American National Standard

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Anaesthetic and Respiratory Equipment—Tracheal Tubes and Connectors

AAMI
Advancing Safety in Medical Technology

This document was approved and published when the U.S. TAG for TC 121 was held by ASTM, but it is now an AAMI standard. The original formatting has been maintained, so there are some variations from the typical AAMI style.

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Anaesthetic and respiratory equipment — Tracheal tubes and connectors

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

This second edition cancels and replaces the first edition (ISO 5361:1999), which has been technically revised.

The requirements of ISO 5361-4, ***Tracheal tubes*** — *Part 4: Cole type*, have been included in this second edition because **Cole type tracheal tubes** are specialized tubes, and as such, are now included in the scope of this International Standard.

Throughout this Particular Standard, terms defined in Clause 3 or in ISO 4135 appear in **bold** type.

Throughout this Particular Standard, text for which a rationale is provided in Annex A is indicated by an asterisk (*).

Introduction

This International Standard provides the essential performance and safety requirements for the design of **tracheal tubes** and **tracheal tube connectors. Tracheal tubes** are intended to be inserted through the larynx into the trachea to convey gases and vapours to and from the trachea.

Tracheal tubes with **cuffs** are intended to seal and protect the trachea from aspiration of secretions and to provide an unobstructed airway in patients during spontaneous, assisted, or controlled ventilation for short or prolonged durations.

A variety of **cuff** designs are available to meet particular clinical requirements. **Cuff** performance requirements with associated test methods have been added to this second edition.

Requirements for paediatric **tracheal tubes** with **cuffs** have been added because these are commercially available and in common use.

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

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

Kink resistance requirements with associated test methods have also been added to the second edition to measure the ability of the shaft of the **tracheal tube** to resist collapse and increased breathing resistance when bent or curved.

Radiopacity requirements and test methods have been added to this second edition to characterize the visibility of **tracheal tubes** in X-rays used to determine proper placement of the tube. The requirements of this International Standard were developed using the hazard identification for **risk assessment** in Annex F.

Anaesthetic and respiratory equipment — Tracheal tubes and connectors

1 *Scope

This International Standard provides essential performance and safety requirements for **oro-tracheal and naso-tracheal tubes** and **tracheal tube connectors. Tracheal tubes** with walls reinforced with metal or nylon, **tracheal tubes** with **shoulders**, tapered **tracheal tubes**, **tracheal tubes** with means for suctioning or monitoring or delivery of drugs or other gases, and the many other types of **tracheal tubes** devised for specialized applications are included in this International Standard, as many specialized **tracheal tubes** are now commonly used, and all share similar essential requirements as defined in this International Standard.

Tracheobronchial (endobronchial) tubes, tracheostomy tubes and supralaryngeal airways are excluded from the scope of this International Standard.

Tracheal tubes intended for use with flammable anaesthetic gases or agents, lasers or electrosurgical equipment are outside the scope of this International Standard.

NOTE ISO/TR 11991, ISO 11990-1, ISO 11990-2, and ISO 14408 cover this[1][2][3][4].

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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 7000, *Graphical symbols for use on equipment – Index and synopsis*[1)]

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11135-1, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11607-1, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14155, *Clinical investigation of medical devices for human subjects – Good clinical practice*

ISO 14971, *Medical Devices - Application of risk management to medical devices*

ISO 15223-1, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

ISO 15223-2, *Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied – Part 2: Symbol development, selection and validation*

1) The graphical symbols in ISO 7000 are also available on line in the ISO web store. For more information, consult http://www.iso.org/iso/publications_and_e-products/databases.htm?=.