American National Standard

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Anaesthetic and Respiratory Equipment—Tracheostomy Tubes—Part 3: Paediatric Tracheostomy Tubes

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Anaesthetic and Respiratory Equipment—

Tracheostomy Tubes—

Part 3:
Paediatric Tracheostomy Tubes

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TECHNICAL CORRIGENDUM 1

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Anaesthetic and respiratory equipment — Tracheostomy tubes —

Part 3: Paediatric tracheostomy tubes

TECHNICAL CORRIGENDUM 1

Matériel respiratoire et d'anesthésie — Tubes de trachéostomie —
Partie 3: Tubes de trachéostomie pédiatriques

RECTIFICATIF TECHNIQUE ##

Technical Corrigendum 1 to ISO 5366-3:2001 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment.*

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Clause A.1

In the first sentence, replace "...axial separation force to the neck-plate" with "...axial separation force to the tube, relative to the neck-plate."

In the second sentence, replace "...axial separation force to the connector" with "...axial separation force to the tube, relative to the connector."

Subclause A.2.2

Replace "...to the tracheostomy tube..." with "...**and the tracheostomy tube**...".

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Subclause A.2.3

Replace "...to the tracheostomy tube..." with "...**and the tracheostomy tube**...".

Subclause A.3.3

Replace "...axial separation force of (50 ± 5) N to the connector..." with "...axial separation force of (50 ± 5) N to the tracheostomy tube, relative to the connector...".

Subclause A.3.5

Replace "...axial separation force to the neck-plate..." with "...axial separation force to the tracheostomy tube, relative to the neck-plate...".

INTERNATIONAL STANDARD

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Anaesthetic and respiratory equipment — Tracheostomy tubes —

Part 3: Paediatric tracheostomy tubes

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this part of ISO 5366 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 5366-3 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This second edition cancels and replaces the first edition (ISO 5366-3:1994), which has been technically revised.

ISO 5366 consists of the following parts, under the general title *Anaesthetic and respiratory equipment — Tracheostomy tubes*:

— *Part 1: Tubes and connectors for use in adults*

— *Part 3: Paediatric tracheostomy tubes*

Annexes A and B form a normative part of this part of ISO 5366. Annex C is for information only.

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.

Anaesthetic and respiratory equipment — Tracheostomy tubes —

Part 3:
Paediatric tracheostomy tubes

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