Australian Standard™

Anaesthetic and respiratory equipment—Tracheal tubes and connectors (ISO 5361:1999, MOD)

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This Australian Standard was prepared by Committee HE-019, Anaesthetic and Breathing Equipment. It was approved on behalf of the Council of Standards Australia on 13 February 2004 and published on 29 March 2004.

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Australasian Society of Anaesthesia Paramedical Officers
Australian Chamber of Commerce and Industry
Australian College of Operating Room Nurses
Australian Industry Group
Australian Society of Anaesthetists
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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee HE-019, Anaesthetic and Breathing Equipment. 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 an adoption with national modifications and has been reproduced from ISO 5361:1999**,** *Anaesthetic and respiratory equipment—Tracheal tubes and connectors*. The modification, as set out in item (d) below was necessary because a particular edition of EN 556 was referenced in a requirement. That edition has since been superseded. Only the referenced document designation and title have changed. The text of the requirement is technically identical. The change is indicated in the text by a marginal bar.

The objective of this Standard is to specify requirements for the dimensions, basic properties and method of size designation of the most commonly used types of oro-tracheal and naso-tracheal tube made of plastics materials and/or rubber (plain and cuffed), and requirements for tracheal tube connectors.

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.

(d) In Clause 6.1 delete 'EN 556:1994' and replace with 'EN 556-1:2001'.

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

Reference to International or European Standard		*Australian Standard*	
ISO		AS	
594	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment	1600	Medical equipment—Conical fittings with a 6 percent (Luer) taper for syringes, needles and certain other medical equipment
594-1	Part 1: General requirements	1600.1	Part 1: General requirements
		AS ISO	
10993	Biological evaluation of medical devices	10993	Biological evaluation of medical devices
10993-1	Part 1: Guidance on selection of tests	10993.1	Part 1: Evaluation and testing
EN		AS EN	
556	Sterilization of medical devices—Requirements for medical devices to be designated 'STERILE'	556	Sterilization of medical devices—Requirements for medical devices to be designated 'STERILE'
556-1	Part 1: Requirements for terminally sterilized medical devices	556.1	Part 1: Requirements for terminally sterilized medical devices

Only international references that have been adopted as Australian Standards have been listed.

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INTRODUCTION

This International Standard specifies the dimensions, basic properties and method of size designation of the most commonly used types of tracheal tube made of plastics materials and/or rubber. Tubes with walls reinforced with metal or nylon, tubes with shoulders, tapering tubes and the many other types of tube devised for specialized applications are not specifically covered, although most may be classified by their inside diameter as required by this International Standard.

While the inside diameter has been specified for size reference, this International Standard requires that the outside diameter also be marked, since this information is of clinical importance.

Clinical considerations have also dictated the apparently excessive specified length of tubes, because long tubes, sometimes of relatively narrow diameter, may be urgently required and therefore should be readily available. Provision has also been included for pre-cut tracheal tubes.

Cuffed tracheal tubes can be characterized by a combination of the tube inside and outside diameters and by the cuff resting diameter.

For tubes intended for re-use, information on the cuff resting diameter is required to be marked on the package or insert but not on the tube itself. This is because re-use may alter the elastic properties, and thereby the diameter, of the cuff.

The relationship between the cuff and tracheal diameters dictates the intracuff pressure required to provide a seal. Excessive pressure on the tracheal wall may obstruct capillary blood flow.

Tracheal tubes, when in position, are intended to conform as closely as possible to human anatomy.

A range of cuff designs is available to meet particular clinical requirements. This International Standard requires that the resting diameter of the cuff be marked on the unit package, as this information allows the clinician to match the product to the application.

Herniation in relation to cuffs is a term widely understood in clinical anaesthetic practice. It is used to describe a cuff which protrudes excessively at its patient end so that it partially or completely occludes the orifice at the bevel. Herniation may be due to a variety of causes, singly or in combination: these may include over-inflation of the cuff, traction of the tube when the cuff is inflated or deterioration of the material of the cuff.

It should be noted that although certain requirements for cuffs apply to tubes of sizes 2,0 to 4,5, cuffs are infrequently used on these smaller sizes of tube.

Flammability of tracheal tubes, for example if flammable anaesthetics, electrosurgical units or lasers are used, is a well-recognized hazard[1] that is addressed by appropriate clinical management, outside the scope of this International Standard.

It is a requirement that tracheal tubes include length mark(s) in centimetres, measured from the patient end. It is recognized, however, that additional marks, easier to see during intubation, may assist the clinician in positioning the tracheal tube within the trachea. There is currently, however, no clear consensus on the optimum style and positioning of these marks and whether the positioning should differ with size of tube. Further clinical data is required in order to support inclusion of recommendations for these marks in a future revision of this International Standard.

1) See ISO/TR 11991.

NOTES

AUSTRALIAN STANDARD

Anaesthetic and respiratory equipment—Tracheal tubes and connectors (ISO 5361:1999, MOD)

1 Scope

This International Standard specifies requirements for the dimensions, basic properties and method of size designation of the most commonly used types of oro-tracheal and naso-tracheal tube made of plastics materials and/or rubber (plain and cuffed), and requirements for tracheal tube connectors.

Specialized tubes are excluded from the scope of this International Standard.

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 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*.

ISO 5356-1, *Anaesthetic and respiratory equipment – Conical connectors — Part 1: Cones and sockets.*

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

ISO 11607, *Packaging for terminally sterilized medical devices.*

EN 556:1994, *Sterilization of medical devices — Requirements for medical devices to be labelled "Sterile".*

3 Terms and definitions

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

3.1
angle of bevel
acute angle between the plane of the bevel and the longitudinal axis of the tracheal tube at the patient end

[ISO 4135:1995]