BS ISO 17853:2010

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Wear of implant materials — Polymer and metal wear particles — Isolation and characterization

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National foreword

This British Standard is the UK implementation of ISO 17853:2010. It supersedes BS ISO 17853:2003 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150/4, Surgical Implants - Bone and Joint Replacements.

A list of organizations represented on this committee can be obtained on request to its secretary.

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ISBN 978 0 580 61309 8

ICS 11.040.40

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2010

Amendments issued since publication

Date	Text affected

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INTERNATIONAL STANDARD

ISO 17853

Second edition
2010-06-15

Wear of implant materials — Polymer and metal wear particles — Isolation and characterization

Usure des matériaux d'implant — Particules d'usure des polymères et des métaux — Isolation, caractérisation et quantification

Reference number
ISO 17853:2010(E)

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Published in Switzerland

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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.

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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 17853 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

This second edition cancels and replaces the first edition (ISO 17853:2003) and ISO 17853:2003/Cor.1:2004, which have been technically revised.

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Introduction

The biological responses to wear particles contribute to the failure of joint implants through bone resorption and consequent implant loosening. A standardized method of particle retrieval from the tissues followed by particle characterization is necessary for a uniform approach to wear particle effect investigations. The characterization of the particles generated from implants in joint simulators also provides valuable information on the wear properties and performance of the implant being studied.

In the protocols included in this International Standard, for isolation and characterization of particles from both tissues or test fluids from joint simulators, the particles are isolated and then dispersed using filtration or embedding in resin for scanning electron microscopy (SEM) or transmission electron microscopy (TEM) analysis. An alternative protocol for isolation and characterization of metal particles from implants tested in joint simulators has recently been developed in which the particles are deposited on to wafers for SEM analysis, without filtration or embedding; see Reference [1]. At the time of writing this International Standard, this alternative method had not been tested for isolation and characterization of particles from tissues and no direct comparison between the different methods is currently available. Therefore, the latter method has not been included in detail.

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