SLOVENSKI STANDARD
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Ustnožrelne (orofaringealne) dihalne cevke

Oropharyngeal airways

Oropharyngealtuben

Canules oro-pharyngées

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ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

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English version

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Canules oro-pharyngées

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This European Standard was approved by CEN on 16 January 1998.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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 is based on the reference standard ISO 5364, Oropharyngeal airways.

It differs from ISO 5364 primarily in that it introduces a limit and test for resistance to distortion which is relevant to the ability of the oropharyngeal airway to assist in keeping the base of the patient's tongue in a forward position while it is in use.

It also introduces a limit and test for resistance to collapse of the buccal end, if bitten by the patient. This is relevant to the ability of the oropharyngeal airway to maintain a patent passage for gases and for passing a suction catheter.

This European Standard also differs from ISO 5364 in that it excludes metal airways because of their particular association with dental trauma.

Annexes A and B are normative and form part of this European Standard. Annexes C and D 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 August 1998, and conflicting national standards shall be withdrawn at the latest by August 1998.

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

Introduction

This European Standard specifies dimensions and requirements for oropharyngeal airways.

Size is designated by length, which is important when selecting an oropharyngeal airway to hold forward the base of the tongue to prevent obstruction of the human airway by the soft tissue.

Flammability of oropharyngeal airways, 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 standard.

1) See ISO/TR 11991.

1 Scope

This European Standard specifies requirements for oropharyngeal airways of plastics materials and/or rubber, including those with a reinforcement insert made of plastics materials and/or metal. Metal oropharyngeal airways are excluded from the scope of this European 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: 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 30993-1	Biological evaluation of medical devices - Part 1: Guidance on selection of tests (ISO10993-1: 1992 and Technical Corrigendum 1: 1992)

3 Definitions

For the purposes of this standard, the following definitions apply.

3.1 oropharyngeal airway : Device intended to maintain the patency of the respiratory passages through the oral cavity and pharynx. [EN ISO 4135: 1996]

3.2 pharyngeal end : That end of the oropharyngeal airway which is intended to be inserted into the patient's oropharynx. [EN ISO 4135: 1996]

3.3 buccal end: flanged end: That end of the oropharyngeal airway which is flanged and is expected to fit between the teeth or gums at the lips. [EN ISO 4135: 1996]

4 Size designation and dimensions

4.1 Size designation

The size of oropharyngeal airways shall be designated by the nominal length (see L, figure 1) expressed in centimetres, in accordance with table 1.

NOTE : The manufacturer's own size designation can additionally be given, but it is not recommended.

Table 1 : Size designation of oropharyngeal airways - Dimensions and tolerances

Designated size (nominal length) cm	Length and tolerance mm	Minimum inside dimension mm
3	30 ± 2,5	2,5
3,5	35 ± 2,5	3,0
4	40 ± 2,5	3,0
4,5	45 ± 2,5	3,0
5	50 ± 2,5	3,5
5,5	55 ± 2,5	3,5
6	60 ± 2,5	4,0
6,5	65 ± 2,5	4,0
7	70 + 5,0 -2,5	4,0
8	80 ± 5,0	4,5
9	90 ± 5,0	4,5
10	100 ± 5,0	5,0
11	110 ± 5,0	5,5
12	120 ± 5,0	5,5

4.2 Dimensions

4.2.1 The length (see L, figure 1) shall be in accordance with table 1.

4.2.2 The minimum inside dimension at any point along the length of the airway shall be not less than that specified in table 1.

NOTE: This is relevant to the ability to pass other devices, e.g. a suction catheter, through the airway.

5 Materials

Oropharyngeal airways, 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.

6 Design

Edges and corners intended to come into contact with the patient's tissues shall have a minimum radius of curvature of 0,5 mm.

7 Performance requirements

7.1 Resistance to collapse of the buccal end

When tested in accordance with annex A, the minimum inside dimension of the buccal end of the airway shall be not less than 75% of that given in table 1 for the size of airway being tested.

7.2 Resistance to distortion

When tested in accordance with annex B, the pharyngeal end of the airway shall not move through an angle of more than 30°.