International Standard 5366/1

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Tracheostomy tubes — Part 1 : Connectors

Tubes de trachéostomie — Partie 1 : Raccords

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 5366/1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment.*

This second edition cancels and replaces the first edition (ISO 5366/1-1980), of which it constitutes a minor revision.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

Tracheostomy tubes — Part 1 : Connectors

0 Introduction

There are many advantages in harmonizing the requirements for connectors for tracheostomy tubes with those already widely used for tracheal tubes.

The patient connection port of the breathing system of an anaesthetic machine or ventilator is a coaxial 22 mm male/15 mm female conical connector, an important purpose of the smaller connector being to mate with the 15 mm male tracheal tube connector. It is, therefore, advantageous to use the same size of fitting for tracheostomy tubes used for patients during surgical operations and for those for whom artificial ventilation or other respiratory support may be required.

Inadvertent disconnection of the breathing system from the tracheostomy tube is a well-recognized hazard and it is therefore specified for the larger sizes of tube (6 mm internal diameter and greater) that the male 15 mm conical fitting shall be permanently attached to the tracheostomy tube.

It is also recommended that the design should permit the fitting of a device to make a more secure attachment between the conical fittings if so desired. Such a device may, however, introduce other hazards such as that of accidental extubation. It should, therefore, be as light and compact as possible with any protuberances designed so as to minimize the likelihood of their catching on attendants' hands, surgical dressings or other equipment.

This International Standard recognizes that a permanently attached conical fitting as specified for the larger tubes may, because of its bulk, prove impracticable for use with infants and small children and that there is a wide variety of acceptable fittings used in clinical paediatric practice. For these reasons it is not a mandatory requirement that the 15 mm conical fitting be permanently attached to the smaller tracheostomy tubes up to and including size 5,5 mm internal diameter. Any other type of connector, however, should either terminate in a 15 mm male conical fitting at its machine end or mate with an adaptor having such a fitting at its machine end.

NOTE — ISO 5366/2 specifies basic requirements for tracheostomy tubes.

1 Scope and field of application

This part of ISO 5366 specifies basic requirements for connectors for tracheostomy tubes for use on patients undergoing surgical operations and/or those for whom artificial ventilation or other respiratory support may be required.

2 Reference

ISO 5356/1, *Breathing attachments for inhalation anaesthetic apparatus, lung ventilators and resuscitators — Part 1 : Conical fittings and adaptors for breathing systems.* 1)

3 Definitions

For the purpose of this part of ISO 5366, the following definitions apply.

3.1 tracheostomy tube (tracheotomy) : Tube designed for insertion into the trachea through a tracheostomy (tracheotomy). 2)

1) At present at the stage of draft.

2) Definition taken from ISO 4135, *Anaesthesiology — Vocabulary.*

3.2 machine end :

(1) End of the tracheostomy tube which is intended to project from the neck of the patient.

(2) End of connector or the adaptor intended to mate with the breathing system of an anaesthetic machine or ventilator.

4 Connectors for tracheostomy tube of size 6 mm internal diameter and greater

4.1 Tracheostomy tubes of size 6 mm internal diameter and greater shall have at the machine end a permanently attached male 15 mm conical fitting in accordance with ISO 5356/1 with the exception that the internal diameter of the conical element shall be not less than the internal diameter of the tube.

4.2 Any transition in internal diameter shall be tapered to give an adequate lead-in for passage of a suction catheter.

5 Connectors for tracheostomy tube of size 5,5 mm internal diameter and less

Connectors for tracheostomy tubes of size 5,5 mm internal diameter and less need not be permanently attached to the tracheostomy tube but shall either

a) have at the machine end a 15 mm male conical fitting,

or

b) mate with an adaptor which shall have a 15 mm male conical fitting in accordance with ISO 5356/1 at its machine end.

6 Retaining devices

6.1 A retaining or locking device may be incorporated in the design to provide added security of attachment of the conical fittings.

6.2 Any projections (for example hooks, lugs or studs) should be so designed as to minimize the risk of their catching on surgical dressings or other equipment.