Plastics — Determination of tensile properties*

[2] ISO 1183 (all parts), *Plastics — Methods for determining the density of non-cellular plastics*

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

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

[5] ISO 5834-4, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 4: Oxidation index measurement method*

[6] ISO 14242 (all parts), *Implants for surgery — Wear of total hip-joint prostheses*

[7] ISO 14243 (all parts), *Implants for surgery — Wear of total knee-joint prostheses*

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

[9] ASTM F1714, *Standard guide for gravimetric wear assessment of prosthetic hip-designs in simulator devices*

[10] ASTM F1715, *Standard guide for wear assessment of prosthetic knee designs in simulator devices*