



Important: If reaction or injury has occurred call

Fenwal Post-Market Quality Assurance at 1-800-933-6925

Complete these four 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

Was product lost? Yes No

AMICUS™ Separator Kit Performance Report

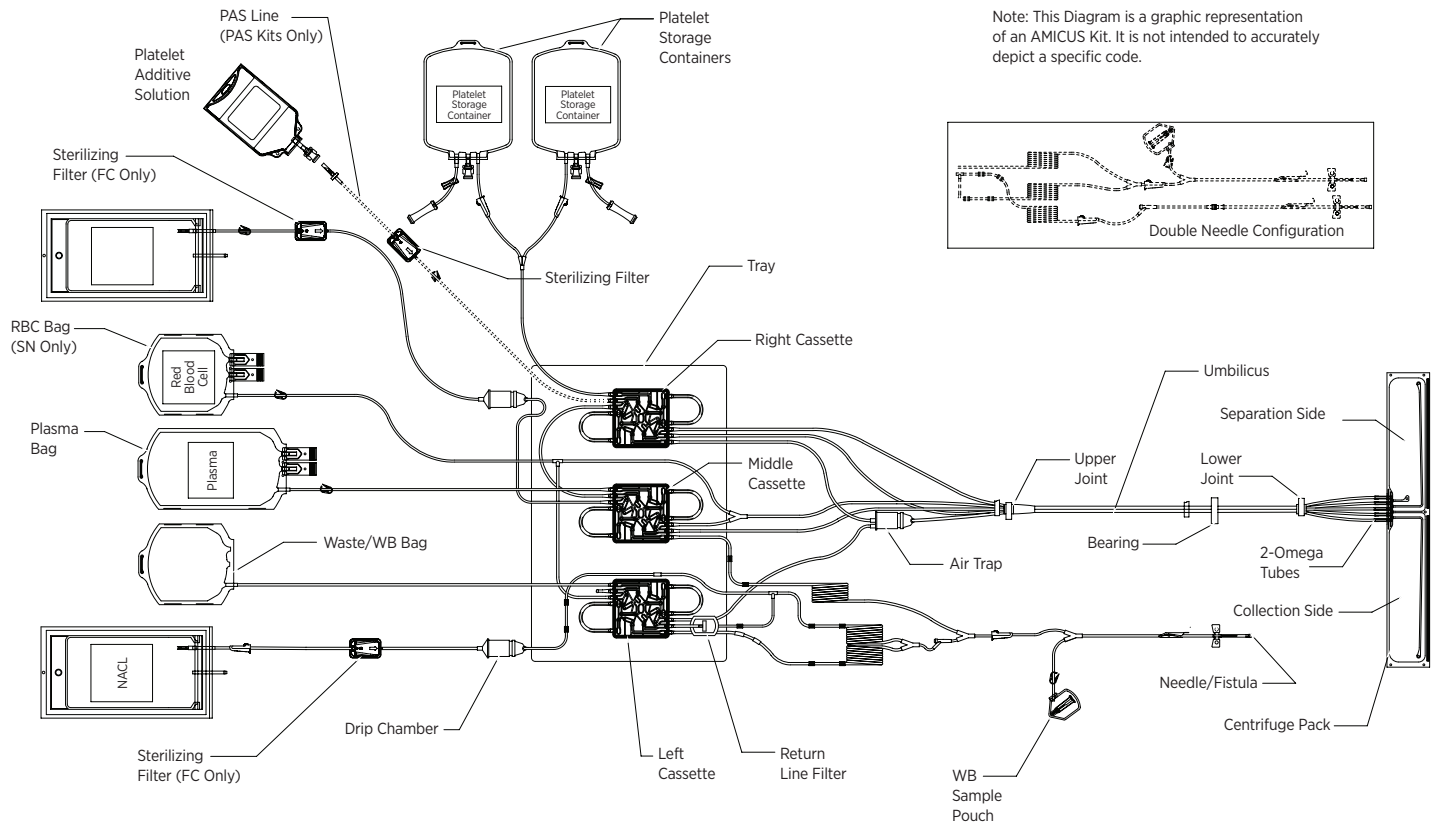
Incident Date: _____ Instrument Serial No.: _____ Software Version: _____
 Apheresis Kit Code: _____ Lot Number: _____ PAS: No Yes (Lot Number _____)

When Was The Problem Detected

Set Up Collection Product Transfer
 Prime _____ % WB Processed _____ mL Reinfusion After Procedure/QC

Problem Type (Mark all applicable) Cut/Slice Kink Particulate Matter Restriction/No Flow
 Alarms (Specify) _____ Leak Platelet Aggregation (After 24 Hrs.) Separated
 Blood Leak Cracked Excess Air Missing RBC Contamination Other

Please circle specific components on the diagram where issues occurred **Spool Version:** _____



Additional Problem 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: _____

Notification No. (Fenwal Personnel Only)