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Anaesthetic and respiratory equipment — Supralaryngeal airways and connectors

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

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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

3.8
pressure drop
pressure differential at a specified flow

3.9
sealing mechanism
that portion of the **device in contact with the patient** that enables isolation of ventilatory gases

3.10
supralaryngeal airway
device placed through the mouth but not through the vocal cords, which is intended to form an **internal seal** in the supralaryngeal area to maintain airway **patency**

3.11
supralaryngeal airway connector
tubular component of an **supralaryngeal airway** intended for connection to a breathing system or ventilation bag

3.12
ventilatory opening
opening in the **supralaryngeal airway** near the patient end and intended to allow passage of gases and/or devices such as a tracheal tube, suction catheter or endoscope

NOTE A supralaryngeal airway can have more than one ventilatory opening.

3.13
ventilatory pathway
part of the **supralaryngeal airway** through which gases are intended to pass

4 General requirements

4.1 This International Standard specifies requirements that are generally applicable to risks associated with **supralaryngeal airways**. An established risk management process shall be applied to the design of the device. See Annex D for an informative list of identified hazards.

4.2 The supralaryngeal airway shall permit ventilation in those head and neck positions, and in those patient positions for which the device is intended.

4.3 The supralaryngeal airway shall permit ventilation when the patient is in the supine position and the head and neck are at neutral positions and at least ± 30° of:

a) flexion;

b) extension;

c) right and left rotation;

d) right and left lateral flexion (tilt).

4.4 The supralaryngeal airway shall also permit ventilation in the following positions and in any position intended for use:

a) Trendelenburg's (head down, 10°);

b) sitting (45°).

Compliance shall be tested by examination of the mitigations described in a risk assessment and associated verification and validation studies.

NOTE 1 See Annex A and Annex D.

If clinical studies are performed, these studies shall document measurements taken during the conditions for which performance is claimed. The clinical studies shall comply with the requirements of ISO 14155-1, and ISO 14155-2.

NOTE 2 See also Annex B for evaluating and documenting the clinical performance of supralaryngeal airways in human subjects.

4.5 The supralaryngeal airway shall, when transported, stored and used as intended by the manufacturer, minimize safety hazards which could reasonably be foreseen in normal and single-fault condition.

4.6 Where the requirements of this International Standard refer to freedom from unacceptable risk, acceptability or unacceptability of this risk is determined by the manufacturer in accordance with the manufacturer's policy for determining acceptable risk.

4.7 The manufacturer may use type tests different from those detailed within this International Standard, if an equivalent degree of safety is obtained. However, in the event of dispute, the methods specified herein shall be used as the reference methods.

4.8 Many of the test clauses within this International Standard establish acceptance criteria for performance aspects. These acceptance criteria shall always be met. If the manufacturer chooses to specify in the accompanying documents higher performance levels than those specified within this International Standard these manufacturer-specified levels become the acceptance levels and shall also be met.

5 *Requirements

5.1 Supralaryngeal airways

5.1.1 *Size designation

The size of a **supralaryngeal airway** shall be designated using the following convention:

a) the range of sizes shall be from 0 to 6; the smallest increment permitted is 0,5;

b) sizes from 0 to 6 shall be designated for the smallest to largest size devices; the transition size from pediatric to adult is size 3.

5.1.2 Materials

5.1.2.1 **Supralaryngeal airways**, including the sealing mechanism and connector in its ready-for-use state after any preparation for use recommended by the manufacturer, shall satisfy appropriate biological safety testing, as indicated in ISO 10993-1. Initial biocompatibility evaluation tests shall include all materials in the **supralaryngeal airway** and be tested as external communicating, tissue/bone/dentin communicating, < 24 h contact devices. If the proposed contact duration is greater than 24 h, biocompatibility tests shall include those tests for > 24 hr duration.

5.1.2.2 The marking of the **supralaryngeal airway** shall be durable and legible.

NOTE See Annex E.

5.1.3 *Ventilatory opening

An opening intended to allow ventilation shall be provided at or near the patient end of the device. Auxiliary ventilatory openings may be provided to reduce the risk from obstruction.

Compliance shall be determined by inspection.

5.1.4 *Safeguards against collapse of the ventilatory pathway

Means shall be provided to resist collapse of the ventilatory pathway from kinking or compression.

The kink resistance of the **supralaryngeal airway** lumen shall be tested in accordance with Annex C.

The resistance to compression shall be evaluated by examination of the mitigations described in a risk assessment and associated verification and validation studies.

5.1.5 *Sealing mechanism

5.1.5.1 A sealing mechanism shall be integrally attached to the **supralaryngeal airway**.

5.1.5.2 The sealing mechanism shall produce no audible leak under a positive pressure of 10 cm/H_2O for a minimum of 3 s.

Compliance shall be tested by clinical study measurements. **Functional testers** or **patient** simulators shall not be used to validate the performance of the supralaryngeal airway. The clinical studies shall document measurements taken during the conditions for which performance is claimed. The clinical studies shall comply with the requirements of ISO 14155-1 and ISO 14155-2.

NOTE See also Annex B.

5.1.5.3 The sealing mechanism shall not occlude the **ventilatory opening** nor collapse the **ventilatory pathway**.

Compliance shall be tested by a method chosen by the manufacturer based upon an examination of the mitigations described in a risk assessment and associated verification and validation studies.

5.1.5.4 Inflation/deflation system.

If provided, the inflation system shall include an inflating tube, a pilot balloon or other device to indicate inflation or deflation.

NOTE This (these) device(s) may also serve as a pressure-indicating or pressure-limiting device.

5.1.5.5 *The free end of the **inflation tube** shall be either open or sealed with a closure device or inflation valve. If interface with an external inflation device is required, the free end of the inflation tube shall be capable of accepting a male conical fitting with a 6 % (Luer) taper, complying with ISO 594-1.

5.1.5.6 The intentional deflation of the sealing mechanism shall not be prevented by the inflation tube, inflation valve or any closure device acting as a non-return valve.

5.1.6 *Internal volume

The internal volume of the **ventilatory pathway** shall be measured in accordance with the following test method.

Cap one end of the **ventilatory pathway**. Measure the volume of water in millilitres required to fill the ventilatory pathway from the **ventilatory opening** up to and including the 15 mm connector at the machine end of the device.

5.1.7 Maximum instrument size

The maximum size of devices that will easily pass through the **ventilatory pathway** shall be specified by the manufacturer. Devices may include (but are not limited to) tracheal tubes, suction catheters, fiberoptic scopes, bougies, etc. The instrument may be lubricated with water or water-soluble lubricant to assist the passage [see 9 e)].

Compliance shall be determined by functional testing.

5.2 Supralaryngeal airway connectors

5.2.1 The **machine end** of a **supralaryngeal airway connector** shall be a male 15 mm conical connector complying with ISO 5356-1. Any transition in the inside diameter shall be smooth to permit an adequate lead-in for smooth passage and removal of an instrument.

5.2.2 The opening at the patient end shall have a plane at 90° ± 5° to the long axis of the **patient end** of the connector.

6 Requirements for supralaryngeal airways and connectors supplied sterile

6.1 Sterility assurance

Supralaryngeal airways with connectors supplied and marked as “STERILE” shall satisfy the requirements of ISO 11134, ISO 11135 or ISO 11137-1, if applicable.

6.2 Packaging for supralaryngeal airways and connectors supplied sterile

Each **supralaryngeal airway** and connector (if supplied) and marked as “STERILE” shall be contained in an individual pack. The pack shall serve as an effective barrier to the penetration of microorganisms and particulate material, in accordance with ISO 11607. The pack shall permit the aseptic extraction of the contents and shall not be capable of reclosure without clearly revealing that the pack has been opened.

7 Cleaning and disinfection or sterilization

Supralaryngeal airways and connectors not intended for single use shall be designed to be suitable for cleaning and disinfection or sterilization by methods described in the accompanying documents.

NOTE See Annex E.

8 Markings

8.1 Use of symbols

Symbols shall be accompanied by equivalent text in United States English on devices intended for use in the United States. The requirements of 8.2 may be met by the appropriate symbols as given in ISO 7000.

8.2 Marking of the supralaryngeal airway

8.2.1 Marking of the **supralaryngeal airways** shall include the following:

a) the name and/or trademark of the manufacturer or supplier;

b) the designated size in bold type in accordance with 5.1.1; devices that encompass a range of sizes shall be marked with the corresponding range;

c) the words “SINGLE USE” or equivalent, for **supralaryngeal airways** not intended for re-use;

d) *normal depth of insertion marking(s) or indicator(s) visible around the shaft of the **supralaryngeal airway** corresponding to patient's incisors or gums to show the typical range of intended depth of insertion;

NOTE Depth of insertion range marking(s) need not be continuously circumferential around the tube.

e) depth mark(s), if provided, in centimeters measured from the **patient end** of the **ventilatory opening**.