

PMDA Medical Safety Information

Pharmaceuticals and Medical Devices Agency



No. 66 October 2023

Precautions in Handling of Tracheostomy Tubes (No. 2)

POINT Points to be noted for safe use

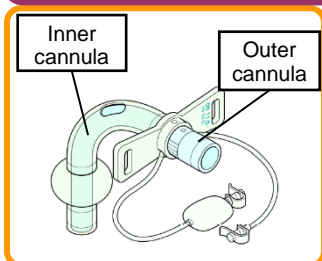
1

Precautions for use of double-tube cannulas (with double structure with inner and outer cannulas)

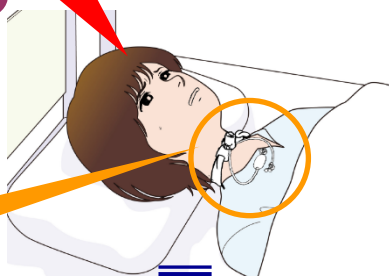
(Case) When using a double-tube speech cannula, since the patient complained of dyspnoea, the inner cannula was removed. After the respiratory condition became stable, the cannula was used from then on for a long time without the inner cannula being attached again. Thereafter, the inside of the outer cannula was occluded due to secretions, and the tracheostomy tube was replaced.

- Do not use a double-tube cannula, such as a speech cannula, for a long time with an outer cannula only.
- For a patient with a large amount of secretions, monitor the patient's condition and periodically perform aspiration or replace/clean the tracheostomy tube.

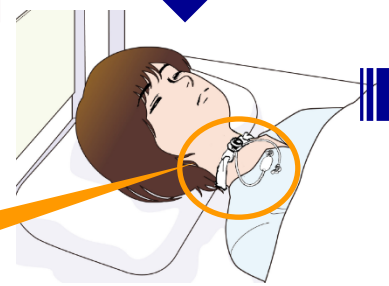
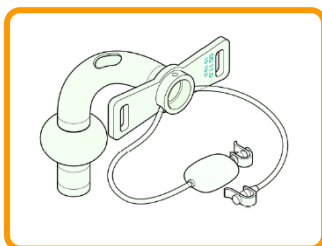
A set of cannula is used with the inner cannula placed in the outer cannula.



Difficulty breathing



Only the outer cannula is used without the inner cannula.



A cannula is used for a long time with the outer cannula only.



Obstruction caused by secretions!

In patients to whom a double-tube cannula is applied, do not use only the outer cannula for a long time. Continuous use without the inner cannula may require replacement of the tracheostomy tube when the outer cannula is obstructed.

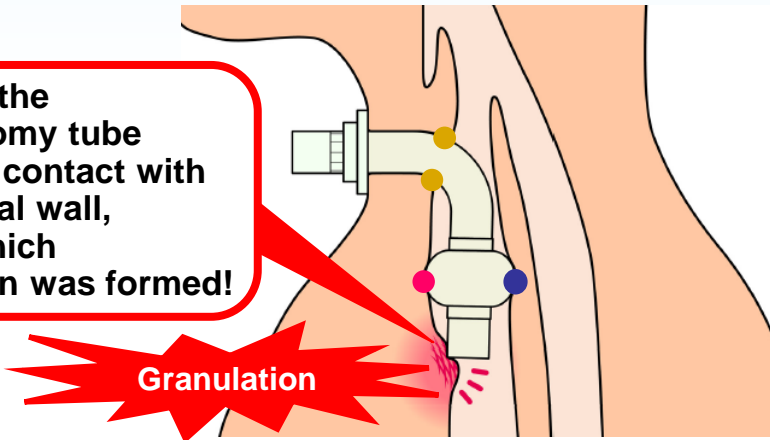


2 Precautions when selecting the size and checking the position of tracheostomy tubes

(Case) A few days after the replacement with a new tracheostomy tube, the patient presented with a stenotic sound. Bronchoscopy revealed granulation around the tip of the tracheostomy tube. The replaced tracheostomy tube was confirmed to be longer than the previously used one.

- Before replacing a tracheostomy tube, ensure that the patient's condition is checked and shared within the team, since the length and angle may differ for each tracheostomy tube.

The tip of the tracheostomy tube came into contact with the tracheal wall, around which granulation was formed!



Sites where bleeding and granulation frequently occur

- Anterior tracheal wall
- Posterior tracheal wall
- Peripheral part of the tracheostomy stoma

Perform **regular bronchoscopic evaluation of the tube tip**. If granulation or bleeding is observed, consider replacing it with a **tracheostomy tube with a movable wing that enables adjustment of the tube length**.

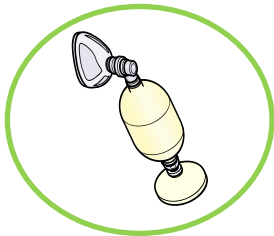


How to check the position of a tracheostomy tube

- Multiple methods can be used to locate the tracheostomy tube.

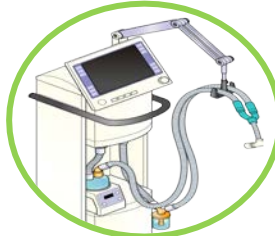
Manual ventilation

Check chest elevation and airway resistance.



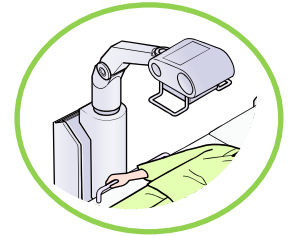
Ventilator

Check airway pressure and ventilation volume.



Chest X-ray image

Check the position of the tracheostomy tube.



Aspiration catheter

Check the insertion resistance.



Bronchoscope

Check the bifurcation of the trachea.



Capnometer

Check the normality of expiratory curve.



3 Precautions concerning the description of the size of tracheostomy tubes

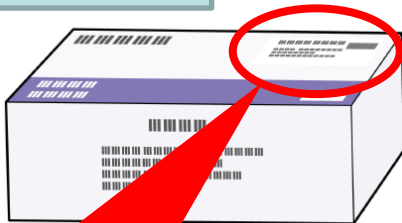
(Case) The previously used tracheostomy tube (Product A) was planned to be replaced with a tracheostomy tube of the same size from another company (Product B). At that time, because the inner diameter (ID) and the outer diameter (OD) were not checked sufficiently, the ID of the newly used tube was smaller than that of the planned tracheostomy tube, thereby causing dyspnoea in the patient.

- **Do not choose the product to be used only by the numerical value of the displayed size, but also by the type of diameter.**



You may choose the wrong product!

Product A



ID 8mm OD 9mm

Product B

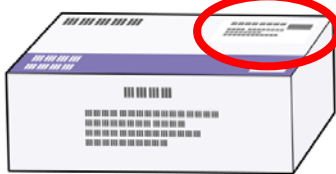


OD 8mm ID 7mm

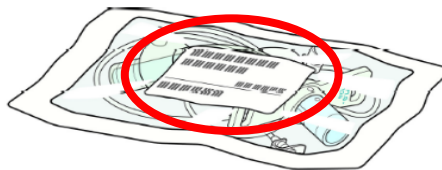
Note) ID: Inner diameter, OD: Outer diameter

Location of description of size (example)

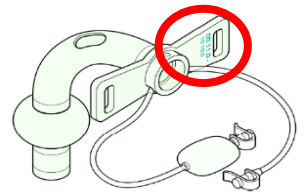
- Outer box



- Inner package



- Product body



The way in which the size, etc. are described may be different depending on the product, so please carefully check the **description of "ID (inner diameter)" and "OD (outer diameter)"!**



About this information

- PMDA Medical Safety Information is issued by the Pharmaceuticals and Medical Devices Agency for the purpose of providing healthcare providers with clearer information from the perspective of promoting the safe use of pharmaceuticals and medical devices. The information presented here has been compiled, with the assistance of expert advice, from cases collected as Medical Accident Information Reports by the Japan Council for Quality Health Care, and collected as Adverse Drug Reaction and Malfunction Reports in accordance with the Law on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices.
- We have tried to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy in the future.
- This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided as a support to promote the safe use of pharmaceuticals and medical devices by healthcare professionals.
- This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Access to the most up-to-date safety information is provided via the PMDA Medi-navi service.

