

INTERNATIONAL STANDARD

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Tracheostomy tubes —

Part 2:

Basic requirements for tubes for adults

Tubes de trachéostomie —

Partie 2: Prescriptions de base pour tubes destinés aux adultes



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Documents

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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.

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.

International Standard ISO 5366-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 2, *Tracheal tubes and other equipment*.

This second edition cancels and replaces the first edition (ISO 5366-2:1985), of which it constitutes a technical revision.

ISO 5366 consists of the following parts, under the general title *Tracheostomy tubes*:

- *Part 1: Connectors for tubes for adults*
- *Part 2: Basic requirements for tubes for adults*
- *Part 3: Paediatric tracheostomy tubes*

Annexes A and B form an integral part of this part of ISO 5366. Annexes C and D are for information only.

Introduction

This part of ISO 5366 is one of a series dealing with anaesthetic equipment and lung ventilators, and is concerned with the basic requirements and method of size designation of tracheostomy tubes made of plastics materials and rubber. Specialized tubes, for example those without a connector at the machine end intended for spontaneously breathing patients, those with reinforced walls, self-inflating cuffs or tubes made of metal, have been excluded from the scope of ISO 5366.

The method of describing tube dimensions has been devised with the aim of assisting the clinician in the selection of a suitable tube. Size is designated by inside diameter, which is important because of its effect on resistance to gas flow. Because the stomal and tracheal diameters are important when selecting tubes, it is considered essential that the outside diameter should also be stated for each size of tube.

Cuffed tracheostomy tubes may be characterized by a combination of the tube inside and outside diameters and by the cuff resting diameter. The relationship of cuff and tracheal diameters dictates the intra-cuff pressures required to provide a seal. Excessive pressure on the tracheal wall may obstruct capillary blood flow. A range of cuff designs is available to meet particular clinical requirements. This part of ISO 5366 requires that the resting diameter of the cuff is marked on the unit package, as this information allows the clinician to match the product to the application.

Tracheostomy tubes —

Part 2:

Basic requirements for tubes for adults

1 Scope

This part of ISO 5366 specifies basic requirements for tracheostomy tubes made of plastics materials and/or rubber, having inside diameters greater than 6 mm. Such tubes are primarily designed for adult patients who may require anaesthesia, artificial ventilation or other respiratory support, but need not be restricted to these uses. Specialized tubes (see the Introduction) are excluded from the scope of ISO 5366.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5366. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5366 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*.

ISO 5356-1:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*.

ISO 5361-5:1984, *Tracheal tubes — Part 5: Requirements and methods of test for cuffs and tubes*.

ISO 5366-1:1986, *Tracheostomy tubes — Part 1: Connectors*.

3 Definitions

For the purposes of this part of ISO 5366, the following definitions apply.

3.1 tracheostomy (tracheotomy) tube: Tube designed for insertion into the trachea through a tracheostomy (tracheotomy).

3.2 machine end: That end of the tracheostomy tube which is intended to project from the patient.

3.3 patient end: That end of the tracheostomy tube which is intended to be inserted into the trachea.

3.4 centreline length: Distance from the patient side of the neck-plate to the patient end along the centreline (see figure 2).

NOTE 1 When the neck-plate is adjustable, the centreline length is variable.

3.5 outer tube: That part of the tracheostomy tube which is normally in contact with the tissues.

3.6 inner tube: Tube which fits closely to the inside contours of the outer tube (tracheostomy tube).

3.7 cuff: Inflatable balloon fitted near the patient end of the tracheostomy tube to provide an effective seal between the tube and the trachea.

3.8 inflating tube: Tube through which the cuff is inflated. [ISO 4135:—, definition 6.7.10]

3.9 pilot balloon: Balloon fitted to the inflating tube to indicate inflation of the cuff. [ISO 4135:—, definition 6.7.11]