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Tracheal tubes and connectors

Trachealtuben und Verbindungsstücke

Tubes trachéaux et raccords

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Tracheal tubes and connectors

Tubes trachéaux et raccords

Trachealtuben und Verbindungsstücke

This European Standard was approved by CEN on 2 March 1998 and includes Amendment 1 approved by CEN on 23 July 2009.

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Foreword

This document (EN 1782:1998+A1:2009) has been prepared by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, the secretariat of which is held by BSI.

This European Standard is based on:

ISO 5361-1, *Tracheal tubes – Part 1: General requirements*

ISO 5361-2, *Tracheal tubes – Part 2: Oro-tracheal and naso-tracheal tubes of Magill type (plain and cuffed)*

ISO 5361-3, *Tracheal tubes – Part 3: Murphy type*

ISO 5361-5, *Tracheal tubes – Part 5: Requirements and methods of test for cuffs and tubes*

ISO 7228, *Tracheal tube connectors*

prepared by the International Organisation for Standardisation (ISO).

This European Standard differs from ISO 7228 and the ISO 5361 series in that it permits the use of 8,5 mm connectors for the smaller sizes of tracheal tubes.

Annexes A, B and C are normative and form part of this European Standard. Annexes D, E and ZA are for information only.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document includes Amendment 1, approved by CEN on 2009-07-23.

This document supersedes EN 1782:1998.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ▌A1〉 〈A1▐.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

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

While the inside diameter has been specified for size designation, the outside diameter should 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, can 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 should 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 of cuff and tracheal diameters dictates the intra-cuff pressures required to provide a seal. Excessive pressure on the tracheal wall can obstruct capillary blood flow.

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

WARNING — Whatever type of cuff is used, it is the responsibility of the user to ensure that at any particular time it is inflated with no more than the minimum amount of air required to provide an effective seal at the desired lung inflation pressure.

A range of cuff designs is available to meet particular clinical requirements. The resting diameter of the cuff should 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 can be due to a variety of causes, singly or in combination: these can 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 would apply to tubes with an inside diameter of 2,0 to 4,5, cuffs are infrequently used on these smaller sizes of tubes.

Tracheal tube connectors should incorporate 8,5 mm or 15 mm male conical connectors in accordance with EN 1281-1, in order to mate with the appropriate female conical connector of the patient connection port of the breathing system of an anaesthetic machine or ventilator. The designated size of each tracheal tube connector should be not less than that of the tracheal tube with which it is designed to fit, thereby avoiding unnecessary restriction of the gas flow and minimising the risk of inadvertent disconnection.

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

1 Scope

This European Standard specifies requirements for oro-tracheal and naso-tracheal tubes (plain and cuffed) made of plastics materials and/or rubber and requirements for tracheal tube connectors. Specialized tubes are excluded from the scope of this standard.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the cited publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 556:1994, *Sterilization of medical devices – Requirements for medical devices to be labelled 'sterile'*

EN 868-1, *Packaging materials and systems for medical devices which are to be sterilized – Part 1: General requirements and test methods*

EN 980, *Graphical symbols for use in the labelling of medical devices*

EN 1281-1, *Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets*

EN 20594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements (ISO 594-1:1986)*

EN 30993-1, *Biological evaluation of medical devices – Part 1: Guidance on selection of tests (ISO 10993-1:1992 – Technical Corrigendum 1:1992)*

3 Definitions

For the purposes of this European Standard, the following 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 [EN ISO 4135:1996]

3.2
bevel
slanted portion at the patient end of the tracheal tube [EN ISO 4135:1996]

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

1) See ISO/TR 11991.

3.4
inflating tube
tube through which the cuff is inflated [EN ISO 4135:1996]

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

3.6
machine end

a) that end of a tracheal tube which is intended to project from a patient [EN ISO 4135:1996]; or

b) that portion of a tracheal tube connector intended to mate with the breathing system of an anaesthetic machine or ventilator.

3.7
Murphy eye
hole through the wall of a tracheal tube near the patient end and on the side opposite to the bevel

3.8
naso-tracheal tube
tracheal tube for insertion through the nose into the trachea [EN ISO 4135:1996]

3.9
oro-tracheal tube
tracheal tube for insertion through the mouth into the trachea [EN ISO 4135:1996]

3.10
patient end

a) that end of a tracheal tube which is intended to be inserted into the trachea [EN ISO 4135:1996]; or

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

3.11
pilot balloon
balloon fitted to an inflating tube to indicate inflation of a cuff [EN ISO 4135:1996]

3.12
tracheal tube
tube designed for insertion through the larynx into the trachea to convey gases and vapours to and from the trachea [EN ISO 4135:1996]

3.13
tracheal tube connector
tubular component that fits directly into a tracheal tube [EN ISO 4135:1996]

3.14
tracheal tube of the "Magill" type
tracheal tube with a radius of curvature (see 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 designed 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 size 6,0 and smaller, or subject to a tolerance of ± 0,20 mm for size 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 size 6,0 and smaller, or subject to a tolerance of ± 0,20 mm for size 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 A (see figures 1 a) and 1 b))		Maximum distance C from the patient end of the tube to the machine end of the inflatable length of the cuff [2]	Minimum distance of point of separation of the inflating tube from the patient end of the tube dimension S_1 [1) 2)] (see figures 1 a) and 1 b))
	Nasal or oral/nasal	Oral [1]		-
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	115
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	320	280	85	170
10,5	320	280	85	170
11,0	320	280	85	170

[1] 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 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.

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

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.

4.2.2.3 The minimum inside diameter of a curved or angled 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 %.

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

NOTE The connector can be straight, curved or angled. If curved or angled, the connector can incorporate a suction port.

4.2.2.5 The machine end of a tracheal tube connector of size 6,0 or smaller shall be an 8,5 mm or 15 mm male conical connector complying with EN 1281-1. The machine end of a tracheal tube connector of size 6,5 or larger shall be a male 15 mm conical connector complying with EN 1281-1. The inside diameter of the (conical) machine end shall be not less than that allowed by table 2 for the patient end. Any transition in inside diameter shall be tapered to give an adequate lead-in for smooth passage of a suction catheter.

4.2.2.6 The basic dimensions of the patient end (see figures 4 and 5) of the connector shall be in accordance with table 2.

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

Table 2 — 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)[1)] (figure 4)	Curved connectors – minimum dimension l_2 (effective length)[1)] (figure 5)
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	8
6,0	6,0	13	8
6,5	6,5	16	8
7,0	7,0	16	8
7,5	7,5	16	8
8,0	8,0	16	8
8,5	8,5	16	8
9,0	9,0	16	8
9,5	9,5	16	8
10,0	10,0	16	8
10,5	10,5	16	8
11,0	11,0	16	8

[1)] The effective length of the patient end of tracheal tube connectors is that length available for insertion into the tracheal tube.