
**Tracheobronchial tubes — Sizing and
marking**

Sondes trachéo-bronchiques — Dimensionnement et marquage



Reference number
ISO 16628:2008(E)

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Foreword

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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.

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.

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

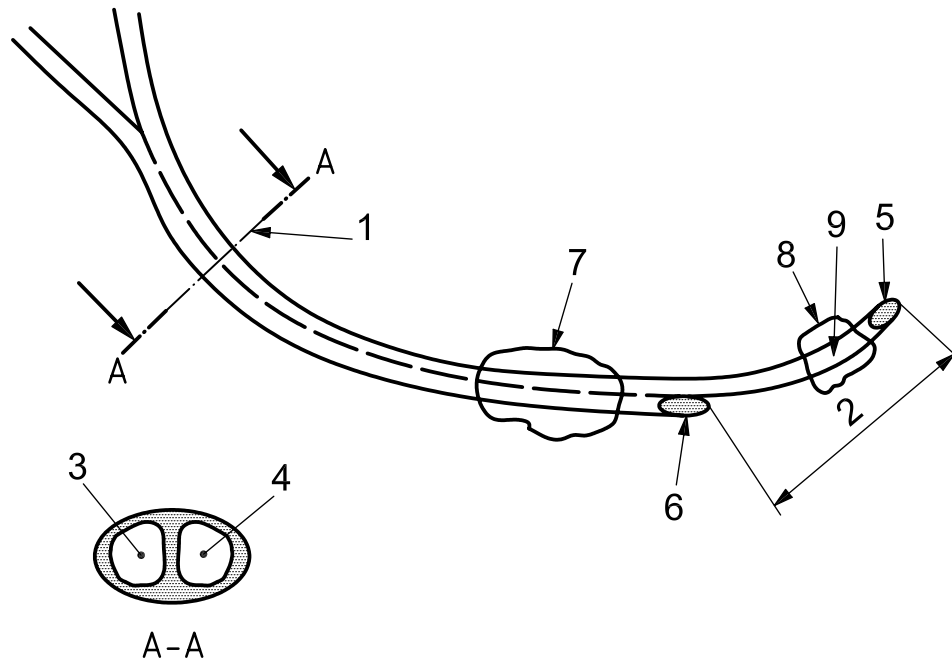
tracheobronchial tube

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.



Key

- 1 machine end of the tracheobronchial tube
- 2 bronchial segment
- 3 cross-section of tracheal lumen (not necessarily circular)
- 4 cross-section of bronchial lumen (not necessarily circular)
- 5 patient end of the bronchial segment
- 6 patient end of the tracheal segment
- 7 tracheal cuff
- 8 bronchial cuff
- 9 point of measurement of the outside diameter of the bronchial segment

Figure 1 — Example of a tracheobronchial tube

4.2 Effective inside diameter

The inside diameter of the lumena of the bronchial and tracheal segments of the tube in millimetres shall be determined in accordance with Annex B.

NOTE The effective inside diameter is intended as a guide to selecting the appropriate diameter bronchoscope or other device to be inserted into the tracheobronchial tube.

4.3 Colour coding

The bronchial cuff and its associated pilot balloon shall be entirely coloured blue.

4.4 Segment differentiation

The tracheal and bronchial segments shall be clearly distinguishable from each other when viewed from the machine end.

5 Marking

5.1 Use of symbols

5.1.1 The recommendations of 4.2 can be met by the appropriate symbols as given in ISO 7000 or ISO 15223-1.

5.1.2 Marking of tracheobronchial tubes, packages, inserts and information supplied by the manufacturer shall comply with EN 1041.

5.2 Marking of tracheobronchial tube

5.2.1 Marking of the tracheobronchial tube shall include the following:

- a) the name and/or trademark of the manufacturer or supplier;
- b) the manufacturer's stated size (e.g. 39 Fr.);
- c) the outside diameter of the bronchial segment, in accordance with 4.1, in millimetres, and prefixed "Br" as shown in the following example:
Br 13,0 OD;
- d) for tracheobronchial tubes for single use, the words "SINGLE-USE" or equivalent;
- e) length marks at 2 cm intervals, measured from the tip of the bronchial segment, and marked on the machine end of the tracheal segment;
- f) the word "right" or "left", as appropriate.

5.2.2 Marking should be of a colour that contrasts with the colour of the tube.

5.3 Marking on tracheobronchial tube individual pack and any insert

The following shall be marked on, or visible through, the tracheobronchial tube individual pack and may additionally be given on an insert:

- a) description of contents;
- b) the word "right" or "left" as appropriate;
- c) the manufacturer's stated size (e.g. 39 Fr.);
- d) the outside diameter of the bronchial segment, in accordance with 4.1, in millimetres, and prefixed "Br" as shown in the following example:
Br 13,0 OD;
- e) the effective inside diameter, as determined in accordance with 4.2;
- f) the name and/or trademark of the manufacturer;
- g) the batch number (it is strongly recommended that the "use-by" date be given);
- h) the word "STERILE" if appropriate (it is recommended that the method of sterilization be given);
- i) the words "single-use" or equivalent for tubes not intended for re-use;

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- j) an indication of the presence of natural rubber (latex), if present in the device;
- k) instructions for cleaning and disinfection or sterilization, unless the tube is marked as for single use;
- l) recommendations for an appropriate sterilization method, if delivered non-sterile.

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Annex A (normative)

Outside diameter determination of the bronchial segment

A.1 Principle

The outside diameter (OD) of the bronchial segment of the tracheobronchial tube is measured by wrapping an inelastic wire or thread around the outside of the bronchial segment of the tube and measuring its length. This method determines the equivalent circular diameter (see A.3.3 below).

A.2 Apparatus

A.2.1 Length of inelastic wire or thread, sufficiently long to be wrapped around the outside of the bronchial segment of the tube five times at the mid-point of the deflated bronchial cuff (see Key 9 of Figure 1).

A.2.2 Means of measuring inelastic wire or thread (A.2.1) in millimetres.

A.3 Procedure

A.3.1 Wrap a piece of inelastic wire or thread (A.2.1) in a close spiral five times around the outside of the bronchial segment of the tube, at the mid-point of the deflated bronchial cuff (see Key 9 in Figure 1).

A.3.2 Measure the length of the inelastic wire or thread in millimetres.

A.3.3 Determine the OD by dividing the length of the wrapped thread by $5 \cdot \pi$ (i.e. $5 \times 3,14 = 15,7$).

A.4 Expression of results

Express the results in millimetres, as determined in A.3.3, to one decimal place, rounded up to the nearest 0,5 mm.

EXAMPLE 9,1 mm is expressed as 9,5 mm
 9,6 mm is expressed as 10,0 mm
 13,1 mm is expressed as 13,5 mm

NOTE The diameter is expressed to the larger 0,5 mm in order to ensure that the selected tube is smaller than the bronchus.

Annex B (normative)

Test methods for determining the effective inside diameter

B.1 Principle

The effective inside diameter (ID) is determined by passing a set of beads through the lumina of the bronchial and tracheal segments of the tube. The diameter of the beads is intended to represent the largest diameter of bronchoscope that can be passed down the tracheal and bronchial lumina of the tracheobronchial tube. This test is used because a bronchoscope is limited in its flexibility to pass around curves and because the cross-section of the inner lumina of the tubes may not be circular, thus precluding measurement (see Figure 1).

B.2 Apparatus

B.2.1 Set of three polished cylindrical beads (see Figure B.1), having the same diameter, D , with rounded ends, and of overall length of twice their diameter ($2D$). The accuracy of the diameter shall be $\pm 0,01$ mm, and the accuracy of the length shall be $\pm 0,1$ mm. The end radius shall be the nominal radius and the knot length between beads shall be 1 mm to 2 mm. In order to establish the nominal maximum bronchoscope diameter, several sets of beads, with diameters increasing in 0,2 mm increments, shall be used. If the manufacturer has a designated maximum bronchoscope diameter, a single set of beads may be used to verify this.

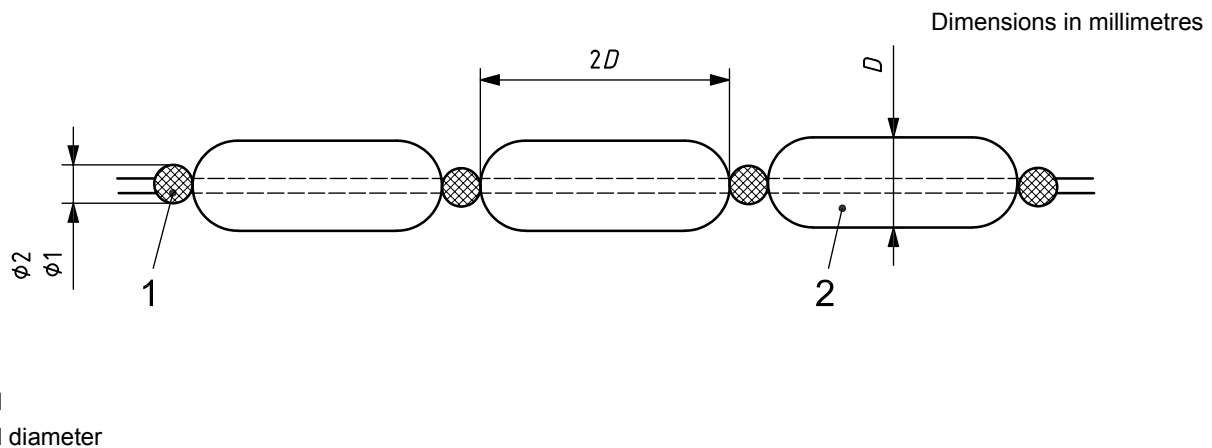


Figure B.1 — Example of a cylindrical bead set

B.2.2 Weight, of mass 100 g, to attach to the set of beads (B.2.1), with a length of thread at one end sufficiently long to draw the beads through the tubes.

B.3 Procedure

B.3.1 Holding the tracheobronchial tube vertically, feed the long end of the thread through the lumen of the bronchial segment of the tube.

B.3.2 Attach the weight to the end of the thread.

B.3.3 Feed the beads into the machine end of the bronchial lumen, allowing the weight to pull the beads through the tube. The lumen may be lubricated with water or water-soluble lubricant to assist the passage.

B.3.4 Repeat steps B.3.1 to B.3.3 for the lumen of the tracheal segment.

B.4 Expression of results

Express the results in millimetres, to one decimal place, rounded down to the nearest 0,2 mm as determined in B.3.

EXAMPLE 2,1 mm is expressed as 2,0 mm

 3,7 mm is expressed as 3,6 mm

 4,8 mm is expressed as 4,8 mm

NOTE The diameter is expressed to the smaller 0,2 mm dimension in order to ensure that the selected tube contains an effective inside diameter large enough to allow passage of the selected bronchoscope.

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