

PLASMACELL-C Product Performance Report



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

Incident Date: _____ Instrument S/N.: _____ Software Version: _____
 Product Code: _____ Lot No.: _____ UDI No.: _____
 Batch Tag Info Time: ____:____:____ Batch Tag No.: _____ Video Jet No.: _____
 Donor Bleed No.: _____ Volume of Plasma Collected: _____ mL

When Was the Problem Detected?

Before Use Set-Up Install Check Solution Prime Blood Prime Collection (specify cycle) _____
 During Venipuncture Reinfusion (specify cycle) _____ After Collection Freezing

Problem Type (Mark all applicable) Alarm/Alert/Help Code _____ Detached/Separated Noise Hole
 Kinked Blood/Plasma Leak Low/No Plasma Flow Cut/Slice Red Plasma (Visual) Illegible Label
 Dented Installation Check Solution Leak HB Detect Missing (not in box) Other (Specify Below)

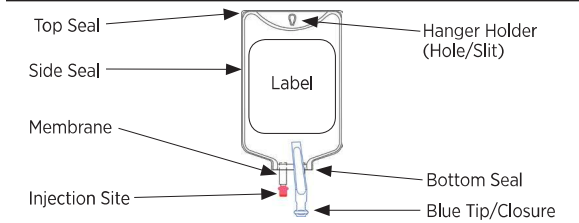
Please answer the following questions:

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.

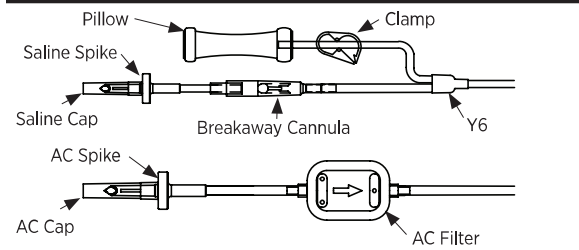
E-mail address for letter recipient (if applicable) _____

Please circle specific components on the diagram where incident occurred

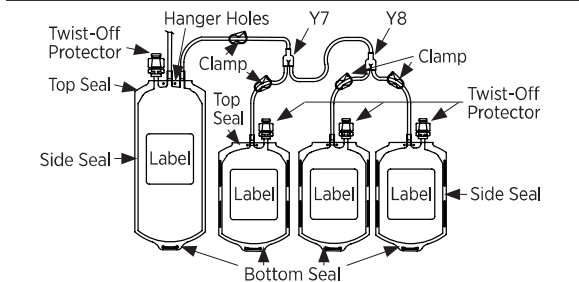
AC Solution or 0.9% Sodium Chloride Solution



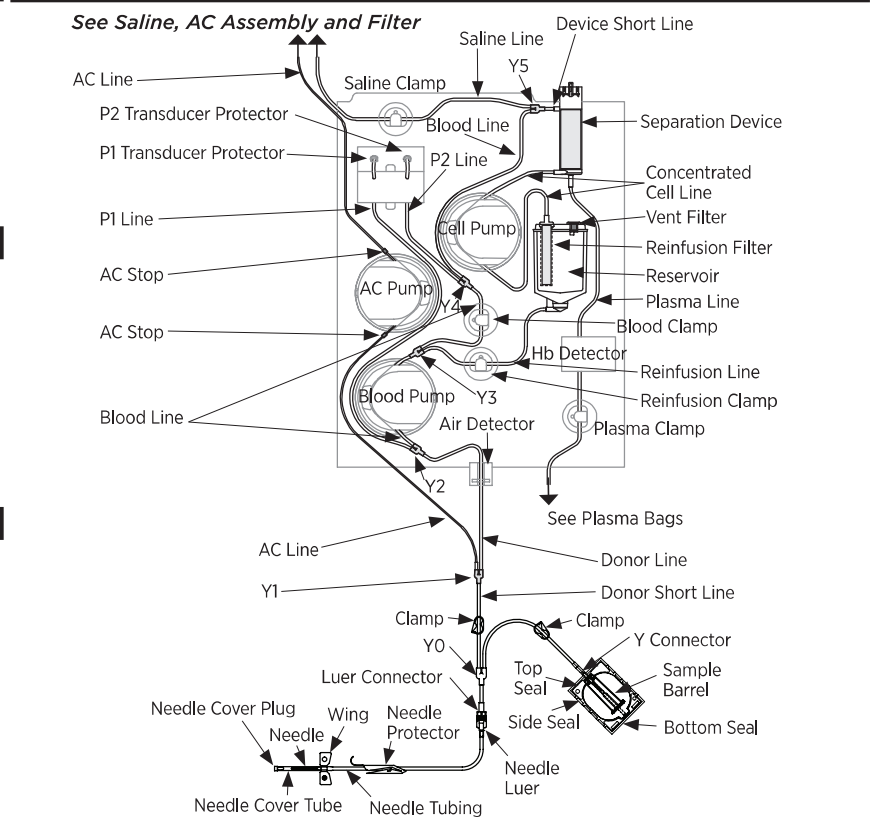
Saline, AC Assembly and Filter



Plasma Bags



PLASMACELL-C Separation Disposable Set



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:

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.

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: _____