



Standard Specification for Pediatric Tracheostomy Tubes¹

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INTRODUCTION

When work on this standard was undertaken, the committee was confronted with a marketplace in which product sizes were designated by different systems. There was unanimous agreement in the committee that consistent use of a single standard system for designating sizes would be very desirable, but it was recognized that the sudden imposition of a single system, which would be foreign to many physicians, would create new problems. Accordingly, the present standard only starts the standardization process by giving emphasis to the sizing system based on inside diameter (ID) of tracheostomy tubes, but it permits other sizing systems to be appended in the labeling, along with other dimensional information.

1. Scope

1.1 This specification covers the basic requirements for tracheostomy tubes intended for use with pediatric patients. Such tubes may be selected for patients who require anesthesia, artificial ventilation, or other respiratory support, but may also be used for others who do not require mechanical ventilation. Provision is made for basic dimensions, materials, and properties, as well as for related items, for example, inner cannula and obturators, if provided.

2. Referenced Documents

2.1 ASTM Standards:

F 640 Test Methods for Radiopacity of Plastics for Medical Use²

2.2 ISO Standards:

ISO 5366/1/1980 Tracheostomy Tubes—Part 1: Connectors³

ISO 5366/1/1981/12/01E (Erratum) Tracheostomy Tubes—Part 1: Connectors³

2.3 Other Document:

United States Pharmacopeia, Revision XX

3. Terminology

3.1 Descriptions of Terms Specific to This Standard:

3.1.1 *disposable*—an item intended to be discarded after a single use.

3.1.2 *inner cannula*—an optional, removable liner which fits inside the tracheostomy tube.

3.1.3 *machine end*—that end of the tracheostomy tube intended to project from the patient.

3.1.4 *neck plate*—that part which approximates the contour of the patient's neck and which is used to secure the tracheostomy tube position. This neck plate may be fixed, adjustable, or rotatable.

3.1.5 *nominal length*—distance from patient surface of the neck plate to the tip of the patient end, as measured along the center line (see Fig. 1). When the neck plate is adjustable, the nominal length is variable.

3.1.6 *obturator*—a device to facilitate introduction of the tracheostomy tube into the trachea.

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

3.1.8 *tracheostomy tube*—tracheal tube designed for insertion through a tracheostomy.

4. Size and Basic Design

4.1 *Size*—The size of tracheostomy tubes shall be specified by the nominal minimum inside diameter (ID) stated to the nearest 0.1 mm. While the ID system is preferred, other dimensions or size designations may be important to the user and may also be included on the tube or package.

4.2 *Shape*—Means to enable the user to visualize the size and shape of the tracheostomy tube without compromising its sterility shall be provided, for example, with a scale drawing, facsimile, or a transparent package.

4.3 *Obturator*—If provided, the obturator shall be easily removable after introduction of the tracheostomy tube into the patient.

5. Materials

5.1 Inertness:

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

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

³ Available from American National Standards Institute, 1430 Broadway, New York, NY 10017.

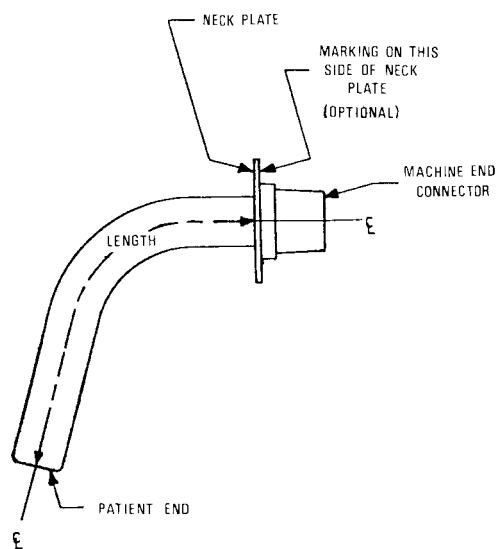


FIG. 1 Typical Pediatric Tracheostomy Tube

determined by the Implantation Test set forth in the United States Pharmacopeia XX, pp. 952 and 953. The biologic test procedure shall be applied to those portions of the finished product intended to be inserted 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 sterilization has been performed. The test is designed to determine the suitability of formulations and is not intended to be used as a routine test for every lot. Cell tissue culture and other tests for biocompatibility may be used, provided they can be shown to be equivalent to the United States Pharmacopeia tests.

5.1.2 Reusable tracheostomy tubes shall be reasonably resistant to agents recommended by the manufacturer for cleansing and sterilization.

5.1.3 Conditions of use require that all tracheostomy tubes be resistant to deterioration from anesthetic agents.

6. Design and Finish

6.1 *Finish*—Tracheostomy tubes, including the neck plate, should have smooth external and internal surfaces. The patient end and other portions of the tube that may contact the patient shall be without sharp points or rough edges.

6.2 *Machine End Connector*—The machine end of the tracheostomy tubes intended for use with mechanical ventilation shall have a male 15-mm connector capable of mating satisfactorily with a female 15-mm connector.

6.3 *Neck Plate*—Tracheostomy tubes shall be provided with a neck plate which shall be well-rounded at the edges, and which adapts to the contour of the patient's neck. The neck plate shall be provided with means to permit attachment to the patient.

7. Marking

7.1 *Marking Materials*—Marking materials to be placed on the tracheostomy tube shall be nontoxic and tissue-compatible

and shall resist deterioration by anesthetic agents. If the tracheostomy tube is intended for reuse, the material shall also resist deterioration by agents recommended for cleansing and sterilizing.

7.2 *Visibility of Markings*—Markings shall be clear and legible.

7.3 *Dimensions*—The minimum inside diameter and maximum outside diameter shall be marked on the neck plate as in Fig. 1, so that they are visible when the tube is in situ.

7.4 *Identity*—The name or trademark of the manufacturer shall be marked on the neckplate.

8. Radiolucency

8.1 The tracheostomy tube shall be radiolucent or a radiolucent marker shall be placed at the patient end of the tube, and the optical density of the tracheostomy tube or of the radiolucent marker, shall be less than or equal to that of the aluminum comparison standard, when tested in accordance with Section 9.

9. Test Method

9.1 *Test Protocol One—Radiolucency*—Using Test Methods F 640, Method B, expose the tracheostomy tube and an aluminum comparison standard. The aluminum comparison standard shall be a piece of aluminum 1 by 1 by 10 mm, or equivalent.

10. Packaging and Labeling

10.1 *Unit Packs*—Minimum units of sale shall be clearly labeled to include the following:

10.1.1 Description of contents.

10.1.2 Size, the minimum inside diameter, and the maximum outside diameter, expressed to the nearest 0.1 mm. When an inner cannula is provided, its inside diameter (ID) shall be stated.

10.1.3 The name of the manufacturer.

10.2 *Sterile Tubes*—Tubes individually packaged sterile, being marketed as disposable, shall have marked on the package:

10.2.1 The word "STERILE."

10.2.2 The words "SINGLE USE ONLY" or "DO NOT REUSE," or equivalent.

10.3 *Nonsterile Tubes*—When the tracheostomy tubes are not supplied sterile, the package information shall include a recommended method or methods of sterilization.

10.4 *Reusable Tubes*—When tracheostomy tubes are supplied with the intention that they can be reused, this shall be stated in the package information. The package information also shall recommend a method or methods for cleaning and sterilizing. Descriptions of the kinds of failures that may occur with reuse shall be included.

10.5 *Storage Conditions*—The manufacturer shall state any known conditions of storage likely to result in deterioration of the tubes.