

Teleflex Recalls NEONATAL ConchaSmart Breathing Circuit Due to Circuit Cracks

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

- NEONATAL ConchaSmart Breathing Circuit with Dual Heated Limb and ConchaSmart Column
- Product Codes: 870-07KIT, 870-09KIT
- Lot Numbers: 74L1802044, 74L1802045
- Manufacturing Dates: November 2018
- Distribution Dates: December 2018 to January 2019
- Devices Recalled in the U.S.: 300
- Date Initiated by Firm: May 10, 2019

Device Use

The Neonatal ConchaSmart Breathing Circuits are intended for neonatal and infant patients requiring mechanical ventilation, positive pressure breathing assistance, or general medical gases. The circuit provides a channel for breathing gas between a patient and a ventilator in a professional health care setting. The circuit also includes heated wires for use with the Hudson RCI Neptune Heated Humidifier. The heated wires are used to help maintain the set patient temperature and minimize condensation in the ventilator tubing.

Reason for Recall

Teleflex is recalling the Neonatal ConchaSmart Breathing Circuit with Dual Heated Limb and ConchaSmart Column due to complaints of cracks being observed, prior to use, on swivel wye adaptors, a part of the device. Cracks in the adapter may cause breathing distress because the gas may leak and not reach the patient. Breathing distress from insufficient oxygenation could result in serious adverse health consequences including death.

Teleflex received two complaints about cracks in the adaptor. Thirty-percent of adaptors are expected to exhibit cracks. No injuries or deaths have been reported.

Who May be Affected

- Hospitals and health care professionals using the Neonatal ConchaSmart Breathing Circuit with Dual Heated Limb and ConchaSmart Column.
- Patients who may receive breathing support from the Neonatal ConchaSmart Breathing Circuit with Dual Heated Limb and ConchaSmart Column.

What to Do

On May 10 2019, Teleflex sent customers an Urgent Medical Device Recall letter. The letter instructed customers to:

- Immediately discontinue use and quarantine any affected products in inventory.
- Complete the enclosed Acknowledgement Form indicating whether you do or do not have stock of affected product. Fax the form to 1-855-419-8507 or email to recalls@teleflex.com (<mailto:recalls@teleflex.com>).

Contact Information

Customers who have questions or need additional assistance regarding this recall should contact Teleflex's customer service by phone at 1-866-396-2111.

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experience using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm>).

Health care professionals employed by facilities that are subject to the FDA's user facility reporting requirements (</medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities>) should follow the reporting procedures established by their facilities.

More information

- Class I Device Recall - NEONATAL ConchaSmart Breathing Circuit with Dual Heated Limb and ConchaSmart Column (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=173297>)