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Anaesthetic and respiratory equipment — Tracheal tubes and connectors

Matériel d'anesthésie et de réanimation respiratoire — Sondes trachéales et raccords

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Contents

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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 3.

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.

International Standard ISO 5361 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This first edition cancels and replaces previous editions of ISO 5361-1:1988, ISO 5361-2:1993, ISO 5361-3:1984, ISO 5361-5:1984 and ISO 7228:1993, which have been technically revised. The requirements of ISO 5361-4:1987, *Tracheal tubes — Part 4: Cole type,* have not been included in this revision because Cole type tubes are specialized tubes, and as such, are excluded from the scope of this International Standard.

Annexes A, B and C form a normative part of this International Standard.

Annex D is for information only.

Introduction

This International Standard specifies the dimensions, basic properties and method of size designation of the most commonly used types of tracheal tube made of plastics materials and/or rubber. Tubes with walls reinforced with metal or nylon, tubes with shoulders, tapering tubes and the many other types of tube devised for specialized applications are not specifically covered, although most may be classified by their inside diameter as required by this International Standard.

While the inside diameter has been specified for size reference, this International Standard requires that the outside diameter also be marked, since this information is of clinical importance.

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

Cuffed tracheal tubes can be characterized by a combination of the tube inside and outside diameters and by the cuff resting diameter.

For tubes intended for re-use, information on the cuff resting diameter is required to be marked on the package or insert but not on the tube itself. This is because re-use may alter the elastic properties, and thereby the diameter, of the cuff.

The relationship between the cuff and tracheal diameters dictates the intracuff pressure required to provide a seal. Excessive pressure on the tracheal wall may obstruct capillary blood flow.

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

A range of cuff designs is available to meet particular clinical requirements. This International Standard requires that the resting diameter of the cuff be marked on the unit package, as this information allows the clinician to match the product to the application.

Herniation in relation to cuffs is a term widely understood in clinical anaesthetic practice. It is used to describe a cuff which protrudes excessively at its patient end so that it partially or completely occludes the orifice at the bevel. Herniation may be due to a variety of causes, singly or in combination: these may include over-inflation of the cuff, traction of the tube when the cuff is inflated or deterioration of the material of the cuff.

It should be noted that although certain requirements for cuffs apply to tubes of sizes 2,0 to 4,5, cuffs are infrequently used on these smaller sizes of tube.

Flammability of tracheal tubes, for example if flammable anaesthetics, electrosurgical units or lasers are used, is a well-recognized hazard[1)] that is addressed by appropriate clinical management, outside the scope of this International Standard.

It is a requirement that tracheal tubes include length mark(s) in centimetres, measured from the patient end. It is recognized, however, that additional marks, easier to see during intubation, may assist the clinician in positioning the tracheal tube within the trachea. There is currently, however, no clear consensus on the optimum style and positioning of these marks and whether the positioning should differ with size of tube. Further clinical data is required in order to support inclusion of recommendations for these marks in a future revision of this International Standard.

1) See ISO/TR 11991.

Anaesthetic and respiratory equipment — Tracheal tubes and connectors

1 Scope

This International Standard specifies requirements for the dimensions, basic properties and method of size designation of the most commonly used types of oro-tracheal and naso-tracheal tube made of plastics materials and/or rubber (plain and cuffed), and requirements for tracheal tube connectors.

Specialized tubes are excluded from the scope of this International Standard.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International 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 International 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.*

EN 556:1994, *Sterilization of medical devices — Requirements for medical devices to be labelled "Sterile".*

3 Terms and definitions

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

3.1
angle of bevel
acute angle between the plane of the bevel and the longitudinal axis of the tracheal tube at the patient end

[ISO 4135:1995]

3.2
bevel
slanted portion at the patient end of the tracheal tube

[ISO 4135:1995]

3.3
cuff
inflatable balloon permanently attached around the tracheal tube near the patient end to provide an effective seal between the tube and the trachea

3.4
inflating tube
tube through which the cuff is inflated

[ISO 4135:1995]

3.5
inflation lumen
lumen within the wall of the tracheal tube for inflating the cuff

3.6
machine end
that end of a tracheal tube which is intended to project from a patient

[ISO 4135:1995]

3.7
machine end
that portion of the tracheal tube connector intended to mate with the breathing system of an anaesthetic machine or ventilator

3.8
Murphy eye
hole through the wall of a tracheal tube near the patient end and on the side opposite to the bevel

3.9
naso-tracheal tube
tracheal tube for insertion through the nose into the trachea

[ISO 4135:1995]

3.10
oro-tracheal tube
tracheal tube for insertion through the mouth into the trachea

[ISO 4135:1995]

3.11
patient end
that end of the tracheal tube which is intended to be inserted into the trachea

[ISO 4135:1995]

3.12
patient end
that end of the tracheal tube connector nearest to the patient, which is inserted into the tracheal tube.

3.13
pilot balloon
balloon fitted to the inflating tube to indicate inflation of the cuff

[ISO 4135:1995]

3.14
tracheal tube
tube designed for insertion through the larynx into the trachea to convey gases and vapours to and from the trachea

[ISO 4135:1995]

3.15
tracheal tube connector
tubular component that fits directly into a tracheal tube

[ISO 4135: 1995]

3.16
tracheal tube of the 'Magill' type
tracheal tube with a radius of curvature (as specified in 4.7)

4 General requirements for tracheal tubes and tracheal tube connectors

4.1 Size designation

The size of tracheal tubes and tracheal tube connectors shall be designated by the nominal inside diameter, expressed in millimetres, in accordance with Table 1 for tracheal tubes and Table 2 for tracheal tube connectors.

4.2 Dimensions

4.2.1 Tracheal tubes

4.2.1.1 The basic dimensions of tracheal tubes shall be in accordance with Table 1.

4.2.1.2 The actual inside diameter shall be the marked inside diameter subject to a tolerance of ± 0,15 mm for sizes 6,0 and smaller, or subject to a tolerance of ± 0,20 mm for sizes 6,5 and larger.

4.2.1.3 The actual outside diameter (OD) shall be the marked outside diameter (OD) subject to a tolerance of ± 0,15 mm for sizes 6,0 and smaller, or subject to a tolerance of ± 0,20 mm for sizes 6,5 and larger [see 7.2.1.1 b)].

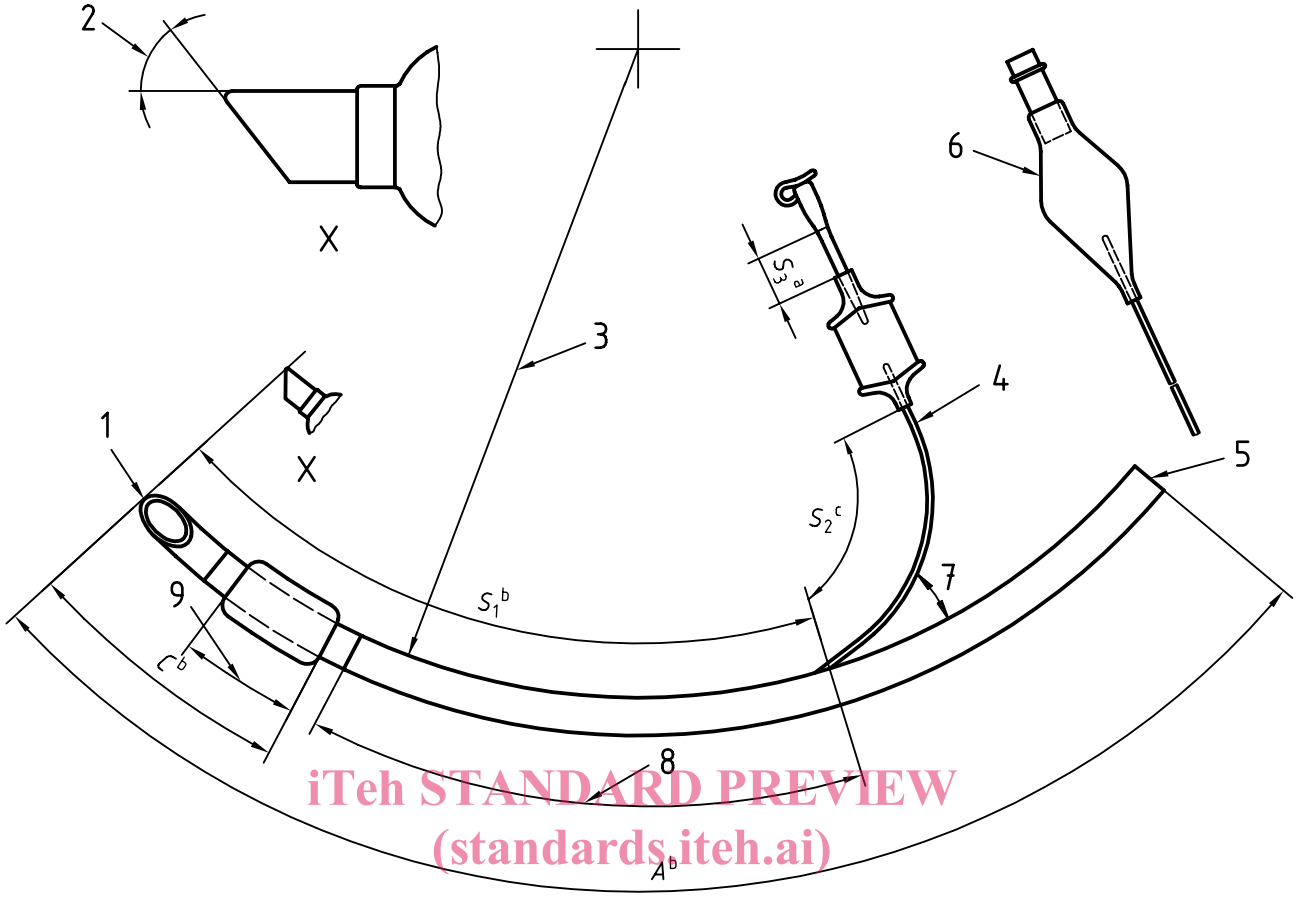
Table 1 — Basic dimensions of tracheal tubes

Dimensions in millimetres

Designated size (nominal inside diameter)	**Minimum length of tube** [see Figure 1 a) and b), dimension *A*]		**Maximum distance** *C* from the patient end of the tube to the machine end of the inflatable length of the cuff[b] [see Figure 1 a) and b)]	**Minimum distance** of point of separation of the inflating tube from the patient end of the tube [see Figure 1 a) and b), dimension S_1[a, b]]
	Nasal or oral/nasal	**Oral** [a]		
2,0	130	110	—	—
2,5	140	110	—	—
3,0	160	120	—	—
3,5	180	130	—	—
4,0	200	140	—	—
4,5	220	150	—	—
5,0	240	160	56	110
5,5	270	170	56	120
6,0	280	190	58	125
6,5	290	210	62	135
7,0	300	230	66	140
7,5	310	240	69	145
8,0	320	250	72	150
8,5	320	260	75	155
9,0	320	270	78	160
9,5	320	280	81	165
10,0	320	280	85	170
10,5	320	280	85	170
11,0	320	280	85	170

[a] Manufacturers desiring to market packaged sterile oral pre-cut tubes with connectors inserted may be guided by the tube lengths shown in the table. However, the user is cautioned that anatomical variations, conditions of use, length of tube inserted or other factors may well result in the use of a tracheal tube either too long or too short for a given patient. The necessity remains for expert clinical judgement in selecting the size and length of tracheal tubes.

[b] These values are not specified for cuffed tracheal tubes of sizes 4,5 or smaller because cuffed tubes of these sizes are infrequently used.



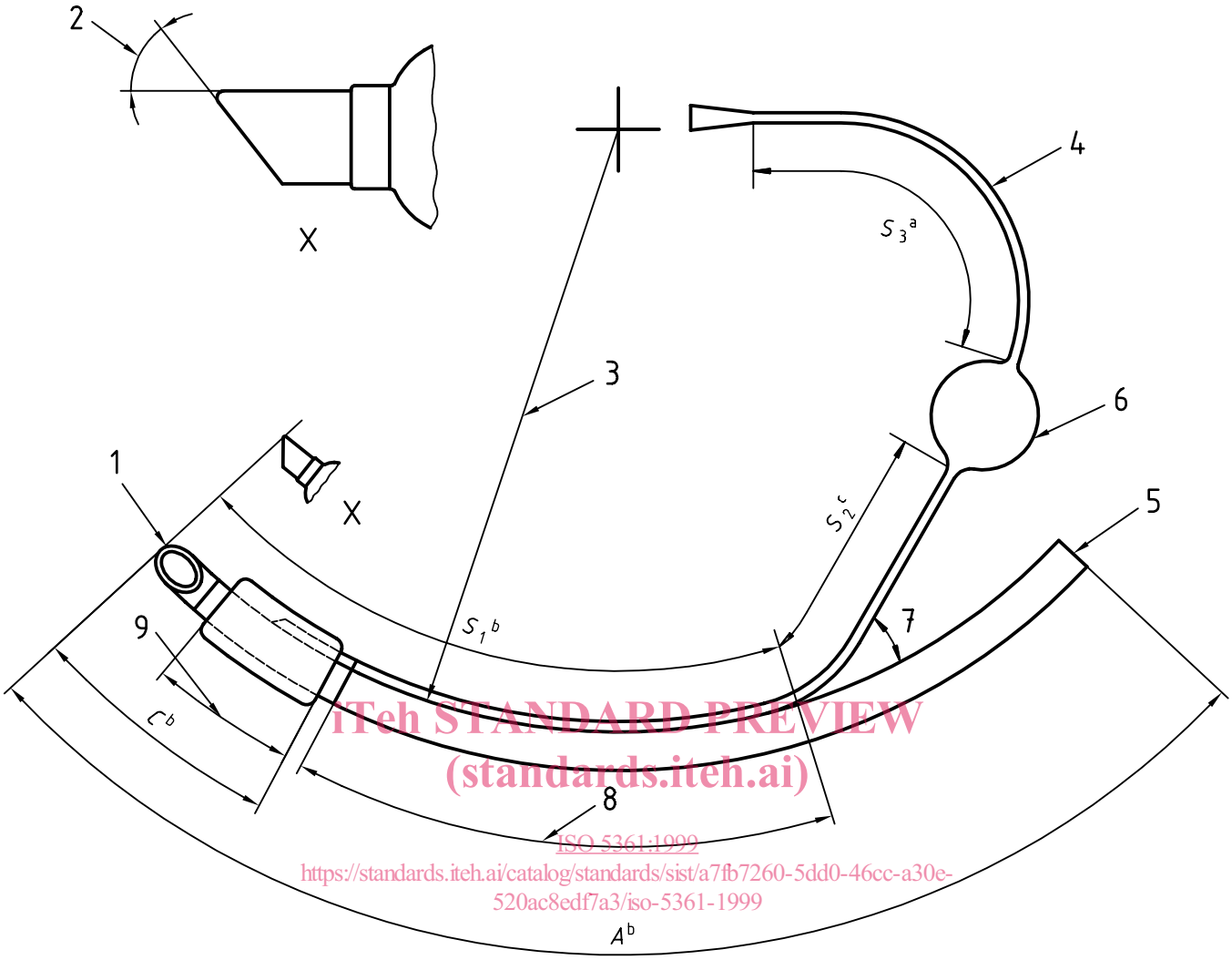
Key

1 Patient end
2 Angle of bevel (see 4.4)
3 Radius of curvature (see 4.7)
4 Inflating tube
5 Machine end
6 Alternative integral pilot balloon/valve assembly
7 Separating angle (see 4.6.2)
8 Region for marking size [see 7.2.1.1 f)]
9 Inflatable length of cuff

a See 4.6.6.
b See Table 1.
c Minimum value for $S_2 = A - S_1$.

a) Typical cuffed tracheal tube ('Magill' type)

Figure 1 — Cuffed tracheal tubes



Key

1 Patient end
2 Angle of bevel (see 4.4)
3 Radius of curvature (see 4.7)
4 Inflating tube
5 Machine end
6 Pilot balloon
7 Separating angle (see 4.6.2)
8 Region for marking size [see 7.2.1.1 f)]
9 Inflatable length of cuff

a See 4.6.6.
b See Table 1.
c Minimum value for $S_2 = A - S_1$.

b) Typical cuffed tracheal tube (“Magill” type), showing alternative design features

Figure 1 — Cuffed tracheal tubes

4.2.2 Tracheal tube connectors

4.2.2.1 The basic dimensions of tracheal tube connectors shall be in accordance with Table 2.

4.2.2.2 When a tracheal tube is supplied with a tracheal tube connector, the designated size of the connector shall be not less than that of the tracheal tube with which it is provided.