



Standard Specification for Labeling and Marking of Cuffed and Uncuffed Tracheal Tubes and Related Treatments Intended for Use During Laser Surgery¹

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1. Scope

1.1 This specification covers the labeling, marking, warnings, and precautions for cuffed and uncuffed tracheal tubes and related materials intended by the manufacturer for use during laser surgery of the airway.

1.2 Rationale for this specification is to provide a standard format for reporting results obtained from Test Method F 1497. Safety and performance tests, with availability of results, are described in this specification to allow a manufacturer the maximum use of technological alternatives in design and materials. This specification addresses the laser resistance of the shaft of the tracheal tubes. Other components of the system, such as the inflation system and cuff, are outside the scope of this specification.

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

2. Referenced Documents

2.1 ASTM Standards:

F 1242 Specification for Cuffed and Uncuffed Tracheal Tubes²

F 1497 Test Method for Determining the Laser Resistance of the Shaft of Tracheal Tubes³

3. Terminology

3.1 *Definitions*—For definitions other than those listed below refer to Specification F 1242 and Test Method F 1497.

3.1.1 *device*—a tracheal tube or tracheal tube treatment material.

3.1.2 *marking*—information permanently affixed by the manufacturer to any surface of a tracheal tube or to any applied component of a laser resistant tracheal tube treatment that is affixed to or protects the component up to the point it is applied to the tracheal tube.

3.1.3 *product*—commercially available device in its packaged and labeled form.

3.1.4 *tracheal tube*—a tube to convey gases or vapors to and from the trachea. This term shall be used rather than synonyms such as “endotracheal,” “intratracheal,” or “catheter.”

3.1.4.1 *laser resistant tracheal tube*—a tracheal tube that is intended by the manufacturer for use during laser surgery. This includes devices that are sold pre-assembled, or in kit form.

3.1.5 *laser resistant tracheal tube treatments*—coverings or surface treatment materials, or both, indicated by the manufacturer for use with standard tracheal tubes where this product is intended to adapt the standard tracheal tube for use in laser surgery.

3.1.5.1 *Discussion*—This definition does not include such materials when provided in kit form with the tracheal tube (see 3.1.4.1).

3.1.6 *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.

3.1.7 *upper airway*—the segment of the anatomical airway above the laryngotracheal junction.

4. Product Marking and Labeling

4.1 All values shall be in SI units.

4.2 *Marking on the Device Shall Include:*

4.2.1 The name or trademark of the manufacturer or supplier.

4.2.2 Model or formulation code that is necessary to distinguish similar products from the same manufacturer, where this distinction is relevant to the laser resistance of the product.

4.2.3 A reference to any preparation steps designated by the manufacturer as essential to the laser resistance of the tracheal tube (that is, saturate covering with saline solution).

4.2.4 For cuffed tracheal tubes, a reference shall be included to any preparation steps designated by the manufacturer as essential for protection of the cuff from ignition (that is, inflate cuff with saline or water).

4.2.5 Depth markings are optional.

¹ This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is under the direct responsibility of Subcommittee F29.18 on Operating Room Fire Safety.

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² Discontinued; See 2001 *Annual Book of ASTM Standards*, Vol 13.01.

³ *Annual Book of ASTM Standards*, Vol 13.01.