

INTERNATIONAL STANDARD

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Tracheal tubes —

Part 2:

Oro-tracheal and naso-tracheal tubes of Magill
type (plain and cuffed)

Tubes trachéaux —

*Partie 2: Tubes orotrachéaux et nasotrachéaux (avec et sans ballonnets)
type Magill*



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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 5361-2 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 5361-2:1984), of which it constitutes a technical revision, introducing a requirement for cuff resting diameter.

ISO 5361 consists of the following parts, under the general title *Tracheal tubes*:

- *Part 1: General requirements*
- *Part 2: Oro-tracheal and naso-tracheal tubes of Magill type (plain and cuffed)*
- *Part 3: Murphy type*
- *Part 4: Cole type*
- *Part 5: Requirements and methods of test for cuffs and tubes*

Annex A forms an integral part of this part of ISO 5361.

Introduction

ISO 5361-2 specifies the dimensions and basic properties of the most commonly used types of tracheal tubes made of plastics materials and/or rubber. Tubes with walls reinforced with metal or nylon, tubes with shoulders, tapering tubes or the many other types of tubes devised for specialized applications are not specifically covered, although most may be classified by their inside diameter as required by this specification.

While the inside diameter has been specified for size reference, this part of ISO 5361 requires that the outside diameter be marked on the smaller sizes of tubes since for these sizes this information is of greater clinical importance.

Clinical considerations have also dictated the apparently excessive specified length of tubes because long tubes, sometimes of relatively narrow diameter, may be urgently required and must therefore be readily available. Provision has also been included for pre-cut tracheal tubes.

Cuffed tracheal tubes may be characterized by a combination of the tube inside diameter (and outside diameter for the smaller sizes) and by the cuff resting diameter. For tubes intended for re-use, information on the cuff resting diameter is required to be marked on the package or insert but not on the tube itself. This is because re-use may alter the elastic properties and so the diameter of the cuff.

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 5361 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.

Tracheal tubes —

Part 2:

Oro-tracheal and naso-tracheal tubes of Magill type (plain and cuffed)

1 Scope

This part of ISO 5361 specifies requirements for oro-tracheal and naso-tracheal tubes of the Magill type (plain and cuffed) made of plastics materials and/or rubber. Specialized tubes (see the Introduction) are excluded from the scope of this part of ISO 5361.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5361. 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 5361 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 5361-1:1988, *Tracheal tubes — Part 1: General requirements*.

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

3 General

Oro-tracheal and naso-tracheal tubes of the Magill type (plain and cuffed) shall comply with the requirements specified in ISO 5361-1.

4 Dimensions

4.1 The basic dimensions of tracheal tubes shall be in accordance with table 1.

4.2 The actual inside diameter shall be the nominal inside diameter subject to a tolerance of $\pm 0,15$ mm for size 6,0 and smaller, and subject to a tolerance of $\pm 0,2$ mm for size 6,5 and larger.

4.3 For size 6,0 and smaller the actual outside diameter (OD) shall be the marked outside diameter (OD) subject to a tolerance of $\pm 0,15$ mm [see 9.1 b)].

5 Curvature of tube

The radius of curvature for both oral and nasal tubes shall be $140 \text{ mm} \pm 15 \text{ mm}$ for tubes of size 6,5 and larger, except that this curvature may be omitted from the tip of the bevel to not more than 30 mm beyond the machine end of the cuff (see table 1). If this curvature (see figure 3) is so omitted, the straight portion shall be tangential to the curve of the tube.

The curvature may also be omitted from uncuffed tubes of size 6,5 and larger over the same equivalent distances as for cuffed tubes.

6 Bevel

All tubes shall have an angle of bevel of $38^\circ \pm 10^\circ$.

The bevel of the tube should have the opening facing to the left when the tube is viewed towards the concave aspect from the machine end [see figures 1a) and 1b)]. The end of the tube at the bevel should be