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ISO 14949:2001

Australian Standard™

Implants for surgery—Two-part addition-cure silicone elastomers

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 21 May 2003 and published on 30 June 2003.

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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/ Standards New Zealand Committee HE-012, Surgical Implants. 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.

This Standard is identical with and has been reproduced from ISO 14949:2001, *Implants for surgery—Two-part addition-cure silicone elastomers.*

The objective of this Standard is to specify the characteristics of, and corresponding test methods for, the two-part addition-cure high consistency or liquid silicone elastomer for use in the manufacture (partially or totally) of surgical implants.

The terms 'normative' and 'informative' are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas an informative annex is only for information and guidance.

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.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards as follows:

Reference to International Standard		*Australian Standard*	
ISO		AS	
34	Rubber, vulcanized or thermoplastic; determination of tear strength	1683	Methods of test for elastomers
34-1	Part 1: trouser, angle and crescent test pieces	1683.12	Method 12: Rubber, vulcanized or thermoplastic—Determination of tear strength (trouser, angle and crescent test pieces)
48	Rubber, vulcanized or thermoplastic—Determination of hardness (hardness between 10 IRHD and 100 IRHD)	1683 1683.15.1	Methods of test for elastomers Method 15.1: International rubber hardness
527	Plastics; determination of tensile properties	1145	Determination of tensile properties of plastics materials
527-2	Part 2: Test conditions for moulding and extrusion plastics	1145.2	Part 2: Test conditions for moulding and extrusion plastics
3417	Rubber; measurement of vulcanization characteristics with the oscillating disc curementer	1683 1683.22	Methods of test for elastomers Method 22: Determination of vulcanization characteristics using the oscillating disc curemeter

Reference to International Standard		*Australian Standard*	
ISO		AS ISO	
10993	Biological evaluation of medical devices	10993	Biological evaluation of medical devices
10993-1	Part 1: Evaluation and testing	10993.1	Part 1: Evaluation and testing
10993-5	Part 5: Tests for in vitro cytotoxicity	10993.5	Part 5: Tests for in vitro cytotoxicity

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INTRODUCTION

Silicones are commercially available in a variety of physical forms and formulations. Silicone-cure products often employ cure mechanisms that utilize metals, free radicals and/or atmospheric moisture. This International Standard was undertaken to describe a subset of silicones with a successful history of use in implant applications; namely, those utilizing two-part addition-cure (platinum-based) chemistry. It was developed in response to a need to standardize the raw materials, formulation, processing, characterization testing and documentation of two-part addition-cure silicone elastomers targeted as implants for surgery.

Two-part addition-cure silicone elastomer is a thermoset elastomer and is commercialized as a two-part (non-crosslinked) product. The two parts should be thoroughly mixed in a fixed ratio before shaping by extrusion, press- or injection-moulding and crosslinking at elevated temperatures.

NOTES

AUSTRALIAN STANDARD

Implants for surgery—Two-part addition-cure silicone elastomers

1 Scope

This International Standard specifies the characteristics of, and corresponding test methods for, two-part addition-cure high consistency or liquid silicone elastomer for use in the manufacture (partially or totally) of surgical implants.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard 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 34-1:1994, *Rubber, vulcanized or thermoplastic — Determination of tear strength — Part 1: Trouser, angle and crescent test pieces*

ISO 48:1994, *Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD)*

ISO 527-2:1993, *Plastics — Determination of tensile properties — Part 2: Test conditions for moulding and extrusion plastics*

ISO 3417:1991, *Rubber — Measurement of vulcanization characteristics with the oscillating disc curemeter*

ISO 6502:1999, *Rubber — Guide to the use of curemeters*

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

ISO 10993-5:1999, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply.

3.1
catalyst
organometallic complex, typically containing platinum substituted by ligands made of any suitable combination of the elements carbon, hydrogen, oxygen, chlorine or silicon (with the exclusion of aromatic rings), which initiates a chemical reaction between a polymer and crosslinking agent

NOTE The catalyst may be dispersed in a silicone oligomer, polymer or mixture of these, such as $RMe_2SiO(SiMe_2O)_x(SiMeR'O)_ySiMe_2R$ where R and R′ are methyl or vinyl groups.