

Medical Safety Information

Pharmaceuticals and Medical Devices Agency

pmda No. 38 May 2013

Improper Assembly of Resuscitator Bags

POINT Key points for safe use

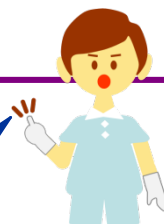
(Case) In emergencies, a resuscitator bag taken from an emergency cart did not provide sufficient ventilation due to being improperly assembled.

1 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.**



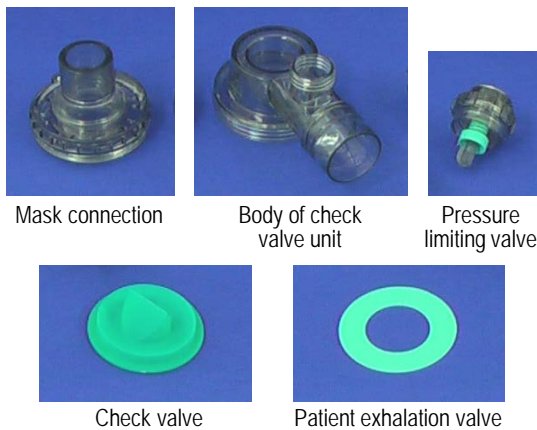
Improper assembling resuscitator bags will lead to serious accidents with inadequate ventilation in emergencies.



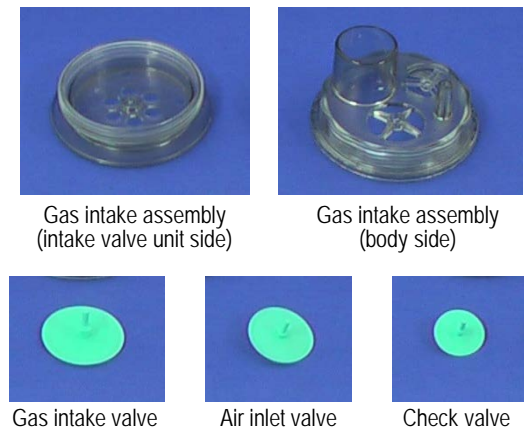
An example of resuscitator bag components



(1) Check valve unit



(2) Gas intake assembly



(3) Silicone resuscitation mask



(4) Silicone bag



(5) Oxygen reservoir bag



(6) Oxygen tube



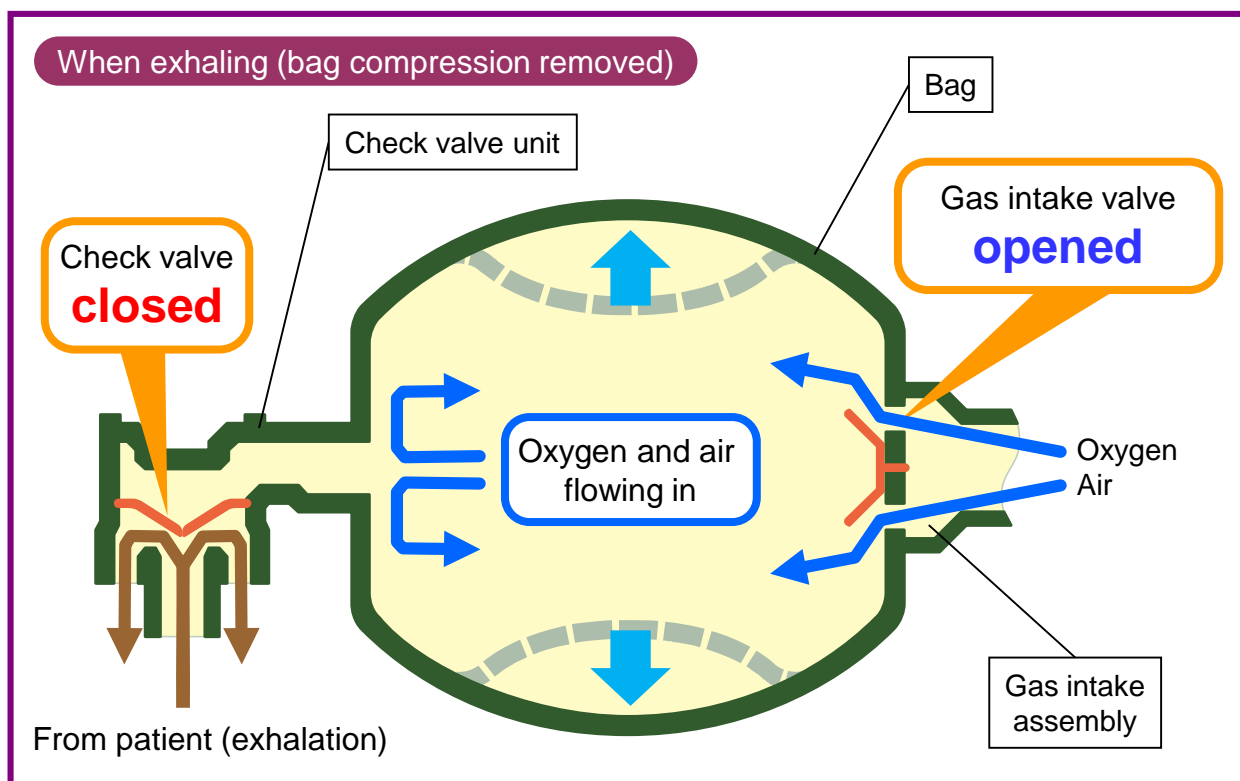
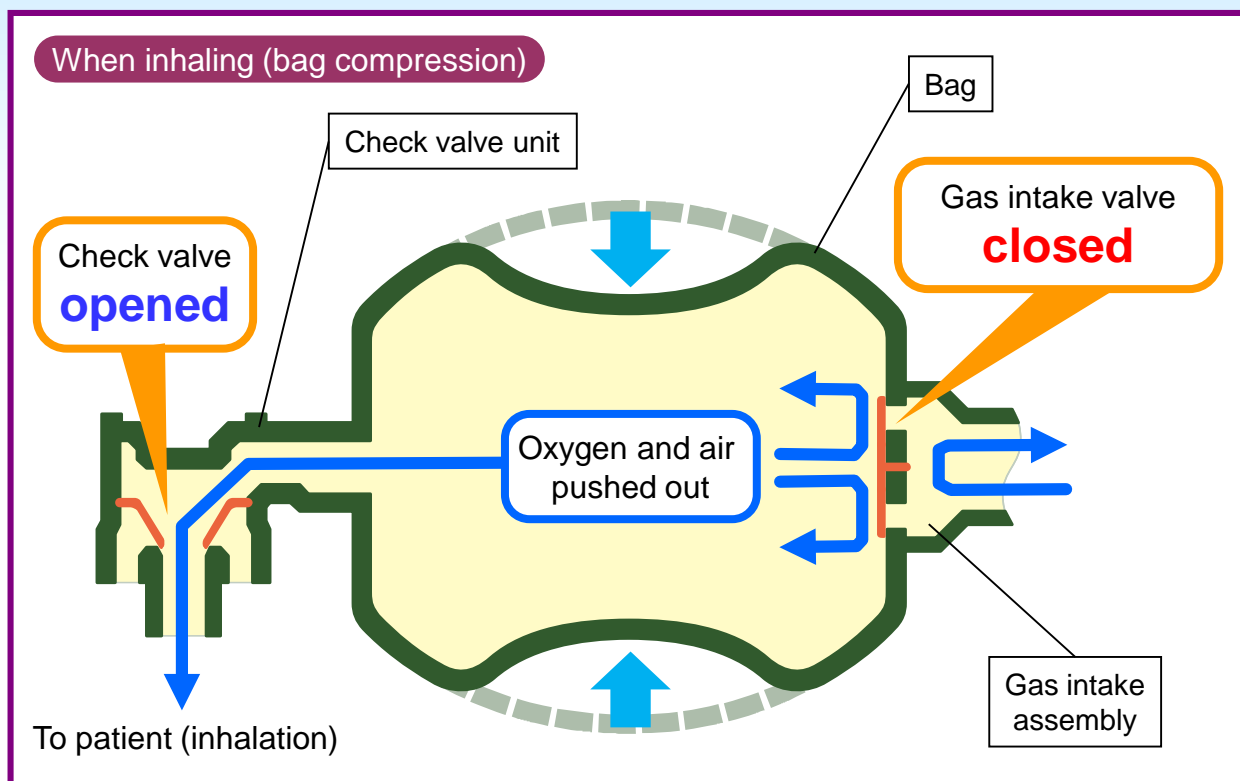
Assembling some of the products with many parts is complicated.



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



* 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.

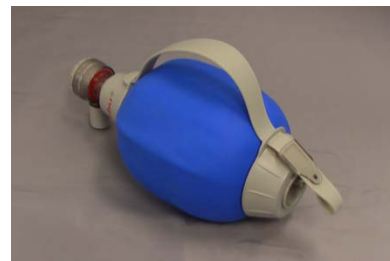
Ambu Oval Plus Silicone Resuscitator



Ambu Oval Silicone Resuscitator



Ambu Mark IV Resuscitator



Ambu Silicone Resuscitator



Ambu Mark III 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

Nakamura Medical Industry Co., Ltd.

N-Ideal Silicone Resuscitator



Contact for inquiries:
TEL 03-3813-3486

MURANAKA MEDICAL
INSTRUMENTS Co., Ltd.

MMI Silicone Manual Resuscitator



Contact for inquiries:
TEL 0725-53-5546

Blue Cross Emergency Co., Ltd.

Blue Cross Silicone Resuscitator



Contact for inquiries:
TEL 03-3815-2220
049-243-9966

Laerdal Medical Japan K.K.

Laerdal Silicone Resuscitator



Contact for inquiries:
TEL 0120-309-060

Wako Shoji Co., Ltd.

Combibag



Contact for inquiries:
TEL 0466-84-2485

KOUSHIN INDUSTRIES, INC.

N-Ideal Silicone Resuscitator
(component of Res-Q-Set)



Contact for inquiries:
TEL 048-624-0526

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.