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Tracheal tubes —

Part 1 : General requirements

Tubes trachéaux —

Partie 1 : Spécifications générales

Reference number
ISO 5361-1:1988(E)

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 approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 5361-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*.

This second edition cancels and replaces the first edition (ISO 5361-1 : 1984), of which it constitutes a minor revision.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

Tracheal tubes —

Part 1: General requirements

0 Introduction

This International Standard is one of a series dealing with anaesthetic equipment and medical breathing machines, and specifies the basic requirements for the more commonly used types of tracheal tubes, whether made of rubber or of other elastomeric material. Tubes with walls reinforced with metal or nylon, tubes with shoulders (except for those in ISO 5361-4), tapering tubes, or the many types of special tubes devised for use in thoracic surgery, are not specifically covered although most may have the size designated by the inside diameter as required by this specification.

The inside diameter has been specified for the purpose of size designation.

1 Scope and field of application

This part of ISO 5361 specifies general requirements for tracheal (endotracheal) tubes.

2 References

ISO 4135, *Anaesthesiology — Vocabulary*.

ISO 5361-4, *Tracheal tubes — Part 4: Cole type*.

3 Definitions

Definitions are taken from ISO 4135, except where marked with an asterisk.

3.1 tracheal tube (endotracheal tube): Tube designed for insertion through the larynx into the trachea to convey gases and vapours to and from the trachea.

3.2 oro-tracheal tube: Tracheal tube for insertion through the mouth into the trachea.

3.3 naso-tracheal tube: Tracheal tube for insertion through the nose into the trachea.

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

3.5 machine end: That end of the tracheal tube which is intended to project from the patient.

3.6 bevel: Slanted portion at the patient end of the tracheal tube.

3.7 angle of bevel*: Acute angle between the plane of the bevel and the longitudinal axis of the tracheal tube at the patient end.

3.8 cuff*: Inflatable sleeve fitted near the patient end of the tracheal tube to provide an effective fit between the tube and the trachea.

3.9 bonded cuff: Cuff permanently attached to the tracheal tube.

3.10 inflating tube: Tube through which the cuff is inflated.

3.11 pilot balloon*: Balloon fitted to the inflating tube to indicate inflation of the cuff.

4 Size designation

The size of tracheal tubes shall be designated by a number giving the nominal inside diameter expressed in millimetres.

5 Size range

The size range 2,5 to 11 (except for Cole tubes specified in ISO 5361-4) of tracheal tubes shall be based on sizes having the nominal inside diameter of a whole number of millimetres or of the intermediate 0,5 mm steps.

6 Materials

6.1 Tracheal tubes, including cuffs, in their ready-for-use state shall be compatible with the human tissues with which they are intended to be used as determined by the implantation test given in the annex.