



F 2560-06

Standard Specification for

Supralaryngeal Airways and Connectors

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F 2560

Foreword

This ASTM standard was developed as an American National Standard by ASTM F29 Anesthesia and Respiratory Equipment, Subcommittee F29.12 Airways, Task Group F29.12.07 Supralaryngeal airways in the format of an ISO standard to serve as a guide for future work as a new ISO Standard.

This is the first edition of this Standard.



Introduction

This ASTM 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.

This ASTM 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 Standard.

The requirements of this standard were developed using the Hazard Identification for Risk Assessment in Annex D.

Annex C is normative; Annexes A, B, D, E, and F are informative.

Throughout this Particular Standard, terms defined in ISO 4135:1995, *Anaesthesiology-Vocabulary* or in this Particular Standard in **bold type**.

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



1. Scope

1.1 * 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 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 standard, as are the connectors inserted into the **machine end** of these devices.

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

1.3 * The following devices are outside the scope of this 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 Standard requires dimensional disclosure so the operator will know which auxiliary instruments, such as **tracheal tubes** and bronchoscopes will be size-compatible.

1.5 * Based on the risk assessment included in this document, requirements have been established to mitigate or reduce patient safety hazards identified during that process. See Annex D.

1.6 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 Standard. See Annex E

2. Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this Standard 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 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 10993-1, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests.*

ISO 11607, *Packaging for terminally sterilized medical devices.*

ISO 11134, *Sterilization of healthcare products-requirements for validation and routine control – industrial moist heat sterilization,*

ISO 11135, *Medical Devices – Validation and routine control of ethylene oxide sterilization,*

ISO 11137, *Sterilization of healthcare products-requirements for validation and routine control – radiation sterilization.*

ANSI-AAMI-ISO 14971, *Medical Devices - Application of Risk Management to Medical Devices.*



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 7000, *Graphical symbols*

ISO 4135, *Anaesthesiology-vocabulary*

3. Terms and definitions

For the purposes of this Standard, the following terms and definitions apply:

3.1

cuff

inflatable balloon permanently attached to the supralaryngeal airway to provide a seal between the tube and the oropharynx

3.2

internal/external seal

An internal seal refers to a device sealing mechanism that occurs inside the patient at some point in the respiratory tract. For **supralaryngeal airway** devices, this seal is typically located in proximity to the glottic inlet. Conversely, an external seal occurs outside the patient, typically against the face (i.e., face mask)

3.3

patency

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

3.4

patient end

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

3.5

machine end

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

3.6

pressure drop

pressure differential at a specified flow

3.7

sealing mechanism

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

3.8

supralaryngeal airway

a device placed through the mouth that is intended to seal the supralaryngeal area to maintain airway **patency** without passing through the vocal cords to facilitate ventilation

3.9

supralaryngeal airway connector

tubular feature of an **supralaryngeal airway** intended for connection to an breathing system or ventilation bag



3.10

ventilatory opening

opening in the **ventilatory pathway** intended for passage of ventilatory gases at or near the patient end

3.11

auxiliary ventilatory opening

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

3.12

ventilatory pathway

conduit through which the ventilatory gases pass

4 General requirements

This 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 Hazard Identification for Risk Assessment for an informative list of identified hazards.

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

Head and neck positions shall include at least a 30° change from neutral:

- a. flexion
- b. extension
- c. right and left rotation
- d. right and left lateral flexion (tilt)

Patient positions shall include at least:

- a. supine
- b. lateral
- c. Trendelenburg's (head down)
- d. Sitting

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

NOTE See also Annex A Rationale (informative) and Annex D, Hazard Identification for Risk Assessment (informative).

If clinical studies are performed, 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 Clinical investigation of medical devices for human subjects -- Part 1: General requirements, and ISO 14155-2 Clinical investigation of medical devices for human subjects -- Part 2: Clinical investigation plans.

NOTE See also Annex B (informative) Guideline for evaluating and documenting the clinical performance of supralaryngeal airways in human subjects.

4.2 The **supralaryngeal airway** shall, when transported, stored, installed, operated in normal use as intended, and maintained according to the instructions of the manufacturer, minimize safety hazards which could reasonably be foreseen, in normal and single-fault condition.

4.3 It is recognized that the manufacturer might not be able to follow all the processes identified in this standard for each constituent component of the **supralaryngeal airway**, such as proprietary components, subsystems of non-medical origin, and legacy devices. In this case, the manufacturer should take special

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account of the need for additional risk control measures.

4.4 Where requirements of this 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.

4.5 Test methods

The manufacturer may use type tests different from those detailed within this 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.

4.6 Acceptance criteria

Many of the test clauses within this standard establish acceptance criteria for performance aspects. These acceptance criteria shall always be met. When the manufacturer chooses to specify in the accompanying documents higher performance levels than those specified within this 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 – 6 shall be designated for the smallest to largest size devices. The transition size from pediatric to adult is size 3.
- c. Devices that encompass a range of sizes shall be marked with the corresponding range

5.1.2 Materials

Supralaryngeal airways, including **cuffs**, and connectors in their 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 hour contact devices. If the proposed contact duration is greater than 24 hours, biocompatibility tests shall include those tests for >24 hour duration.

NOTE See Annex E for Guidance on Materials and Design

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

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5.1.5 Sealing mechanism

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

5.1.5.2 Sealing mechanism shall produce no audible leak under a positive pressure of 10 cm/H₂O for a minimum of 3 seconds.

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

NOTE See also Annex A (informative) and Annex D Hazard Identification for Risk Assessment (informative).

If clinical studies are performed, 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 Clinical investigation of medical devices for human subjects -- Part 1: General requirements, and ISO 14155-2 Clinical investigation of medical devices for human subjects -- Part 2: Clinical investigation plans.

NOTE See also Annex B (informative).

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 inflation 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 -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 mL 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 instruments that will easily pass through the **ventilatory pathway** shall be determined. Instruments 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.

Compliance shall be determined by inspection.

5.2 Supralaryngeal airway connectors

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