Irish Standard
I.S. EN 1782:1998+A1:2009

Tracheal tubes and connectors

I.S. EN 1782:1998+A1:2009

Incorporating amendments/corrigenda issued since publication:
EN 1782:1998/A1:2009

This document replaces:	*This document is based on:*	*Published:*
EN 1782:1998	EN 1782:1998+A1:2009 EN 1782:1998	19 August, 2009 10 July, 1998

This document was published
under the authority of the NSAI
and comes into effect on:
15 September, 2009

ICS number:
11.040.10

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W **NSAI.ie**

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Price Code:
K

Údarás um Chaighdeáin Náisiúnta na hÉireann

I.S. EN 1782:1998+A1:2009

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1782:1998+A1

August 2009

ICS 11.040.10

Supersedes EN 1782:1998

English Version

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.

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 CEN 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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 1782:1998+A1:2009: E

Contents

Page

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.