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An American National Standard

Standard Specification for Adult Tracheostomy Tubes[1]

This standard is issued under the fixed designation F 1666; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

ε[1] NOTE—Editorial change was made to the title in October 1999.

1. Scope

1.1 This specification describes basic requirements for tracheostomy tubes made of plastic materials or rubber, or both; having inside diameters greater than 5.0 mm. Such tubes are primarily designed for adult patients who may require anesthesia, artificial ventilation, or other respiratory support, but need not be restricted to these uses. Specialized tubes are excluded from the scope of this specification.

2. Referenced Documents

2.1 The following standards contain provisions which, through reference in this text, constitute provisions of this standard. All standards are subject to revision, and parties to agreements based on this specification are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

2.2 *ASTM Standards:*

F 640 Test Methods for Radiopacity of Plastics for Medical Use[2]

F 813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices[2]

F 1054 Specification for Conical Fittings of 15 mm and 22 mm sizes[2]

F 1242 Specification for Cuffed and Uncuffed Tracheal Tubes[2]

2.3 *ISO Standards:*

ISO 4135 Anesthesiology—Vocabulary[3]

ISO 5366-1 Tracheostomy Tubes—Part 1: Connectors[3]

ISO 7000 Graphical Symbols for Use on Equipment—Index and Synopsis[3]

2.4 *ANSI Standard:*

ANSI/HIMA MD70.1 Medical Material—Leur Fittings—Performance[3]

3. Terminology

3.1 *Definitions:*

3.1.1 *angle of bevel*—acute angle between the plane of the bevel and the longitudinal axis of the tracheostomy tube at the patient end. (See Angle B in Fig. 1.)

3.1.2 *bevel*—slanted portion at the patient end of the tracheostomy tube.

3.1.3 *center-line length*—distance from the patient side of the neck-plate to the patient end of the outer tube along the center line.

3.1.4 *cuff*—inflatable balloon fitted near the patient end of the tracheostomy tube to provide a leak-resistant seal between the tube and the trachea.

3.1.5 *inflating tube*—tube through which the cuff is inflated.

3.1.6 *inner tube*—tube that fits closely to the inside contours of the outer tube (tracheostomy tube).

3.1.7 *introducer (obturator)*—specifically adapted stylet to facilitate the introduction of the outer tube into the trachea.

3.1.8 *machine end*—that end of the tracheostomy tube which is intended to project from the patient.

3.1.9 *neck-plate (shield)*—that part of the tracheostomy tube which approximates to the contour of the patient's neck and is used to secure the tube in position.

3.1.10 *outer tube*—that part of the tracheostomy tube which is normally in contact with the tissues.

3.1.11 *patient end*—that end of the tracheostomy tube which is intended to be inserted into the trachea.

3.1.12 *pilot balloon*—balloon fitted to the inflating tube to indicate inflation status of the cuff.

3.1.13 *tracheostomy (tracheotomy) tube*—tube designed for insertion into the trachea through a tracheostomy.

4. Materials and Manufacture

4.1 Tracheostomy tubes, including cuffs, in their ready-for-use state shall be compatible with the human tissues with which they are intended to be used. Compatibility shall be indicated by the implantation test given in Annex A1, a cell tissue culture test (see Practice F 813) or other tests that give an equivalent indication of freedom from biological hazard.

NOTE 1—See Annex A3 for guidance on materials and design.

5. Size and Dimensions

5.1 *Designation of Tube Size*:

5.1.1 The size designation of a single tracheostomy tube (no

[1] This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is under the direct responsibility of Subcommittee F29.12 on Airways.

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[2] *Annual Book of ASTM Standards*, Vol 13.01.

[3] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

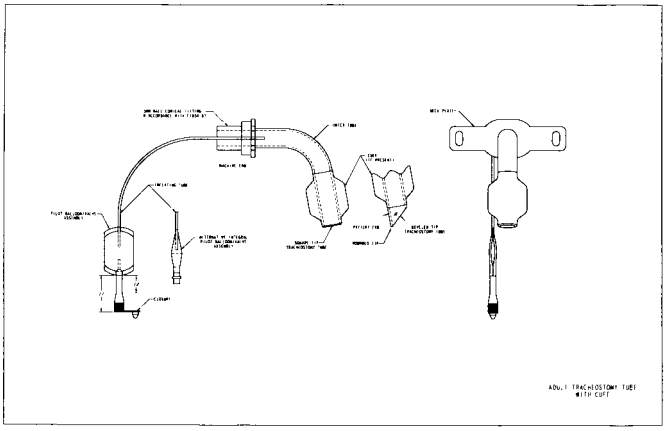

FIG. 1 Typical Tracheostomy Tube

inner cannula) shall be the nominal inside diameter (ID) of the tube expressed in millimetres, as measured at the minimum diameter, in accordance with Table 1, excluding any encroachment allowed by 6.5.1.

5.1.2 The size designation of a tracheostomy tube with inner cannula shall be indicated by both the nominal inner diameter (ID) of the outer tube and the inner diameter (ID) of the inner tube expressed in millimetres. The two numbers shall be juxtaposed by a slash or by a hyphen (*example:* 8/7 or 8–7).

5.2 *Outside Diameter*:

5.2.1 The outside diameter (OD) of sections A and B (see Fig. 2) of the outer tube, other than at the cuff, if provided, shall be expressed in millimetres, subject to a tolerance of ± 0.20 mm. Section "C" of the outer tube shall have a tolerance of ± 0.50 mm.

NOTE 2—The marked outside diameter relates to that portion of the tube intended to be within the wall and lumen of the trachea.

5.3 *Length*:

5.3.1 The center-line length (dimensions A + B + C in Fig. 2) shall extend from the patient side of the neck-plate (datum plane) to the patient end of the outer tube including to the tip of the bevel, if present (see Fig. 1), and shall be expressed in millimetres.

5.3.2 The actual center-line length shall not vary by more than 2.0 mm from the marked length.

5.3.3 Dimensions A, B and C shall be expressed in millimetres.

TABLE 1 Size Range of Single Tracheostomy Tubes

NOTE 1—Dimensions and tolerances are in millimetres.

Designed Size (Nominal Inside Diameter, (ID))	Inside Diameter and Tolerance
5.0	5.0 ± 0.20
5.5	5.5 ± 0.20
6.0	6.0 ± 0.20
6.5	6.5 ± 0.20
7.0	7.0 ± 0.20
7.5	7.5 ± 0.20
8.0	8.0 ± 0.20
8.5	8.5 ± 0.20
9.0	9.0 ± 0.20
9.5	9.5 ± 0.20
10.0	10.0 ± 0.20
11.0	11.0 ± 0.20

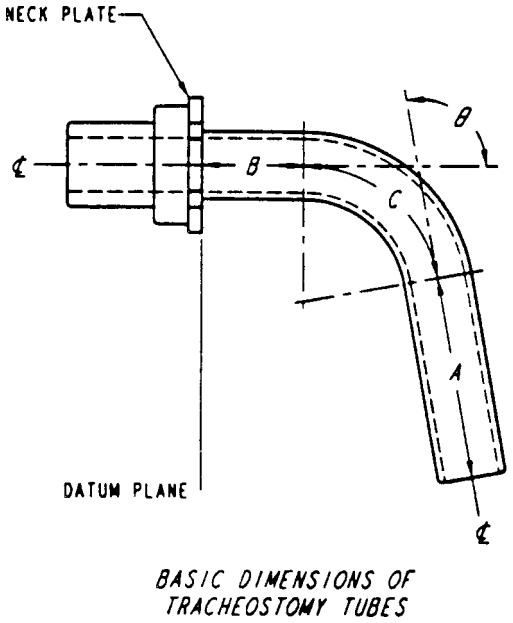

FIG. 2 Basic Dimensions of Tracheostomy Tubes

NOTE 3—Dimensions A or B, or both, may be, or approach, zero.

5.3.4 For tubes with an adjustable neck-plate, the range of center-line lengths shall be expressed in millimetres.

5.4 *Angle* θ—The angle θ (see Fig. 2) shall be expressed in degrees.

NOTE 4—Angle θ is the obtuse angle formed between the tangents to the longitudinal axes of the tube at the machine and the patient ends. As Dimensions A or B, or both, approach or equal zero, the angle θ shall be the obtuse angle formed between the tangents (planes perpendicular) to the longitudinal axes.

6. Design

6.1 *Machine End*— The machine end of tracheostomy tubes shall comply with the requirements specified in Specification F 1054.

6.2 *Neck-Plate*:

6.2.1 A tracheostomy tube shall have a neck-plate (see Fig. 1 and Fig. 2).

6.2.2 The neck-plate shall be provided with holes or other means to permit attachment to the patient.

6.2.3 If a tracheostomy tube has an adjustable neck-plate, it shall be securable to the tube, but not removable.

6.3 *Inner Tube*—The inner tube shall extend to within 1.0 mm of the patient end and not more than 3.0 mm beyond the patient end of the tracheostomy tube with which it is provided.

6.4 *Cuff*:

6.4.1 The cuff, if provided, shall be permanently attached to the tube.

6.4.2 Cuffs of tracheostomy tubes shall comply with the requirements specified in Specification F 1242.

6.5 *Inflating Tubes for Cuffs*:

6.5.1 *Inflating Tube*— The inflating tube, if fitted, shall have an outside diameter of not more than 2.5 mm. The secondary (inflation) lumen shall not encroach on the lumen of the tracheostomy tube by more than 10 % of the inside diameter of the tracheostomy tube.

NOTE 5—The wall around the secondary (inflation) lumen should not project substantially on the outside surface.

6.5.2 *Pilot Balloon*:

6.5.2.1 The inflating tube shall have a pilot balloon or other means to indicate inflation of the cuff, or both.

NOTE 6—This (these) device(s) may also serve as a pressure indicating or limiting device.

6.5.2.2 Neither the inflating tube nor any device shall act as a non-return valve to prevent the intentional evacuation of the cuff.

6.5.3 *Free End of Inflating Tubes for Cuffs*:

6.5.3.1 The end of the inflating tube may be open or sealed with a closure device or inflation valve, but in all instances it shall be capable of accepting a male conical fitting with a 6 % taper (Leur), complying with the requirements specified in ANSI/HIMA MD70.1. The length (see Fig. 1, Dimension 1_1) of the free end of the inflating tube shall be not less than 40 mm unless an inflation valve or closure device is provided.

If an inflation valve or closure device is provided, the length (see Fig. 1, Dimension 1_2) between the pilot balloon (or other device) and the 6 % conical fitting shall be not less than 10 mm unless the pilot balloon and valve or closure device are integral.

6.6 *Patient End*:

6.6.1 The patient end may be square, beveled, or of other configuration.

6.6.2 If a bevel is present, the angle of bevel β shall be not less than 45° (see Fig. 1).

6.7 *Introducer (Obturator)*:

6.7.1 Provision of an introducer is optional.

6.7.2 The introducer shall be smooth and facilitate rapid intubation.

6.7.3 The introducer shall be easy to insert and remove.

6.7.4 When correctly seated, the introducer should not fall out of the tracheostomy tube under its own weight when the tube is held by the neck-plate with the patient end uppermost.

7. Packaging and Package Marking

7.1 The following information shall be apparent on visual examination of the intact unit container:

7.1.1 The size and shape of the tube;

7.1.2 Whether a cuff is provided; and

7.1.3 Whether an introducer/obturator is provided.

NOTE 7—For example, the unit container may be transparent and the tube visible, or a drawing to scale, preferably full scale, may be used. If a drawing is provided, product dimensions may be included.

7.2 Each tracheostomy tube supplied and marked as “sterile” shall be contained in an individual pack. The pack shall serve as a microbiological barrier. The pack shall permit the aseptic extraction of the contents and shall not be capable of re-closure without clearly revealing that it has been opened.

7.3 *Marking of Tracheostomy Tubes*:

7.3.1 The neck-plate or tracheostomy tube, or both, shall be marked with the following:

7.3.1.1 The designated size expressed in millimetres in accordance with 5.1;

7.3.1.2 The outside diameter of the outer tube expressed in millimetres in accordance with 5.2; and

7.3.1.3 The name or trademark of the manufacturer, or both.

NOTE 8—The center line length (or maximum length for tubes having an adjustable neck plate) expressed in millimetres (see 5.3) may also be marked.

7.4 *Labelling of Unit Packs*:

7.4.1 Individual packs or a package insert shall be clearly labeled to indicate the following information:

7.4.1.1 A description of contents;

7.4.1.2 Designated size in mm in accordance with 5.1;

7.4.1.3 The nominal outside diameter of the outer tube expressed in mm (see 5.2);

7.4.1.4 The nominal centerline length expressed in mm (see 5.3);

7.4.1.5 The name or trademark, or both, of the manufacturer or supplier, or both;

7.4.1.6 The batch number;

7.4.1.7 The expiry date;

7.4.1.8 If relevant, instructions for cleaning and disinfection or sterilization;

7.4.1.9 The word “STERILE” or “NON-STERILE” as appropriate;

7.4.1.10 For tubes not intended for re-use, the words“ For Single Patient Use Only” or equivalent.

NOTE 9—Symbol No. 1051 (“Do not re-use”) given in ISO 7000 should also be used (see Fig. 3).

NOTE 10— For cuffed tubes, the resting diameter of the cuff, determined in accordance with Annex A2 and expressed in millimetres may be marked, or may be readily available from the manufacturer.

7.5 *Labeling of Inner Tube Unit Packs*:

7.5.1 Individual packs shall be clearly labelled to indicate the following:

7.5.1.1 The size designation of the tracheostomy tube (outer tube) into which it is designed to fit;

7.5.1.2 The inside diameter (ID) of the inner tube;

7.5.1.3 A description of the contents;

7.5.1.4 The name or trademark, or both, of the manufacturer or supplier, or both;

7.5.1.5 The batch number;

7.5.1.6 The expiry date;

7.5.1.7 The word “STERILE” or “NON-STERILE”, as appropriate; and

7.5.1.8 For tubes not intended for re-use, the words“ For Single Patient Use” or equivalent:

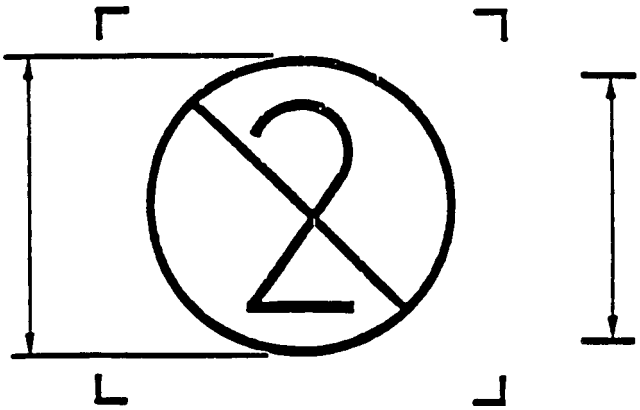

FIG. 3 ISO Symbol 7000/1051 “Do Not Re-Use”

NOTE 11—Symbol No. 1051 ("Do not re-use") given in ISO 7000 should also be used (see Fig. 3).

8. Keywords

8.1 anesthetic equipment; artificial breathing apparatus; dimensions; labelling; manufacturing requirements; marking; medical equipment; packaging; pipes (tubes); specifications; tests; tracheostomy tubes

ANNEXES

(Mandatory Information)

A1. IMPLANTATION TEST[4]

A1.1 General

A1.1.1 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.

A1.2 Preparation of Test Samples

A1.2.1 Prepare for implantation eight strips of the sample and four strips of USP Negative Control Plastics RS[5]. Each strip shall measure not less than 10 by 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 gage needle with intravenous point and of 19 mm (0.75 in.) cannula length, and a sterile trocar. Use either presterilized needles into which the sterile plastics strips are aseptically inserted, or insert each 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 A1.1—Allowance should be made for proper de-gassing if agents such as ethylene oxide are used.

A1.3 Test Animal

A1.3.1 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.

A1.4 Procedure

A1.4.1 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.

A1.4.1.1 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 plastic strips 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.

A1.4.1.2 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 should appear 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 Plastics RS.

NOTE A1.2—Another biocompatibility test recommended by the FDA is the *Tripartite Biocompatibility Guidance for Medical Devices.*[6]

[4] Taken from "United States Pharmacopeia."

[5] USP Negative Control Plastic RS is a trade name for a commercial product available from the US Pharmacopeial 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 specification and does not constitute an endorsement of this product.

[6] Copies may be obtained from Food and Drug Administration, Center for Devices and Radiological Health, Office of Small Manufacturers Assistance (HF2 220), 1350 Piccard Drive, Rockville, MD 20850.

A2. METHOD FOR DETERMINING THE RESTING DIAMETER OF THE CUFF

A2.1 Principle

A2.1.1 The resting diameter of the cuff is measured when the cuff is inflated with a pressure that is intended to remove creases but minimize stretching of its walls.

A2.2 Apparatus

A2.2.1 Means to inflate the cuff with sufficient air to create an intracuff pressure of 2.0 kPa (20 cm H_2O) ± 5 %.

A2.3 Procedure

A2.3.1 Inflate the cuff with sufficient air to create an intracuff pressure of 2.0 kPa (20 cm H_2O) ± 5 % and leave to stabilize for 5 min at (23 ± 2)°C, maintaining that pressure.

A2.3.2 Measure the maximum cuff diameter in a plane perpendicular to the axis of the tube at intervals of 45°.

A2.4 Expression of Results

A2.4.1 Calculate the arithmetic mean of the measurements obtained in A2.3.2A2.3.2 and express the result in millimetres.

A3. GUIDANCE ON MATERIALS, DESIGN, AND FINISH

A3.1 Materials

A3.1.1 The material used for the manufacture of the tubes should have sufficient rigidity to allow the construction of a tube with the thinnest possible wall that, at the same time, maintains resistance to kinking. Tubes claimed by the manufacturer to be flexible and soft should conform to the patient's anatomy without exerting undue pressure on the body tissues.

A3.1.2 Unless intended and marked for single use, tracheostomy tubes should be reasonably resistant to deterioration by methods of cleaning, disinfection and sterilization as recommended by the manufacturer or the supplier.

A3.1.2.1 The recommended method(s) of sterilization should not produce changes in the tube material which will render the tracheotomy tube incompatible with human tissues with which it is intended to be used (see Annex A1).

A3.1.3 Tracheostomy tubes under normal conditions of use should be reasonably resistant to deterioration by anaesthetic vapors and gases.

A3.1.4 Tracheostomy 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 radiopaque marker at the patient end. The radiopaque marker shall have an optical density less than or equal to that of the aluminum comparison standard. The radiopaque marking shall be tested in accordance with Method B of Test Method F 640.

A3.1.5 Prior to use and in the case of tubes intended for re-use, between uses, the tube should maintain its intended shape when stored in accordance with the manufacturer's instructions.

A3.2 Design

A3.2.1 If provided, the introducer should be easily removable after introduction of the tracheostomy tube into the patient.

A3.2.2 The neck-plate or other means of attachment to the patient should be rounded at the edges and its shape should adapt to the contour of the patient.

A3.3 Finish

A3.3.1 Tracheostomy tubes, including the neck-plate or other means of attachment to the patient, should have smooth external and internal surfaces.

A3.3.2 The cuff should have a smooth surface.