Dräger Recalls VentStar Oxylog 3000 Pediatric Patient Breathing Circuit Due to Potential Valve Leakage

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product:

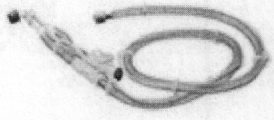
- VentStar Oxylog 3000 Disposable Pediatric Patient Circuit
- Catalog Number: 5704964
- Manufacturing dates: May 2013 to March 2016
- Distribution dates: May 2013 to March 2016
- Devices recalled in the U.S.: 1,530 units in Alaska, California, Florida, Indiana, Illinois, Kentucky, Louisiana, Massachusetts, Maryland, Mississippi, Minnesota, Missouri, Montana, North Carolina, New Hampshire, New York, Ohio, Oklahoma,

Oregon, Pennsylvania, Tennessee, Texas, Utah, Virginia, Washington, and Wisconsin

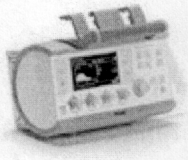
Device Use

The VentStar Oxylog 3000 disposable pediatric patient breathing circuit is used with the Dräger Oxylog 3000 and Oxylog 3000 plus Emergency Transport Ventilators for pediatric patients who require ventilation

The primary users of this device are doctors, nurses, emergency medical technicians, respiratory therapists, and paramedics. Use environments include during transport, in emergency departments or in the recovery room.



Oxylog Circuits



Oxylog 3000 plus

Reason for Recall

The firm discovered that the check valve on the circuit may leak. This could result in the patient re-breathing exhaled gas with reduced oxygen concentration and increased carbon dioxide levels. This can lead to serious health consequences, including excessive carbon dioxide in the bloodstream (hypercapnia) and increased acidity in the blood (acidosis), which could lead to death.

Note: This issue pertains only to the VentStar Oxylog 3000 Disposable Pediatric Patient Circuit. There is no issue or problem with the Oxylog 3000/3000 plus ventilator.

Who May be Affected

- Pediatric patients requiring ventilators
- Health care professionals using this device to provide ventilation

What to do

On May 31, 2016, the firm notified consignees of the problem via an Urgent Medical Device Recall letter. The letter directed consignees to identify and dispose of the affected products.

Date Recall Initiated

May 31, 2016

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) either online, by regular mail or by FAX to 1-800-FDA-0178.

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Silver Spring, MD 20993
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