INTERNATIONAL STANDARD

First edition 2005-05-01

Implants for surgery — Ultra-high molecular weight polyethylene —

Part 4: **Oxidation index measurement method**

Implants chirurgicaux — Polyéthylène à très haute masse moléculaire —

Partie 4: Méthode de mesurage de l'indice d'oxydation



Reference number ISO 5834-4:2005(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

The series of th

© ISO 2005

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office Case postale 56 • CH-1211 Geneva 20 Tel. + 41 22 749 01 11 Fax + 41 22 749 09 47 E-mail copyright@iso.org Web www.iso.org Published in Switzerland

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.

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 5834-4 was prepared by Technice Committee ISO/TC 150, Implants for surgery, Subcommittee SC 1, Materials.

, under the general title Implants for surgery — Ultra-high molecular the work of the the surgery is a surgery of the surgery ISO 5834 consists of the following parts, 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

Introduction

This part of ISO 5834 describes a method for the measurement of the relative extent of oxidation present in ultra-high molecular weight polyethylene (UHMWPE) intended for use in surgical implants. The material is analysed by infrared spectroscopy. The intensity of the carbonyl absorptions (>C=O) centred near 1 720 cm⁻¹ is related to the amount of chemically bound oxygen present in the material. Other forms of chemically bound oxygen (R_1OR_2 , R_1OOR_2 , ROH, etc.) are not detected by this method.

Although this method might give the investigator a means to compare the relative extent of carbonyl oxidation present in various UHMWPE samples, it is recognized that other forms of chemically bound oxygen can be important contributors to characteristics of these materials.

The applicability of the infrared method has been demonstrated by many literature reports. This particular

The applicability of the infrared nethod has been demonstrated by many literature reports. This particular method, using the intensity (area) of the C-H absorption centred near 1 370 cm⁻¹ to normalize for the sample's thickness, has been validated an interlaboratory study (ILS).

Implants for surgery — Ultra-high molecular weight polyethylene —

Part 4: Oxidation index measurement method

1 Scope

This part of ISO 5834 specifies a method for the measurement of the relative extent of oxidation present in ultra-high molecular weight polyer plene (UHMWPE).

It is applicable to ultra-high molecular weight polyethylene (UHMWPE) intended for use in surgical implants.

2 Normative references

The following referenced documents are indepensable 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 poryethylene (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

3 Terms and definitions

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

3.1

aperture size

 L_{a}

length and width of a rectangular aperture, or the diameter of a circular aperture used by an infrared spectrometer to make spectral measurements

3.2

bulk oxidation index

I_{ox,b}

(sample) mean of the oxidation indices collected over a range of about 1,5 mm near the centre of the sample's oxidation index profile

NOTE Typically this is a plateau region with the smallest oxidation indices. For samples less than about 8 mm to 10 mm thick, this central region might display the sample's highest oxidation indices, depending on its state of oxidation.