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MEDICAL DEVICE RECALL – TYPE I – URGENT

CompoStop Flexible

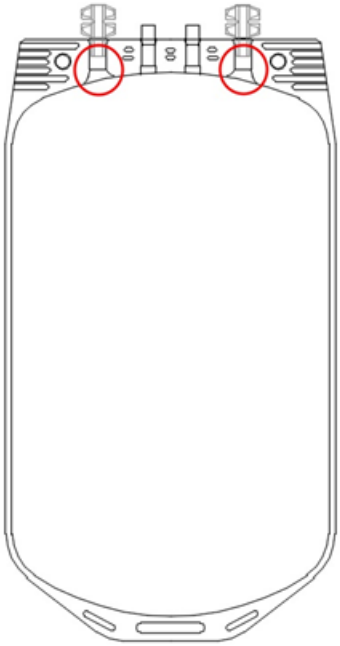
Date:	April 5, 2019
Hazard Classification:	**Type I Recall * URGENT ***
Device:	CompoStop Flexible
Device Identifier:	PD51600
Device Licence:	74766
Device Class:	II
Distributed Lots:	41MC12GA00, 41ME01GA00, 41MH01GA00, 41MI30GA00

Dear Canadian Blood Services,

Based on routine post-market surveillance Fresenius Kabi globally has identified an increased number of complaints for visible leakage of the platelet storage bag in CompoStop products. Such leakage predominantly occurs near the twist-off ports and has become apparent during processing of platelets in the storage bag. This type of defect has been identified by the user under routine handling conditions. The observed location of the leakage is in the area of the twist-off port weld in platelet storage bags.

Fresenius Kabi Canada globally has not received any complaints related to microbiological contamination of these platelet storage bags, or complaints on potentially associated patient injury.

The location of the leakage is in the area of the twist-off port weld in platelet storage bags. Refer to schematic below:



The instruction for use of CompoStop products indicates that if a visible damage or defect to the product is noticed and represents a risk to the integrity of the system, the product should not be used.

In the unlikely event of not detecting the leakage, the defect could potentially lead to a microbiological contamination of the platelet concentrate.

Accordingly, Fresenius Kabi has decided to initiate a recall action as a precautionary measure.

Fresenius Kabi has implemented additional control measures and corrective actions to assure supply continuation of CompoStop products. Fresenius Kabi will work to replace products as requested by the customer.

1. If platelets are already collected and/or CompoStop products in stock are needed for medical treatment, it is recommended to perform a detailed visual inspection for leakage of the processed platelet bag during the de-aeration process of the product and/or perform any additional applicable control measures.

2. For all lots/batches affected (Lots: 41MC12GA00, 41ME01GA00, 41MH01GA00, 41MI30GA00) it is requested to segregate the units and send remaining CompoStop products of the affected lots back to Fresenius Kabi Canada.