Australian Standard™

Anaesthetic respiratory equipment—Tracheostomy tubes

Part 3: Paediatric tracheostomy tubes (ISO 5366-3:2001, MOD)

STANDARDS AUSTRALIA

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 1 April 2004.

The following are represented on Committee HE-019:

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

Australian and New Zealand College 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 5366-3:2001, *Anaesthetic and respiratory equipment—Tracheostomy tubes,* Part 3: *Paediatric tracheostomy tubes* and includes ISO 5366-3:2001 Technical Corrigendum 1:2003. The ISO corrigendum has been added following the appendices. 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 That edition has since been superseded.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 paediatric tracheostomy tubes made of plastics materials and/or rubber having inside diameters from 2.0 mm to 6.0 mm. Requirements for paediatric tracheostomy tube connectors and adaptors are also given.

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 7.1 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:

References 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: Evaluation and testing	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

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Annexes

INTRODUCTION

ISO 5366 is concerned with the basic requirements and method of size designation of tracheostomy tubes made of plastics materials and/or rubber.

ISO 5366-1 gives requirements for adult tracheostomy tubes made of plastics materials and/or rubber.

This part of ISO 5366 gives requirements for paediatric tracheostomy tubes with an inside diameter from 2,0 mm to 6,0 mm.

Paediatric tracheotomy tubes are primarily intended for use with infants and children who may require anaesthesia, artificial ventilation, relief of upper airway obstruction or other respiratory therapy.

An infant or child differs from an adult, not only in size but especially with regard to airway anatomy and respiratory physiology; thus airway equipment for paediatric patients differs from that for adults in size and also in basic design. It should be noted that, although this part of ISO 5366 gives some requirements for cuffs, cuffs are seldom provided on the smaller sizes of paediatric tubes.

This part of ISO 5366 gives requirements for those characteristics of tracheostomy tubes that can be standardized and which are important for patient safety. It does not require the connector to be permanently attached to the tube, as this may be impractical with infants and small children. Other acceptable methods of connecting these components are available, and this part of ISO 5366 makes provision for them. This part of ISO 5366 does not limit the range of tube designs needed to match the variety of paediatric anatomy, lesions and space limitations encountered.

The method of describing tube dimensions and configuration has been devised with the aim of assisting the clinician in the selection of a suitable tube to conform as far as possible to a particular patient's anatomy. Size is designated by inside diameter, which is important because of its relation to resistance to gas flow. Because the stomal and tracheal diameters are important when selecting tubes, it is considered essential that the outside diameter be stated for each size of tube.

A tracheostomy tube can increase resistance to gas flow. For tubes with a given outside diameter, differences in wall thickness have a major influence on the resistance to gas flow, especially in the smaller sizes of paediatric tracheostomy tubes.

Flammability of tracheostomy tubes, for example if flammable anaesthetics, electrosurgical units or lasers are used in oxidant-enriched atmospheres, is a well-recognized hazard[1)] addressed by appropriate clinical management, which is outside the scope of this part of ISO 5366.

1) See ISO/TR 11991.

AUSTRALIAN STANDARD

Anaesthetic and respiratory equipment—Tracheostomy tubes

Part 3:
Paediatric tracheostomy tubes (ISO 5366-3:2001, MOD)

1 Scope

This part of ISO 5366 gives requirements for paediatric tracheostomy tubes made of plastics materials and/or rubber having inside diameters from 2,0 mm to 6,0 mm. Requirements for paediatric tracheostomy tube connectors and adaptors are also given.

This part of ISO 5366 is not applicable to specialized tracheostomy tubes.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 5366. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 5366 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 5361, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*.

ISO 5366-1:2000, *Anaesthetic and respiratory equipment — Tracheostomy tubes — Part 1: Tubes and connectors for use in adults*.

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

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 part of ISO 5366, the terms and definitions given in ISO 5366-1 and the following apply.

3.1
paediatric tracheostomy tube
tube designed for insertion into the trachea of an infant or child through a tracheostomy

3.2
paediatric tracheostomy tube connector
tubular component which fits directly into the paediatric tracheostomy tube