



HALMED Agencija za lijekove i medicinske proizvode
Ksaverska cesta 4,
10000 Zagreb,
Croatia

February 17th, 2020

Subject: Field Safety Notice – Safety Alert – FA-2020-006 - Prismaflex - Warnings Against Connector Use Not Followed

Product Name: Prismaflex Control Unit

Product Code	Product Description	Serial Numbers
107493	Prismaflex Control Unit	All
955052		

Dear Sir or Madam,

Baxter is communicating important safety information regarding the use of connectors with the Prismaflex system. Per Prismaflex Operator's Manual, 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 connectors may prevent a secure connection between the return line and the patient's blood access device.

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.

Our records indicate that one customer (Agmar d.o.o.) have received this product in Croatia. For your information, please find attached the communication that is being sent to the customer.

Should you have any questions, please contact local representative at Agmar Jasmina Jurač, MPharm on email address jasmina.jurac@agmar.com or via phone number +38516610304. To reach out directly to Baxter please contact the undersigned FA coordinator, Ági Zag.

Yours Sincerely,

Ági Zag
Železna cesta 18, 1000 Ljubljana
Slovenia
CQA Specialist SEE
T: +38614201692/ M: +386 40 456 096

Ági Zag
Ljubljana, 17/FEB/2020