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Anaesthetic and respiratory equipment — Tracheostomy tubes —

Part 1: Tubes and connectors for use in adults

Matériel d'anesthésie et de réanimation respiratoire — Tubes de trachéostomie —

Partie 1: Tubes et raccords pour adultes

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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. 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 3.

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 part of ISO 5366 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 5366-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This fourth edition cancels and replaces the third edition of ISO 5366-1 and the second edition of ISO 5366-2 (ISO 5366-1:1994 and ISO 5366-2:1993), which have been technically revised.

ISO 5366 consists of the following parts, under the general title *Anaesthetic and respiratory equipment — Tracheostomy tubes*:

— *Part 1: Tubes and connectors for use in adults*

— *Part 3: Paediatric tracheostomy tubes*

Annexes A and B form a normative part of this part of ISO 5366. Annex C is for information only.

Introduction

ISO 5366-1 is one of a series of International Standards dealing with anaesthetic equipment, and is concerned with the basic requirements and method of size designation of tracheostomy tubes made of plastics materials and/or rubber. Specialized tubes, for example those without a connector at the machine end intended for spontaneously breathing patients, and those with reinforced walls or tubes made of metal are excluded from the scope of this part of ISO 5366.

This part of ISO 5366 specifies requirements for tracheostomy tubes with an inside diameter of 6,5 mm or greater. ISO 5366-3 specifies requirements for tracheostomy tubes with an inside diameter from 2,0 to 6,0 mm for paediatric use.

The method of describing tube dimensions and configuration has been devised in order to assist the clinician in the selection of a suitable tube to conform as far as possible to a particular patient's anatomy. Size is designated by inside diameter, which is important because of its relation to resistance to gas flow. Because the stomal and tracheal diameters are important when selecting tubes, it is considered essential that the outside diameter be stated for each size of tube.

Cuffed tracheostomy tubes can be characterized by a combination of the tube inside and outside diameters and by the cuff resting diameter.

The relationship of cuff and tracheal diameters dictates the intra-cuff pressures required to provide a seal. Excessive pressure on the tracheal wall can obstruct capillary blood flow.

A range of cuff designs is available to meet the particular clinical requirements. This part of ISO 5366 requires that the resting diameter of the cuff is marked on the unit package, as this information allows the clinician to match the product to the application.

A 15 mm male conical connector in accordance with ISO 5356-1 should be used for tracheostomy tubes, as for tracheal tubes, to ensure compatibility with the breathing system of an anaesthetic machine or ventilator.

The tracheostomy tube connector should be permanently attached to the tracheostomy tube to prevent inadvertent disconnection of the connector from the tube.

Flammability of tracheostomy tubes, for example if flammable anaesthetics, electrosurgical units, or lasers are used in oxidant-enriched atmospheres, is a well-recognized hazard[1)] that is addressed by appropriate clinical management, and is outside the scope of this part of ISO 5366.

1) See ISO/TR 11991.

Anaesthetic and respiratory equipment — Tracheostomy tubes —

Part 1:
Tubes and connectors for use in adults

1 Scope

This part of ISO 5366 specifies requirements for tracheostomy tubes made of plastics materials and/or rubber having inside diameters of 6,5 mm or greater. Such tubes are primarily designed for patients who require anaesthesia, artificial ventilation or other respiratory support, but need not be restricted to these uses.

This part of ISO 5366 is not applicable to specialized tubes, and does not address flammability of tracheostomy tubes.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 5366. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 5366 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 International Standards.

ISO 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*.

ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*.

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*.

ISO 5361, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*.

ISO 11607, *Packaging for terminally sterilized medical devices*.

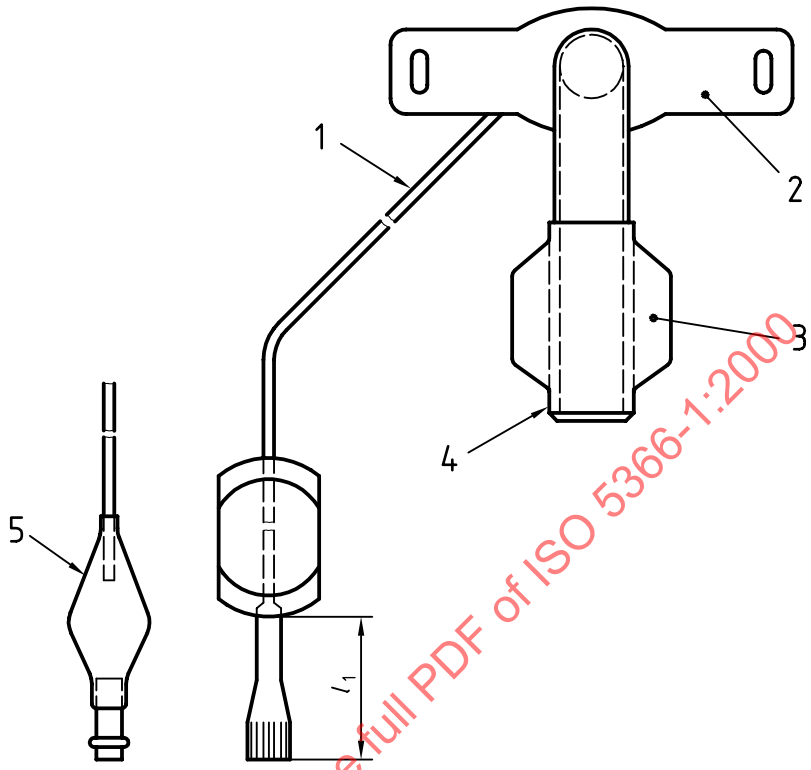
EN 556 :1994, *Sterilization of medical devices — Requirements for medical devices to be labelled "STERILE"*.

3 Terms and definitions

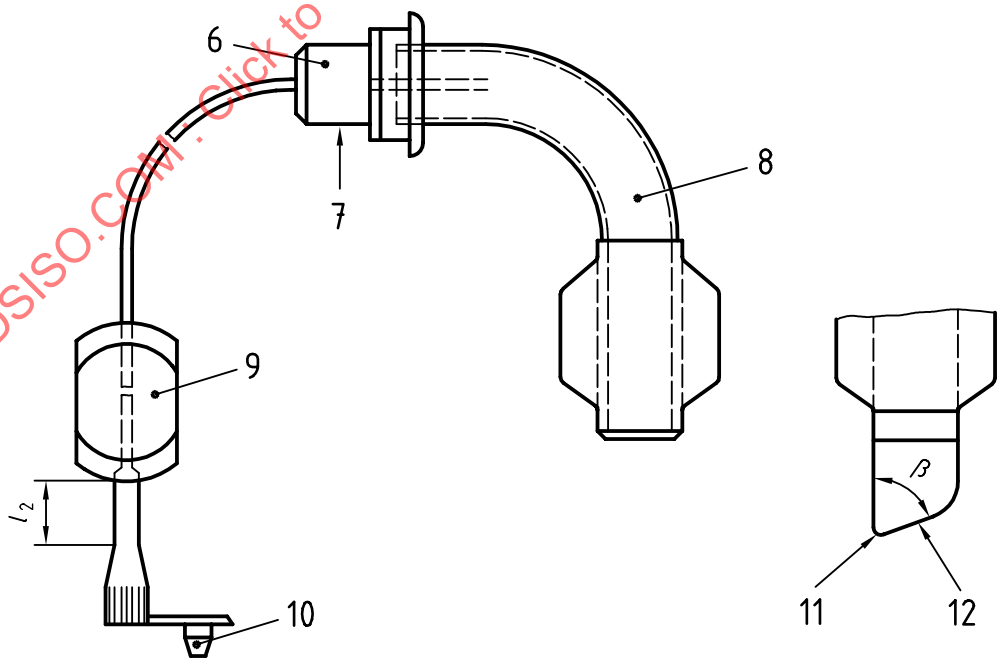
For the purposes of this part of ISO 5366, the terms and definitions given in ISO 4135 and the following apply.

3.1
tracheostomy tube
tube designed for insertion into the trachea through a tracheostomy

NOTE See Figure 1 a) and b) for an illustration of a typical tracheostomy tube and the associated nomenclature.



a) View 1



b) View 2

Key

1	Inflating tube
2	Neck-plate
3	Cuff, if present
4	Patient end
5	Alternative integral pilot balloon/valve assembly
6	15 mm male conical fitting in accordance with ISO 5356-1
7	Machine end
8	Outer tube
9	Pilot balloon
10	Inflation valve or closure device
11	Tip rounded
12	Bevel, if present

Figure 1 — Typical tracheostomy tube

3.2
machine end
⟨of a tracheostomy tube⟩ that end which is intended to project from the neck of a patient

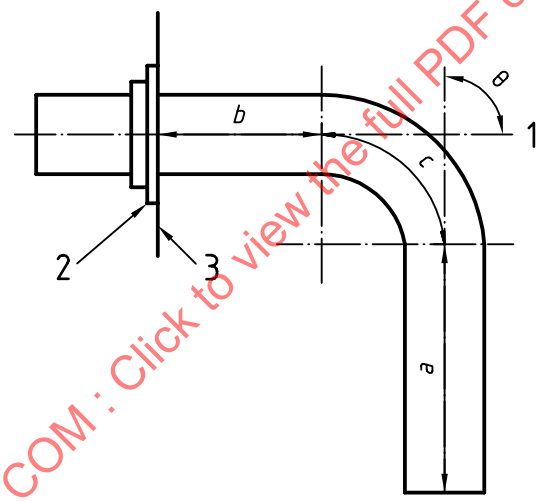
3.3
machine end
⟨of a connector or an adaptor⟩ that end intended to mate with the breathing system of an anaesthetic machine or ventilator

3.4
patient end
that end of a tracheostomy tube which is intended to be inserted into the trachea

3.5
nominal length
distance from the patient side of the neck-plate to the patient end along the centreline

See Figure 2.

NOTE When the neck-plate is movable, the nominal length is variable.



Key

1	Centreline
2	Neck-plate
3	Datum plane

NOTE The angle θ is the obtuse angle formed between the long axes of the tube at the machine and patient ends.

Figure 2 — Basic dimensions of tracheostomy tubes

3.6

outer tube

that part of the tracheostomy tube which is normally in contact with the tissues

3.7

inner tube

tube which fits closely to the inside contours of the outer tube (i.e. a tracheostomy tube)

3.8

cuff

inflatable balloon permanently attached around the tracheostomy tube near the patient end to provide a seal between the tube and the trachea

3.9

inflating tube

tube through which a cuff is inflated

3.10

pilot balloon

balloon fitted to an inflating tube to indicate inflation of a cuff

3.11

neck-plate

shield

that part of a tracheostomy tube which approximates to the contour of a patient's neck and is used to secure the tube in position

3.12

introducer

obturator

specially adapted stylet to facilitate the introduction of the outer tube into the trachea

3.13

bevel

slanted portion at the patient end of a tracheostomy tube

3.14

angle of bevel

acute angle between the plane of the bevel and the longitudinal axis of a tracheostomy tube at the patient end

4 Size designation and dimensions

4.1 Inside diameter

4.1.1 The size of the tracheostomy tube (outer tube) shall be designated by the nominal inside diameter (ID) of the tube, expressed in millimetres, as measured at the minimum inside diameter, in accordance with Table 1, excluding any encroachment allowed by 6.5.1.

4.1.2 For tracheostomy tubes with the conical connector permanently attached to the inner tube, the size shall be designated by the nominal inside diameter (ID) of the inner tube, expressed in millimetres, in accordance with Table 1.

Table 1 — Size designation of tracheostomy tubes — Dimensions and tolerances

Dimensions in millimetres

Designated size	Inside diameter and tolerance
6,5	6,5 ± 0,2
7,0	7,0 ± 0,2
7,5	7,5 ± 0,2
8,0	8,0 ± 0,2
8,5	8,5 ± 0,2
9,0	9,0 ± 0,2
9,5	9,5 ± 0,2
10,0	10,0 ± 0,2
10,5	10,5 ± 0,2
11,0	11,0 ± 0,2

4.2 Outside diameter

4.2.1 The outside diameter (OD) of sections a and c (see Figure 2) of the tube, other than at the cuff, if provided, shall be expressed in millimetres to the nearest 0,1 mm.

NOTE The stated outside diameter relates to that portion of the tube intended to be within the wall and the lumen of the trachea.

4.2.2 The actual outside diameter of section a (see Figure 2) other than at the cuff, if provided, shall be the marked outside diameter subject to a tolerance of ± 0,2 mm.

4.2.3 The actual outside diameter of section c shall be the marked outside diameter subject to a tolerance of ± 0,5 mm.

4.3 Length

4.3.1 The nominal length (dimensions $a + b + c$ in Figure 2) shall be measured from the patient side of the neck-plate to the patient end including the bevel, if present, and expressed in millimetres.

4.3.2 The actual nominal length (dimensions $a + b + c$ in Figure 2) shall be the marked nominal length subject to a tolerance of ± 2 mm.

4.3.3 For tubes with an adjustable neck-plate, the range of measurements for nominal length (see Figure 2) shall be expressed in millimetres.

4.3.4 Dimensions a, b and c shall be expressed in millimetres (see Figure 2).

NOTE Dimensions a and/or b can be, or approach, zero.

4.4 Angle θ

The angle θ (see Figure 2) shall be expressed in degrees.

5 Materials

Tracheostomy tubes, including cuffs and tracheostomy tube connectors, in their ready-to-use state after any preparation for use recommended by the manufacturer, shall satisfy appropriate biological safety testing, as indicated in ISO 10993-1.

NOTE See annex C for guidance on materials and design.

6 Design and finish

6.1 Machine end

6.1.1 Tracheostomy tubes or their inner cannulae shall have at the machine end a permanently attached male 15 mm conical connector in accordance with ISO 5356-1.

NOTE In this context, permanently attached means it does not become detached when subject to the forces described in the test method given in annex A.

6.1.2 The inside diameter of the conical connector at the machine end shall be not less than the designated inside diameter of the tube to which it is attached.

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

6.1.4 When tested in accordance with annex A, the connector shall not move longitudinally relative to the tube.

6.2 Neck-plate

6.2.1 Tracheostomy tubes shall have a neck-plate which shall be adjustable or permanently attached to the tube.

6.2.2 The neck-plate shall be provided with holes or other means to permit attachment to the patient.

6.2.3 If a tracheostomy tube has an adjustable neck-plate, it shall be securable to the tube. (See also C.2.4.)

6.2.4 When tested in accordance with annex A, the neck-plate shall not move longitudinally relative to the tube.

6.3 Inner tube

6.3.1 The inner tube, if provided with the outer tube, shall extend to within 1,0 mm of the patient end of the tracheostomy (outer) tube and not more than 1,0 mm beyond the patient end.

6.3.2 The machine end of the inner tube shall either comply with 6.1 or shall not prevent the tracheostomy (outer) tube connector mating with the breathing system of an anaesthetic machine or lung ventilator.

6.4 Cuff

6.4.1 A cuff, if provided, shall be permanently attached to the tube.

6.4.2 Cuffs of tracheostomy tubes shall satisfy the requirements of ISO 5361.

6.4.3 The cuff resting diameter shall be within $\pm$ 15 % of the marked value, when determined in accordance with annex B.

6.5 Inflating tubes for cuffs

6.5.1 Inflating tube

The inflating tube shall have an outside diameter of not more than 2,5 mm. The wall around the inflation lumen shall not encroach on the lumen of the tracheostomy tube by more than 10 % of the inside diameter of the tracheostomy tube.

The wall around the inflation lumen should not project substantially on the outside surface of the tracheostomy tube.

6.5.2 Pilot balloon

6.5.2.1 The inflating tube shall have a pilot balloon and/or other means to indicate inflation/deflation of the cuff.

NOTE This (these) device(s) can also serve as a pressure-indicating or -limiting device.

6.5.2.2 The intentional evacuation of the cuff shall not be prevented by the inflating tube, inflating valve or any closure device.

6.5.3 Free end of inflating tubes for cuffs

The end of the inflating tube shall be either open or sealed with a closure device or inflation valve, but in all instances it shall be capable of accepting a male conical fitting with a 6 % taper (Luer) complying with ISO 594-1. The length [see Figure 1 a), dimension l_1] of the free end of inflating tubes shall be not less than 40 mm unless an inflation valve or closure device is provided.

If an inflation valve or closure device is provided, the length [see Figure 1 b), dimension l_2] between the pilot balloon (or other device) and the female fitting which accepts a male Luer conical fitting shall be not less than 10 mm unless the pilot balloon and valve or closure device are integral.

NOTE This is to facilitate clamping of the inflating tube.

6.6 Patient end

If a bevel is present, the angle of bevel (β) shall be not less than 50° (see Figure 1 inset).

6.7 Introducer

If provided, the introducer, when correctly seated, shall not fall out of the tracheostomy tube under its own weight when the tube is held by the neck-plate with the patient end uppermost.

The introducer should be freely removable in use.

7 Requirements for tracheostomy tubes supplied sterile

7.1 Sterility assurance

Tracheostomy tubes supplied and marked as “STERILE” shall satisfy the requirements of 4.1 of EN 556:1994.

7.2 Packaging for tracheostomy tubes supplied sterile

7.2.1 The following information shall be apparent on visual examination of the intact unit container:

a) the size and pre-formed shape of the tube;

b) whether a cuff is provided.

NOTE For example, the unit container can be transparent and the tube visible, or a drawing to scale, preferably full-scale, can be used.

7.2.2 Each tracheostomy tube supplied and marked as “STERILE” shall be contained in an individual pack. The pack shall serve as an effective barrier to the penetration of microorganisms and particulate material, in accordance with ISO 11607. The pack shall permit the aseptic extraction of the contents and shall not be capable of re-closure without clearly revealing that it has been opened.

8 Marking and labelling

8.1 General

Marking and labelling of unit packs and of shelf or multi-packs and information to be supplied by the manufacturer should comply with EN 1041.

8.2 Marking of the neck-plate

8.2.1 The following information shall be marked on the neck-plate and shall be visible from the machine end:

a) the designated size in accordance with 4.1;

b) the nominal outside diameter expressed in millimetres in accordance with 4.2.1;

c) the name and/or trade mark of the manufacturer.

NOTE The nominal length (or the maximum length for tubes with an adjustable neck-plate) expressed in millimetres (see 4.3) can also be provided.

8.2.2 Cuffed tubes intended for reuse shall be marked with the resting diameter of the cuff determined in accordance with annex B and expressed in millimetres to two significant figures.

8.3 Labelling of unit packs

8.3.1 Use of symbols

The requirements of 8.3.2 and 8.3.3 may be met by use of appropriate symbols as given in EN 980.

8.3.2 Labelling of tracheostomy tube unit packs

Individual packs or a package insert shall be clearly labelled to indicate the following:

a) a description of contents;

b) the designated size in accordance with 4.1;

c) the nominal outside diameter, expressed in millimetres (see 4.2);

d) the nominal length, expressed in millimetres (see 4.3.1). For tubes with an adjustable neck-plate, the range of nominal lengths shall be given;

e) dimension a as shown in Figure 2. For tubes without an adjustable neck-plate, dimension b as shown in Figure 2;

f) the angle θ in accordance with 4.4;

g) the name and/or trade mark of the manufacturer and/or supplier;

h) the batch number;

i) unless the tracheostomy tube is intended and marked as being for single use, instructions for cleaning and disinfection or sterilization;

j) the word “STERILE” or “NON-STERILE” as appropriate;

k) for tubes not intended for re-use, the words “single-use” or equivalent;

l) for cuffed tubes, the resting diameter of the cuff, determined in accordance with annex B and expressed in millimetres to two significant figures;

m) if an inner tube is provided in the unit pack, the nominal inside diameter of the inner tube.

It is strongly recommended that the 'use by' date also be given.

8.3.3 Labelling of inner tube unit packs

Inner tube unit packs shall be clearly labelled to indicate the following:

a) a description of the contents;

b) the designated size (nominal inside diameter) of the tracheostomy tube (outer tube) into which it is designed to fit;

c) the nominal inside diameter of the inner tube;

d) the name and/or trademark of the manufacturer and/or supplier;

e) the batch number;

f) unless the tracheostomy tube is intended and marked as being for single use, instructions for cleaning and disinfection or sterilization;

g) the word “STERILE” or “NON-STERILE”, as appropriate;

h) for inner tubes not intended for re-use, the words “single use” or equivalent.

It is strongly recommended that the 'use by' date also be given.

Annex A
(normative)

Test method for the security of attachment of connector and neck-plate to tracheostomy tube

A.1 Principle

The security of attachment of the connector and neck-plate to the tracheostomy tube is tested by applying an axial separation force to the connector or the neck-plate, as appropriate.

A.2 Apparatus

A.2.1 **Means of conditioning** the tracheostomy tube at (37 ± 2) °C at not less than 80 % relative humidity for 24 h.

A.2.2 **Means of securing** the connector and tracheostomy tube and applying an axial separation force of (50 ± 5) N at a rate of (50 ± 5) mm · min^{-1}.

A.2.3 **Means of securing** the neck-plate and tracheostomy tube and applying an axial separation force of $(15 \pm 1{,}5)$ N or (50 ± 5) N at a rate of (50 ± 5) mm · min^{-1}.

A.3 Procedure

A.3.1 Condition the tracheostomy tube at (37 ± 2) °C at not less than 80 % relative humidity for 24 h.

A.3.2 Remove the tracheostomy tube from the conditioning chamber and secure the connector and tracheostomy tube (A.2.2).

NOTE For tracheostomy tubes with the conical connector permanently attached to the inner tube, the mechanism which secures the inner tube within the outer (tracheostomy) tube should first be engaged in accordance with manufacturer's instructions before securing the connector and tracheostomy tube.

A.3.3 Within 10 min of removing the tracheostomy tube from the conditioning chamber, apply an axial separation force of (50 ± 5) N to the tracheostomy tube relative to the connector at a rate of (50 ± 5) mm · min^{-1}.

A.3.4 Having already removed the tracheostomy tube from the conditioning chamber, secure the neck-plate and tracheostomy tube (A.2.3).

A.3.5 Within 10 min of removing the tracheostomy tube from the conditioning chamber, apply an axial separation force to the tracheostomy tube relative to the neck-plate as follows:

a) for tracheostomy tubes with an adjustable neck-plate, apply an axial force of $(15 \pm 1{,}5)$ N at a rate of (50 ± 5) mm · min^{-1};

b) for tracheostomy tubes with a permanently attached neck-plate, apply an axial force of (50 ± 5) N at a rate of (50 ± 5) mm · min^{-1}.

A.4 Expression of results

Record whether or not the connector or neck-plate moves longitudinally relative to the tracheostomy tube.