INTERNATIONAL STANDARD

**ISO 16628**

Second edition
2022-06

# Anaesthetic and respiratory equipment — Tracheobronchial tubes

*Matériel d'anesthésie et de réanimation respiratoire — Sondes trachéobronchiques*

This document is a preview generated by EVS

Reference number
ISO 16628:2022(E)

© ISO 2022

This document is a preview generated by EVS



## COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland



© ISO 2022 – All rights reserved

# Contents

Page

**Foreword** ... **iv**
**Introduction** ... **v**
**1 Scope** ... **1**
**2 Normative references** ... **1**
**3 Terms and definitions** ... **1**
**4 General requirements** ... **2**
4.1 General ... 2
4.2 Safety ... 2
**5 Materials** ... **2**
5.1 General ... 2
5.2 Biological safety testing ... 2
**6 Design requirements** ... **3**
6.1 General ... 3
6.2 *Designated size* ... 3
6.3 Dimensions ... 3
6.4 Connectors ... 3
6.5 *Cuffs* ... 3
6.6 *Cuff* inflation system ... 4
6.7 Bronchial segment ... 4
**7 Requirements for *tracheobronchial tubes* supplied sterile** ... **5**
**8 Packaging** ... **5**
**9 Information supplied by the manufacturer** ... **6**
9.1 General ... 6
9.2 Marking ... 6
9.2.1 Durability and legibility ... 6
9.2.2 Marking on the *tracheobronchial tube* ... 6
9.3 Colour coding ... 7
9.4 Marking on the individual packaging or insert ... 7
**Annex A** (informative) **Rationale** ... **8**
**Annex B** (normative) **Test method to determine the outside diameter of the bronchial segment** ... **10**
**Annex C** (normative) **Test method to determine the *effective inside diameters*** ... **11**
**Bibliography** ... **13**

This document is a preview generated by EVS

© ISO 2022 – All rights reserved

# Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 16628:2008), which has been technically revised.

The main changes are as follows:

— alignment with the general standard for airway devices, ISO 18190;

— inclusion of requirements in addition to marking and sizing;

— updating of references.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

This document is a preview generated by EVS


© ISO 2022 – All rights reserved

# Introduction

*Tracheobronchial tubes* are double lumen *tracheal tubes* that enable isolation of the airways of one lung from the other. This allows protection of one lung if there is bleeding or a leak in the airways of the other. They facilitate selective ventilation of each lung. One lumen ends in the trachea, with a tracheal *cuff* above the opening. The other lumen is designed to lie either in the right or the left main bronchus with a *cuff* sealing that bronchus. The *cuff* of a right-sided tube is usually shaped to permit ventilation of the right upper lobe.

The first edition of ISO 16628 only specified requirements for the marking and sizing of *tracheobronchial tubes*.

Throughout this document the following print types are used:

— requirements and definitions: roman type;

— informative material appearing outside of tables, such as notes, examples and references: smaller type. The normative text of tables is also in smaller type;

— *terms defined in Clause 3: italics.*

This document is a preview generated by EVS

© ISO 2022 – All rights reserved

This document is a preview generated by EVS

# Anaesthetic and respiratory equipment — Tracheobronchial tubes

This document is a preview generated by EVS

## 1 Scope

This document specifies requirements for safety, materials, design and information supplied with *tracheobronchial tubes.* These devices are used when isolation of the airways of one or both lungs is required.

*Tracheal tubes* that include bronchus blockers are excluded from the scope of this document

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5361:2016, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*

ISO 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 18562-1, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, ISO 18190 and the following apply:

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

**3.1**
**cuff**
inflatable balloon permanently attached around the *tracheobronchial tube* (3.8) near the patient end of the tracheal segment and patient end of the bronchial segment, that is used to provide a seal between the tube and the trachea or bronchus

Note 1 to entry: See Figure 1.

**3.2**
**designated size**
circumference of the tracheal segment of the *tracheobronchial tube* (3.8)

© ISO 2022 – All rights reserved