TECHNICAL SPECIFICATION

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Tracheobronchial tubes — Recommendations for size designation and labelling

Sondes trachéo-bronchiques — Recommandations pour la désignation de grandeur et le marquage

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

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

Introduction

This Technical Specification is intended to provide recommendations to assist 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. It is designed for either right or left mainstem bronchus placement, and has both a tracheal and a bronchial cuff.

Tracheobronchial tubes — Recommendations for size designation and labelling

1 Scope

This Technical Specification provides recommendations for the 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 Technical Specification.

2 Terms and definitions

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

2.1
tracheobronchial tube
double-lumen tube designed for insertion through the larynx into the trachea and a main stem bronchus to separate right and left lung ventilation

3 General requirements

3.1 Size designation of bronchial segment

The size of the bronchial segment of the tube should be designated by the outside circumference measured at the mid-point of the bronchial cuff (see 1 in Figure 1), in millimetres ± 0,5 mm, determined in accordance with Annex A.

3.2 Nominal maximum bronchoscope diameter

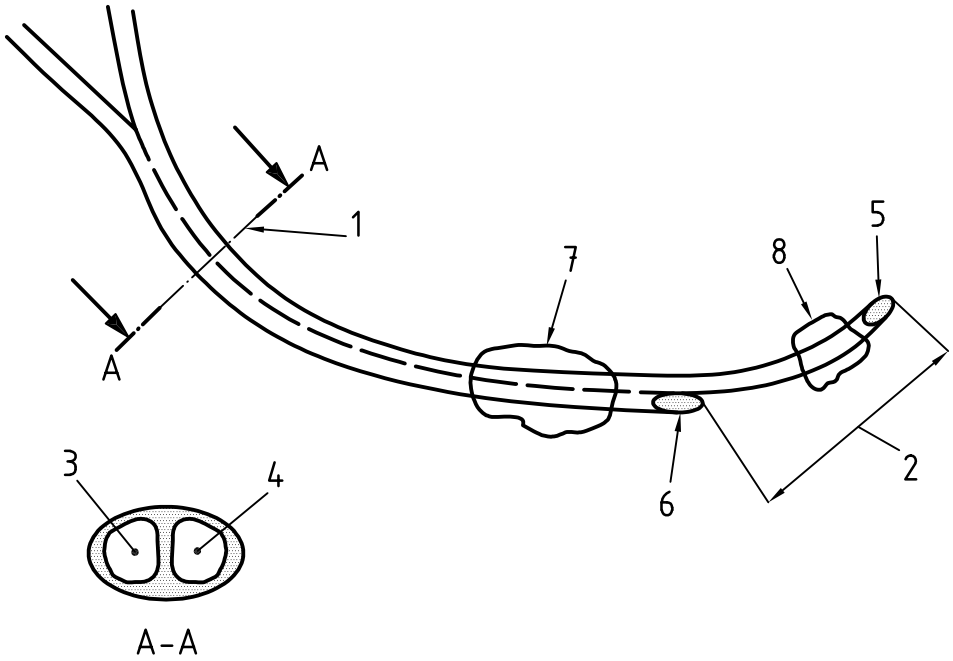
The nominal maximum bronchoscope diameter (representing the maximum size of bronchoscope that will pass through the lumina of the bronchial and tracheal segments of the tube) should be determined in accordance with Annex B.

3.3 Colour coding

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

3.4 Segment differentiation

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



Key

1 point of measurement of circumference of 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 bronchial segment
6 patient end of tracheal segment
7 tracheal cuff
8 bronchial cuff

Figure 1 — Typical example of a tracheobronchial tube

4 Marking

4.1 Use of symbols

4.1.1 The recommendations of 4.2 may be met by the appropriate symbols given in ISO 7000[1] or ISO 15523[2].

4.1.2 Marking of tracheobronchial tubes, packages and inserts and information to be supplied by the manufacturer should comply with EN 1041[3].

4.2 Marking of tracheobronchial tubes

4.2.1 Marking of the tracheobronchial tube should include the following:

a) the name and/or trademark of the manufacturer or supplier;

b) the manufacturer's stated size;

c) the circumference of the bronchial segment, in accordance with 3.1 and prefixed "Br";

d) for tracheobronchial tubes for single use, the words "single-use" or equivalent;

e) length marks at 20 mm intervals, measured from the tip of the bronchial segment and marked on the proximal end of the tracheal segment;

f) the word “right” or “left”, as appropriate.

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

4.3 Marking on tracheobronchial tube individual pack and any insert

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

a) a description of the contents;

b) the word “right” or “left”, as appropriate;

c) the manufacturer’s stated size;

d) the circumference of the bronchial segment, in accordance with 3.1 and prefixed “Br”;

e) the nominal maximum bronchoscope diameter, determined in accordance with 3.2;

f) the name and/or trademark of the manufacturer;

g) the batch number;

NOTE It is strongly recommended that the “use-by” date be given.

h) the word “STERILE”, if appropriate;

NOTE It is recommended that the method of sterilization be given.

i) for tubes not intended for re-use, the words “single-use” or equivalent;

j) an indication of the presence of natural rubber (latex), if present in the device;

k) instructions for cleaning and disinfecting or sterilizing, unless the tube is intended and marked as being for single use,

l) recommendations for an appropriate sterilization method, if delivered non-sterile.