In emergencies, a resuscitator bag taken from an emergency cart did not provide sufficient ventilation due to being improperly assembled.

**Key points for safe use**

**Case**

In emergencies, a resuscitator bag taken from an emergency cart did not provide sufficient ventilation due to being improperly assembled.

**Precautions when assembling resuscitator bags**

- Make sure to assemble resuscitator bags properly while checking their user's manuals.
- Be careful not to mix parts especially when assembling multiple resuscitator bags at once.

Improper assembling resuscitator bags will lead to serious accidents with inadequate ventilation in emergencies.
An example of resuscitator bag components

(1) Check valve unit
- Mask connection
- Body of check valve unit
- Pressure limiting valve
- Check valve
- Patient exhalation valve

(2) Gas intake assembly
- Gas intake assembly (intake valve unit side)
- Gas intake assembly (body side)
- Gas intake valve
- Air inlet valve
- Check valve

(3) Silicone resuscitation mask
- Mask body
- Cover
- Silicone rubber (check valve unit connection)

(4) Silicone bag

(5) Oxygen reservoir bag

(6) Oxygen tube

Assembling some of the products with many parts is complicated.

For each company’s product, there have been case reports of improper assembling as described below:
1) Parts forgotten to be fixed, 2) Incorrectly positioned parts, 3) Parts fixed in the incorrect direction, and 4) Doubling of parts, etc.
Mechanism of resuscitator bag

When inhaling (bag compression)

- Check valve unit
- Gas intake valve closed
- Oxygen and air pushed out
- To patient (inhalation)

When exhaling (bag compression removed)

- Check valve unit
- Gas intake valve opened
- Oxygen and air flowing in
- From patient (exhalation)

* Name of parts differ among manufacturers or products.

After assembling resuscitator bags, make sure that they provide proper ventilation with operation checks using test bags.
Resuscitator bags used after being assembling (reusable resuscitator bags)

- **IMI Co., Ltd.**
  - Ambu Oval Plus Silicone Resuscitator
  - Ambu Oval Silicone Resuscitator
  - Ambu Mark IV Resuscitator
  - Ambu Mark III Resuscitator
  - Ambu Silicone Resuscitator
  - Ambu Baby Resuscitator Model R

  Contact for inquiries:
  TEL 048-988-4411

- **Air Water Inc.**
  - Smart Bag (milky white)
  - Smart Bag (blue)

  Contact for inquiries:
  TEL 03-3578-7812 / 03-3578-7810

- **GE Healthcare Japan Corporation**
  - Manual Resuscitator

  Contact for inquiries:
  TEL 0120-187-855

- **Smiths Medical Japan Ltd.**
  - LSP Bag Mask Resuscitator

  Contact for inquiries:
  TEL 03-3405-9300

- **Tokion, Inc.**
  - Silicone Resuscitator

  Contact for inquiries:
  TEL 03-3812-6101
  (Igarashi Ika Kogyo Co., Ltd.)

- **Pacific Medico Co., Ltd.**
  - Manual Resuscitator

  Contact for inquiries:
  TEL 03-5844-3507
Make sure to prepare manuals on assembling and checking methods. The latest user’s manuals can be obtained from manufacturers. When deciding which products to purchase, consider the simplicity of assembling the product and user’s manuals.

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.