Endotracheal tube

Technical Data

2 Brief introduction

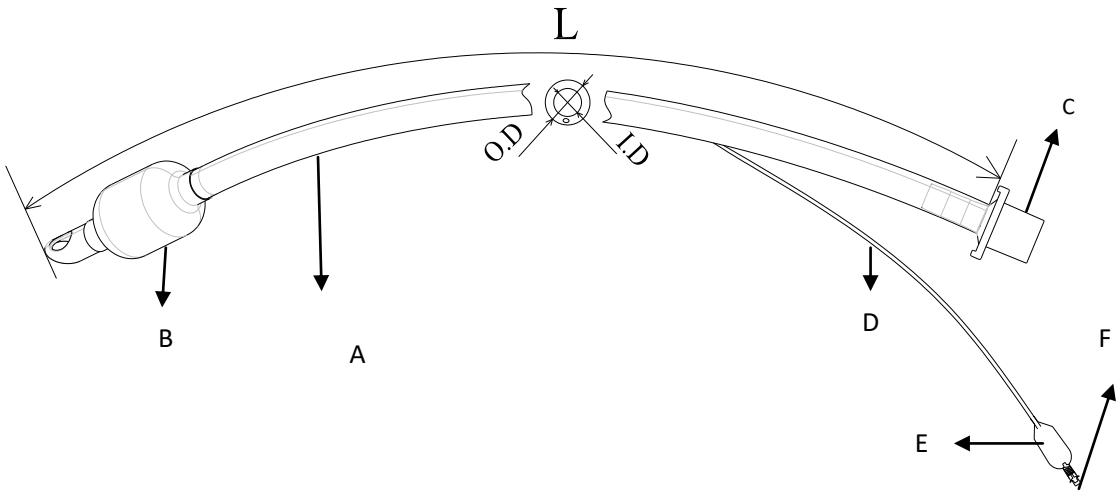
2.1 Features

- High volume low pressure cuff.
- Spiral reinforcement minimized crushing or kinking.
- High volume cuff positive tracheal wall seal.
- Flex conform to any patient positions, especially to OPS of decubitus.
- Transparent, soft and smooth.
- Radio opaque line through the length for x-ray visualization.
- Available with Murphy hole for PVC Endotracheal Tube.

2.2 The type and structure of product

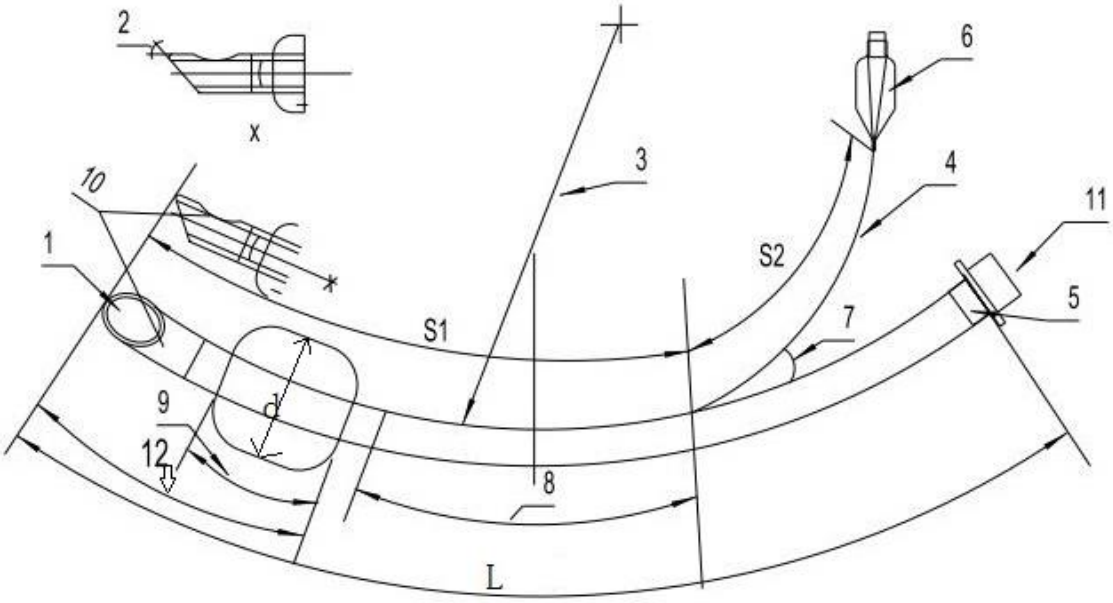
2.2.1 According to the material of airway tube, we have PVC Endotracheal Tube. According to the structure, we have Cuffed Endotracheal Tube and Uncuffed Endotracheal Tube.

2.2.2 Cuffed Endotracheal Tube is composed of Composed of airway tube, cuff, 15mm connector, inflation line, pilot balloon, valve, and guide wire. The structure of it sees Figure 1-1 and Figure 1-2.



A: Airway tube B: Cuff C: 15mm connector D: Inflation line
E: Pilot balloon F: Valve H: Guide wire

Figure 1-1: Structure of Cuffed Endotracheal Tube



2:θ=38°±10°,3:r=140±20mm7:θ≦45°, 8:printing 10:murphy eye:the area not less than 80%the cross seational area derived of tube

Figure 1-2: Structure of Cuffed Endotracheal Tube

2.2.3 Uncuffed Endotracheal Tube is just composed of airway tube, 15mm connector.

2.2.4 Size of Endotracheal Tube see tale 3 to table 5.

Table 3 Size of PVC Airway Tube （mm）

Specification （Nominal I.D）	O.D	Minimum Length of tube(L)		Maximum Length from the patient end of the tube to the machine end of the inflatable length of the cuff (12)	Minimum Length of point of separation of the inflation line from the patient end of the tube(S1)
		Oral/Nasal	Oral		
2.0	3.3±0.15	130	110	--	--
2.5	3.7±0.15	140	110		
3.0	4.0±0.15	160	120	--	--
3.5	4.7±0.15	180	130	--	--
4.0	5.3±0.15	200	140	--	--
4.5	6.0±0.15	220	150	--	--
5.0	6.7±0.15	240	160	56	110
5.5	7.3±0.15	270	170	56	120
6.0	8.0±0.15	280	190	58	125

6.5	8.7±0.20	290	210	62	130
7.0	9.3±0.20	300	230	66	135
7.5	10.0±0.20	310	240	69	140
8.0	10.7±0.20	320	250	72	145
8.5	11.3±0.20	320	260	75	155
9.0	12.0±0.20	320	270	78	160
9.5	12.7±0.20	320	280	81	165
10.0	13.3±0.20	320	280	85	170

Table 4 Size of connector（mm）

Specification （Nominal I.D）	I.D d (± 0,15)	Straight connectors — minimum dimension (5)
2.0	2.0	9
2.5	2.5	9
3.0	3.0	9
3.5	3.5	11
4.0	4.0	11
4.5	4.5	12
5.0	5.0	12
5.5	5.5	12
6.0	6.0	13
6.5	6.5	13
7.0	7.0	16
7.5	7.5	16
8.0	8.0	16
8.5	8.5	16
9.0	9.0	16
9.5	9.5	16
10.0	10.0	16
10.5	10.5	16
11.0	11.0	16

Table 5 Size of Cuff (mm)

Specification	Diameter(d) (mm)	Specification	Diameter(d) (mm)	Specification	Diameter (mm)
2.0	12	5.0	18	8.0	26
2.5	12	5.5	19	8.5	26
3.0	14	6.0	21	9.0	28
3.5	15	6.5	23	9.5	30
4.0	16	7.0	25	10.0	30
4.5	17	7.5	26	/	/
Note: tolerance= 15%*nominal value					

2.3 Appearance of product is smooth and clean.

2.4 This product is sterile, non-toxic, and non-pyrogenic.

2.5 The validity period is five years from end of manufacturing

2.6 Production environment and sterilization

The production and assembly of all product parts and accessories are completed in 100,000 clean workhouses which are in line with the requirements. Inner packing uses paper-plastic single bag. And after large packing, all the products are sterilized by ethylene oxide (EO) for one-time use.

3 Intended Use

This product is used for the patients who is required to establish patency and rapid acess to breaths in surgery of clinical anesthesia, first and resuscitation.

4 Operation Procedure

4.1 Select optimal size of Endotracheal Tube.

4.2 Empty the cuff totally to avoid damage to the cuff, and inject enough air into the cuff for good seal performance.

4.3 Do the Lung auscultation carefully to check the appropriateness of the location of the Endotracheal Tube. If find some abnormal phenomenon, please adjust the tube rightly.

4.4 When using the Endotracheal Tube, please use the chest radio-graph to confirm the position of head of Endotracheal Tube.

4.5 After using, deflate the air completely, and then pull out the product.

5 Contraindication

Not used for the patients with laryngeal edema, acute airway inflammation, throat edema, aortic compression of the trachea, severe bleeding.

6 Caution

6.1 This product is used to build a short-term non-deterministic artificial airway for patients, please do not use for other purposes.

6.2 The users shall be trained medical personnel.

6.3 For single use only, re-use or re-sterilization is not allowed.

6.4 Use immediately after unpack and discard after use.

6.5 Do not use if inner packing is damaged; or the product is damp or moldy.

6.6 Sterile valid is three years and please use in valid time.

6.7 Prohibit contact with electron beam or laser beam to avoid burning.

6.8 The product should be placed when the patient supine. When the position of patient changes (observe position), please recheck the position of the product.

6.9 When the cuff can not deflated after use, locate the position of cuff at first and then puncture it by using a syringe with needle.

7 Storage environments

The products shall be stored in non-corrosive gas, cool, dry, well ventilated and clean environment of which relative humidity is no more than 80%.

8 The production flow chart of Endotracheal Tube see KMT/WI7.5.1-01《Flow Chart of PVC Endotracheal Tube》.

9 Classification of product

Standard Endotracheal Tube is a short time invasive device through body orifice (mouth, throat) and sterilized by EO. So it belongs to Class Ⅱa according to Annex Ⅸ rule 5 of MDD 93/42/EEC

10 Product Certification Conformity Assessment Route: Annex V.3 of MDD 93/42/EC

11 Manufacturer and European Representative

11.1 European Representative:
Name： Shanghai International Holding Corp.GmbH (Europe)
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Tel：0049-40-2513175 Fax：0049-40-255726

12 Annex 1 <European Authorized Representation Agreement>No.M/A2017-157