

Distributor Teleflex Recalls the Galemed Babi.Plus Pressure Relief Manifolds Due to Dislodged Valve

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

- Galemed Babi.Plus® 12.5 cm H₂O Pressure Relief Manifold
- Product code: 2691
- Lots: 180806, 180910, 181029, 181105, 181204, 190225, 190327
- Distribution Dates: October 2018 to May 2019
- Devices Recalled in the U.S.: 14,964
- Date Initiated by Firm: June 14, 2019

Device Use

The Babi.Plus Pressure Relief Manifold is used as part of a breathing circuit designed to assist the breathing of infant patients who weigh no more than 10 kilograms. The affected devices are sold in multiples sizes, identified above under recalled product. They are used in health care facilities, such as neonatal critical care units, delivery rooms, and pediatric critical care units.

Reason for Recall

Teleflex is recalling the Babi.Plus Pressure Relief Manifold system because the Pressure Relief Manifold (PRM) in the Babi.Plus 12.5 cm H₂O Pressure Relief Manifold does not hold pressure when initially set up on a patient. This issue is due to a dislodged valve not being properly seated, resulting in loss of pressure in the system.

Use of the affected devices may cause serious adverse health consequences, including lower blood oxygen levels, slow heart rate, stopped breathing (apnea), rebreathing of exhaled carbon dioxide by the patient and need for medical intervention and resuscitation.

Galemed has separately recalled the Babi.Plus Pressure Relief Manifold system due to two complaints it received associated with device malfunction.

Teleflex, a distributor for Galemed, has not received any complaints for this issue. No injuries or deaths were reported.

Who May be Affected

- Pediatric patients who undergo procedures involving the Babi.Plus Pressure Relief Manifold system.
- Health care providers, distributors, Maintenance/Repair or Engineering Departments of facilities using the Babi.Plus Pressure Relief Manifold system.

What to Do

On June 14, 2019, Teleflex issued a Medical Device Recall Notice instructing customers to:

- Immediately discontinue use and quarantine the products, if you have affected stock inventory.
- Please complete the enclosed Recall Acknowledgement Form as soon as possible indicating whether

you do or do not have stock and fax it to 1-855-419-8507 **or** email to recalls@teleflex.com (mailto:recalls@teleflex.com) **or** hand it to your sales representative. (A customer service representative will contact you with a Return Goods Authorization (RGA) number and provide instructions for the return of products.)

Additional Resources

- Recall Database Entry
(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=173770>)

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?action=reporting.home>) either online, by regular mail or by FAX.