Urgent Field Safety Notice

Prismaflex Control Unit
FA-2020-006
Safety Alert

February 2020

Dear Director of Nursing:

Problem Description

Baxter is communicating important safety information regarding the use of connectors with the Prismaflex system. The use of connectors may prevent a secure connection between the return line and the patient's blood access device. To ensure a proper connection, users must follow the Prismaflex Operator's Manual, 7.xx, G5039912 which lists the following warnings:

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WARNING:

> ⚠ Always connect the return line directly to the blood access device. Do not connect additional devices between the return line and the blood access device. The use of additional devices, such as three-way valves, stopcocks, or extension lines, may impair return pressure monitoring. Their use can impede the detection of return disconnections, potentially resulting in severe blood loss.

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WARNING:

> ⚠ During priming and operation, observe the system closely for leakage at joints and connections within the set. Leakage can cause blood loss or air embolism. If leakage cannot be stopped by tightening the connections, replace the set.

Affected Product

Product Code	Product Description	Serial Numbers
107493	Prismaflex Control Unit	All
113082		
113874		
114489		
114870		
955052		

Hazard Involved

Baxter cannot guarantee connectors will establish and maintain secure connections with Prismaflex sets. Additionally, use of connecting devices with the Prismaflex Control Unit could interfere with the ability of the Prismaflex Control Unit to accurately detect pressure drops in the blood circuit. As a result, vascular access disconnects may go undetected, leading to clinically significant blood loss and fatal exsanguination. Baxter has received two reports of serious injury and one report of patient death as a result of blood loss related to the use of a connecting device between the return line and the blood access device.

Actions to be Taken by Customers

1. Operators may continue to safely use the Prismaflex control units according to the warnings and cautions in the Prismaflex Operator's Manual.
2. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form** and return it to Baxter by faxing it to 224-270-5457 or scanning and e-mailing it to fca@baxter.com. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
3. If you purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.
4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
5. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please distribute this notification to customers and **check the associated box on the reply form.**

Further information and support

For general questions regarding this communication, contact Baxter Corporate Product Surveillance at 800-437-5176, between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.

We thank you for your attention to this important safety information.

Sincerely,

Baxter Healthcare Corporation