TC 121

International Standard ISO 5361/2

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION•МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ•ORGANISATION INTERNATIONALE DE NORMALISATION

Tracheal tubes — Part 2: Oro-tracheal and naso-tracheal tubes of the Magill type (plain and cuffed)

Tubes trachéaux — Partie 2: Tubes orotrachéaux et nasotrachéaux (avec et sans ballonnets) type Magill

First edition — 1984-08-15

UDC 621.643 : 616.231 — 089.5 **Ref. No. ISO 5361/2-1984 (E)**

Descriptors : medical equipment, anaesthesia, endotracheal tubes, specifications, dimensions, marking.

Price based on 7 pages

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of developing International Standards is carried out through ISO technical committees. Every member body interested in a subject for which a technical committee has been authorized 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.

International Standard ISO 5361/2 was developed by Technical Committee ISO/TC 121, *Anaesthetic equipment and medical breathing machines*, and was circulated to the member bodies in December 1981.

It has been approved by the member bodies of the following countries:

Australia	Germany, F.R.	South Africa, Rep. of
Canada	Japan	Sweden
China	Mexico	Switzerland
Czechoslovakia	Netherlands	United Kingdom
Egypt, Arab Rep. of	New Zealand	USA
France	Romania	USSR

No member body expressed disapproval of the document.

Printed in Switzerland

Tracheal tubes —
Part 2: Oro-tracheal and naso-tracheal tubes of the Magill type (plain and cuffed)

0 Introduction

This International Standard is one of a series dealing with anaesthetic equipment and medical breathing machines, and specifies the dimensions and basic properties of the most commonly used types of tracheal tubes, whether made of rubber or of other elastomeric material. Tubes with walls reinforced with metal or nylon, tubes with shoulders, tapering tubes, or the many types of special tubes devised for use in thoracic surgery, are not specifically covered, although most may be classified by their inside diameter as required by this specification.

While the inside diameter has been specified for size reference, this part of ISO 5361 requires that the outside diameter be marked on the smaller sizes of tube where this information is of greater clinical importance.

Clinical considerations have also dictated the apparently excessive specified length of tubes, because long tubes, sometimes of relatively narrow diameter, may be urgently required, and must therefore be readily available. Cognizance has been taken of developments in the use of pre-cut tracheal tubes supplied as sterile in unit packs (see the table and note).

1 Scope and field of application

This part of ISO 5361 specifies requirements for oro-tracheal and naso-tracheal tubes of the Magill type (plain and cuffed).

2 References

ISO 594/1, *Fittings with a 6 % Luer taper for syringes, needles and certain other medical equipment — Part 1: General requirements.* [1)]

ISO 5361, *Tracheal tubes —*

Part 1: General requirements.

Part 5: Requirements and methods of test for cuffs and tubes.

3 General

Oro-tracheal and naso-tracheal tubes of the Magill type (plain and cuffed) shall meet the requirements of ISO 5361/1.

4 Dimensions

4.1 The basic dimensions of tracheal tubes shall be in accordance with the table.

4.2 The inside diameter shall be the nominal diameter subject to a tolerance of ± 0,15 mm for size 6,0 and smaller, and subject to a tolerance of ± 0,20 mm for size 6,5 and larger.

4.3 For size 6,0 and smaller the actual outside diameter (OD) shall be within 0,15 mm of the marked outside diameter (OD) [see 9 b)].

5 Curvature of the tube

5.1 The radius of curvature for both oral and nasal tubes shall be 140 ± 15 mm for tubes of size 6,5 and larger.

5.2 This curvature may be omitted if desired from the tip of the bevel to not more than 30 mm beyond the machine end of the cuff. When this curvature (see figure 3) is so omitted, the straight portion shall be tangential to the curve of the tube.

The curvature may also be omitted from uncuffed tubes of size 6,5 and larger over the same equivalent distance as for cuffed tubes.

6 Bevel

6.1 All tubes shall have an angle of bevel of 38 ° ± 10°.

1) At present at the stage of draft. (Revision of ISO/R 594-1967.)

6.2 The end of the tube at the bevel shall be rounded and the orifice(s) shall be free from sharp edges.

6.3 The bevel of oral tubes shall have the opening facing to the left when the tube is viewed towards the concave aspect from the machine end (see figure 1). Nasal tubes may have the bevel facing in either direction.

7 Cuff

7.1 A cuff, if provided, shall be a bonded cuff and shall comply with the requirements of ISO 5361/5.

7.2 For tracheal tubes of size 5,0 and larger, dimension B in figures 1 a) and 1 b) shall not exceed 15 mm.

7.3 The maximum distance from the patient end of the tube to the machine end of the inflatable length of the cuff (C) shall be as given in the table [see figures 1 a) and 1 b)].

NOTE — Many cuffs have virtually no residual volume and are consequently easier to pass through the vocal cords than are some high volume cuffs. Small volume cuffs which generally need a relatively high pressure to inflate them are usually satisfactory, when correctly inflated, for anaesthetic use, i.e. for a few hours.

Attention is drawn to the many reports of tracheal damage when tracheal (or tracheostomy) tubes with small volume high pressure cuffs have been used for extended periods as is commonly the case in respiratory care. In these circumstances, it would appear desirable that cuffs should be made of soft material of low extensibility and have a relatively large residual volume. These factors reduce both the required inflation pressure and the pressure exerted on the tracheal wall. Attention is directed to the rapidly growing literature on this subject.

WARNING — Whatever type of cuff is used it is the responsibility of the user to ensure that it is inflated with no more than the minimum amount of air required to provide an effective seal at the desired lung inflation pressure.

8 Inflating tubes for cuffs

8.1 The inflating tube, if fitted, shall have an external diameter of not more than 3,0 mm and shall be situated on the concave aspect of the parent tube. The inflating tube shall not encroach on the lumen of the tracheal tube. The dimensions of the inflating tube shall be calculated in accordance with the table and figures 1 a) and 1 b).

8.2 If the inflating tube is attached externally to the tracheal tube between the cuff and the point of separation [see figures 1 a) and 1 b)], the attachment shall be in such a manner that the inflating tube may be partly stripped off the tracheal tube, if required.

8.3 The inflating tube shall be attached to the parent tube and shall join the cuff in such a manner to ensure that there is no undue projection to interfere with clinical use of the tube. The angle between the inflating tube and the parent tube at the point of separation [see figures 1 a) and 1 b)] shall not exceed 45°.

8.4 The inflating tube may be provided with a pilot balloon [see figures 1 a) and 1 b)]. The pilot balloon, if provided, shall be so constructed as to give an indication of inflation of the cuff. Neither the inflating tube nor the balloon shall act as a non-return valve to prevent the intentional evacuation of the cuff.

8.5 The minimum length of dimension S_3 [see figures 1 a) and 1 b)] shall be 40 mm except where an inflation valve or closure device is provided. Where such a closure device is provided, the length between the pilot balloon and the Luer conical fitting shall be not less than 10 mm to facilitate clamping except where the balloon and valve are built together.

8.6 The free end of the inflating tube may be open, or fitted with an appropriate plug or valve. Where the end is open, it shall be capable of accepting a male conical fitting with a 6 % taper (Luer) in accordance with ISO 594/1.

Alternatively, the inflating tube shall be fitted with an insert having a female conical fitting with a 6 % taper (Luer) in accordance with ISO 594/1.

9 Marking

In addition to the general requirements for marking given in part 1 of ISO 5361, tracheal tubes of the Magill type shall be marked as follows:

a) The word "Oral", "Nasal" or "Oral/Nasal" as appropriate on tubes of sizes 5,0 and larger.

b) For sizes 6,0 and smaller, the outside diameter shall be marked in millimetres.

If both the inside diameter and the outside diameter are marked the marking shall be in accordance with either of the following examples:

4,0 Oral 5,7 or ID **4,0** Oral 5,7 OD

The figures preceding the word "Oral" denote the internal diameter and should be in larger and bolder type.

c) Cuffed tubes and/or the package shall be additionally marked with the letter S (short) or L (long) as appropriate in accordance with the table.

d) Should the straight portion of the tube extend beyond the machine end of the cuff (see clause 5.2), then this shall be stated on the package, for example by the words "Straight patient end".

e) The marking of the size of the tracheal tube shall be situated as shown in the figures, on the bevelled side of the tube reading from the patient end to the machine end. Plain tubes shall have the size marked in a region equivalent to cuffed tubes of similar size.

Table — Basic dimensions of tracheal tubes

Dimensions in millimetres

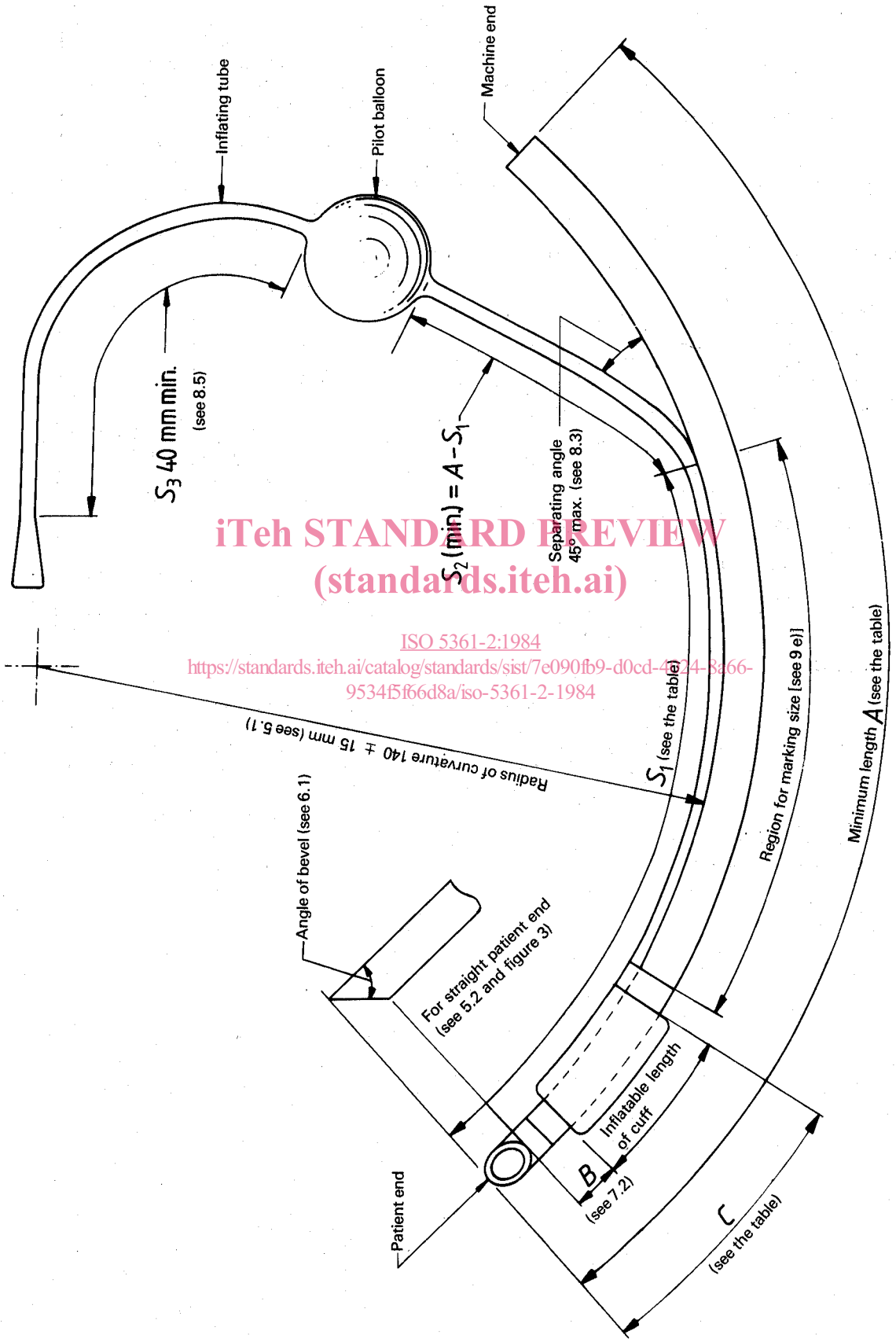
Designated size (nominal inside diameter)	**Minimal length of tube** [see figures 1 a) and 1 b), dimension *A*]		**Maximum *distance C* from the patient end to the machine end of the inflatable length of the cuff**	**Distance of point of separation of the inflating tube from the patient end** [see figures 1 a) and 1 b), dimension S_1]	
	Oral, Nasal or Oral/Nasal	Oral "precut" (see note 1)		Short (S)	Long (L)
2,5	140	110	—	—	—
3,0	160	120	—	—	—
3,5	180	130	—	—	—
4,0	200	140	—	—	—
4,5	220	150	—	—	—
5,0	240	160	50	—	—
5,5	270	170	54	—	—
6,0	280	190	58	—	—
6,5	290	210	62	145 ± 10	170 ± 10
7,0	300	230	66	150 ± 10	180 ± 10
7,5	310	240	69	155 ± 10	190 ± 10
8,0	320	250	72	160 ± 10	205 ± 10
8,5	320	260	75	165 ± 10	210 ± 10
9,0	320	270	78	170 ± 10	220 ± 10
9,5	320	280	81	175 ± 10	230 ± 10
10,0	320	280	85	180 ± 10	230 ± 10
10,5	320	280	85	180 ± 10	230 ± 10
11,0	320	280	85	180 ± 10	250 ± 10

NOTES

1 Manufacturers desiring to market packaged sterile oral "precut" tubes with connectors inserted may be guided by the tube lengths shown in the table. However, the user is cautioned that anatomical variations, conditions of use, length of tube inserted or other factors may well result in the use of a tracheal tube either too long or too short for a given patient. The necessity remains for expert clinical judgement in selecting the size and length of tracheal tubes.

2 Provision has not been made for inclusion of dimension *C* for cuffed tracheal tubes of sizes 4,5 or less because they are seldom required.

3 Two lengths for dimension S_1 are specified to cater for wide variations in clinical practice.



1 a) — Typical cuffed tracheal tube (Magill type)

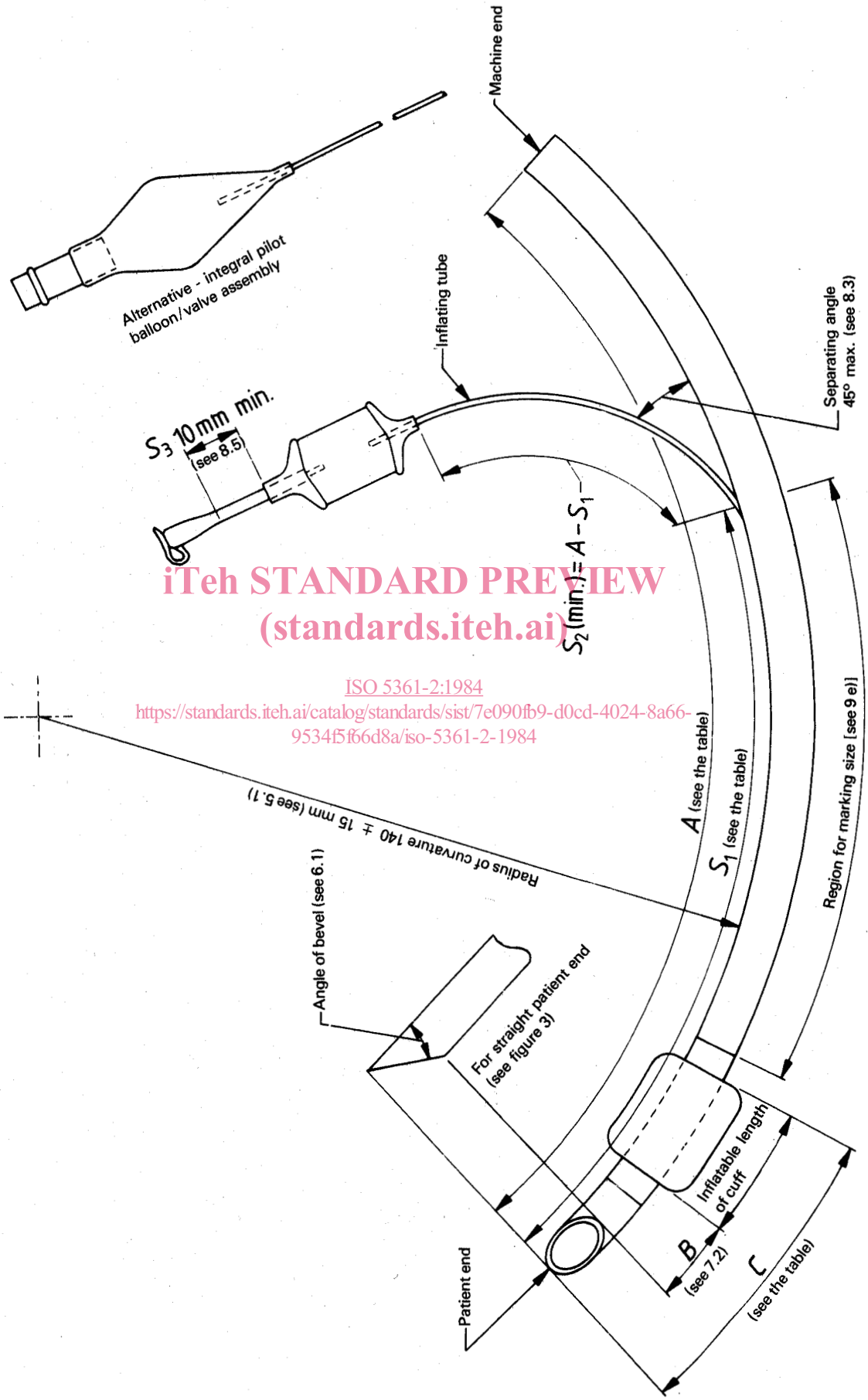


Figure 1 b) — Typical cuffed tracheal tube (Magill type)
(showing alternative design features)

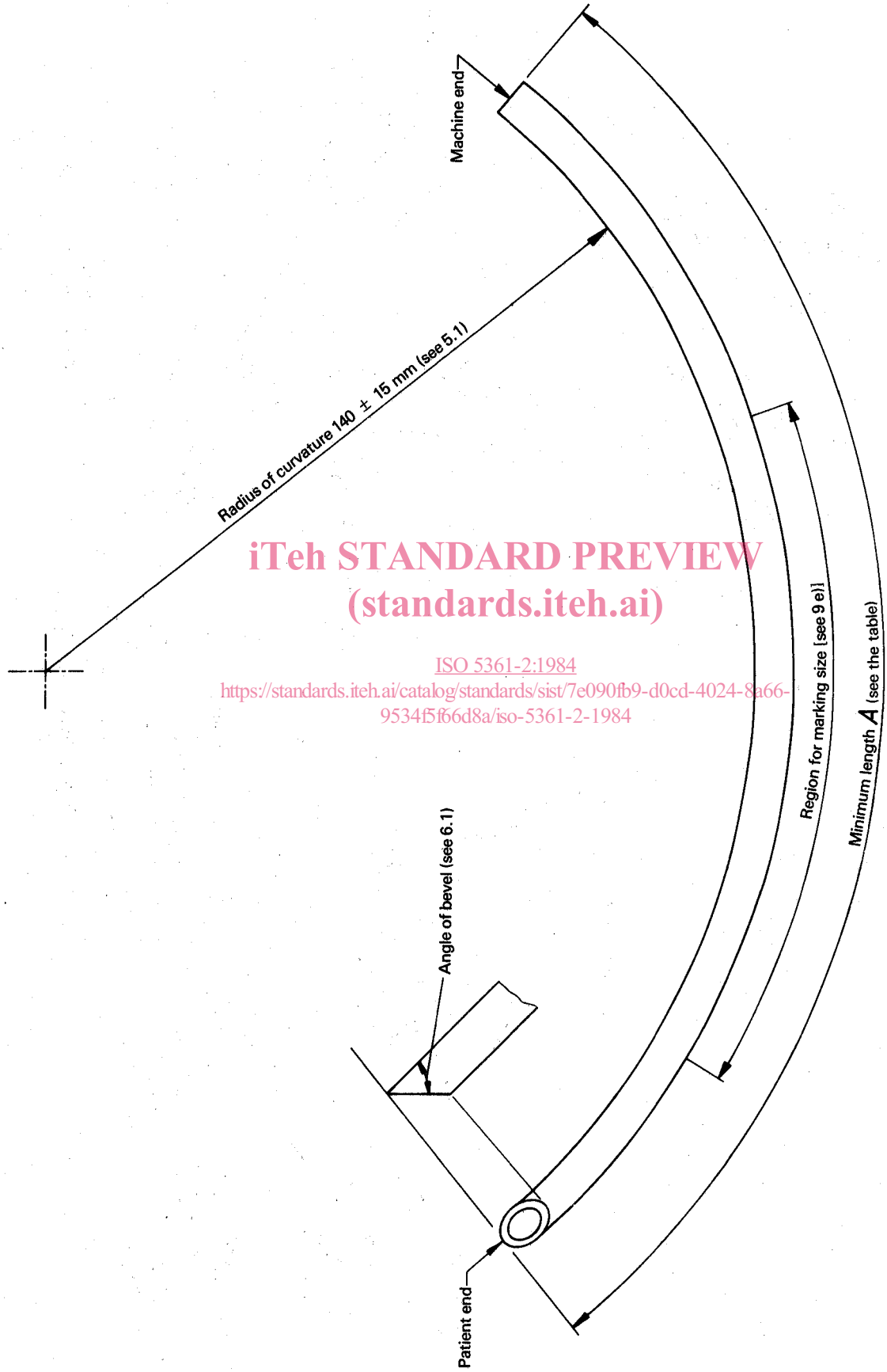


Figure 2 — Typical plain tracheal tube (Magill type)

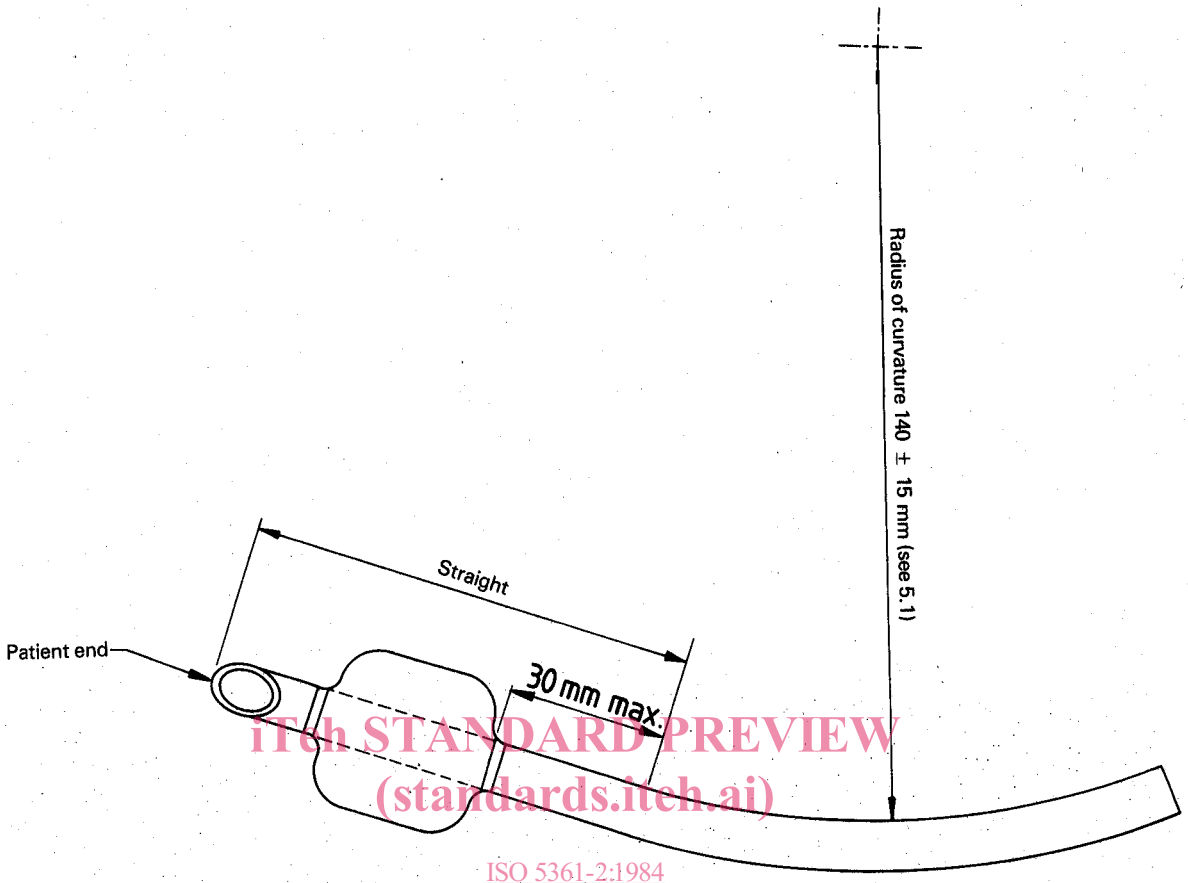


Figure 3 — Typical straight patient end (see 5.2)