AS ISO 10993.10—2002
ISO 10993-10:1995

Australian Standard™

Biological evaluation of medical devices

Part 10: Tests for irritation and sensitization

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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Part 10: Tests for irritation and sensitization

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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 10993-10:1995, *Biological evaluation of medical devices — Part 10: Tests for irritation and sensitization.*

The objective of this Standard is to describe test methods for biological evaluation of the potential of medical devices and their constituent materials to produce irritation and sensitization.

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 ISO 10993 assesses possible contact hazards from device-released chemicals that may produce skin and mucosal irritation, eye irritation, and delayed contact sensitization.

Some materials that are included in these devices have been tested, and their skin or mucosal irritation or sensitization potential has been documented. Other materials and their chemical components have not been tested and may act differently when exposed to biological tissues. It is incumbent upon the manufacturer to evaluate each device for its human toxic potential prior to marketing.

Traditionally, small animal tests are performed prior to human testing to help predict human response. More recently, *in vitro* tests have been added as an alternative. Despite progress and considerable effort in this direction, a review of findings suggests that currently no satisfactory *in vitro* test has been devised to eliminate the requirement for *in vivo* testing. Where appropriate, the preliminary use of *in vitro* methods is encouraged as screening tests prior to animal testing. In order to reduce the number of animals used, these standards use a step-wise approach with review and analysis of test results at each stage.

It is incumbent upon the investigator to conduct these studies using good scientific laboratory practices, complying with regulations related to animal welfare. Since the number of animals is restricted, the data obtained may be insufficient to warrant the application of statistics.

AUSTRALIAN STANDARD

Biological evaluation of medical devices

Part 10: Tests for irritation and sensitization

1 Scope

This part of ISO 10993 describes test methods:

a) to evaluate the potential of devices and their constituent materials to produce irritation; and

b) to evaluate the potential of devices and their constituent materials to produce sensitization.

These test methods are recommended for most categories of device and mode of body contact given in ISO 10993-1. Of the tests listed, those appropriate to the end use of the device are to be selected. Guidance is also given for the preparation of materials specifically in relation to the above tests.

NOTE 1 Guidance on the conduct of supplementary tests which may be required specifically for use in the oral, rectal, penile and vaginal areas is given in annex D.

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 10993-1:1992, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests.*

ISO 10993-12:—[1], *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials.*

3 Definitions

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

3.1 (allergic contact) sensitization; delayed contact hypersensitivity: Allergic response involving immunological systems that have been activated by prior exposure.

3.2 irritation: Localized inflammatory response to single, repeated or continuous application of the test substance, without involvement of an immunological mechanism.

3.3 oedema: Swelling due to abnormal infiltration of fluid into the tissues.

3.4 erythema: Reddening of the skin or mucous membrane.

3.5 eschar: Scab or discoloured slough of skin.

3.6 corrosion: Production of irreversible tissue damage at the site of contact with the skin following the application of a test substance.

1) To be published.