Second edition
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Biological evaluation of medical devices —

Part 13: Identification and quantification of degradation products from polymeric medical devices

Évaluation biologique des dispositifs médicaux —

Partie 13: Identification et quantification de produits de dégradation de dispositifs médicaux à base de polymères

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 10993-13 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

This second edition cancels and replaces the first edition (ISO 10993-13:1998), which has been technically revised.

ISO 10993 consists of the following parts, under the general title *Biological evaluation of medical devices*:

— *Part 1: Evaluation and testing within a risk management process*

— *Part 2: Animal welfare requirements*

— *Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

— *Part 4: Selection of tests for interactions with blood*

— *Part 5: Tests for* in vitro *cytotoxicity*

— *Part 6: Tests for local effects after implantation*

— *Part 7: Ethylene oxide sterilization residuals*

— *Part 9: Framework for identification and quantification of potential degradation products*

— *Part 10: Tests for irritation and skin sensitization*

— *Part 11: Tests for systemic toxicity*

— *Part 12: Sample preparation and reference materials*

— *Part 13: Identification and quantification of degradation products from polymeric medical devices*

— *Part 14: Identification and quantification of degradation products from ceramics*

— *Part 15: Identification and quantification of degradation products from metals and alloys*

— *Part 16: Toxicokinetic study design for degradation products and leachables*

— *Part 17: Establishment of allowable limits for leachable substances*

— *Part 18: Chemical characterization of materials*

— *Part 19: Physico-chemical, morphological and topographical characterization of materials* [Technical specification]

— *Part 20: Principles and methods for immunotoxicology testing of medical devices* [Technical specification]

Introduction

Degradation products covered by this part of ISO 10993 are formed primarily by chemical bond scission due to hydrolytic and/or oxidative processes in an aqueous environment such as the human body. It is recognised that additional biological factors, such as enzymes, other proteins and cellular activity, can alter the rate and nature of degradation.

It should be kept in mind that a polymeric device can contain residuals and leachables such as monomers, oligomers, solvents, catalysts, additives, fillers and processing aids. These components which, if present, can interfere with the identification and quantification of the degradation products need to be considered and accounted for. It should be recognised that residual monomers can generate the same degradation products as the polymer itself. If the reader is solely interested in using the results from a degradation test as input to further biological evaluation tests, the reader might not be interested in distinguishing between a leachable and a degradation product. If this is the case, then the care taken to separate the leachable from the degradation product may not be needed.

Because of the generalized nature of this part of ISO 10993, product standards, when available, that address degradation product formation under more relevant conditions of use, may be considered as an alternative. This part of ISO 10993 is suitable for screening new polymeric materials and/or modified polymeric materials with unknown degradation behaviour in body contact. This part of ISO 10993 does not reproduce degradation *in vivo*. The user of this part of ISO 10993 can consider running additional degradation tests addressing *in vivo* degradation issues.

Long-term implants might not degrade within the time frame of the tests shown in this part of ISO 10993. The intention of this part of ISO 10993 is to help determine the biological hazards from potential degradation products from polymer components of medical devices. As noted above, those products might come from a variety of degradation mechanisms. This part of ISO 10993 is not intended to be a complete analysis of the degradation of the medical device and the impact on its performance. The interested user is referred to the relevant product standards.

The identified and quantified degradation products form the basis for biological evaluation in accordance with ISO 10993-1, for risk assessment in accordance with ISO 10993-17 and, if appropriate, for toxicokinetic studies in accordance with ISO 10993-16.