
Tracheobronchial tubes — Sizing and marking

Sondes trachéo-bronchiques — Dimensionnement et marquage



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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

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ISO 16628 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This first edition cancels and replaces the Technical Specification ISO/TS 16628:2003.

Introduction

Originally a Technical Specification, this document is being revised as an International Standard to provide requirements for size designation and labelling of tracheobronchial tubes. Such requirements will have the benefit of enabling clinicians to select the most appropriate device for their patient population and to select accessories such as fiberoptic bronchoscopes based on the measured internal diameter of the bronchial segment of the tracheobronchial tube.

This International Standard provides requirements for manufacturers in establishing a standard method of size designation for tracheobronchial tubes and their parts. A tracheobronchial tube is a double lumen tracheal tube that facilitates selective ventilation to one or both lungs and allows isolation of one lung from the other. It is designed for either right or left mainstem bronchus placement, and has both a tracheal and bronchial cuff.

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Tracheobronchial tubes — Sizing and marking

1 Scope

This International Standard provides requirements for size designation and labelling of tracheobronchial tubes, including colour coding of the bronchial cuff and its associated pilot balloon. Tracheobronchial tubes that include bronchus blockers are excluded from the scope of this International Standard.

2 Normative References

The following referenced documents are indispensable for the application 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 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

EN 1041, *Information supplied by the manufacturer with medical devices*

3 Terms and definitions

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

3.1

tracheobronchial tube

double-lumen tube designed for insertion into the trachea and a main bronchus to separate the right and left lungs

4 General requirements

4.1 Outside diameter of bronchial segment

The outside diameter of the bronchial segment of the tube shall be the outside diameter measured at the mid-point of the deflated bronchial cuff (see Key 9 of Figure 1) in millimetres, determined in accordance with Annex A.