AS ISO 10993.13—2002
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AS ISO 10993.13

Australian Standard™

Biological evaluation of medical devices

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

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

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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 10993-13:1998, *Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices.*

The objective of this Standard is to provide guidance on requirements for the design of tests to identify and quantify degradation products from finished polymeric medical devices ready for clinical use.

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.

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INTRODUCTION

This part of ISO 10993 was developed from ISO/TR 10993-9. Degradation products covered by this standard are formed primarily by chemical bond scission due to hydrolytic and/or oxidative processes in an aqueous environment. It is recognized 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 may contain residuals and leachables such as monomers, oligomers, solvents, catalysts, additives, fillers and processing aids. These components which, if present, may interfere with the identification and quantification of the degradation products, need to be considered and accounted for. It should be recognized that residual monomers may generate the same degradation products as the polymer itself.

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 14538 and, if appropriate, for toxicokinetic studies in accordance with ISO 10993-16.

AUSTRALIAN STANDARD

Biological evaluation of medical devices

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

1 Scope

This part of ISO 10993 provides guidance on general requirements for the design of tests for identifying and quantifying degradation products from finished polymeric medical devices ready for clinical use.

This part of ISO 10993 describes two test methods to generate degradation products, an accelerated degradation test as a screening method and a real-time degradation test. For materials which are intended to polymerize *in situ*, the set or cured polymer is used for testing. The data generated are used in the biological evaluation of the polymer.

This part of ISO 10993 considers only those degradation products generated by a chemical alteration of the finished polymeric device. It is not applicable to degradation of the device induced during its intended use by mechanical stress, wear or electromagnetic radiation.

The biological activity of the debris and soluble degradation products is not addressed in this part of ISO 10993, but should be evaluated according to the principles of ISO 10993-1 and ISO 14538.

Because of the wide range of polymeric materials used in medical devices, no specific analytical techniques are identified or given preference. No specific requirements for acceptable levels of degradation products are provided in this part of ISO 10993.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10993. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10993 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

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

ISO 10993-9: —[1)], *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products.*

ISO 10993-12:1996, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials.*

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1) To be published.