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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

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 second edition cancels and replaces the first edition (ISO 5834-3:2005) which has been technically revised.

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

— 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 3: Accelerated ageing methods

1 Scope

This document 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 document 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 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 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 F2003:2015, *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.

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/

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 test specimens

The apparatus and test specimens shall be in accordance with ASTM F2003:2015, Section 5 and 6, respectively.

7 Validation of apparatus

Validation of the apparatus shall be conducted in accordance with ASTM F2003:2015, Section 7.

8 Conditioning

Conditioning of the test specimens shall be conducted in accordance with ASTM F2003:2015, Section 8.

9 Significance and use

The method described in this document 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 can take months or years to produce changes that may result in deleterious mechanical performance. The method outlined in this document 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 the ISO 14242 series (hip wear), and/or the ISO 14243 series (knee wear).

Although the accelerated ageing method described by this document 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 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.

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 document until the next revision.

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 have their limitations. Even though the protocol outlined in this document 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 document 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 ASTM F2003:2015, Section 9.

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

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