

Composelect with Fenwal Bioflex RC Performance Report



Important: If reaction or injury has occurred call Fresenius Kabi Post-Market Quality Assurance at 1-800-933-6925.

Incident Date: _____ Lot No.: _____ UDI No. (if applicable): _____
 Product Code: _____ Filter No.:* _____ Donor Bleed/ID No.: _____
*Note: Number may be found on filter skirt below inlet (branded) side of filter

When Was the Problem Detected?

- Before Use After Donation (at collections) Centrifugation Storage (of collected product)
 Donation Filtration Plasma Expression From Hospital Other (specify) _____

- Problem Type** (Mark all applicable) Discolored Flat Leak (solution) Mis-assembled Pre-activated Cannula
 Broken Cut/Slice Hole Dull/Drag Kink Leak (blood) Excess Moisture Blocked/Restricted
 Missing Difficult to Break Illegible Bent Separated Particulate Matter Other (specify) _____

Please answer the following questions:

1. Was there any adverse event or injury? Yes No
2. Was the procedure successfully completed? Yes No N/A
3. If no, was the procedure stopped due to a soft goods incident? Yes No N/A
4. Was product lost? Yes No N/A

Check box if you do **NOT** wish to receive response letters.

_____ E-mail address for letter recipient (if applicable)

Please circle specific components on the diagram where incident occurred

BPU Configuration

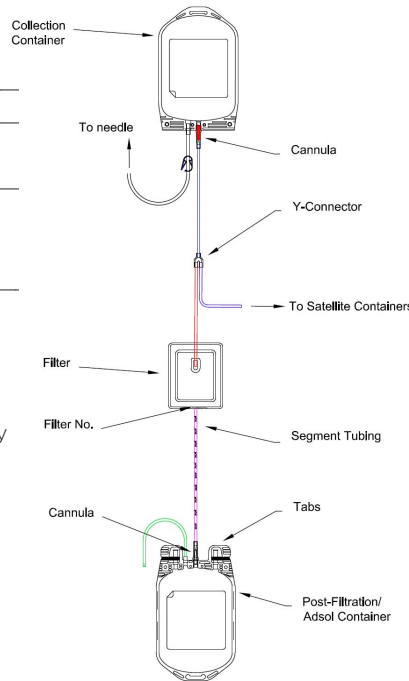
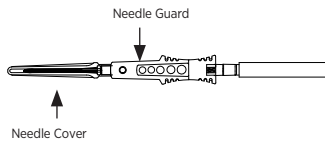
If filter related issues, please provide feedback or circle a response below, as applicable:

- How were the filters processed: RT or Cold? _____
 Which centrifuge cup/liner was used? _____
 How long was the filtration time? _____
 How much blood, relatively speaking, was left in the primary bag at the time of the incident? _____
 Was the filter inlet side flat or filled at the time of the incident: Flat or Filled? (circle one)
 If WBC failure, what was the actual value? _____

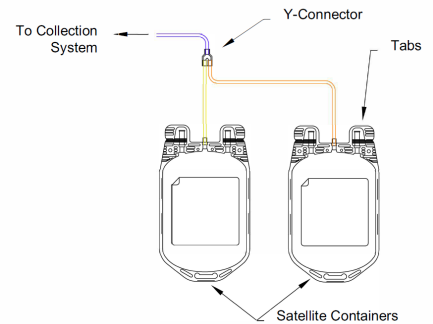
Notes:

- When performing QC testing, please retain the entire BPU until testing is completed and is passing.
- QC samples if failed should be returned in their entirety (primary container filter and RBC container).

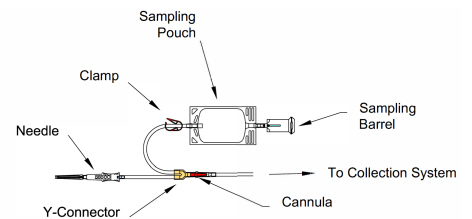
Needle



Satellite/Secondary Containers



Needle/Sampling System



Additional Problem Description / Explanation

Kit Return To Fresenius Kabi

1. Sample available for evaluation? Yes No
 2. Sample return box needed? Yes No Return label only
 3. Picture available for evaluation? Yes No
- Please e-mail a clear picture **along with this report** to **mdpmqa.usa@fresenius-kabi.com**

Center Authorized Signature/Date: _____

Customer Information (please print)

The following information is required to receive a credit

Facility Name: _____
 Contact Person: _____
 Account Number (if known): _____
 Operator Name: _____
 Street Address: _____
 City/State/Zip: _____
 Phone Number: _____
 Contact Person's E-mail: _____

Fax this report to 1-888-858-2983 or E-mail to mdpmqa.usa@fresenius-kabi.com and include a copy of this form when returning a kit.