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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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# Contents

Page

|  |           |
|--|-----------|
| Foreword.....  | iv        |
| Introduction.....  | v         |
| <b>1 Scope.....</b>  | <b>1</b>  |
| <b>2 Normative references.....</b>   | <b>1</b>  |
| <b>3 Terms and definitions.....</b>  | <b>1</b>  |
| <b>4 General requirements.....</b>   | <b>3</b>  |
| 4.1 General.....   | 3         |
| 4.2 Test methods.....  | 3         |
| <b>5 Materials.....</b>  | <b>3</b>  |
| 5.1 General.....   | 3         |
| 5.2 Biological safety testing.....   | 3         |
| 5.3 Guidance on materials specific to <i>supralaryngeal airways and connectors</i> .....                     | 3         |
| <b>6 Design requirements.....</b>  | <b>3</b>  |
| 6.1 General.....   | 3         |
| 6.2 Ventilation positions of use.....  | 3         |
| 6.3 Size designation.....  | 4         |
| 6.4 <i>Ventilatory openings</i> .....  | 4         |
| 6.5 Safeguards against collapse of the <i>ventilatory pathway</i> .....                                      | 4         |
| 6.6 <i>Seating mechanisms</i> .....  | 4         |
| 6.7 <i>Cuff inflation/deflation system</i> .....   | 5         |
| 6.8 Internal volume.....   | 5         |
| 6.9 Maximum device size.....   | 5         |
| 6.10 <i>Supralaryngeal airway connectors</i> .....   | 6         |
| 6.11 Cleaning, disinfection and sterilization.....   | 6         |
| <b>7 Requirements for <i>supralaryngeal airways and connectors</i> supplied sterile.....</b>                 | <b>6</b>  |
| <b>8 Packaging.....</b>  | <b>6</b>  |
| <b>9 Information supplied by the manufacturer.....</b>   | <b>6</b>  |
| 9.1 General.....   | 6         |
| 9.2 Marking on the <i>supralaryngeal airway</i> .....  | 6         |
| 9.3 Marking on <i>supralaryngeal airway</i> individual packs.....  | 7         |
| 9.4 Instructions for use.....  | 7         |
| <b>Annex A (informative) Rationale.....</b>  | <b>10</b> |
| <b>Annex B (informative) Evaluation and documentation of the clinical performance in human subjects.....</b> | <b>16</b> |
| <b>Annex C (normative) Test methods to determine kink resistance.....</b>                                    | <b>18</b> |
| <b>Annex D (informative) Hazard identification for risk management.....</b>                                  | <b>23</b> |
| <b>Annex E (informative) Guidance on materials and design.....</b>   | <b>27</b> |
| <b>Bibliography.....</b>   | <b>29</b> |

## 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at [www.iso.org/patents](http://www.iso.org/patents). ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment* Subcommittee SC 2, *Airway devices and related equipment*.

This second edition cancels and replaces the first edition (ISO 11712:2009), which has been technically revised.

The main changes are as follows:

- the format of this document has changed to align with ISO 18190; and
- conformity checks for each requirement have been added.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

A *supralaryngeal airway* is a medical device placed through the mouth, without passing through the vocal cords, intended to seal the supralaryngeal area to isolate the respiratory pathway from gases and liquids in the pharynx and to maintain airway patency to facilitate ventilation in anaesthetized or unconscious patients with or without delivery of anesthetic gases. Ventilation may be spontaneous, assisted or controlled. *Supralaryngeal airways* 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 document, as are the *connectors* inserted into the *machine end* of these devices.

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

The requirements of this document were developed using the hazard identification for risk assessment in [Annex D](#).

The requirements for testing and disclosure apply to *supralaryngeal airways* introduced to the market after the publication of this document.

This document is written following the format of ISO 18190. The requirements in this document take precedence over any conflicting requirements in ISO 18190.



# Anaesthetic and respiratory equipment — Supralaryngeal airways and connectors

## 1 Scope

NOTE There is guidance or rationale for this Clause in Annex [A.2](#).

**1.1** This document provides the essential requirements for the design of *supralaryngeal airways* and *connectors*. These devices are intended to provide a distinct respiratory pathway to the top of the larynx to provide an unobstructed airway in patients during spontaneous, assisted or controlled ventilation.

**1.2** This document 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 document.

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

**1.5** Flammability of airways, for example if used with certain flammable anesthetic gases, electrosurgical units or lasers, is a well-recognized hazard that is outside the scope of this document. (See [E.1.7](#)).

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 4135, *Anaesthetic and respiratory equipment — Vocabulary*

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

ISO 18190, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 18562-1, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, ISO 18190 and the following apply.