

Nanchang Kaimed Medical Apparatus Co., Ltd. CE Technical Documentation		
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**1Brief introduction**

Construction of tracheotomy tubes

1.1 Tracheotomy tubes are composed of machine end connector,tube with X lines,inflation tube, neck-plate, introducer obturator ect, The products is magill tracheotomy tubes. patient end is smooth.

1.2 Tracheostomy tubes:

Paediatric tracheostomy tubes size:3.0;3.5;4.0;4.5;5.0;5.5;6.0;

Adult tracheostomy tubes:size:6.5;7.0;7.5;8.0;8.5;9.0;9.5;10.0;10.5;11.0

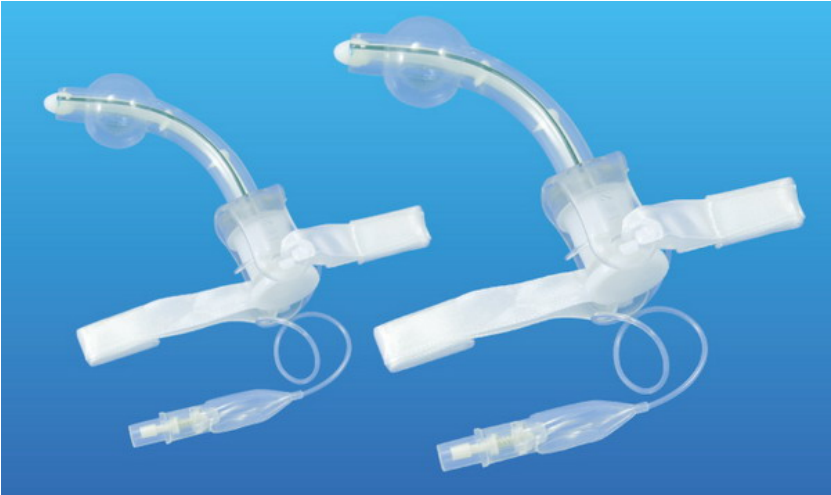
1.3Design of connectors

- ① Form connector by injection mouldiong , Connectors are made of PE
- ② Tubes by extrusion moulding , Tubes are made of PVC(PVC TYPE:MT-8710 Made of Hopfinder polymer sci,& tech.co.ltd.),with X lines tubes and inflation tube.

Cuff ,O.D.

Site			3. 0	3. 5	4. 0	4. 5	5. 0	5. 5	6. 0
Inflating tube O.D			12	13	14	15	16	17	18
Site	6. 5	7. 0	7. 5	8. 0	8. 5	9. 0	9. 5	10. 0	
Inflating tube O.D	19	20	21	22	23	24	26	28	

2.4 as shown in the following figures.



1.5Appearance of product is smooth and clean.

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

1.7 The validity period is five years from end of manufacturing

1.8Production 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

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one-time use.

**2 Intended Use**

Tracheostomy tube :use in treatment of anaesthesia, artificial aerate,clean out respiration tract, Intended to remain in place for less than 7days.belong to short term.

**3 Directions:**

- 3.1 Select the suitable size of tracheostomy tube according to different patients.
- 3.2 Inflate the cuff using the minimum volume of air to check up it. When you find the cuff have some leaking, just injecting proper air to the cuff. But if there is a big breach you must change another for the same spec in no time.
- 3.3 The product is intended to be inserted into patient trachea by physicians who have received medical professional training and are qualified for medical practice. The X lines on the outer surface of the tube are intended to examine the insertion depth.
- 3.4 Infuse proper gas according to different size.
- 3.5 In order to avoiding damage the tube, you should deflate proper air if used over 24h, and renew the cuff after 1 hour.
- 3.6 After using, deflate the air and take it out, discard and destroy after use.

**4 Caution and Contraindication**

- 4.1 Tension pneumothorax (can use the computer after intubation closed drainage), low blood volume shock, heart failure, especially the right heart failure;Pulmonary bulla, pneumothorax, pneumomediastinum before drainage;Big hemoptysis patients of myocardial infarction, cardiac pulmonary edema) is disabled.
- 4.2 Do not use if package is opened or damaged.
- 4.3 Valid date five years from sterilize date.
- 4.4 For single use only. Discard after use. Do not reuse.

**5 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%.

**10.1 Manufacturer:**

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