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Aspiracijski katetri za ļ iģ ļ enje dihalnih poti

Suction catheters for use in the respiratory tract

Absaugkatheter zur Verwendung im Atemtrakt

Sondes d'aspiration pour les voies respiratoires

Ta slovenski standard je istoveten z: **EN 1733:2002**

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Suction catheters for use in the respiratory tract

Sondes d'aspiration pour les voies respiratoires

Absaugkatheter zur Verwendung im Atemtrakt

This European Standard was approved by CEN on 16 October 2002.

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 Management Centre 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 Management Centre 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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Contents

Foreword

This document (EN 1733:2002) 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of an identical text or by endorsement, at the latest by May 2003, and conflicting national standards shall be withdrawn at the latest by May 2003.

This document supersedes EN 1733:1998.

This European Standard is based on ISO 8836:1997 *Suction catheters for use in the respiratory tract*, prepared by ISO/TC 121.

It differs from ISO 8836:1997 in that it recognises a distinction between tracheal and endobronchial suction catheters.

Annex A is informative. Annexes B and C are normative.

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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard specifies dimensions and requirements for suction catheters for use in the respiratory tract.

Size is designated by outside diameter which is important when selecting catheters, because of its relationship to the ease with which the catheter can be passed through a tracheal or tracheostomy tube (see EN 1782 for details of tracheal tube standards and EN 1282-1 and EN 1282-2 for details of tracheostomy tube standards). Requirements for suction catheters made of rubber have been deleted because such catheters are no longer in general use.

This European Standard recognises the potential for damage to the mucosa through the use of suction catheters with a terminal orifice only and restricts this tip configuration to endobronchial suction catheters, which are used under visual guidance.

Flammability of suction catheters, for example if flammable anaesthetics or lasers are used, is a well-recognized hazard that is addressed by appropriate clinical management, and is outside the scope of this standard (See ISO/TR 11991)

1 Scope

This European Standard specifies requirements for suction catheters made of plastics materials and intended for use in suction of the respiratory tract. Specialized suction catheters, e.g. those with more than one lumen, are excluded from the scope of this standard. Angled tip suction catheters (e.g. Coudé catheters) are not considered to be specialized and are therefore included in the scope.

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 (including amendments).

EN 556-1:2001, *Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices*

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

EN ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:1997)

3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

3.1
adaptor
specialized connector to establish functional continuity between otherwise disparate or incompatible components

[EN ISO 4135:2001]

3.2
connector
fitting to join together two or more components

[EN ISO 4135:2001]

3.3
eye
lateral aperture near the patient end of a suction catheter

[EN ISO 4135:2001]

3.4
machine end
that end of a suction catheter which is intended to be connected to a source of vacuum

[EN ISO 4135:2001]

3.5
patient end
that end of a suction catheter which is intended to be inserted into a patient

[EN ISO 4135:2001]

3.6
residual vacuum
negative pressure at the patient end of a suction catheter when the vacuum control device is in the relief position

3.7
shaft
that part of a suction catheter between the connector or conical expansion at the machine end and the tip

[EN ISO 4135:2001]

3.8
tracheal suction catheter
flexible tube designed for introduction into a respiratory tract to remove material by suction

3.9
endobronchial suction catheter
flexible tube designed for introduction into a bronchial tree to remove material by suction under visual guidance

3.10
terminal orifice
central aperture at the patient end of a suction catheter

[EN ISO 4135:2001]

3.11
tip
extremity of the patient end of a suction catheter

[EN ISO 4135:2001]

3.12
vacuum control device
means provided at the machine end of a suction catheter to control the flow of air and entrained material

[EN ISO 4135:2001]

4 Size designation and dimensions

4.1 Size designation

4.1.1 The size of suction catheters shall be designated by the following:

a) the nominal outside diameter of the shaft, expressed in millimetres.

NOTE The size can additionally be expressed in French (Charrière) gauge size.

b) the nominal shaft length, expressed in millimetres.

4.1.2 If a colour code is additionally used to designate the size of the suction catheter, it shall be in accordance with Table 1. The colour coding shall be applied at the machine end of the suction catheter.

NOTE Use and choice of colour coding for designated sizes not listed in Table 1 are at the manufacturer's discretion.

4.2 Dimensions

4.2.1 The outside diameter and the minimum inside diameter of suction catheters, excluding the tip, shall be in accordance with Table 2.

NOTE For the purposes of this European Standard, the French (Charrière) gauge system of size is based on the outside diameter of the shaft gauged in steps of thirds of a millimetre (1 millimetre corresponds to 3F); the French gauge size is not an

SI unit. Size designation in millimetres facilitates matching suction catheter outside diameter to the inside diameter of the tracheal or tracheostomy tube.

4.2.2 The minimum inside diameter at the tip shall be not less than 90 % of the minimum inside diameter specified in Table 2.

4.2.3 The actual shaft length shall be the marked shaft length subject to a tolerance of ± 5 %.

Table 1 - Colour identification for designated size of suction catheter

Designated size		Colour
Nominal outside diameter **mm**	French (Charrière) size equivalent	
1,67	5	grey
2,0	6	light green
2,5	7,5	pink
2,67	8	light blue
3,0	9	turquoise
3,33	10	black
4,0	12	white
4,67	14	green
5,0	15	brown
5,33	16	orange
6,0	18	red
6,67	20	yellow