

# Medical Safety Information

Pharmaceuticals and Medical Devices Agency

**pmda** No. 9 February, 2009

## Recall of Jackson-Rees Circuits

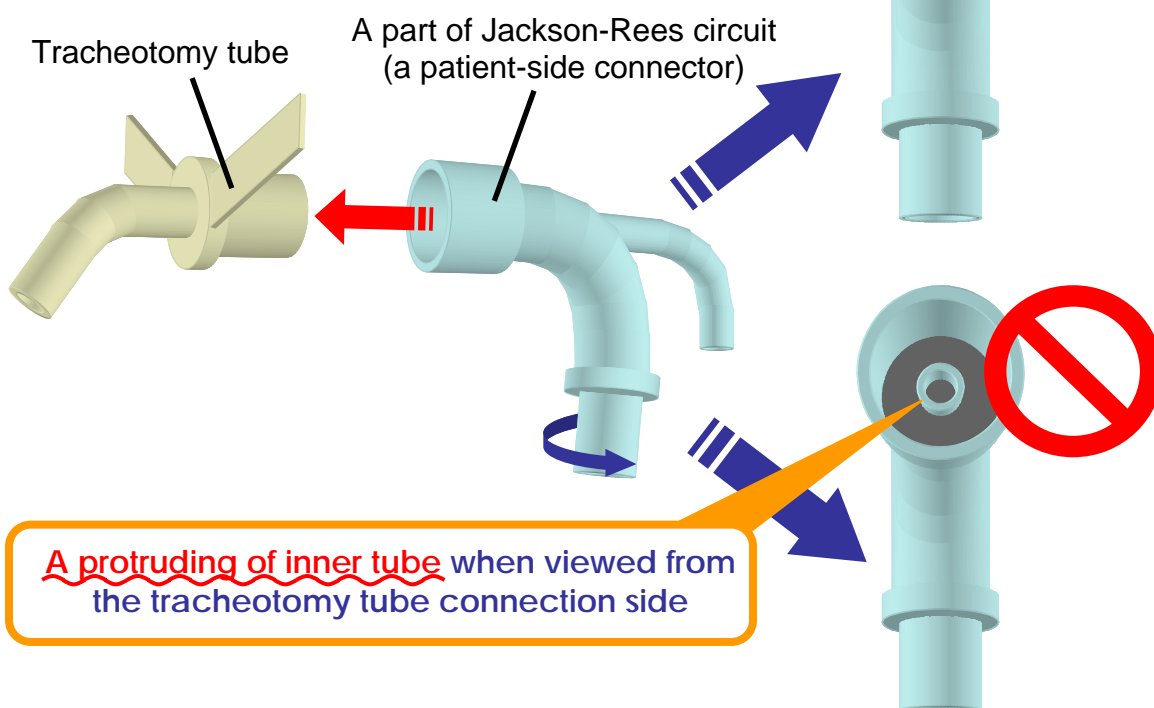
### **POINT** Key points for safe use

**(Case)** Obstruction in a respiratory circuit occurred when a Jackson-Rees circuit is used with a heat and moisture exchanger. That led to increased airway pressure and resulted in lung injury.

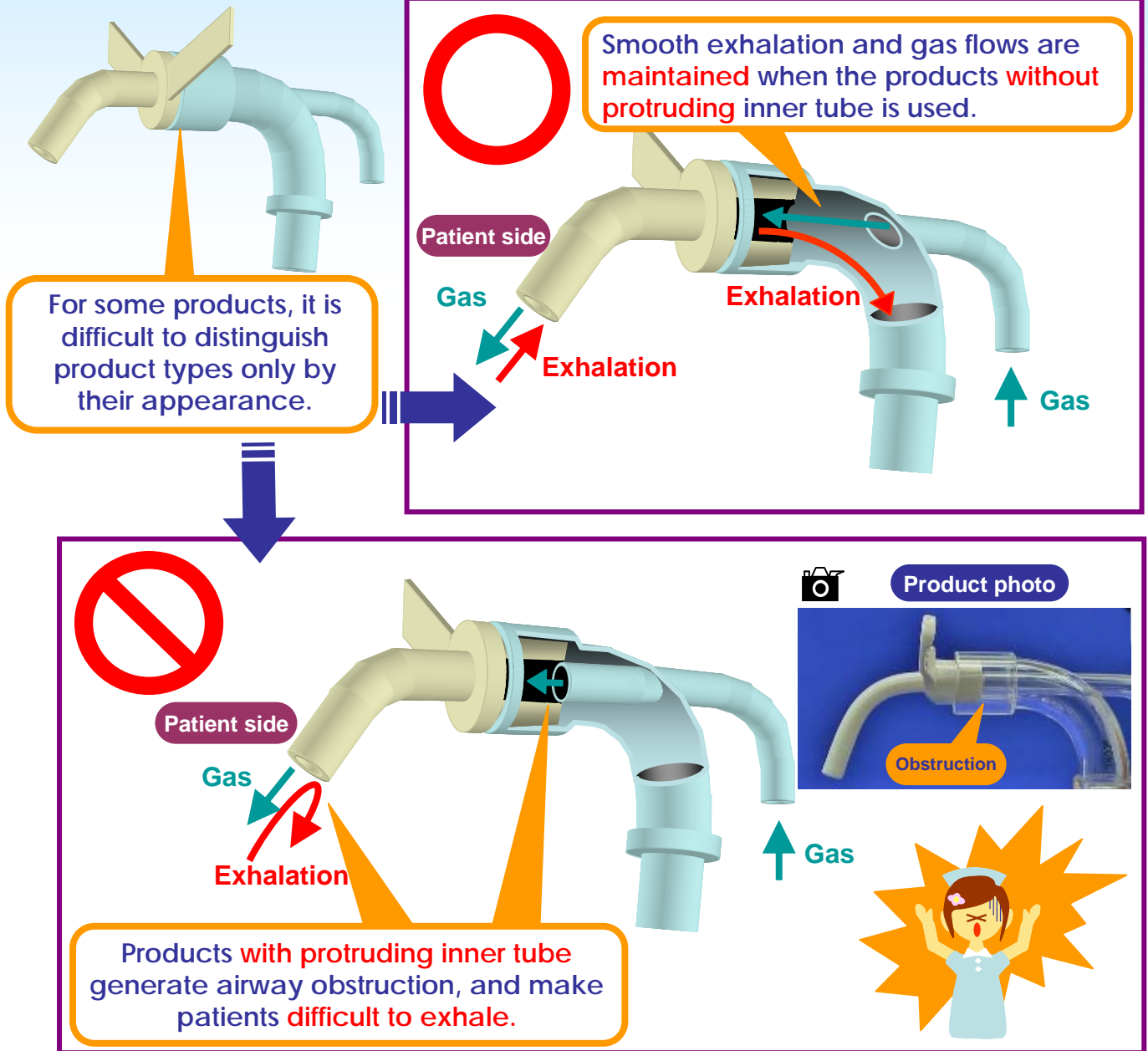
The troubled Jackson-Rees circuits were voluntarily recalled in the years of 2001 and 2002 by the manufacturers because of the airway obstruction occurred by the combination use with a tracheotomy tube.

#### 1 How to find Jackson-Rees circuits with a risk of airway obstruction

No protruding of inner tube when viewed from the tracheotomy tube connection side



## Obstruction mechanism in Jackson-Rees circuit



Other than tracheotomy tube, Jackson-Rees circuits is allowed some combination uses.

Check for no generation of obstruction prior to and during application when a Jackson-Rees circuit is used in combination with various apparatuses.

### Examples of connectable products



Tracheal tube



Expired gas detector



Heat and moisture exchanger



CO<sub>2</sub> Sensor for capnography



## 2 Recalled Jackson-Rees circuit products

In 2001 and 2002, the following products were voluntarily recalled by four manufacturers due to the risk of obstruction when used in combination with different manufacturer's products.

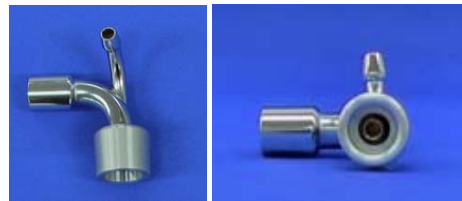
Serious adverse health effects including pediatric deaths have been reported.

If you still keep or store any of following products, immediately stop using and return them to the manufacturers or distributors.



Igarashi Medical Ind. Co., Ltd. TEL: +81-3-3812-6101

### OR Jackson-Rees Set



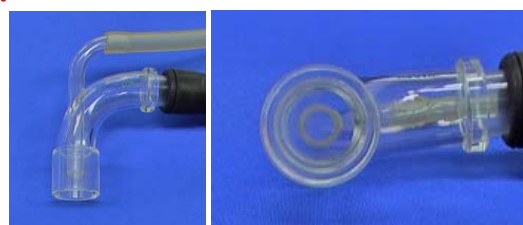
### B Swim Jackson-Rees Set



Acoma Medical Industry Co., Ltd. TEL: +81-3-3811-4151

### Accessory of "Acoma Anesthesia Apparatus PRO"

[http://www.acoma.com/oshirase/oshirase\\_jackson.html](http://www.acoma.com/oshirase/oshirase_jackson.html)  
(in Japanese)



Many Jackson-Rees circuits have been found, being left at medical institutions even after the recall in 2001 and 2002.  
Please check for no remaining at your hospital once again.

Anes Corp. TEL: +81-4-2960-1820

### Dupaco's Norman Mask Elbow



[http://www.anes-med.co.jp/noma\\_aika.pdf](http://www.anes-med.co.jp/noma_aika.pdf)  
<http://www.anes-med.co.jp/>  
(in Japanese)



Kobayashi Pharmaceutical Co., Ltd. TEL: +81-6-6222-6606

### Jackson-Rees Resuscitation Circuit Tail Valve Type (Vertical-elbow type)

[http://www.kobayashi-medical.com/file/file/jackson\\_shock.pdf](http://www.kobayashi-medical.com/file/file/jackson_shock.pdf)  
(in Japanese)



### Jackson-Rees Resuscitation Circuit APL (adjustable pressure limiting) Valve Type



## Ministry of Health, Labour and Welfare (MHLW) issued notifications related to PMDA Medical Safety Information No. 9:

- Pharmaceuticals and Medical Devices Safety Information No. 166 dated on May 30, 2001  
"Combination use of a Jackson-Rees anesthetic circuit for pediatrics with a tracheotomy tube for pediatrics and newborn infants"
- PFSB/SD Notification No. 1119001 issued by the Safety Division of the Pharmaceutical and Food Safety Bureau of MHLW on November 19, 2008  
"Recall, etc. of Jackson-Rees circuits (Caution and request for dissemination)"

Information on this notification is available

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

<http://www.info.pmda.go.jp/iryujiko/file/20081119.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.