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Standard Specification for Cuffed and Uncuffed Tracheal Tubes¹

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^{ε1} NOTE—Editorial changes were made May 1997.

1. Scope

1.1 This specification covers the dimensions, rationale, labeling specifications, selected performance requirements, and test methods of cuffed and uncuffed Magill and Murphy-type tracheal tubes. These tubes are commonly used as airway catheters in human patients in the practice of anesthesiology and in respiratory care. This specification represents the state of the art at the time of publication and will be subject to periodic review.

1.2 This specification also provides test protocols to assess the performance and safety of cuffed oral and nasal tracheal tubes for prolonged use. Supporting rationale for the requirements is provided in Appendix X1, and references are included. Required safety and performance tests, together with availability of results, are relied upon in this specification, whenever possible, to allow a manufacturer the maximum use of technological alternatives in design and materials.

1.3 The values stated in SI units are to be regarded as standard.

1.4 The following precautionary caveat pertains to the test method portions, Annex A1 and Appendix X2, of this specification: *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

1.5 The following is a list of subject headings and subheadings included in this specification and the sections in which they appear:

	Sections
Scope	1
Referenced Documents	2
Terminology	3
Materials	4
Inertness	4.1

	Sections
Surface Characteristics	4.2
Rigidity	4.3
Integrity of Lumen	4.4
Requirements for Tubes With Cuffs	5
Cuffs	5.1
Cuff Pressure, Volume, and Diameter Characteristics	5.2
Inflation System	5.3
Dimensions, and Permissible Variations of Tracheal Tubes	6
Measurement System	6.1
Size and Dimensions	6.2
Radius of Curvature	6.3
Bevel	6.4
Murphy Eye	6.5
Product Marking	7
Marking Materials	7.1
Tracheal Tube Markings	7.2
Required Markings	7.3
Packaging and Labeling	8
Gas Effects	8.1
Sterile Tubes	8.2
Nonsterile Tubes	8.3
Disposable Tubes	8.4
Reusable Tracheal Tubes	8.5
Storage Conditions	8.6
Tracheal Tube Dimensions	Tables
Dimensions of Cuffed Tracheal Tubes	Table 1
	Table 2
Tracheal Tube	Figures
Cuffed Tracheal Tube	Fig. 1
Typical Murphy Tips	Fig. 2
Rationale for Requirements	Fig. 3
Test Methods	Appendix X1
Implantation Test	Annex A1
Tube Collapse	A1.1
Cuff Symmetry	A1.2
Cuff Herniation	A1.3
Cuff Pressure, Volume, and Diameter Assessment; and	A1.4
Tube Lumen Closure	A1.5
Radiopaque Markers	A1.6
Leak Test	A1.7
Determination of Test Inflation Pressure	Table A1.1
Test for Tube Collapse	Fig. A1.1
Test Rig	Fig. A1.2
Visual Inspection of Tube Cuff	Fig. A1.3
Cuff Herniation Test	Fig. A1.4
Clear Polyvinyl Chloride Adult Model Trachea	Fig. X2.2
Schematic of Cuffed Tracheal Tube in Model Trachea	
Mounted Vertically in Test Apparatus	Fig. X2.1
Discontinued Test Protocols	Appendix X2
Test Protocol One—Tracheal Seal, Slope Pressure, and	
Lumen Closure Conditions	X2.1
Test Protocol Two—Ability to Conform to Human Anatomy	
and Resistance to Kinking	X2.3
Coordinates for Positioning Pegs on Test Board	Table X2.1
Test Board	Fig. X2.3

¹ This specification is under the jurisdiction of ASTM Committee F-29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.12 on Airways.

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This specification, which is a consolidation and revision of ANSI Z79.14-1983 and ANSI Z79.16-1983, supersedes these older standards. No attempt has been made to delineate all types of tracheal tubes. This specification is not intended to inhibit innovation, variation, and future development.

2. Referenced Documents

2.1 ASTM Standards:

NOTE 1—This specification is intended to be used in conjunction with the following standards. When the standards referred to in this specification are superseded by an approved revision, the revision shall apply.

F 640 Test Methods for Radiopacity of Plastics for Medical Use²

F 813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices²

2.2 ANSI Standards:³

ANSI/HIMA MD70.1-1983 American National Standard for Medical Material—Luer Taper Fittings—Performance

ANSI Z79.14-1983 American National Standard For Anesthetic Equipment—Tracheal Tubes

ANSI Z79.16-1983 American National Standard for Anesthetic Equipment—Cuffed Oral Tracheal and Nasal Tracheal Tubes for Prolonged Use

3. Terminology

3.1 Definitions:

3.1.1 *bevel*—the slanted patient end of the tracheal tube (see Figs. 1 and 2).

3.1.2 *disposable*—an item intended for single use.

3.1.3 *inflation lumen*—the lumen within the wall of the tracheal tube for inflating the tracheal tube cuff.

3.1.4 *inflation tube*—the attached secondary tube for inflating the tracheal tube cuff (see Fig. 2).

3.1.5 *inflation valve*—a valve attached to the inflation system for inflating and deflating the cuff.

3.1.6 *machine end*—the end of the tracheal tube intended to project from the patient.

3.1.7 *Murphy eye*—a hole through the wall of a tracheal tube near the patient end and on the side opposite to the bevel. A Murphy type eye is illustrated in Fig. 3(a) to Fig. 3(d).

3.1.8 *patient end*—the end of the tracheal tube intended to be inserted into the patient's trachea.

3.1.9 *pilot balloon*—a small balloon attached to the inflation tube to indicate inflation or deflation of the tracheal cuff.

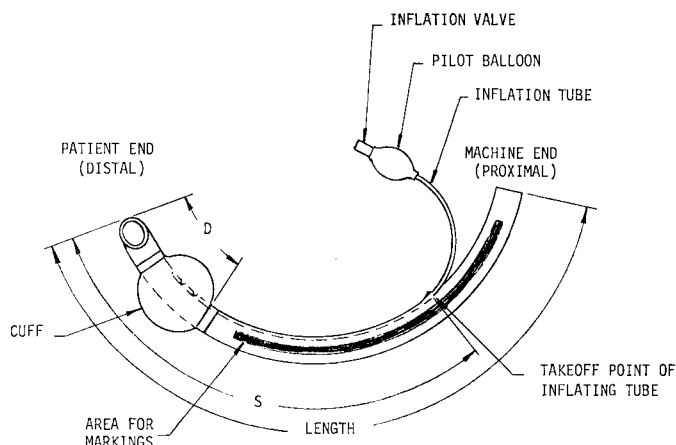


FIG. 2 Cuffed Tracheal Tube

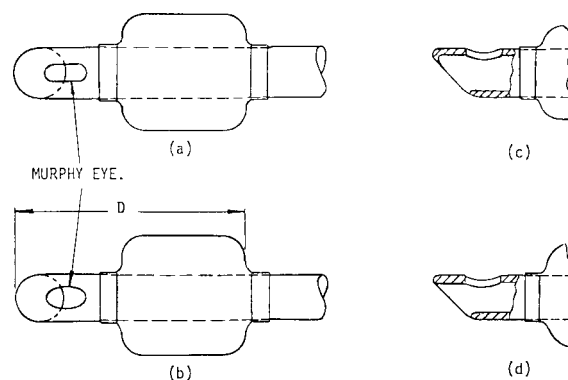


FIG. 3 Typical Murphy Tips

3.1.10 *tracheal tube*—a tube inserted either orally or nasally to convey gases or vapors to and from the trachea. This term shall be used rather than synonyms such as “endotracheal”, “intratracheal”, or “catheter”. Typical tracheal tubes are illustrated in Figs. 1 and 2.

3.1.10.1 *Magill-type tracheal tube*—a Magill-type tracheal tube is illustrated in Fig. 1. Adult sizes of Magill tubes usually are provided with cuffs as illustrated in Fig. 2. A Magill tracheal tube does not have a Murphy eye.

3.1.10.2 *Murphy-type tracheal tube*—a tracheal tube that has a Murphy eye at the patient end as illustrated in Fig. 3(a) to Fig. 3(d). (See Refs (1)⁴ and (2) for the original descriptions of Magill-type and Murphy-type tracheal tubes.)

3.1.11 *tracheal tube cuff*—an inflatable sleeve fastened to the patient end of the tracheal tube to provide an effective, leak-resistant fit between the tube and the trachea. A tracheal tube cuff is illustrated in Fig. 2.

3.1.12 *tracheal tube cuff resting diameter*—the diameter of the cuff when tested in accordance with A1.5.

4. Materials

4.1 Inertness:

4.1.1 Materials intended to be inserted into the patient shall be of a nontoxic substance compatible with human tissue, as

² Annual Book of ASTM Standards, Vol 13.01.

³ Available from American National Standards Institute, 1430 Broadway, New York, NY 10018.

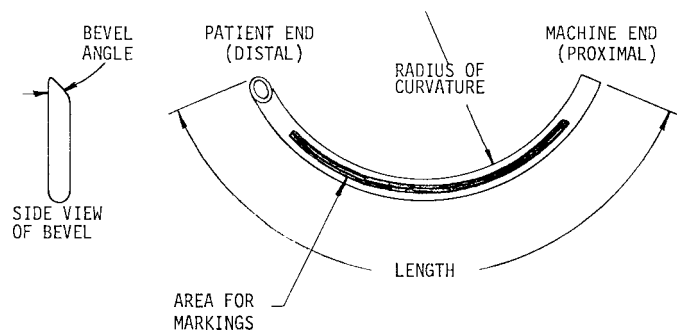


FIG. 1 Tracheal Tube

⁴ The boldface numbers in parentheses refer to a list of references at the end of this specification.

determined by A1.1. Other tests may be used, including cell culture tests, provided they are shown to be equivalent. The biologic test procedure shall be applied to those portions of the finished product intended for insertion into the patient and in the form that they are supplied to the consumer. For tubes supplied sterile, the test shall be applied after sterilization. For tubes supplied nonsterile, the test shall be applied after the recommended method of sterilization. The test is designed to determine the suitability of formulations and is not intended to be used as a routine test for every lot.

4.1.2 Reusable tracheal tubes should be reasonably resistant both to deterioration by agents used in chemical cleansing and sterilizing and to deterioration from autoclaving, if steam sterilization is recommended.

4.1.3 Conditions of use require that all tracheal tubes be resistant to deterioration from anesthetic agents.

4.2 Surface Characteristics:

4.2.1 *Tubes*—The patient end of the tube shall be rounded without sharp points or rough edges. The tube surface should be smooth externally and internally. The external edge of the Murphy eye, if provided, and all bevel edges shall be smooth and well rounded. See Fig. 3.

4.2.2 *Cuffs*—The external surface should be smooth.

4.3 *Rigidity*—All sizes of tracheal tubes should be sufficiently flexible or should soften sufficiently at body temperature, to conform to the patient's airway anatomy without kinking.

4.4 *Integrity of Lumen*—The materials should be such as to allow construction of tracheal tubes with the thinnest possible walls, whose lumen will not be compromised by collapse under the inflated cuff at body temperature. Tubes shall be able to pass the tube collapse test (see A1.2).

5. Requirements for Tubes with Cuffs

5.1 *Cuffs*—The cuff shall be reliably attached to the tracheal tube. (See Ref (3) for information on cuff characteristics.) The maximum distance, D , from the tip of the tube to the machine end of the cuff shall be as illustrated in Figs. 2 and 3 and stated in Table 2. Upon visual inspection, the bonded edge of the cuff shall not encroach upon the Murphy eye, if present. The general requirement for tracheal tube materials shall also apply to cuff materials (see Section 4). The cuff position and size shall not cause the cuff to herniate over the tube tip under normal conditions of use (see Annex A1.4). The cuff shall inflate symmetrically (see Annex A1.3).

5.2 *Cuff Pressure, Volume, and Diameter Characteristics*—The manufacturer shall determine the resting diameter of the cuff. The diameter shall be stated in millimetres. (See Refs (4), (5), and (6) for background information on assessments of cuffs; see Refs (7) and (8) for reports on variations in sizes and shapes of human tracheas.) The cuff resting diameter shall be tested in accordance with A1.5 and be within $\pm 15\%$ of the marked value referenced in Section 8.7.

5.3 *Inflation System*—The typical inflation system includes an inflation lumen in the wall of the tracheal tube, an external inflation tube, an optional pilot balloon, and an optional inflation valve (see Fig. 2). The inflation lumen within the wall of the tracheal tube shall not encroach upon the lumen of the tracheal tube and should not bulge outward. The external

TABLE 1 Tracheal Tube Dimensions

Inside Diameter, mm		Minimum Tube Length, mm	Precut Length, mm ^A
Size	Tolerance		
2.0	± 0.15	140	110
2.5	± 0.15	140	110
3.0	± 0.15	160	120
3.5	± 0.15	180	130
4.0	± 0.15	200	140
4.5	± 0.15	220	150
5.0	± 0.15	240	160
5.5	± 0.15	270	170
6.0	± 0.15	280	190
6.5	± 0.20	290	210
7.0	± 0.20	300	230
7.5	± 0.20	310	240
8.0	± 0.20	320	250
8.5	± 0.20	320	260
9.0	± 0.20	320	270
9.5	± 0.20	320	280
10.0	± 0.20	320	280
11.0	± 0.20	320	280

^A Manufacturers desiring to market prepackaged sterilized oral tracheal precut tubes with connectors inserted may be guided by the lengths shown. However, the user is cautioned that anatomical variations, conditions of use, actual outside diameter of the tube, length of tube inserted, or other factors may well result in use of a tracheal tube either too long or too short for a given patient. Use of a tracheal tube precut to a standard length should not, under any circumstances, be substituted for expert clinical judgment in selecting tube size and length.

TABLE 2 Dimensions of Cuffed Tracheal Tubes

Size	Inflation Tube Take-Off Distance, (S), mm, ± 10 mm ^A	Maximum Distance, (D), mm, from Tip to Machine End of Effective Cuff ^B
5.0	120	56
5.5	130	56
6.0	150	58
6.5	170	62
7.0	180	66
7.5	190	69
8.0	205	72
8.5	210	75
9.0	220	78
9.5	230	81
10.0	230	85
10.5	230	85
11.0	230	85

^A See Fig. 2.

^B See Figs. 2 and 3.

inflation tube shall not exceed 2.5 mm external diameter and should be attached to the tracheal tube at a small angle without undue projection. The external inflation tube shall be fitted, either with an inflation valve with an inlet that will mate with a male luer syringe tip or shall have a female end capable of accepting a standard luer syringe tip. (See ANSI/HIMA MD70.1.) The external inflation tube shall be attached to the tracheal tube at a distance S as described in Fig. 2 and stated in Table 2. The external inflation tube shall extend at least 3 cm beyond the machine end of the tracheal tube, in accordance with minimum tube length in Table 1, before any system is incorporated, for example, pilot balloon, valve, or connector. The pilot balloon, if provided, should give an indication of the degree of inflation or deflation of the cuff. The inflation system shall not leak when tested in accordance with X1.7. If the inflation tube is clamped, the lumen of the inflation tube should reopen after unclamping to enable the intentional deflation of the cuff.