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Tracheal tubes —

Part 1 :
General requirements

Tubes trachéaux —

Partie 1 : Spécifications générales

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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 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.

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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.

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6.2 Unless designated for single use, tracheal tubes should be reasonably resistant to deterioration by methods of cleaning, disinfection and sterilization as recommended by the manufacturer or the supplier. Such tubes should withstand accepted methods of steam sterilization.

The recommended method or methods of sterilization should not produce changes in the tube material which will render the tracheal tube incompatible with human tissues with which it is intended to be used (see also 6.1).

6.3 Tracheal tubes under normal conditions of use should be reasonably resistant to deterioration by anaesthetic vapours and gases.

6.4 The material used for the manufacture of the tubes shall have sufficient rigidity to allow the construction of a tube with the thinnest possible wall which, at the same time, maintains resistance to kinking. When in place it shall be flexible and soft enough to conform to the patient's anatomy without exerting undue pressure on the body tissues.

6.5 Tracheal tubes should be readily detectable by X-ray either by the nature of the material of which they are made or by the provision of a marker at the patient end.

7 Lumen

The lumen of the tracheal tube shall be essentially circular in a plane at right angles to the long axis.

8 Finish

Tracheal tubes shall be smooth on the outside and inside. The cuffs shall have a smooth surface.

9 Marking

9.1 Marking materials used on tracheal tubes shall be of a contrasting colour, shall be compatible with the human tissues with which the tubes are intended to be used, shall resist anaesthetic agents and, unless designated for single use, shall resist agents and methods commonly used for cleaning and sterilizing (see also clause 6).

9.2 The marking of tracheal tubes shall be durable and legible and shall include the following:

a) the name or trade-mark of the manufacturer or supplier;

b) the size designation in accordance with clause 4;

c) name of country of origin, if required;

d) tracheal tubes intended for single use shall be clearly marked to indicate single use or marked in accordance with the requirements of the relevant national regulatory authorities;

e) depth (length) mark(s) in centimetres measured from the patient end. This requirement is optional for Cole tubes.

10 Information to be supplied by manufacturer

The manufacturer shall provide a warning with the tracheal tube that cuff volume or pressure can either increase or decrease owing to diffusion of nitrous oxide/oxygen mixtures or air, and shall include recommendations for minimizing this effect.

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Annex

Implantation test[1)]

(This annex forms an integral part of the Standard.)

A.1 General

The implantation test is designed for the evaluation of a plastics material in direct contact with living tissue. Care shall be taken in the preparation of the implant strips and their proper implantation under aseptic conditions.

A.2 Preparation of test samples

Prepare for implantation eight strips of the sample and four strips of USP Negative Control Plastic RS[2)]. Each strip shall measure not less than 10 mm × 1 mm. The edges of the strips should be as smooth as possible to avoid additional mechanical trauma upon implantation. Strips of the specified minimum size shall be implanted by means of a hypodermic needle such as a 15 gauge needle with intravenous point and of 19 mm (0.75 inch) cannula length, and a sterile trocar. Use either pre-sterilized needles into which the sterile plastics strips are aseptically inserted, or insert each clean strip into a needle, the cannula and hub of which are protected with an appropriate cover, and then subjected to the appropriate sterilization procedure.

NOTE — Allowance should be made for proper de-gassing if agents such as ethylene oxide are used.

A.3 Test animal

Select healthy, adult rabbits weighing not less than 2,5 kg, and whose paravertebral muscles are sufficiently large in size to allow for implantation of the test strips. Do not use any muscular tissue other than the paravertebral site. The animals may be anaesthetized with a commonly used anaesthetic agent to a degree deep enough to prevent muscular movements, such as twitching.

A.4 Procedure

Perform the test in a clean area. On the day of the test or up to 20 h before testing, clip the fur of the animals on both sides of the spinal column. Remove loose hair by means of vacuum.

Implant four strips of the sample into the paravertebral muscle on one side of the spine of each of two rabbits, 2,5 to 5 cm from the mid-line and parallel to the spinal column, and about 2,5 cm apart from each other. In a similar fashion implant two strips of USP Negative Control Plastic RS in the opposite muscle of each animal. Insert a sterile stylet into the needle to hold the plastics strip in the tissue while withdrawing the needle. If excessive bleeding is observed after implantation of a strip, place a duplicate strip at another site. Close the incision after implantation is complete.

Keep the animals for a period of not less than 72 h and sacrifice them at the end of the observation period by administering an overdose of an anaesthetic agent. Allow sufficient time to elapse for the tissue to be cut without bleeding. Examine macroscopically the area of the tissue surrounding the centre portion of each implant strip. Use a magnifying lens if necessary. The tissue immediately surrounding the USP Negative Control Plastic RS strips appears normal and entirely free from hemorrhage, film, or encapsulation. The requirements of the test are met if, in each rabbit, the reaction to not more than one of the four sample strips is significantly greater than that to the strips of USP Negative Control Plastic RS.

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1) Taken from US Pharmacopea.

2) USP Negative Control Plastic RS is a trade name for a commercial product available from the US Pharmacopeal Convention Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, USA. At present, no other products intended for this purpose are known to be available commercially. This information is given for the convenience of the users of this International Standard and does not constitute an endorsement of this product by ISO.

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