GE Healthcare Recalls Giraffe Incubators and OmniBeds Due to Potential for Infants to Fall

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

- Giraffe Incubator, Giraffe OmniBed, Giraffe Incubator Carestation, Giraffe OmniBed Carestation.
- All Giraffe Incubators and Giraffe OmniBeds
- Manufacturing Dates: April 2008 to September 2019
- Distribution Dates: April 2000 to September 2019
- Devices Recalled in the U.S.: 22,961
- Date Initiated by Firm: October 11, 2019

Device Use

Incubators and warmers are used for infant care in a hospital setting. Incubators are small beds enclosed in clear, hard plastic that is temperature-controlled for infants who are unable to maintain their body temperature on their own. Infant warmers are small beds with heaters over them to warm infants who are unable to maintain their body temperature on their own. Healthcare providers can give care to the baby through holes in the sides of the incubator, also called portholes.

Reason for Recall

GE Healthcare is recalling the Giraffe Incubator, Giraffe OmniBed, Giraffe Incubator Carestation, and Giraffe OmniBed Carestations because the bedside panels can be upright and look closed but not be securely latched. The portholes can also look closed when not securely latched. If a canopy cover is used, it can hold the bedside panel or porthole door closed without being securely latched. If an infant comes in contact with a bedside panel or porthole that is unlatched, the panel or porthole can disengage and fall open, no longer protecting the infant from falling.

The firm has received 6 reports of infant falls with injuries such as skull fractures, hematoma and edema. No deaths were reported.

Who May be Affected

- Infants who are placed in the Giraffe Incubators or OmniBed
- Healthcare professionals using the Giraffe Incubator or OmniBed

What to Do

On November 8, 2019 GE Healthcare sent an updated letter to customers stating that users can continue to use their Giraffe Incubator, Giraffe OmniBed, Giraffe Incubator Carestation, and Giraffe OmniBed Carestation systems by following these instructions:

1. Every time the bedside panel is closed, users must pull on the bedside panel to make sure the bedside panel is latched, and the red tab is no longer visible (see Figures 1 and 2).
2. Users must pull on the porthole doors every time the bedside panel or porthole is closed to make sure the porthole door is latched (see Figure 3).
3. Apply the safety warning labels that were included with the letter to the Incubator or OmniBed using the instructions provided.
4. Review the user manual Addendum and place it with the Incubator or OmniBed User Manual.
5. Place all three (3) of the provided "Giraffe Incubator/OmniBed Risk of Patient Fall" posters in prominent locations for healthcare staff and ensure the posters are displayed for the lifetime of the Incubator or OmniBed(s).
6. Confirm that the information from the customer letter and user manual Addendum are properly disseminated to all users that handle the Incubator or OmniBed.
7. Ensure that all hospital staff who open panels or portholes or otherwise come into contact with the device understand these instructions.
8. Ensure that any spare bedside panels or end panels that are not installed on incubator or OmniBed units are appropriately labeled according to the instructions. Additional labels can be obtained from a local GE representative.
9. Complete and return the provided form to document that all hospital staff who come into contact with the incubator or OmniBed are trained on the proper closing and latching of the devices and that the steps provided in the instructions are followed.

Contact Information

Customers who have questions or concerns regarding this recall are instructed to contact GE Healthcare Service at 1-800-437-1171 or their local Service Representative.

Additional Resources

- Medical Device Recall Database Entries: (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm)
    - Giraffe Incubator Carestation (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=177149), Giraffe Incubator Carestation CS1 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=177149)
    - Giraffe OmniBed Carestation (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=177148), Giraffe OmniBed Carestation CS1 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=177148)
    - Giraffe OmniBed (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=177147)
    - Giraffe Incubator (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=177303)
- GE Customer Recall Letter (https://www.gehealthcare.com/October2019) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

How do I report a problem?

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