Australian Standard™

Biological evaluation of medical devices

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

Standards Australia

This Australian Standard was prepared by Committee HE-012, Surgical Implants. It was approved on behalf of the Council of Standards Australia on 26 June 2002 and published on 28 June 2002.

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Australian College of Operating Room Nurses
Australian Dental Association
Australian Industry Group
Australian Orthopaedic Association
Commonwealth Department of Health and Ageing
Department of Defence (Australia)
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PREFACE

This Standard has been developed to assist in the process of implementation of the Australian Medical Device legislation.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard, through the Joint Standards Australia/Standards New Zealand Committee HE-012 on Surgical Implants.

This Standard is identical with and has been reproduced from ISO 10993-9:1999, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products.*

The objective of this Standard is to provide general principles for the systematic evaluation of the potential and observed biodegradation of medical devices and for the design and performance of biodegradation studies.

As this Standard is reproduced from an international Standard, the following applies:

(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text 'this International Standard' should read 'this Australian Standard'.

(c) A full point substitutes for a comma when referring to a decimal marker.

CONTENTS

INTRODUCTION

This part of 10993 is intended to present the general principles on which the specific material investigations to identify and quantify degradation products described in ISO 10993-13 (polymers), ISO 10993-14 (ceramics) and ISO 10993-15 (metals and alloys) are based.

Information obtained from these studies is intended to be used in the biological evaluations described in the remaining parts of ISO 10993.

The materials used to construct medical devices may form degradation products when exposed to the biological environment, and these products may behave differently than the bulk material in the body.

Degradation products can be generated in different ways, either mechanically (by relative motion between two or more different components), by fatigue loading, as a result of fracture and/or by release from the medical device due to interactions with the environment, or combinations thereof.

Mechanical wear causes mostly particulate debris, whereas the release of substances from surfaces due to leaching, chemical breakdown of structures or corrosion can lead to free ions or to different kinds of reaction products in the form of organic or inorganic compounds.

The degradation products may be either reactive, or stable and without biochemical reaction with their environment. Accumulations of substantial quantities of stable degradation products may, however, have physical effects on the surrounding tissues. Degradation products may remain at the location of their generation or may be transported within the biological environment by various mechanisms.

The level of biological tolerability of degradation products depends on their nature and concentration, and should be primarily assessed through clinical experience and focused studies. For theoretically possible, new and/or unknown degradation products, relevant testing is necessary. For well-described and clinically accepted degradation products, no further investigation may be necessary.

AUSTRALIAN STANDARD

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1 Scope

This part of ISO 10993 provides general principles for the systematic evaluation of the potential and observed biodegradation of medical devices and for the design and performance of biodegradation studies.

This part of ISO 10993 is not applicable to:

a) viable-tissue engineered products;

b) methodologies for the generation of degradation products by mechanical processes. Methodologies for the production of this type of degradation product are described in specific product standards, where available;

c) leachable components which are not degradation products.

Where product standards provide applicable product-specific methodologies for the identification and quantification of degradation products, those standards shall be considered as alternatives.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 10993. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 10993 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 10993-1:1997, *Biological evaluation of medical devices — Part 1: Evaluation and testing*.

ISO 10993-2:1992, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*.

3 Terms and definitions

For the purposes of this part of ISO 10993, the terms and definitions given in ISO 10993-1 and the following apply.

3.1
degradation
decomposition of a material