AS ISO 10993.6—2002
ISO 10993-6:1994

Australian Standard™

Biological evaluation of medical devices

Part 6: Tests for local effects after implantation

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 Dental Association

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Part 6: Tests for local effects after implantation

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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 10993-6:1994, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation.*

The objective of this Standard is to specify test methods for the assessment of the local effects of an implant material on living tissue.

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 International Standard gives methods of biological testing of medical and dental materials and devices, and their evaluation in regard to their biocompatibility.

ISO 10993-1 offers a guide for selection of methods for biological testing. The intention is to reduce animal tests to the justifiable minimum (see ISO 10993-2). A search of the literature precedes any testing, as data concerning the biological safety of the candidate material could be available.

The test methods described in this part of ISO 10993 are based on established implantation tests. This part of ISO 10993 describes animal tests for the study of local effects after implantation. The use of *in vivo* implantation techniques for characterizing the biological response of tissues to materials allows for the assessment of such materials not achieved by other procedures.

These test methods may not be appropriate for all types of medical devices. The user is cautioned to consider the appropriateness of the method in view of the materials being tested, their potential applications, and the recommendations contained in ISO 10993-1.

ISO/TC 194 appreciates any information for the further development of this part of ISO 10993.

AUSTRALIAN STANDARD

Biological evaluation of medical devices

Part 6: Tests for local effects after implantation

1 Scope

This part of ISO 10993 specifies test methods for the assessment of the local effects of an implant material on living tissue, at both the macroscopic and microscopic level.

The test specimen is implanted into a site and tissue appropriate for evaluation of the biological safety of the material. The implant is not intended to be subjected to mechanical or functional loading. The local effects are evaluated by a comparison of the tissue response caused by a test specimen to that caused by materials used in medical devices whose clinical acceptability has been established.

The test methods for local effects after implantation are used to assess subchronic effects (short-term, up to 12 weeks), or chronic effects (long-term, longer than 12 weeks).

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

3 Common provisions for implantation test methods

3.1 General

For the purposes of this part of ISO 10993, the definitions given in ISO 10993-1 and ISO 10993-2 apply.

The provisions in this clause shall apply to the test methods described in clauses 4 to 6.

It is important that the researcher plans the study in such detail that the maximum of information can be extracted from the use of each animal (see ISO 10993-2).

3.2 Preparation of specimens for implantation

3.2.1 Solid specimens (excluding powders)

Physical characteristics (that is form, density, hardness, surface finish) can influence the character of the tissue response to the test material.

Each implant shall be manufactured, processed, cleaned of contaminants and sterilized by the method intended for the final product.

After final preparation and sterilization, the implant specimens shall be handled in such a way as to en-