

Medical Safety Information

Pharmaceuticals and Medical Devices Agency

 No. 13 October, 2009

Medical Gas Mix-Ups

POINT Key points for safe use

(Case) A cylinder containing liquid carbon dioxide was erroneously connected to the oxygen delivery system, and the patient was administered carbon dioxide instead of oxygen when returning from the operation room to the ward after surgery.

1 Precautions for handling of gas cylinders

- Every time a gas is used, correctly identify the gas cylinder by the label.
- Do not store cylinders of different gases in the same place.
- Do not use industrial grade gas cylinders in the facility.

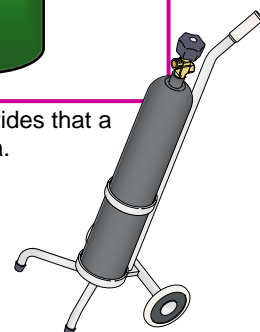
* This label is written in Japanese.
The illustration shows examples.

| Oxygen (O ₂) | Carbon dioxide (CO ₂) (Liquid carbon dioxide) |
|--------------------------|--|
| Black cylinder Note) | Green cylinder Note) |
| | |



Note) Ordinance for Container Safety under the High Pressure Gas Safety Act provides that a container has to be given a coat of the designated color over half of its surface area.

Each cylinder has a **gas-specific color**. Common causes of many accidents are **mix-ups (erroneous connections) of small cylinders used at the bedside or during transportation of patients**.



Cause of mix-ups (1)

Insufficient examination of labels

Medical gases always have a package insert attached!

Industrial gases do not carry the label!

* 日本薬局方 二酸化炭素
 JP Carbon Dioxide

When "Oxygen" is a part of the name of manufacturer, do not confuse it!

Always make sure that the cylinder carries the label indicating that the gas is for medical use!

Medical Oxygen
 (株) 酸素
 Oxygen Inc.
 (Medical gas)

Liquid Carbon Dioxide
 液化炭酸ガス
 (株) 酸素
 Oxygen Inc.
 (Industrial gas)


* This label is written in Japanese.

Cause of mix-ups (2)

Cylinders containing different gases are stored together!

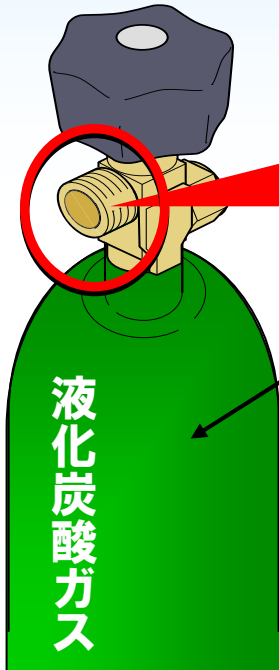
Mixed storage of different gas products

Storing cylinders containing different gas products together can cause mix-ups! In dark storage sites, recognizing the correct cylinder by its color can be difficult and may lead to serious consequences.



Cause of mix-ups (3)

Use of cylinder for industrial liquid carbon dioxide



The container for the **industrial liquid carbon dioxide** used in the facility was found to be equipped with the same fitting (same diameter and threaded portion) as the oxygen cylinder.

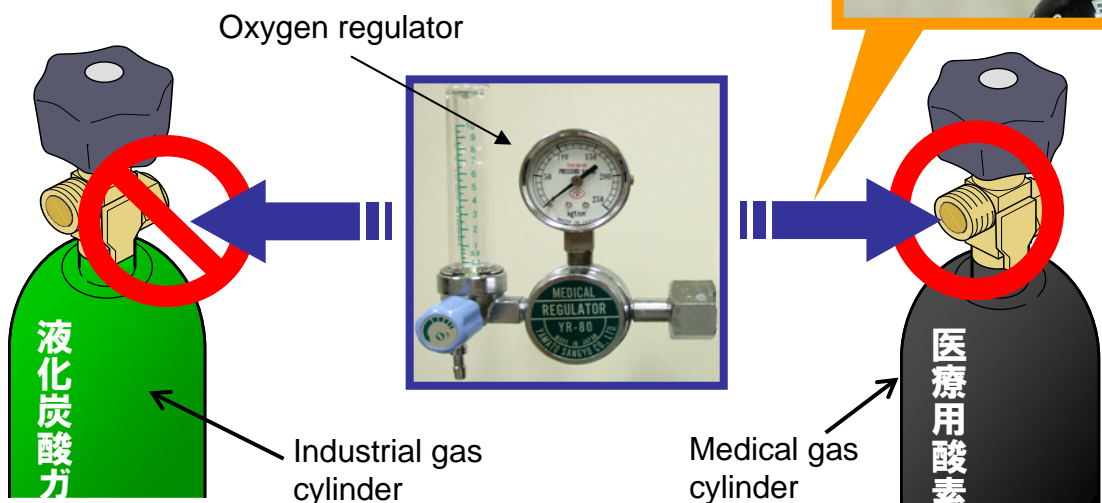
Note) An industrial gas cylinder does not have a package insert attached and does not carry a label indicating that the gas is for medical use, such as "JP (Japanese Pharmacopoeia)".



There are concerns that industrial liquid carbon dioxide is used for laparoscopic surgery.

Regulator compatibility

An oxygen regulator **can also be connected** to an industrial liquid carbon dioxide cylinder **causing erroneous connection**.
A mix-up can lead to serious consequences.



2 Measures to prevent misconnections

- Use medical gas in small cylinders equipped with gas-specific (yoke-type) valves.

Use of yoke-type valve (medical gas)

The valve is specific for each gas and cannot be connected mechanically to a delivery system for a gas other than the intended one (**connection incompatibility is ensured**).

Switching to yoke-type valves at your facility helps to prevent accidents.

Yoke-type valve of a medical carbon dioxide cylinder Gas outlet Yoke-type valve of a medical oxygen cylinder

Pin configuration for carbon dioxide Pin configuration for oxygen

Pin configuration is gas-specific.

- * For information regarding switching to yoke-type valves, please contact Medical Gas Division, Japanese Industrial and Medical Gases Association <http://www.jimga.or.jp/medical/>.

The Ministry of Health, Labour, and Welfare (MHLW) has issued notifications that are related to issues in this PMDA Medical Safety Information No. 13:

- "Thorough implementation of preventive measures against misconnections in medical gas distribution system" (HPB/GMSD Notification No. 0303001 issued on March 3, 2009)

Information on this notification is available

at the Pharmaceuticals and Medical Devices Information website (in Japanese)

<http://www.info.pmda.go.jp/iryujiko/file/20090303.pdf>

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.