

Important: If adverse reaction or injury has occurred call Fenwal at 1-800-933-6925

Complete these three questions if issue occurred during a donation.
 Was there any injury / adverse donor reaction? Yes No
 Was the donation successfully completed? Yes No
 If No, was the donation stopped due to a soft goods incident? Yes No

PLASMACELL-C™ Product Performance Report

Incident Date: _____ Instrument Serial Number: _____ Software Ver _____
 Product Code: _____ Lot Number: _____
 Batch Tag Info Time: _____:_____:_____ Number _____ Video Jet Number: _____
 Donor Bleed Number: _____ Volume of Plasma Collected: _____ mL

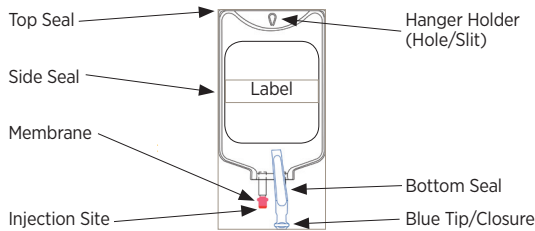
When Was The Incident Detected

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

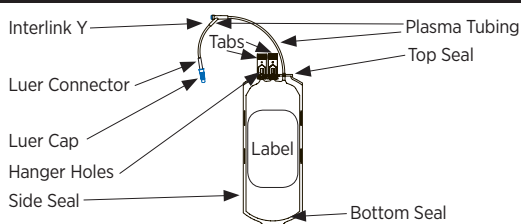
Incident Type (Mark all applicable) Alarm/Alert/Help Code _____ Detached/Separated Noise
 Kinked Blood/Plasma Leak Low/No Plasma Flow Cut/Slice Red Plasma (Visual) Illegible Label
 Installation Check Dented Solution Leak Missing (not in box) HB Detect Hole Other (Specify Below)

Please circle **NAME** of the specific components on the diagram where incident occurred

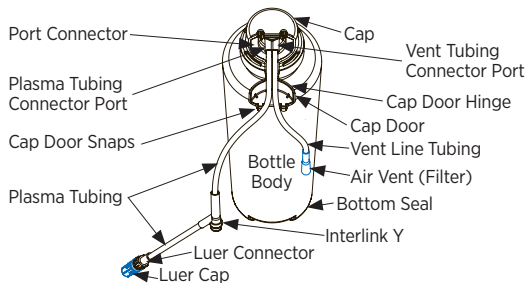
Sodium Citrate Solution 0.9% Sodium Chloride



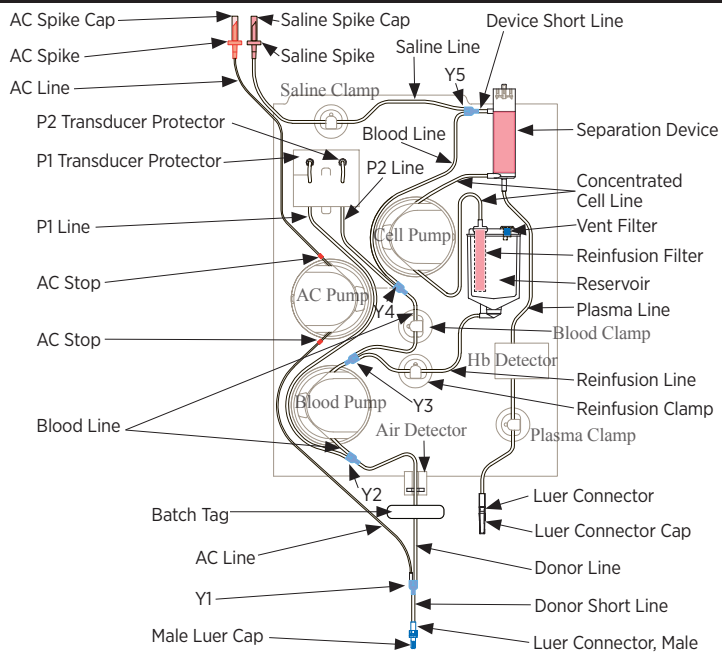
Plasma TRANSFER-PACK™



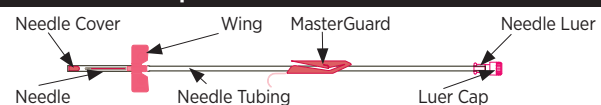
Plasma Pooling Bottle



PLASMACELL-C™ Separation Disposable Set



Apheresis Needle



Additional Incident Description / Explanation

Kit Return To Fenwal

1. Check box if sample is available for evaluation.
2. Sample return box needed? Yes No Return label only
3. Do you request a letter regarding the investigation results? Yes No
4. Picture taken of defective kit? Yes No (if yes, send picture to fenwal.quality@fenwalinc.com)

Center Authorized Signature/Date: _____ Fenwal Reviewed By/Date: _____

Please Print

Account #: _____
 Site Name: _____
 Contact Person: _____
 Operator Name: _____
 Street Address: _____
 City/State/Zip: _____
 Phone Number: _____
 E-Mail: _____
 Fax Number: _____

Notification No. (Fenwal Personnel Only)