
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



This document is a preview generated by EMS



COPYRIGHT PROTECTED DOCUMENT

© ISO 2019

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

Contents

	Page
Foreword.....	iv
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Classification, designation and coding.....	2
5 Material.....	2
6 Apparatus and test specimens.....	2
7 Validation of apparatus.....	2
8 Conditioning.....	2
9 Significance and use.....	2
10 Accelerated ageing procedure.....	3
11 Reporting.....	3
11.1 Test sample preparation.....	3
11.2 Chronology.....	3
11.3 Test sample storage conditions.....	3
11.4 Ageing method.....	3
Bibliography.....	4

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