Designation: F 1628 – 95 (Reapproved 2000)

# Standard Specification for Labeling and Marking of Cuffed and Uncuffed Tracheal Tubes and Related Treatments Intended for Use During Laser Surgery[1]

This standard is issued under the fixed designation F 1628; 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.

## 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 Tubes[2]

F 1497 Test Method for Determining the Laser Resistance of the Shaft of Tracheal Tubes[3]

## 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.

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[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.

4.2.5.1 **Caution:** When markings on the device are applied to an area of the shaft considered to be laser resistant, the determination of laser resistance by the manufacturer must include testing of the shaft directly upon these markings.

4.3 *Labeling on the Unit of Use Package*:

4.3.1 The following information shall be included in product labeling on product container. This information is supplemental to other descriptive labeling regulated by applicable standards, and is not intended to replace said labeling.

4.3.1.1 A description of the package contents.

4.3.1.2 The name or trademark of the manufacturer or supplier.

4.3.1.3 The product code or catalog number.

4.3.1.4 A reference to the batch, lot, or control number.

4.3.1.5 The word “sterile,” if appropriate.

4.3.1.6 For devices not intended for reuse, the words“ single patient use.”

4.3.1.7 For devices intended to be sterilized by the user, detailed information necessary to maintain laser resistance shall be included or referenced.

4.3.1.8 *Storage Conditions*—a caution statement of known conditions of storage likely to result in rapid deterioration of the materials, for example, high temperature, ultraviolet light, or fluorescent lighting.

4.3.1.9 Expiration date.

4.3.1.10 Prominent notice shall be listed to refer to information describing laser resistance required by 4.4.4.

4.4 The following information shall be included with each unit of sale package, such as in a package insert:

4.4.1 *Preparation and Use of the Device*—For protective treatments that require setup and routine maintenance to achieve the stated laser resistance, explicit information must include applicable precautionary statements.

4.4.2 Indications for use, including laser type, nominal wavelength, and contraindications.

4.4.3 Warnings and precautions relative to the use of the device including descriptions of damage and effects that are likely to occur from contact with lasers that could result in harm to the patient or operating room personnel. These sections shall include events other than ignition, which were reported during laser resistance testing conducted in accordance with Test Method F 1497.

4.4.4 The laser resistance test results for each laser type indicated including nominal laser wavelength. These test results shall be derived from testing conducted in accordance with Test Method F 1497. The presentation of the data shall be in graphical format depicting power from 0 to 100 W (unless warranted by higher power levels) versus laser energy duration from 1 to 30 s. No values less than 1 s or greater than 30 s shall be included. (See Fig. 1.)

4.4.4.1 Individual data points shall be connected by straight lines. Data shall be presented for laser energy durations of 1, 10, 20, and 30 s. Additional data points shall be included to limit the change from adjacent data points to no more than 20 % of the larger value, or 2 W, whichever is greater.

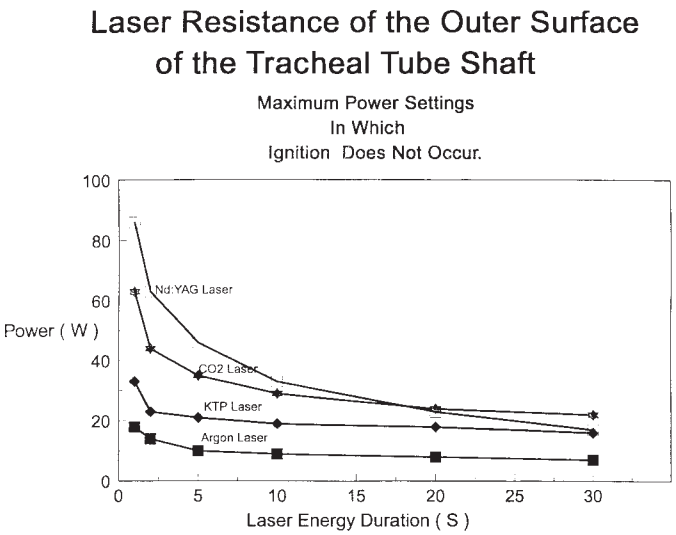


**FIG. 1 Laser Resistance of the Outer Surface of the Tracheal Tube Shaft**

4.4.5 Graph axes shall be linear, with power (watts) as the vertical axis and laser energy duration (seconds) as the horizontal axis, as listed in Test Method F 1497. The power curves for each laser type and nominal wavelengths shall be clearly indicated. The graph shall be titled “Maximum Power Settings In Which Ignition Does Not Occur.” The graph shall include a note stating that the data was derived from Test Method F 1497 (Fig. 1).

4.4.5.1 The length of the horizontal axis at 30 s shall be 160 ± 10 % of the height of the vertical axis at 100 W.

4.4.6 The following statements must appear in reasonable proximity to the graphs, such that it is clear that the statements apply to the data presented in the graphs.

4.4.6.1 The test method used to obtain these data addresses the laser resistance of the shaft of the tracheal tube. Other components of the system, such as the inflation system and cuff, are outside the scope of this test method.

4.4.6.2 Caution should be observed since the direct applicability of the results of the test method to the clinical situation has not been fully established.

4.4.6.3 These data were derived with a 0.5 mm spot size laser beam continuously applied perpendicularly to the tracheal tube shaft in a 98 % oxygen atmosphere. Refer to Test Method F 1497 for further information.

4.4.6.4 The test method data measures and describes the properties of materials, products, or assemblies in response to heat and flame under controlled laboratory conditions and does not describe or appraise the fire hazard or fire risk of materials, products, or assemblies under actual fire conditions. However, results of this test may be used as elements of a fire risk assessment which takes into account all of the factors that are pertinent to an assessment of the fire hazard of a particular end use.

4.4.6.5 Storage conditions (see 4.3.1.8).

4.5 *Shelf or Multi-Unit Containers*—The following supplemental information shall be displayed in addition to the other regulated labeling requirements for the product:

4.5.1 The name or trademark of the manufacturer or supplier.

4.5.2 The product code or catalog number.

4.5.3 The descriptive name of the device (trademark, etc.).

4.5.4 A reference to the batch, lot, or control number.

4.5.5 The word “sterile” as appropriate.

4.5.6 For products not intended for reuse, the words“ single patient use.”

4.5.7 Expiration date.

4.5.8 Quantity of unit packages contained in the package.

4.5.9 Storage conditions (see 4.3.1.8).