

Medical Safety Information

Pharmaceuticals and Medical Devices Agency

mda No.3 January, 2008

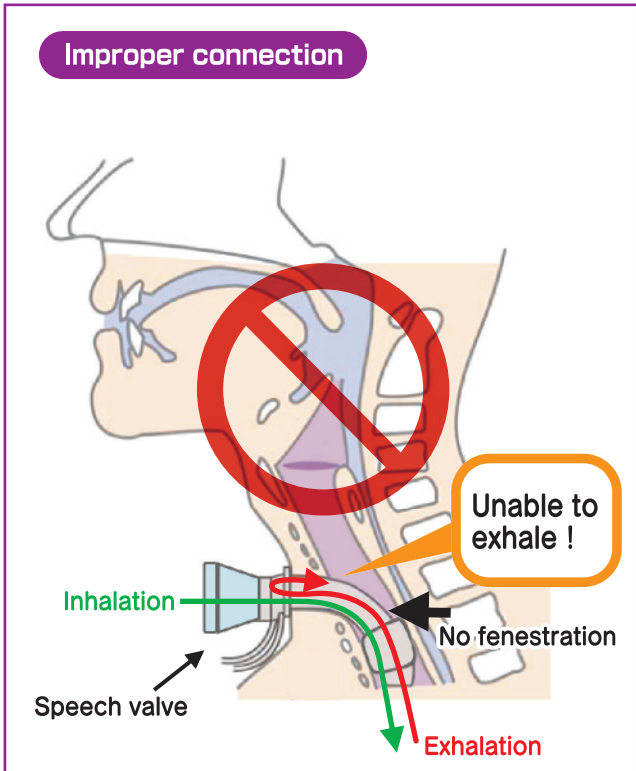
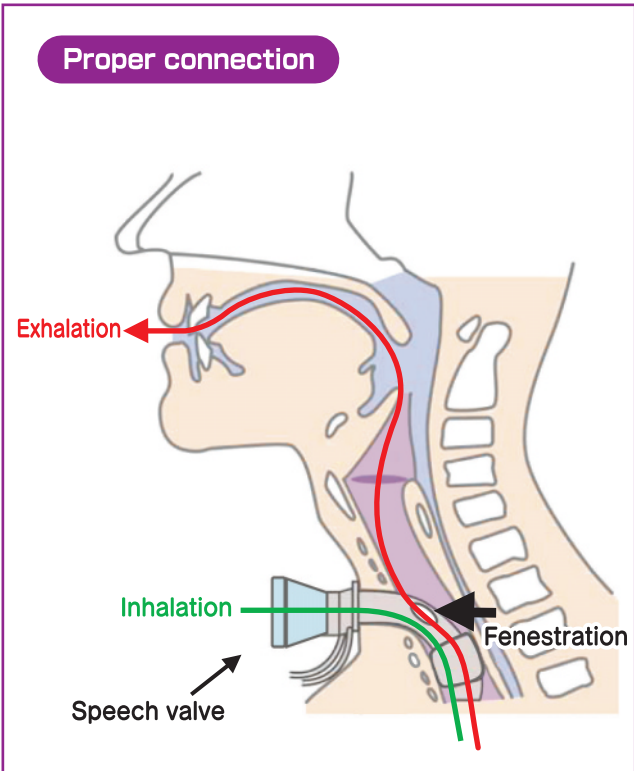
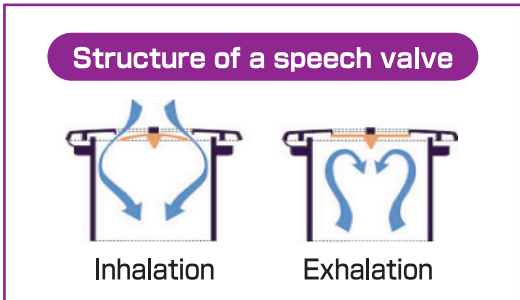
Precautions against improper connection of speech valves etc. to tracheostomy tubes

POINT Key points for safe use

(Case 1) Airway obstruction occurred from connection of a speech valve to a fenestrated tracheostomy tube after inadvertent insertion of a non-fenestrated inner cannula, instead of a fenestrated inner cannula.

1 Precautions for speech valve connection — 1

- Speech valves have a one-way valve structure (see the structure of a speech valve in the figure on the right). Connection of a speech valve to a non-fenestrated inner cannula or tracheostomy tube will prevent exhalation.
- It should be ensured to check breath sounds after connecting a speech valve.



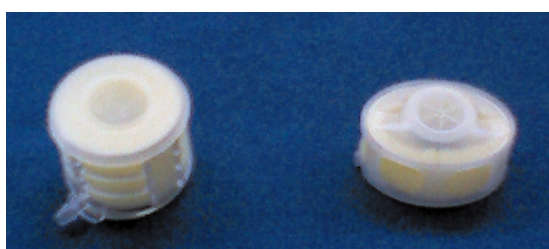
This translation of the original Japanese text is for information purpose only (in the event of inconsistency, the Japanese text shall prevail).

(Case 2) Airway obstruction occurred from inadvertent connection of a speech valve, instead of a heat and moisture exchanger (HME), to a non-fenestrated tracheostomy tube.

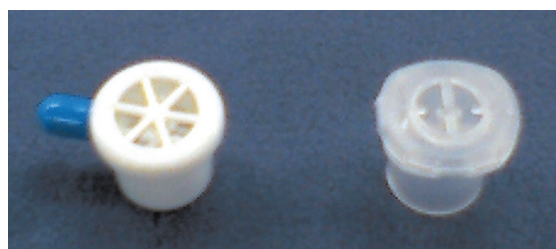
2 Precautions for speech valve connection — 2

- HMEs and speech valves are similarly shaped but differ in intended purpose and structure. Caution should be exercised not to confuse one with the other.
- Generally, speech valves are 15 mm in diameter, which is the same as the diameter of HMEs. It should be ensured that the correct device is connected to the tracheostomy tube.

Examples of HMEs

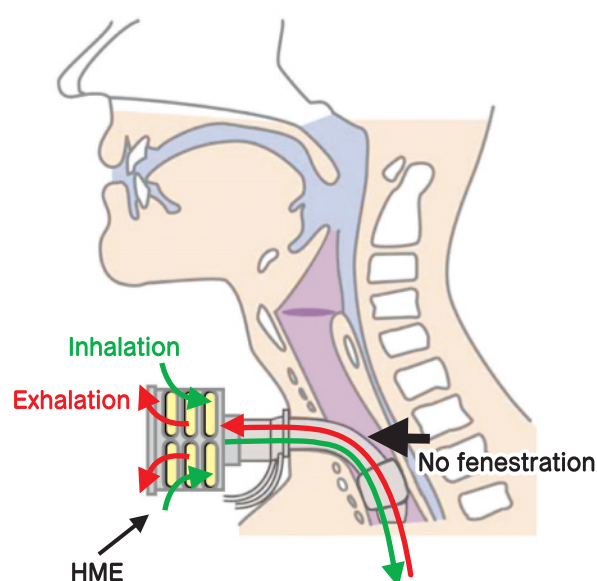


Examples of speech valves

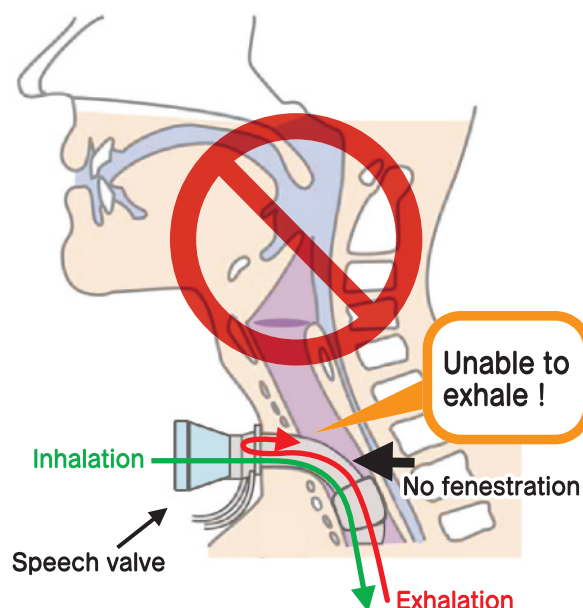


Caution should be exercised
not to confuse them !

Proper connection



Improper connection



3 Products at risk of improper connection

- Medical institutions using the following products should take measures to ensure medical safety, including informing the staff of risks and establishing handling procedures.
- The contraindication's section in the package inserts for the following products already warns of the risk of improper connection. Please refer to it again.

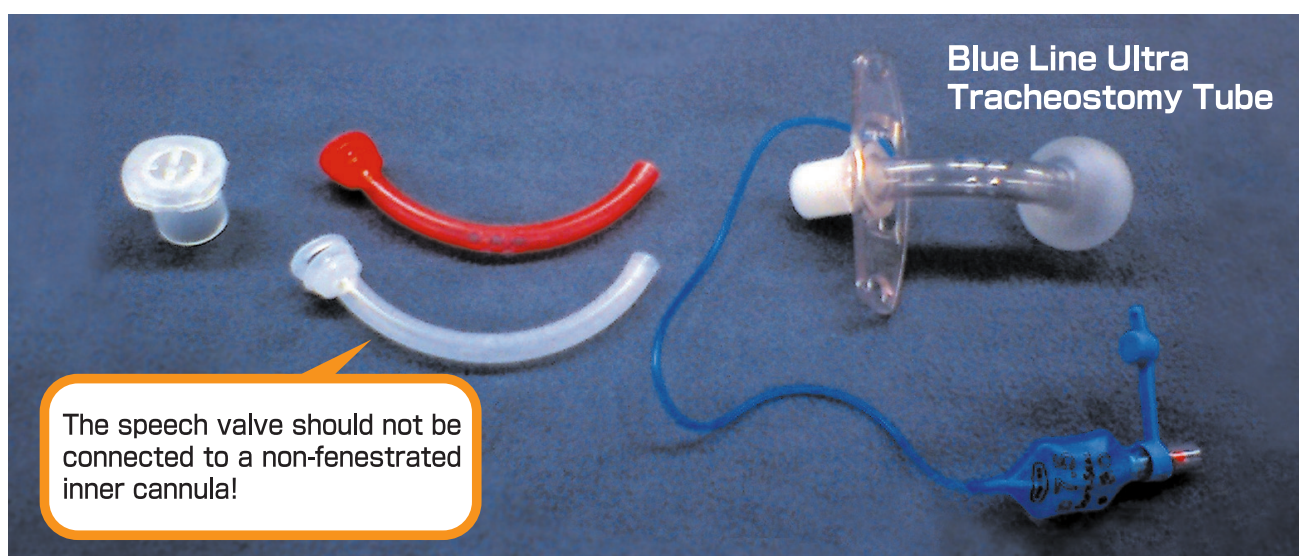
These speech valves are 15 mm in diameter, allowing them to be connected to other tracheostomy tube brands. Caution should be exercised to prevent connection to other brands also !



Picture 1 Tyco Healthcare Japan Inc. Products



Picture 2 Smiths Medical Japan Ltd. Products



Package insert information for medical devices is also available at the Pharmaceuticals and Medical Devices Information website (http://www.info.pmda.go.jp/info/iryo_index.html) (in Japanese).

4 Products designed to prevent improper connection

- Some manufacturers have developed products designed to prevent improper connection of speech valves to other components manufactured by their companies and by other manufacturers. Some examples of such products are shown below to aid medical safety measures at medical institutions.

These speech valves are designed in diameters other than 15 mm and eliminate concerns about improper connection!



Information on products designed to prevent improper connection is also available under the Topics page for "Safe Use Information" of the Japan Medical Devices Manufacturers Association website (<http://www.jmed.jp>) (in Japanese).

Picture 1 KOKEN CO. LTD. Products

- The speech valve is structured to prevent connection to a non-fenestrated inner cannula.
- The speech valve can only be connected directly to a fenestrated tracheostomy tube manufactured by this company.



Picture 2 Senko Medical Instrument Manufacturing Co., Ltd. Products

- The speech valve is structured to prevent connection to a non-fenestrated inner cannula.
- The speech valve can only be directly connected to a fenestrated tracheostomy tube or fenestrated inner cannula manufactured by this company.



The Ministry of Health, Labour and Welfare (MHLW) issued a notification related to PMDA Medical Safety Information No. 3: "Handling of Devices Attached to Tracheostomy Tubes" (HPB/GAD Notification No. 0118001 issued by the General Affairs Division of the Health Policy Bureau/PFSB/SD Notification No. 0118001 issued by the Safety Division of the Pharmaceutical and Food Safety Bureau, MHLW, on January 18, 2008)

Information on this notification is available at the Pharmaceuticals and Medical Devices Information website (<http://www.info.pmda.go.jp/iryujiko/file/20080118.pdf>) (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 endeavored to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy into 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.