INTERNATIONAL STANDARD

ISO 17853

Second edition
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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
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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.

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 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.

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.

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

1 Scope

This International Standard specifies methods for sampling wear particles generated by joint implants in humans and in joint simulators. It specifies the apparatus, reagents and test methods to isolate and characterize both polymer and metal wear particles from samples of tissue excised from around the joint implant, obtained at revision surgery or post mortem, and from samples of joint simulator test fluids. Some of these procedures could certainly be adapted for isolation and characterization of particles from human biological fluids (e.g. synovial fluid).

The methods given in this International Standard do not quantify the level of wear the implant produces; neither do they determine the amount of wear from any particular surface. This International Standard does not cover the biological effects of wear particles or provide a method for evaluation of biological safety.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
polymer wear particles
particles generated from the wear of polymeric components of an implant

2.2
metal wear particles
particles and particulate corrosion products generated from the wear of metal components of an implant

2.3
ceramic wear particles
particles generated from the wear of ceramic components of an implant

3 Principle, reagents and apparatus

3.1 Principle

Particles of polymeric and metal wear are isolated from tissue samples and simulator lubricants by digestion. The yield of each particle species is then purified by eliminating any remaining organic debris.

NOTE The methods involved in polymer and metal particle isolation are different and are described in 4.2 and 4.3, respectively.

The particles are collected, and are characterized and counted (where applicable) using scanning electron microscopy (SEM) or transmission electron microscopy (TEM).