

# Blood-Pack Unit 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.: \_\_\_\_\_ 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:

- Was there any adverse event or injury?    Yes  No
- Was the procedure successfully completed?    Yes  No  N/A
- If no, was the procedure stopped due to a soft goods incident?    Yes  No  N/A
- 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)

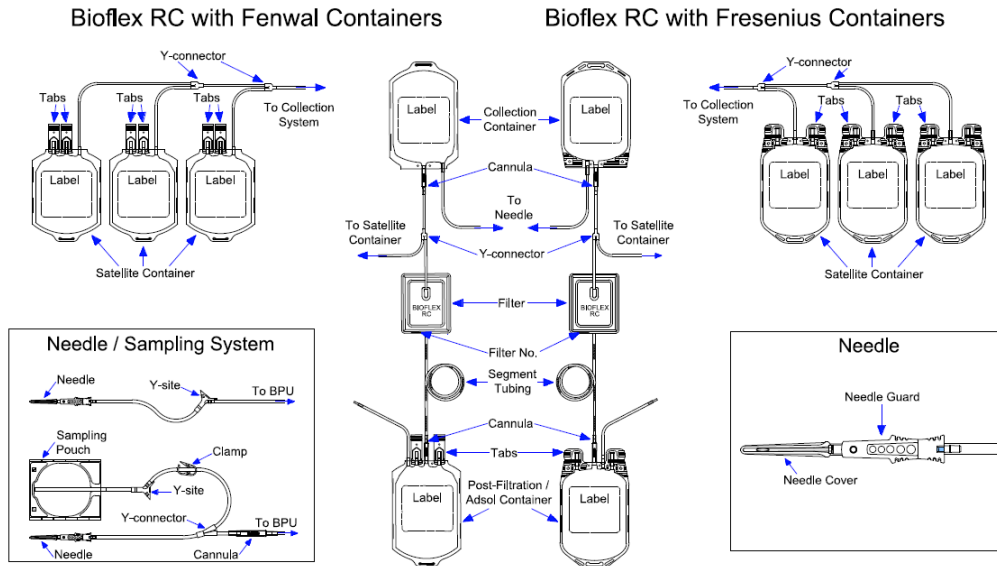
**If filter related issues, please provide feedback or circle a response below, as applicable:**

- 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 \_\_\_\_\_

**If Needle related issues, please select the applicable answer below:**

- When was the condition detected?
- Removal from Foil Pouch     During Labeling  
 After Labeling     Removal of Needle Cover  
(at the time of phlebotomy)
- 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).

### Please circle specific components on the diagram where incident occurred



### Additional Problem Description / Explanation

#### Kit Return To Fresenius Kabi

- Sample available for evaluation?    Yes  No  Not Required
  - Sample return box needed?    Yes  No  Return label only
  - Picture available for evaluation?    Yes  No
- Please e-mail a clear picture along with this report to [mdpmqa.usa@fresenius-kabi.com](mailto: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](mailto:mdpmqa.usa@fresenius-kabi.com) and include a copy of this form when returning a kit.