
**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

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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).

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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 5834-4:2005) 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.

Introduction

This document 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 $1\,720\text{ cm}^{-1}$ 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 method, using the intensity (area) of the C-H absorption centred near $1\,370\text{ cm}^{-1}$ to normalize for the sample's thickness, has been validated by an interlaboratory study (ILS).

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