American National Standard

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Tracheal tubes designed for laser surgery—Requirements for marking and accompanying information

AAMI
Advancing Safety in Medical Technology

This document was approved and published when the U.S. TAG for TC 121 was held by ASTM, but it is now an AAMI standard. The original formatting has been maintained, so there are some variations from the typical AAMI style.

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INTERNATIONAL STANDARD

ANSI/ISO 14408

Second edition
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Tracheal tubes designed for laser surgery — Requirements for marking and accompanying information

Tubes trachéaux destinés aux opérations laser — Exigences relatives au marquage et aux informations d'accompagnement

Approved as an American National Standard with deviations by ASTM International

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14408 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This second edition cancels and replaces the first edition (ISO 14408:1998), Clauses 4 and 5 and Figure 1 of which have been technically revised.

For the purposes of this International Standard, the CEN annex regarding fulfilment of European Council Directives has been removed.

Introduction

This International Standard is intended to provide requirements for marking, labelling and information supplied for tracheal tubes which are designed for resistance to ignition by a laser and which have been tested for laser resistance in accordance with ISO 11990 including a standard format for reporting results obtained when tested in accordance with ISO 11990. It is intended that, by limiting the requirements to disclosure of information determined in accordance with standard test methods, the manufacturer will be allowed maximum use of alternatives in design and materials.

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Tracheal tubes designed for laser surgery — Requirements for marking and accompanying information

1 Scope

This International Standard specifies marking, labelling and information to be supplied by the manufacturer for cuffed and uncuffed tracheal tubes and related materials designed to resist ignition by a laser.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11990, *Optics and optical instruments — Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shafts*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
tracheal tube
tube designed for insertion through the larynx into the trachea to convey gases and vapours to and from the trachea

[ISO 4135:2001]

3.2
cuff
inflatable balloon permanently attached around the tracheal tube near the patient end to provide an effective seal between the tube and the trachea

NOTE Adapted from ISO 4135:2001.

3.3
laser-resistant tracheal tube
tracheal tube specifically designed by the manufacturer for use during laser surgery of the airway

NOTE This includes devices sold preassembled or in kit form.

3.4
laser-resistant tracheal tube treatment
covering and/or surface treatment that adapts or modifies non-laser-resistant tracheal tubes for use in laser surgery of the airway

