



F 2726-08

**Standard specification for fixation devices for
tracheal tubes and other airway devices**



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Foreword

This ASTM standard was developed as an American National Standard by ASTM Committee F29, *Anesthesia and Respiratory Equipment*, Subcommittee F29.12, *Airways*, Task Group 29.12.08, *Tracheal Tube Fixation Devices*, in the format of an ISO standard to serve as a guide for future work as a new ISO Standard.

This is the first edition of this standard.



Introduction

This ASTM Standard provides the essential requirements for the design of fixation devices for tracheal tubes and other airway devices, hereafter referred to as fixation devices. These devices are intended to secure and stabilize the position of tracheal tubes and other airway devices.

This ASTM standard specifies the dimensions and method of size designation of fixation devices so that the operator will know which airway device(s) will be size compatible with these fixation devices. Certain fixation devices which are devised for specialized applications are not covered, although most may be classified by the sizing and dimensions required by this standard.

Unintentional movement of the tracheal tube or other airway device continues to be a leading cause of patient injury. Fixation devices are designed to stabilize and fix the position of tracheal tubes and other airway devices to prevent injury. Commercially available fixation devices typically differ from the classical means to secure tracheal tubes or other airway devices (e.g. adhesive or cloth tape) by providing clamps, clips, or other adhesive or non-adhesive based fasteners intended to attach the device to the head of the patient and to secure the tracheal tube or other airway device in one place. The 2005 American Heart Association³ recommends the use of fixation devices rather than tape.

These devices may be easier to use and more comfortable for the patient than the classical means. They offer the advantage of ease of relocation or reapplication on the same patient. While these devices have reduced injuries related to the use of adhesive surgical tape, many injuries are still caused by deficiencies in the manufactured devices. Many devices lack the integrity, security, strength, and immobilization characteristics needed. Some devices, if used improperly, have been demonstrated to create the additional risk of tissue ischemia and necrosis caused by excessive pressure. Several designs have proven difficult to use, especially in emergency conditions, due to lack of clear instructions, markings, and labeling.

Annexes C, D, and E are normative; Annexes A, B, F, G, and H are informative.

Annex A contains rationale statements for some of the requirements of this part of ISO. The clauses and sub classes marked with an asterisk (*) after their number have corresponding rationale contained in annex A, included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this standard. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this standard, but will expedite any subsequent revisions.



1. Scope

1.1 *This standard covers basic safety and essential performance requirements for fixation devices designed to be attached to the head, face, or mouth of the patient and equipped with a means to secure and stabilize a tracheal tube or other airway device in its intended position. Devices within the scope of this standard may be provided with a wide variety of patient attachment mechanisms and tube locking mechanisms.

1.2 *Devices intended to secure tracheostomy tubes are outside the scope of this standard.

NOTE These requirements are addressed in ISO 5366-1¹ and 5366-3².

1.3 *Fixation devices intended to secure devices such as gastric tubes, feeding tubes and suction catheters are outside the scope of this standard.

1.4 Flammability of fixation devices, for example if used in the presence of certain flammable anesthetics, electrosurgical units, or lasers is a well-recognized hazard that is outside the scope of this standard. See Annex F for guidance.

2. Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid Standards.

ASTM D 2665-07, *Standard specification for poly (vinyl chloride) (PVC) plastic drain, waste, and vent pipe and fittings*

ASTM F 1573, *Standard specification for anesthetic equipment---Oropharyngeal and nasopharyngeal airways*

ASTM F 2560-2006, *Anesthetic and respiratory equipment – Standard specification for supralaryngeal airways and connectors*

ISO 4135, *Anaesthesiology-vocabulary*

ISO 5361:2005, *Anaesthetic and respiratory equipment -- Tracheal tubes and connectors*

ISO 5364:2001 *Anaesthetic and respiratory equipment - Oropharyngeal airways*

ISO 5367:2000 *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 7000, *Graphical symbols*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests.*

ISO 11134, *Sterilization of healthcare products-requirements for validation and routine control – Industrial moist heat sterilization*

ISO 11135, *Medical Devices – Validation and routine control of ethylene oxide sterilization*



ISO 11137, *Sterilization of healthcare products - Requirements for validation and routine control – Radiation sterilization*

ISO 11607, *Packaging for terminally sterilized medical devices*

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

ISO 11991, *Guidance on airway management during laser surgery of upper airway*

ISO 14155-1, *Clinical investigation of medical devices for human subjects -- Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects -- Part 2: Clinical investigation plans*

ISO 14408, *Tracheal tubes and related treatments designed for resistance to ignition by a laser - Requirements for marking, labeling and accompanying information*

ISO 14971, *Medical devices – Applications of risk management to medical devices*

3. Terms and definitions

For the purposes of this Standard, the following terms and definitions apply:

3.1

fixation device

device that contains a patient attachment mechanism and a tube locking mechanism to secure and stabilize a tracheal tube or other airway device in its intended position.

NOTE The fixation device may incorporate a bite block.

3.2

machine side

the side of the fixation device intended to face away from the patient and toward the breathing system

3.3

patient attachment mechanism

the portion of the fixation device that stabilizes the device on the patient

NOTE 1 The patient attachment mechanism may be attached to the head, face, or mouth.

NOTE 2 Patient attachment mechanisms include tape, straps, bands, wires, or pads that either surround the head and/or attach directly to the face.

3.4

patient side

the surface of the fixation device intended to be placed on or inserted into the patient

3.5

single fault condition

condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present



3.6

tube locking mechanism

the portion of the fixation device that locks the tracheal tube or other airway device to the patient attachment mechanism

NOTE The tube locking mechanism may consist of tape, adhesives, fasteners, locks, collets (which squeeze and compress the tracheal tube or other airway device), clips or other means to stabilize the tracheal tube or other airway device.

4. *General requirements

This standard specifies requirements that are generally applicable to risks associated with fixation devices.

4.1 An established risk management process shall be applied to the design of the device.

NOTE See Annex E for a list of identified hazards.

4.2 Fixation devices shall, when used and maintained in accordance with the instructions of the manufacturer, present no risks that are not reduced to an acceptable level using risk management procedures in accordance with ISO 14971 and which are connected with their intended application in normal condition and single fault condition.

4.3 Fixation devices shall, when transported, stored, installed, operated in normal use as intended, and maintained according to the instructions of the manufacturer, minimize safety hazards which could reasonably be foreseen, in normal condition and single fault condition.

4.4 *It is recognized that the manufacturer might not be able to follow all the processes identified in this standard for each constituent component of the fixation device, such as proprietary components, subsystems of non-medical origin, and legacy devices. In this case, the manufacturer should take special account of the need for additional risk control measures.

4.5 The manufacturer may use type tests different from those detailed within this standard, if an equivalent degree of safety is obtained. However, in the event of dispute, the methods specified herein shall be used as the reference methods.

5. *Requirements

NOTE The requirements of this standard were developed using the Hazard Identification for Risk Assessment in Annex E.

5.1 *Fixation devices shall prevent unintended movement of tracheal tubes or other airway devices in those head and neck positions and patient positions for which the device is intended to be used.

The following head and neck positions shall include at least a 30° change from a neutral position:

- a. flexion
- b. extension
- c. right and left rotation
- d. right and left lateral flexion (tilt)



All these shall be performed in the following patient body positions:

- a. supine
- b. prone
- c. 30-degree Trendelenburg (head down)
- d. 60-degree sitting
- e. 90-degree lateral (right and left)

Compliance shall be tested by functional testing. If clinical studies are performed, the clinical studies shall document measurements taken during the conditions for which performance is claimed. The clinical studies shall comply with the requirements of ISO 14155-1 and ISO 14155-2.

NOTE See also Annex B and Annex E.

5.2 Size designation

The size of a fixation device shall be designated using the same convention as that of the tracheal tube or other airway device that it is intended to secure. Devices that are intended for a range of sizes shall be marked with the corresponding range.

- a. For devices intended to be used with tracheal tubes, the size designation shall be the ID size of the tracheal tube in mm, as indicated in ISO 5361.
- b. For devices intended to be used with supralaryngeal airways, the range of sizes shall be from 0 to 6 for the smallest to largest size devices, as indicated in ASTM F 2560. The smallest increment permitted is 0.5. The transition size from pediatric to adult is size 3.
- c. For devices intended to be used with oropharyngeal airways, the size shall be the designated length in cm of the airway, as indicated in ISO 5365.
- d. For devices intended to be used with nasopharyngeal airways, the size shall be the inside diameter in mm, as designated in ASTM F1573.

5.3 Materials

Fixation devices, including patient attachment mechanisms, tube locking mechanisms, and all related accessories in their ready-for-use state after any preparation for use recommended by the manufacturer, shall satisfy appropriate biological safety testing, as indicated in ISO 10993-1. Initial biocompatibility evaluation tests shall include all materials in the fixation device. These shall be tested as external communicating, tissue/bone/dentin communicating, and <24 hour contact devices. If the proposed contact duration is greater than 24 hours, biocompatibility tests shall include those tests for >24 hour duration.

NOTE See Annex F for guidance on materials and design.

5.4 Patient attachment mechanism

5.4.1 The patient attachment mechanism shall be attached or integral to the fixation device and not require assembly by the user before use.

Compliance shall be tested by examination.

5.4.2 *For tracheal tube sizes ≥ 4.0 , supralaryngeal airway sizes ≥ 1.5 and oropharyngeal airway sizes ≥ 5 , it shall be possible to affix the patient attachment mechanism to the head or face of the patient in such a manner that movement under a strain of 45 N shall not exceed 1 cm in the ventral axis direction.

For tracheal tube sizes < 4.0 , supralaryngeal airway sizes < 1.5 and oropharyngeal airway sizes < 5 , it shall be possible to affix the patient attachment mechanism to the head or face of the patient in such a manner that movement under a strain of 9.8 N shall not exceed 0.5 cm in the ventral axis direction.