SLOVENSKI STANDARD
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Traheostomske cevke - 2. del: Cevke, ki se uporabljajo pri otrocih

Tracheostomy tubes - Part 2: Pediatric tubes

Tracheotomietuben - Teil 2: Pädiatrische Tuben

Tubes de trachéostomie - Partie 2: Tubes pédiatriques

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English version

Tracheostomy tubes - Part 2: Paediatric tubes

Tubes de trachéostomie - Partie 2: Tubes pédiatriques

Tracheotomietuben - Teil 2: Pädiatrische Tuben

This European Standard was approved by CEN on 1997-01-27. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart,36 B-1050 Brussels

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by August 1997, and conflicting national standards shall be withdrawn at the latest by June 1998.

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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

This European Standard applies to tracheostomy tubes and has been prepared in two Parts. This Part addresses tubes for paediatric use; Part 1 specifies requirements for tracheostomy tubes with an inside diameter of 6,5 mm or greater for adult use. This Part of this European Standard differs from Part 1 in that it does not require the connector to be permanently attached to the tube.

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

Introduction

This European Standard is concerned with the basic requirements and method of size designation of tracheostomy tubes made of plastics materials and/or rubber.

This Part of this European Standard specifies requirements for paediatric tracheostomy tubes with an inside diameter from 2,0 mm to 6,0 mm.

Paediatric tracheostomy tubes are primarily intended for use with infants and children who may require anaesthesia, artificial ventilation, relief of upper airway obstruction or other respiratory therapy.

An infant or child differs from an adult, not only in size but especially with regard to airway anatomy and respiratory physiology; thus airway equipment for paediatric patients differs from that for adults in size and also in basic design. It should be noted that, although this Part of this European Standard specifies some requirements for cuffs, cuffs are seldom provided on the smaller sizes of paediatric tubes.

This Part of this European Standard specifies requirements for those characteristics of tracheostomy tubes that can be standardized and which are important for patient safety. It does not require the connector to be permanently attached to the tube, as this may be impractical with infants and small children. Other acceptable methods of connecting these components are available and this standard makes provision for them. This Part of this European Standard does not limit the range of tube designs needed to match the variety of paediatric anatomy, lesions and space limitations encountered.

The method of describing tube dimensions and configuration has been devised with the aim of assisting the clinician in the selection of a suitable tube to conform as far as possible to a particular patient's anatomy. Size is designated by inside diameter, which is important because of its relation to resistance to gas flow. Because the stomal and tracheal diameters are important when selecting tubes, it is considered essential that the outside diameter should be stated for each size of tube.

A tracheostomy tube may increase resistance to gas flow. For tubes with a given outside diameter, differences in wall thickness have a major influence on the resistance to gas flow, especially in the smaller sizes of paediatric tracheostomy tubes.

Flammability of tracheostomy tubes, for example if flammable anaesthetics, electrosurgical units or lasers are used in oxidant-enriched atmospheres, is a well-recognized hazard[1)] which is addressed by appropriate clinical management, which is outside the scope of this standard.

[1)] See ISO/TR 11991

1 Scope

This Part of this European Standard specifies requirements for paediatric tracheostomy tubes made of plastics materials and/or rubber having inside diameters from 2,0 mm to 6,0 mm. Requirements for paediatric tracheostomy tube connectors and adaptors are also specified. Specialized tracheostomy 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 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	Sterilization of medical devices - Requirements for medical devices to be labelled 'STERILE'
prEN 868-1	Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods
EN 980	Terminology, symbols and information provided with medical devices - Graphical symbols for use in the labelling of medical devices
prEN 1281-1	Anaesthetic and respiratory equipment - conical connectors - Part 1: Cones and sockets
EN 1282-1 : 1996	Tracheostomy tubes - Part 1: Tubes for use in adults
prEN 1782	Tracheal tubes and connectors
EN 20594-1 : 1993	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 Part of the standard, the definitions given in EN 1282-1, together with the following definitions, apply:

3.1 paediatric tracheostomy tube: Tube designed for insertion into the trachea of an infant or child through a tracheostomy.

3.2 paediatric tracheostomy tube connector: Tubular component which fits directly into the paediatric tracheostomy tube.

3.3 machine end of paediatric tracheostomy tube connector: End of the component nearest the machine which is intended to mate with the breathing system of an anaesthetic machine or lung ventilator.

3.4 patient end of paediatric tracheostomy tube connector: End of the component nearest the patient which is inserted into the paediatric tracheostomy tube.

3.5 adaptor: Specialized connector to establish functional continuity between otherwise disparate or incompatible components.

4 Size designation and dimensions

4.1 Designation of the size of tube

4.1.1 The size of a tracheostomy tube (outer tube) shall be designated by the nominal inside diameter (ID) of the tube expressed in millimetres, as measured at the minimum diameter, in accordance with table 1, excluding any encroachment allowed by 6.7.1.

4.1.2 For tracheostomy tubes provided with an inner tube to which is attached an 8,5 mm or 15 mm male conical connector complying with the requirements of prEN 1281-1 (see 6.1a)), the size shall be designated by the nominal inside diameter (ID) of the inner tube expressed in millimetres in accordance with table 1.

Table 1: Size designation, inside diameter and tolerances of paediatric tracheostomy tubes

Dimensions in millimetres

Designated size	Inside diameter and tolerance
2,0	$2{,}0\ ^{+0{,}2}_{0}$
2,5	$2{,}5\ ^{+0{,}2}_{0}$
3,0	$3{,}0\ ^{+0{,}2}_{0}$
3,5	$3{,}5\ ^{+0{,}2}_{0}$
4,0	$4{,}0\ ^{+0{,}2}_{0}$
4,5	$4{,}5\ ^{+0{,}3}_{0}$
5,0	$5{,}0\ ^{+0{,}3}_{0}$
5,5	$5{,}5\ ^{+0{,}3}_{0}$
6,0	$6{,}0\ ^{+0{,}3}_{0}$

4.2 Outside diameter

4.2.1 The outside diameter (OD) of sections A and C (see figure 1) of the tube, other than at the cuff if provided, shall be expressed in millimetres to the nearest 0,1 mm.

NOTE: The marked outside diameter relates to that portion of the tube intended to be within the wall and lumen of the trachea.

4.2.2 The actual outside diameter of section A, other than at the cuff if provided, shall be the marked outside diameter subject to a tolerance of $\pm$ 0,2 mm.

4.2.3 The actual outside diameter of section C shall be the marked outside diameter subject to a tolerance of $\pm$ 0,5 mm.

4.3 Length

4.3.1 The centre-line length (dimension A + B + C in figure 1) shall be measured from the patient side of the neck-plate to the patient end including the bevel, if present (see figure 1), and expressed in millimetres.

4.3.2 The actual centre-line length (dimension A + B + C in figure 1) shall be the marked length subject to a tolerance of ± 1,5 mm for tubes with a marked inside diameter of less than 4,5 mm, or subject to a tolerance of ± 2 mm for tubes with a marked inside diameter of 4,5 mm or greater.

4.3.3 For tubes with an adjustable neck-plate, the range of measurements for centre-line length (see figure 1) shall be expressed in millimetres.

4.3.4 Dimensions A, B and C shall be expressed in millimetres (see figure 1 a).

NOTE: Dimensions A and/or B can be, or approach, zero.

4.4 Angle θ

The angle θ (see figure 1) shall be expressed in degrees.

5 Materials

Tracheostomy tubes, including cuffs and tracheostomy tube connectors and/or adaptors provided with the tube, in their ready-for-use state after any preparation for use recommended by the manufacturer, shall satisfy appropriate biological safety testing, as indicated in EN 30993-1.

NOTE: See annex C for guidance on materials and design.

6 Design and finish

6.1 Machine end

The machine end of a paediatric tracheostomy tube shall:

a) have a permanently attached 8,5 mm or 15 mm male conical connector complying with the requirements of prEN 1281-1; or

NOTE: In this context, permanently attached means it does not become detached when subject to the forces described in the test method of annex A.

b) accept a paediatric tracheostomy tube connector in accordance with 6.2; or

c) mate with an adaptor in accordance with 6.3.

6.2 Paediatric tracheostomy tube connector

6.2.1 The nominal size of a paediatric tracheostomy tube connector shall be designated by its inside diameter in accordance with table 2.

NOTE: A connector is intended to fit a tracheostomy tube of the same designated size.

6.2.2 The connector supplied with a tracheostomy tube shall have an inside diameter not less than the inside diameter of that tube as stated by the manufacturer (see 8.1 a)).

6.2.3 The machine end shall be an 8,5 mm or 15 mm male conical connector complying with prEN 1281-1. The inside diameter of the conical connector at the machine end shall be not less than that allowed by table 2 for the patient end.

6.2.4 Any transition from one inside diameter to another shall be tapered to give an adequate lead-in for passage of a suction catheter.

6.3 Adaptor

6.3.1 If supplied with the tube (see 6.1 c)), the adaptor shall have at its machine end, an 8,5 mm or 15 mm male conical connector complying with the requirements of prEN 1281-1.

6.3.2 Any transition from one inside diameter to another shall be tapered to give an adequate lead-in for passage of a suction catheter.