


## Urgent Field Safety Notice

18<sup>th</sup> February 2020


Dear Director of Nursing / Engineers,

**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 (G5036005) & 8.xx (G5036007) which lists the following warnings:

**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.

**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 either faxing it to 01 206 5577 or scanning and e-mailing it to qa\_dublin@baxter.com or sending it by post to Baxter Healthcare, Unit 7 Deansgrange Business Park, Blackrock, Co. Dublin A94 XD50. 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**.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Baxter Representative or Technical Services.

Yours sincerely,



Gerard Spicer  
Country QA Manager – UK & Ireland

Attachment 1: Customer Reply Form