INTERNATIONAL STANDARD

ISO 11712

First edition
2009-05-15

Anaesthetic and respiratory equipment — Supralaryngeal airways and connectors

Matériel d'anesthésie et de réanimation respiratoire — Canules supralaryngées et raccords

Reference number
ISO 11712:2009(E)

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Published in Switzerland

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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.

ISO 11712 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

Introduction

* A **supralaryngeal airway** is a device placed through the mouth, intended to seal the supralaryngeal area to maintain airway **patency** without passing through the vocal cords and to independently facilitate ventilation with or without delivery of anesthesia gases. Devices intended to provide a breathing airway and/or to simultaneously provide a guide for the intubation of **tracheal tubes**, bronchoscopes and suction devices are also included in the scope of this International Standard, as are the connectors inserted into the **machine end** of these devices.

***** Examples of **supralaryngeal airway** devices are laryngeal masks, laryngeal tubes, airways and seals, cuffed **oropharyngeal airways**, and pharyngeal airways, and combination airway/esophageal obturators.

The requirements of this International Standard were developed using the hazard identification for risk assessment in Annex D.

The requirements for testing and disclosure apply to devices introduced to the market after the publication of this International Standard.

Throughout this International Standard, terms defined in ISO 4135 or in this International Standard appear in **bold type**.

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

Anaesthetic and respiratory equipment — Supralaryngeal airways and connectors

1 Scope

1.1 This International Standard provides the essential requirements for the design of supralaryngeal airways and connectors. These devices are intended to open and seal the supralaryngeal area to provide an unobstructed airway in patients during spontaneous, assisted or controlled ventilation.

1.2 This International Standard specifies the dimensions, basic properties and method of size designation of the available types of supralaryngeal airways. Airways devised for specialized applications are not specifically covered, although most may be classified by the sizing and dimensions (or other characteristics) required by this International Standard.

1.3 The following devices are outside the scope of this International Standard: nasal and oropharyngeal airways, anesthetic masks, oro- and naso-tracheal tubes, cricothyrotomy devices, dental appliances, tracheal stents, tracheal tubes, ventilating laryngoscopes, CPAP devices, esophageal obturators, bougies and devices that require surgical placement.

1.4 This International Standard requires dimensional disclosure so the operator will know which auxiliary instruments, such as tracheal tubes and bronchoscopes will be size-compatible.

1.5 Flammability of airways, for example if used with certain flammable anesthetics, electrosurgical units or lasers, is a well-recognized hazard that is outside the scope of this International Standard. See E.1.7.

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 4135, *Anaesthetic and respiratory equipment — Vocabulary*

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

ISO 5361:1999, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

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

ISO 11607:2003, *Packaging for terminally sterilized medical devices*

ISO 11134, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization*

ISO 11135:1994, *Medical Devices — Validation and routine control of ethylene oxide sterilization*

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 11990, *Optics and optical instruments — Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shafts*

ISO/TR 11991, *Guidance on airway management during laser surgery of upper airway*

ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 14408, *Tracheal tubes designed for laser surgery — Requirements for marking and accompanying information*

3 Terms and definitions

For the purposes of this document, the terms and definitions in ISO 4135 and the following apply.

3.1
auxiliary ventilatory opening
secondary opening in the ventilatory pathway intended for passage of ventilatory gases at or near the patient end

3.2
cuff
compliant seal permanently attached to the supralaryngeal airway to provide a seal between the tube and the oropharynx

3.3
external seal
seal that is positioned outside the patient

EXAMPLE A seal between a face mask and the face.

3.4
internal seal
seal that is positioned inside the patient at some point in the respiratory tract

NOTE For **supralaryngeal airways** the **internal seal** is typically located in proximity to the glottic inlet.

3.5
patency
openness (lack of obstruction) of the **supralaryngeal airway**

3.6
patient end
that end of the **supralaryngeal airway** intended to be inserted into the patient

3.7
machine end
that end of the supralaryngeal airway or the supralaryngeal airway connector intended to connect to the breathing system

