SLOVENSKI STANDARD
SIST EN 1282-1:2000

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Anestezijska in dihalna oprema - Traheostomske cevke - 1. del: Cevke, ki se uporabljajo pri odraslih

Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes for use in adults

Anästhesie- und Beatmungsgeräte - Tracheotomietuben - Teil 1: Tuben zur Anwendung bei Erwachsenen

Matériel respiratoire et d'anesthésie - Tubes de trachéostomie - Partie 1: Tubes pour adultes

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English version

Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes for use in adults

Matériel respiratoire et d'anesthésie - Tubes de trachéostomie - Partie 1: Tubes pour adultes

Anästhesie- und Beatmungsgeräte - Tracheotomietuben - Teil 1: Tuben zur Anwendung bei Erwachsenen

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CEN

European Committee for Standardization
Comité Européen de Normalisation
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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of an identical text or by endorsement, at the latest by April 1997, and conflicting national standards shall be withdrawn at the latest by June 1998.

This European Standard is based on ISO 5366-1: 1986, "Tracheostomy tubes - Part 1: Connectors", and ISO 5366-2: 1985 "Tracheostomy tubes - Part 2: Basic requirements". It is one of two parts dealing with tracheostomy tubes and connectors. EN 1282-2 specifies requirements for paediatric tracheostomy tubes made of plastics materials and/or rubber.

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 Directives, see informative annex ZA, which is an integral part of this standard.

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

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.

Introduction

EN 1282-1 is one of a series dealing with anaesthetic equipment and lung ventilators, and is concerned with the basic requirements and method of size designation of tracheostomy tubes made of plastics materials and/or rubber. Specialized tubes, for example those without a connector at the machine end intended for spontaneously breathing patients, and those with reinforced walls or tubes made of metal are excluded from the scope of this European Standard.

This Part of EN 1282 specifies requirements for tracheostomy tubes with an inside diameter of 6,5 mm or greater. EN 1282-2 specifies requirements for tracheostomy tubes with an inside diameter from 2,0 to 6,0 mm for paediatric use.

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 was considered essential that the outside diameter should be stated for each size of tube.

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

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.

A range of cuff designs is available to meet the particular clinical requirements. This Part of EN 1282 requires that the resting diameter of the cuff is marked on the unit package as this information allows the clinician to match the product to the application.

A 15 mm male conical connector in accordance with prEN 1281-1 should be used for tracheostomy tubes, as for tracheal tubes, to ensure compatibility with the breathing system of an anaesthetic machine or ventilator.

The tracheostomy tube connector should be permanently attached to the tracheostomy tube to prevent inadvertent disconnection of the connector from the tube.

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)] that is addressed by appropriate clinical management, and is outside the scope of this standard.

[1)] See ISO/TR 11991

1 Scope

This Part of EN 1282 specifies requirements for tracheostomy tubes made of plastics materials/and or rubber having inside diameters of 6,5 mm or greater. Such tubes are primarily designed for patients who require anaesthesia, artificial ventilation or other respiratory support, but need not be restricted to these uses. This standard does not apply to specialized tubes.

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: 1994	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
prEN 1782	Tracheal tubes and connectors
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 tracheostomy tube: Tube designed for insertion into the trachea through a tracheostomy. (EN ISO 4135: 1996)

NOTE: See figures 1a and 1b for an illustration of a typical tracheostomy tube and the associated nomenclature.

3.2 machine end:

a) That end of the tracheostomy tube which is intended to project from the neck of a patient;

or

b) That end of the connector or the adaptor intended to mate with the breathing system of an anaesthetic machine or ventilator. (EN ISO 4135: 1996)

3.3 patient end: That end of the tracheostomy tube which is intended to be inserted into the trachea. (EN ISO 4135: 1996)

3.4 centre-line length: Distance from the patient side of the neck-plate to the patient end along the centre-line (see figure 2).

NOTE: If the neck-plate is adjustable, the centre-line length is variable.

3.5 outer tube: That part of the tracheostomy tube which is normally in contact with the tissues. (EN ISO 4135: 1996)

3.6 inner tube: Tube which fits closely to the inside contours of the outer tube (i.e. a tracheostomy tube). (EN ISO 4135: 1996)

3.7 cuff: Inflatable balloon fitted near the patient end of the tracheostomy tube to provide an effective seal between the tube and the trachea. (EN ISO 4135: 1996)

3.8 inflating tube: Tube through which a cuff is inflated. (EN ISO 4135: 1996)

3.9 pilot balloon: Balloon fitted to an inflating tube to indicate inflation of a cuff. (EN ISO 4135: 1996)

3.10 neck-plate; shield: That part of a tracheostomy tube which approximates to the contour of a patient's neck and is used to secure a tube in position. (EN ISO 4135: 1996)

3.11 introducer; obturator: Specially adapted stylet to facilitate the introduction of the outer tube into the trachea. (EN ISO 4135: 1996)

3.12 bevel: Slanted portion at the patient end of tracheostomy tube
(EN ISO 4135:1996)

3.13 3.14 angle of bevel: Acute angle between the plane of the bevel and the longitudinal axis of the tracheostomy tube at the patient end. (EN ISO 4135: 1996)

4 Size designation and dimensions

4.1 Inside diameter

4.1.1 The size of the tracheostomy tube (outer tube) shall be designated by the nominal inside diameter (ID) of the tube expressed in millimetres, as measured at the minimum inside diameter, in accordance with table 1, excluding any encroachment allowed by 6.5.1.

4.1.2 For tracheostomy tubes with the conical connector permanently attached to the inner tube, 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 of tracheostomy tubes - Dimensions and tolerances

Dimensions in millimetres

Designated size	Inside diameter and tolerance
6,5	6,5 ± 0,2
7,0	7,0 ± 0,2
7,5	7,5 ± 0,2
8,0	8,0 ± 0,2
8,5	8,5 ± 0,2
9,0	9,0 ± 0,2
9,5	9,5 ± 0,2
10,0	10,0 ± 0,2
10,5	10,5 ± 0,2
11,0	11,0 ± 0,2

4.2 Outside diameter

4.2.1 The outside diameter (OD) of sections A and C (see figure 2) of the tube, other than at the cuff, if provided, shall be expressed in millimetres to the nearest 0,1 mm.

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

4.2.2 The actual outside diameter of section A (see figure 2) other than at the cuff, if provided, shall be the marked outside diameter subject to a tolerance of ± 0,2 mm.

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

4.3 Length

4.3.1 The centre-line length (dimensions A + B + C in figure 2) shall be measured from the patient side of the neck-plate to the patient end including the bevel, if present, and expressed in millimetres.

4.3.2 The actual centre-line length (dimensions A + B + C in figure 2) shall be the marked centre-line length subject to a tolerance of ± 2 mm.

4.3.3 For tubes with an adjustable neck-plate, the range of measurements for centre-line length (see figure 2) shall be expressed in millimetres.

4.3.4 Dimensions A, B and C shall be expressed in millimetres (see figure 2).

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

4.4 Angle θ

The angle θ (see figure 2) shall be expressed in degrees.

5 Materials

Tracheostomy tubes, including cuffs and tracheostomy tube connectors, in their ready-to-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

6.1.1 Tracheostomy tubes shall have at the machine end a permanently attached male 15 mm conical connector in accordance with prEN 1281-1.

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.

6.1.2 The inside diameter of the conical connector at the machine end shall be not less than the designated inside diameter of the tube to which it is attached.

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

6.1.4 When tested in accordance with annex A the connector shall not move longitudinally relative to the tube.