AS ISO 10555.1—2002
ISO 10555-1:1995

Australian Standard™

Sterile, single-use intravascular catheters

Standards Australia

This Australian Standard was prepared by Committee HE-009, Hypodermic Equipment - General Medical. 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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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-009 on Hypodermic Equipment - General Medical.

This Standard is identical with and has been reproduced from ISO 10555-1:1995, *Sterile, single-use intravascular catheters — Part 1: General requirements.*

The objective of this Standard is to specify requirements for single-use intravascular catheters.

This Standard provides for the use of the following Australian/New Zealand Standards as equivalents to the ISO Standards referenced herein:

Reference to International Standard or other publication		*Equivalent Australian/New Zealand Standard*	
ISO		AS/NZS ISO	
594-1	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment; Part 1 : General requirements	1600.1	Medical equipment — Conical fittings with a 6 percent (Luer) taper for syringes, needles and certain other medical equipment Part 1: General requirements

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(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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NOTES

AUSTRALIAN STANDARD

Sterile, single-use intravascular catheters

Part 1: General requirements

1 Scope

This part of ISO 10555 specifies general requirements for intravascular catheters, supplied in the sterile condition and intended for single use, for any application.

It does not apply to intravascular catheter accessories, which will be covered by a separate standard.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10555. 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 10555 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 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.*

ISO 594-2:1991, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings.*

ISO 7886-1:1993, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use.*

3 Definitions

For the purposes of this part of ISO 10555, the following definitions apply.

3.1 intravascular catheter: Tubular device, single or multilumen, designed to be partially or totally inserted or implanted into the cardiovascular system for diagnostic and/or therapeutic purposes.

3.2 distal end: End of the catheter inserted furthest into the patient.

3.3 proximal end; access end: End of the catheter to which connection can be made.

3.4 hub: Connector(s) at the proximal end of the catheter which may either be integral with the catheter or be capable of being securely fitted to the proximal end of the catheter.

3.5 effective length, *l*: Length of the catheter that can be inserted into the body. (See figure 1.)

3.6 outside diameter: Maximum diameter of that part of the catheter that can be inserted into the vessel.

3.7 junction: That portion of the catheter that joins one tube to multiple tubes.

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