Australian Standard™

Anaesthetic respiratory equipment—Tracheostomy tubes

Part 1: Tubes and connectors for use in adults (ISO 5361-1:2000, MOD)

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Australian Chamber of Commerce and Industry

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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 5366-1:2000, *Anaesthetic and respiratory equipment—Tracheostomy tubes,* Part 1*: Tubes and connectors for use in adults.* 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 That edition has since been superseded.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 tracheostomy tubes made of plastics materials and/or rubber having inside diameters of 6.5 mm or greater. Such tubes are primarily designed for patients who require anaesthesia, artificial ventilation or other respiratory support, but need not be restricted to these uses.

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 part of ISO 5366' 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:

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 or European references that have been adopted as Australian Standards have been listed.

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Annexes

INTRODUCTION

ISO 5366-1 is one of a series of International Standards dealing with anaesthetic equipment, and is concerned with the basic requirements and method of size designation of tracheostomy tubes made of plastics materials and/or rubber. Specialized tubes, for example those without a connector at the machine end intended for spontaneously breathing patients, and those with reinforced walls or tubes made of metal are excluded from the scope of this part of ISO 5366.

This part of ISO 5366 specifies requirements for tracheostomy tubes with an inside diameter of 6,5 mm or greater. ISO 5366-3 specifies requirements for tracheostomy tubes with an inside diameter from 2,0 to 6,0 mm for paediatric use.

The method of describing tube dimensions and configuration has been devised in order to assist 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.

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

The relationship of cuff and tracheal diameters dictates the intra-cuff pressures required to provide a seal. Excessive pressure on the tracheal wall can obstruct capillary blood flow.

A range of cuff designs is available to meet the particular clinical requirements. This part of ISO 5366 requires that the resting diameter of the cuff is marked on the unit package as this information allows the clinician to match the product to the application.

A 15 mm male conical connector in accordance with ISO 5356-1 should be used for tracheostomy tubes, as for tracheal tubes, to ensure compatibility with the breathing system of an anaesthetic machine or ventilator.

The tracheostomy tube connector should be permanently attached to the tracheostomy tube to prevent inadvertent disconnection of the connector from the tube.

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)] that is addressed by appropriate clinical management, and is outside the scope of this part of ISO 5366.

1) See ISO/TR 11991.