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ISO 5361

Fourth edition
2023-01

Anaesthetic and respiratory equipment — Tracheal tubes and connectors

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

Reference number
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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.

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 documents 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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 5361:2016), which has been technically revised.

The main changes are as follows:

— alignment with the general standard for airway devices ISO 18190;

— to provide additional requirements and design guidance for *tracheal tubes* designed for use in paediatric and neonatal patients;

— to clarify the requirements for speciality *tracheal tubes* such as *preformed tracheal tubes;*

— updating of references.

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.

Introduction

This document provides the essential performance and safety requirements of *tracheal tubes* and *tracheal tube connectors*. *Tracheal tubes* are intended to be inserted orally or nasally through the larynx into the trachea to convey gases and vapours to and from a patient's lungs during spontaneous, assisted or controlled ventilation for short or prolonged durations.

In addition, *tracheal tubes* with *cuffs* are intended to seal and protect the trachea from aspiration.

A variety of *cuff* designs are available to meet particular clinical requirements. *Cuff* performance requirements with associated test methods remain unchanged from the second edition.

Requirements for paediatric *tracheal tubes*, with and without *cuffs*, have been updated from the third edition to include new guidance on the design of *tracheal tubes* used in paediatric and neonatal patients. The maximum distance from the *patient end* of the *tracheal* tube to the *machine end* of the inflatable length of the *cuff* has been revised in this edition to minimise the *risk* of the inflatable length of the *cuff* aligning with the larynx of neonatal and paediatric patients.

Clinical considerations have also dictated the historical maximum distance from the *patient end* of the *tracheal* tube to the *machine end* of the inflatable length of the *cuff* be maintained for tracheal tubes designed for the general population. Anatomical abnormalities or disease states can require smaller tracheal tube sizes to be used in adult patients than would typically be appropriate. Because long *tracheal tubes*, sometimes of relatively narrow diameter, can be required, *tracheal tubes* designed to the historical specification should be readily available.

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

Kink resistance requirements with associated test methods to measure the ability of the shaft of the *tracheal tube* to resist collapse and avoid increased breathing resistance when bent or curved remain unchanged from the second edition.

Radiopacity requirements and test methods to characterize the visibility of *tracheal tubes* in X-rays used to determine proper placement of the tube remain unchanged from the second edition.

Where applicable a rationale for some of the requirements in this document are included in Annex A

The requirements of this document were developed using the hazard identification for *risk assessment* in Annex G.

Throughout this document the following print types are used:

— Requirements and definitions: roman type;

— Informative material appearing outside of tables, such as Notes, examples and references: smaller type. The normative text of tables is also in smaller type;

— *terms defined in Clause 3: italics.*

Anaesthetic and respiratory equipment — Tracheal tubes and connectors

1 Scope

This document provides specific requirements for the basic safety and essential performance for *oro-tracheal* and *naso-tracheal tubes* and *tracheal tube connectors*, *tracheal tubes* with walls reinforced with metal or plastic, *tracheal tubes* with *shoulders*, tapered *tracheal tubes*, *tracheal tubes* with means for suctioning, monitoring or delivery of drugs or other gases, and the many other types of *tracheal tubes* devised for specialized applications.

Tracheobronchial (including endobronchial) tubes (see ISO 16628), tracheostomy tubes (see ISO 5366), and supralaryngeal airways (see ISO 11712) are excluded from the scope of this document.

Tracheal tubes intended for use with flammable anaesthetic gases or agents, lasers, or electrosurgical equipment are outside the scope of this document.

NOTE 1 There is guidance or rationale for this clause contained in Annex A.2.

NOTE 2 ISO 11990-1, ISO 11990-2, and ISO 14408 deal with laser surgery of the airway.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 14971, *Medical devices — Application of risk management to medical devices*

ISO 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 18562 (all parts), *Biocompatibility evaluation of breathing gas pathways in healthcare applications*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ASTM F640-20, *Standard test methods for determining radiopacity for medical use*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, ISO 14971, ISO 18190 and the following apply:

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
Cole-type tracheal tube
tracheal tube combining a short *laryngo-tracheal portion* (3.5) of small diameter and a longer *oral portion* (3.9) of larger diameter with transition from one to the other resulting in a *shoulder* (3.12)

Note 1 to entry: See Figure 2.

3.2
cut line
point where a *tracheal tube* can be reduced to its minimum length

Note 1 to entry: The cut line on a cuffed *tracheal tube* is adjacent to the inflating tube separation point and towards the *machine end.*

3.3
glottic depth mark
indicator on the *tracheal tube* to assist in determining the tip insertion depth beyond the vocal cords (VC)

3.4
inflation lumen
lumen within the wall of the *tracheal tube* for inflating the *cuff*

3.5
laryngo-tracheal portion
portion of a *Cole-type tracheal tube* (3.1) of small diameter and extending from the *bevel* tip to the point at which there is an increase in the outside diameter

3.6
machine end of the tracheal tube connector
portion of the *tracheal tube connector* intended to mate with an anaesthetic breathing system (ABS) or ventilator breathing system (VBS)

3.7
Magill-type tracheal tube
subset of curved *tracheal tubes* with a particular radius (6.7.2) and having a particular *bevel* at the *patient end*

Note 1 to entry: See Figure 5.

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

Note 1 to entry: See Figure 7.

3.9
oral portion
portion of a *Cole-type tracheal tube* (3.1) of a larger diameter extending from the *machine end* to the point at which there is a decrease in the outside diameter

3.10
patient end of the connector
end of the *tracheal tube connector* intended to be inserted into the *tracheal tube*

3.11
preformed tracheal tube
subset of curved *tracheal tubes* with an acute radius of curvature intended to direct the *machine end* of the *tracheal tube* in a specific direction

Note 1 to entry: See Annex A.3 for rationale.

3.12
shoulder
portion of a *Cole-type tracheal tube* (3.1) at which transition from the *oral portion* (3.9) to the *laryngo-tracheal portion* (3.5) occurs

3.13
subglottic suction port
opening in the *tracheal tube*, proximal to the *machine end* of the inflatable portion of the *cuff* intended for the suctioning of secretions

4 General requirements

NOTE There is guidance or rationale for this clause contained in Annex A.4.

4.1 General

The requirements of ISO 18190:2016, Clause 4 shall apply.

Check conformance by inspection of the risk management file.

4.2 Safety

The manufacturer may use type tests different from those detailed within this document, if an equivalent degree of safety is obtained. Alternative test methods shall be validated against the test methods specified in this document.

5 Materials

NOTE There is guidance or rationale for this clause contained in Annex A.5.

5.1 General

The applicable requirements of ISO 18190:2016, Clause 5 shall apply.

5.2 Biological safety testing

NOTE There is guidance or rationale for this subclause contained in Annex A.6.

Material used to manufacture *tracheal tubes connectors* shall be tested and evaluated for biocompatibility of the breathing gas pathways as specified in the ISO 18562 series as appropriate.

Check conformance by inspection of the technical file.

5.3 Reuse requirements

Tracheal tubes and *tracheal tube connectors* marked for reuse shall be resistant to deterioration by the methods of cleaning, disinfection, and sterilization recommended by the manufacturer. The recommended method or methods of sterilization shall not produce material changes which will compromise the biological safety.

5.4 Flexibility

Tracheal tubes constructed from materials and at dimensions which enhance flexibility for the purpose of minimizing tracheal trauma, the *risks* associated with the flexibility of the tube and implication on the user's ability to insert the *tracheal tube* through the larynx into the trachea shall be assessed and documented.

Check conformance by inspection of the risk management file.

6 Design requirements

6.1 General

The applicable requirements of ISO 18190:2016, Clause 6 shall apply.

6.2 Size designation

The size of *tracheal tubes* and *tracheal tube connectors* shall be designated in accordance with Table 1 for *tracheal tubes*, Table 2 for *Cole-type tracheal tubes*, and Table 3 for *tracheal tube connectors*.

6.3 Dimensions

6.3.1 *Tracheal tubes*

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

NOTE There is guidance or rationale for Table 1 contained in Annex A.7.

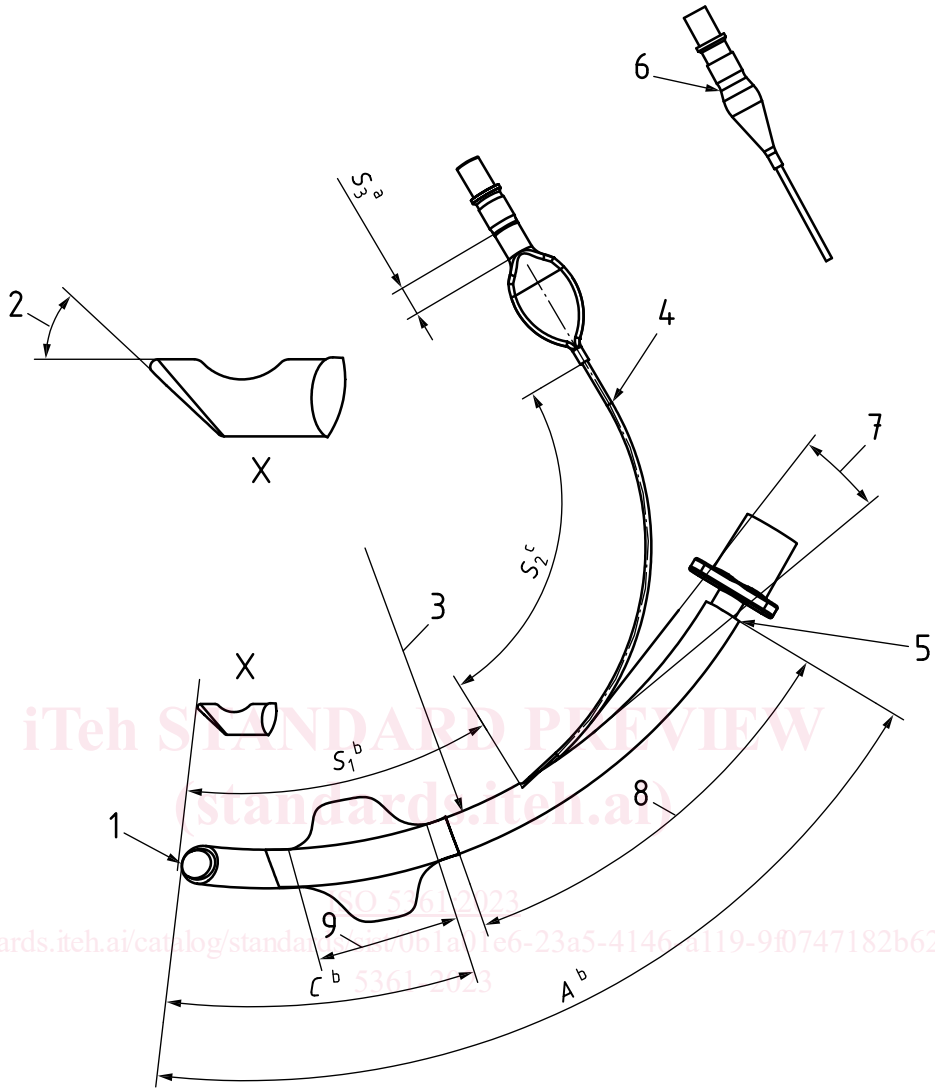
6.3.1.2 The basic dimensions of *Cole-type tracheal tubes* shall be in accordance with Table 2.

6.3.1.3 The designated size of the *tracheal tube* shall be subject to a tolerance of ±0,15 mm for the actual inside dimeter for sizes 6,0 and smaller, and subject to a tolerance of ±0,20 mm for sizes 6,5 and larger. The lumen of the *tracheal tube* should be essentially circular in a plane at right angles to the long axis. The maximum circular instrument diameter that can pass through the *tracheal tube* shall be disclosed to the user [see 9.5 j)].

6.3.1.4 For *tracheal tubes*, the marked outside diameter (OD) shall be the actual 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 (excluding any protuberance caused by a suction line, *cuff*, etc., if provided). For *Cole-type tracheal tubes*, the market outside diameter shall be the actual outside diameter of the *laryngo-tracheal portion* (OD).

6.3.1.5 For *Cole-type tracheal tubes*, the axial length of the outside surface of the *shoulder* region, S_1 - S_2 (see Figure 2), shall not exceed 4 mm for sizes up to and including size 3.

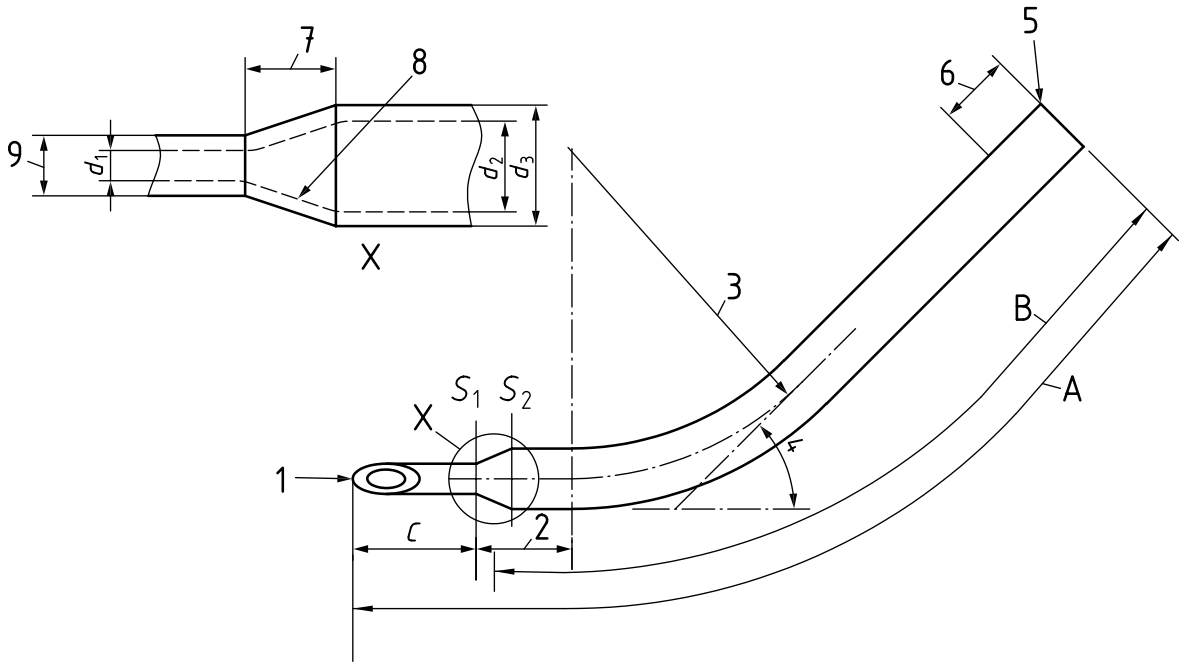
6.3.1.6 Dimensions A in Table 1 are not applicable for *preformed tracheal tubes*.



Key

1	*patient end*	7	separating angle
2	angle of the *bevel* (see 6.4)	8	region for marking size [see 3)]
3	radius of curvature (see 6.7)	9	inflatable length of *cuff*
4	*inflating tube*	a	See 6.6.9 and 6.6.10.
5	*machine end*	b	See Table 1.
6	alternative integral pilot balloon/valve assembly	c	Minimum value for $S_2 = A - S_1$.

Figure 1 — Typical *cuffed tracheal tube*



Key

1 *patient end*
2 maximum distance of start of curvature from beginning of taper S_1, 20 mm max. (see 6.7.3)
3 radius of curvature
4 angle of the curvature of the tube from the *machine end* to the *patient end*, (45 ± 15)° (see 6.7.4)
5 *machine end*
6 region for marking, 20 mm min. (see 6.7.4)
7 shoulder region for dimension S_1, S_2 (see 6.3.1.5)
8 smooth reduction of lumen
9 maximum outside diameter of the *laryngo-tracheal portion* that is marked (OD)

NOTE For dimensions A, B, C, d_1, d_2, and d_3, see Table 2.

Figure 2 — *Cole-type tracheal tube*

Table 1 — Basic dimensions of *tracheal tubes* (see Figure 1)

Dimensions in millimetres

Designated size	**Dimension *A* Minimum length of tube** (see Figure 1)		**Dimension *C*** (For *tracheal tubes* designed for a general patient population) **Maximum distance** from the *patient end* of the *tracheal tube* to the *machine end* of the inflatable length of the *cuff* (see Figure 1)	**Dimension *C*** [b] (For *tracheal tubes* designed specifically for neonatal and paediatric patients) **Maximum distance** from the *patient end* of the *tracheal tube* to the *machine end* of the inflatable length of the *cuff* [a] (see Figure 1)	**Dimension S_1** **Minimum distance** of point of separation of the *inflating tube* from the *patient end* of the tube (see Figure 1) Orotracheal Intubation / Nasotracheal Intubation
	Nasal or oral/nasal	**Oral**			
2,0	130	110	-	-	-
2,5	140	110	-	-	-
3,0	160	120	33	24	121/147
3,5	180	130	35	27	127/154
4,0	200	140	41	31	136/163
4,5	220	150	45	35	148/176
5,0	240	160	56	41	160/189
5,5	270	170	56	48	172/202
6,0	280	190	58	46	185/215
6,5	290	210	62	52	196/227
7,0	300	230	66	59	209/240
7,5	310	240	69	-	221/253
8,0	320	250	72	-	221/253
8,5	320	260	75	-	221/253
9,0	320	270	78	-	221/253
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] Clinical literature suggests that a shorter Dimension *C* can decrease likelihood of endobronchial intubations for paediatric patients (see Annex A and Annex B).

NOTE There is guidance or rationale for Table 1 contained in Annex A.7.

Table 2 — Basic dimensions of *Cole-type tracheal tubes* (see Figure 2)

Dimensions in millimetres

Designated size[a] (tracheal portion) d_1	**Length of *laryngo-tracheal portion*** C		**Oral portion** B			**Overall length** A	
			Inside diameter d_2		**Outside diameter of the *oral portion*** d_3		
	min	max	min	max	max	min	max
1,5	20	24	3,9	5,0	7,0	110	140
1,75	20	24	4,1	5,0	7,0	110	140
2,0	20	25	4,2	5,0	7,0	120	140
2,25	25	30	4,3	5,0	7,0	120	140
2,5	25	30	4,3	5,0	7,5	125	140
3,0	25	30	4,3	5,0	7,5	125	140
3,5	25	35	5,0	6,0	9,5	130	150
4,0	25	35	5,5	6,5	9,5	140	160
4,5	28	38	6,5	7,0	10,5	150	170

[a] For convenience in size designation, the second decimal place can be omitted.

6.3.2 *Tracheal tube connectors*

NOTE There is guidance or rationale for this subclause contained in Annex A.8.

6.3.2.1 The basic dimensions of the *patient end* of the *tracheal tube connector* (see Figures 3 and 4) shall be in accordance with Table 3. For curved *tracheal tube connectors* (Figure 4), angle θ shall be greater than 45°.

6.3.2.2 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 of the *tracheal tube* with which it is provided.

6.3.2.3 The inside diameter of a curved or angled *tracheal tube connector* shall be not less than 80 % of the designated size, and the corresponding cross-sectional area shall not be reduced by more than 10 %.

6.3.2.4 A suction port, if provided, shall be designed so that its closure does not obstruct or narrow the lumen of the *tracheal tube connector*.

6.3.2.5 The *machine end* of the *tracheal tube connector* shall be a 15 mm conical connector cone complying with ISO 5356-1.

6.3.2.6 The inside diameter of the (conical) *machine end* of the *tracheal tube connector* shall be not less than that allowed by Table 3 for the *patient end*. Any transition in the inside diameter shall be tapered to permit an adequate lead-in for smooth passage of a suction catheter.

6.3.2.7 The opening at the *patient end* shall have a plane at (90 ± 5)° to the long axis of the *patient end* of the *tracheal tube connector*.

6.3.2.8 The *tracheal tube connector* shall be retained by the *tracheal tube* under typical use conditions. The *risk* associated with accidental disconnection of the *tracheal tube connector* from the *tracheal tube* shall be addressed through the *risk assessment* process.

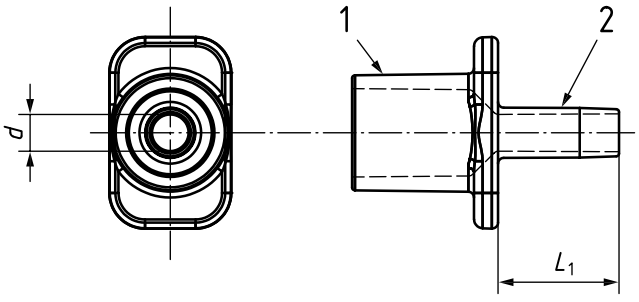
Check conformance by inspection of the risk management file.

Table 3 — *Tracheal tube connectors* — Size range and basic dimensions of *patient end*

Dimensions in millimetres

Designated size (nominal inside diameter)	**Inside diameter** *d* (±0,15)	**Straight *connectors* — minimum dimension**, L_1 (effective length)[a] (Figure 3)	**Curved *connectors* — minimum dimension**, L_2 (effective length)[a] (Figure 4)
2,0	2,0	9	—
2,5	2,5	9	—
3,0	3,0	9	—
3,5	3,5	11	—
4,0	4,0	11	—
4,5	4,5	12	—
5,0	5,0	12	—
5,5	5,5	13	10
6,0	6,0	13	10
6,5	6,5	16	10
7,0	7,0	16	10
7,5	7,5	16	10
8,0	8,0	16	10
8,5	8,5	16	10
9,0	9,0	16	10
9,5	9,5	16	10
10,0	10,0	16	10
10,5	10,5	16	10
11,0	11,0	16	10

[a] The effective length of the *patient end* of a *tracheal tube connector* is that length available for insertion into the *tracheal tube*.



Key

1 *machine end*

2 *patient end*

L_1 effective length of the *patient end* of the *tracheal tube connector* (see Table 3)

d internal diameter of a *tracheal tube connector*

Figure 3 — Example of a Straight *tracheal tube connector*