

Medical Safety Information

Pharmaceuticals and Medical Devices Agency

Pmda No. 39 September 2013

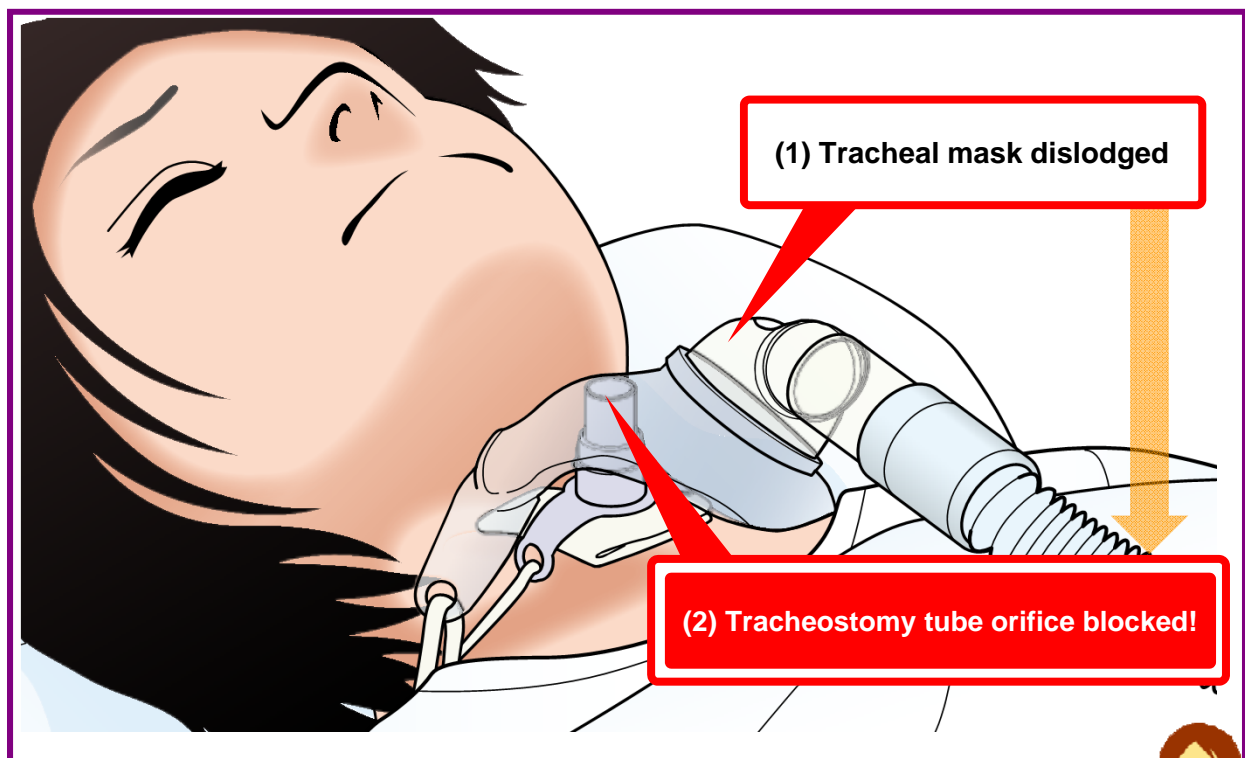
Precautions in Handling of Tracheal Mask

POINT Key points for safe use

(Case) Medical staff visited the patient's room since the ECG monitor alarm had gone off. It was found that the patient was in respiratory arrest with cyanosis, due to the fact that the tracheal mask, which had been dislodged, was blocking the tracheostomy tube orifice.

1 Precautions when using tracheal mask

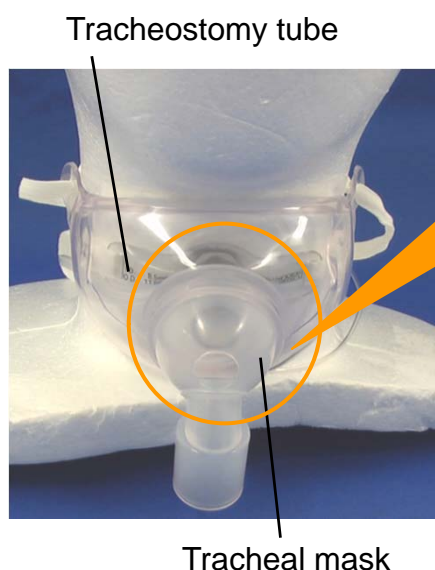
- Ensure appropriate attachment of tracheal mask (not dislodged or loosely attached) during use.



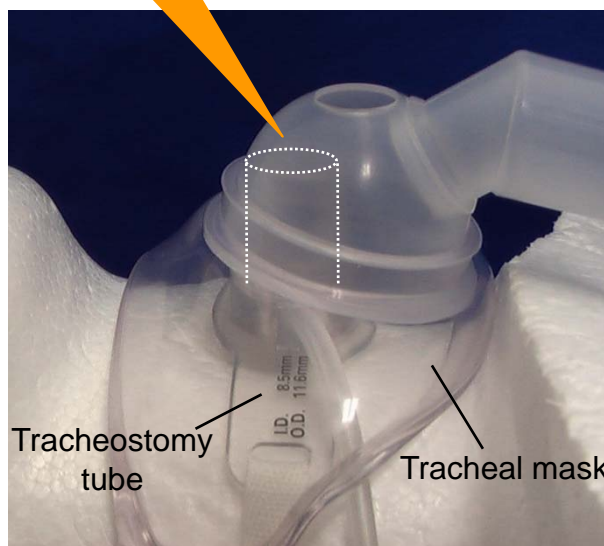
A patient will be unable to breathe if the tracheal mask has been dislodged due to the patient's movements or a loose attachment so the tracheostomy tube orifice is blocked.



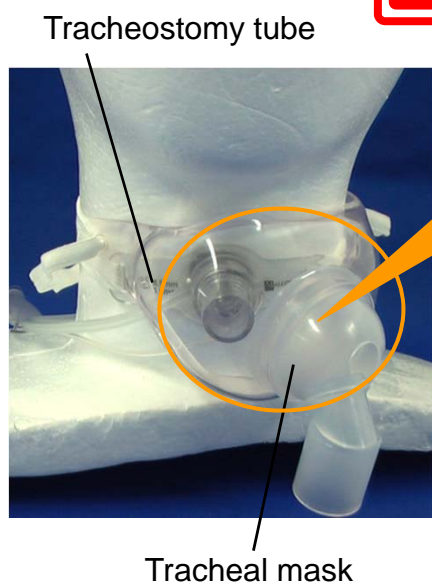
Correct attachment



Tracheal mask is not blocking the tracheostomy tube orifice



If mask is dislodged



Tracheal mask has been dislodged and is blocking the tracheostomy tube orifice



Please consider the risk of unexpected block of tracheostomy tube orifice when using tracheal mask!

Furthermore, patient should be monitored the biological information in accordance with his/her condition during the use of tracheal mask.

Examples of tracheal mask

Intermed Japan, Inc.



Tracheostomy Mask

MC Medical, Inc.



Adult ECO Tracheostomy Mask

Japan Medicalnext Co., Ltd.



Tracheal Mask

Smiths Medical Japan Ltd.



Portex First Breath
Tracheostomy Mask



Portex First Breath Tracheostomy
Venturi Oxygen Mask

Fuji Medical Corporation



Oxygen Mask
(Tracheostomy Mask)

The Ministry of health, Labour and Welfare (MHLW) has issued notification that are related to the issue in this PMDA Medical Safety Information No.39.

- "Revision of the Precautions of Tracheal Masks" (Joint Notification of PFSB/ELD/OMDE No. 0920-1 and PFSB/SD No. 0920-5 dated on September 20, 2013)

Information on this notification is available at the Pharmaceuticals and Medical Devices Information website (in Japanese)

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 Pharmaceutical Affairs Law.
- * 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.