

# 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?

- Incoming Inspection  Kitting  Before Use  Set-Up  Install Check  Solution Prime  Blood Prime  
 Collection (specify cycle) \_\_\_\_\_  During Venipuncture  Reinfusion (specify cycle) \_\_\_\_\_  After Collection  Freezing

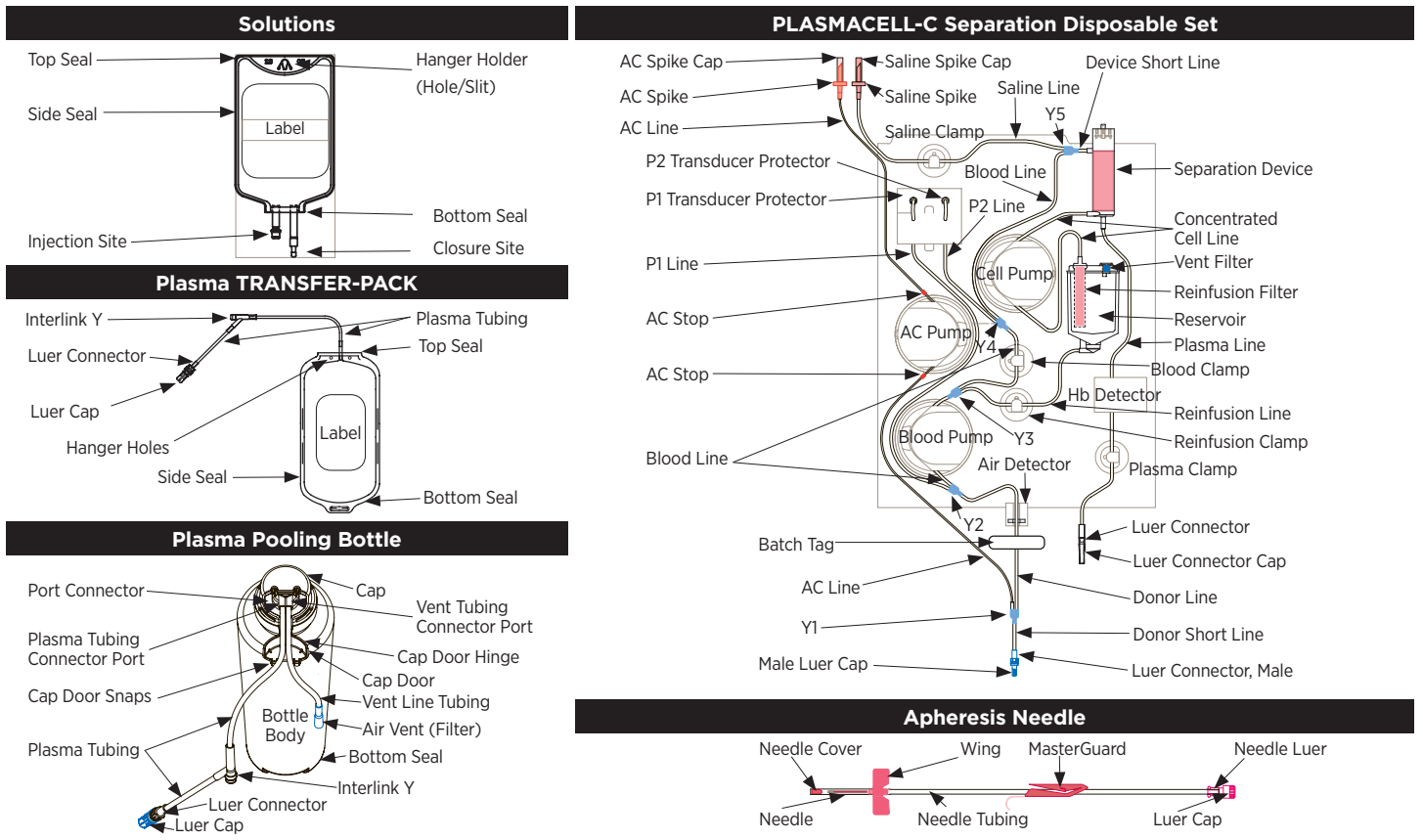
- Problem Type** (Mark all applicable)  Alarm/Alert/Help Code \_\_\_\_\_  Detached/Separated  Noise  Hole  
 Kinked  Blood/Plasma Leak  Low/No Plasma Flow  Cut/Slice  Red Plasma (Visual)  Illegible Label  
 Dented  Installation Check  Solution Leak  HB Detect  Missing (not in box)  Other (Specify Below)

### 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



### 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](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.