

AMICUS Separator Kit 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: _____ UDI No.: _____
 Product Code: _____ Lot No.: _____ WB Processed: _____ mL

When Was the Problem Detected?

- Set Up Collection Plasma Transfer
 Prime Step No. _____ Reinfusion After Procedure/QC

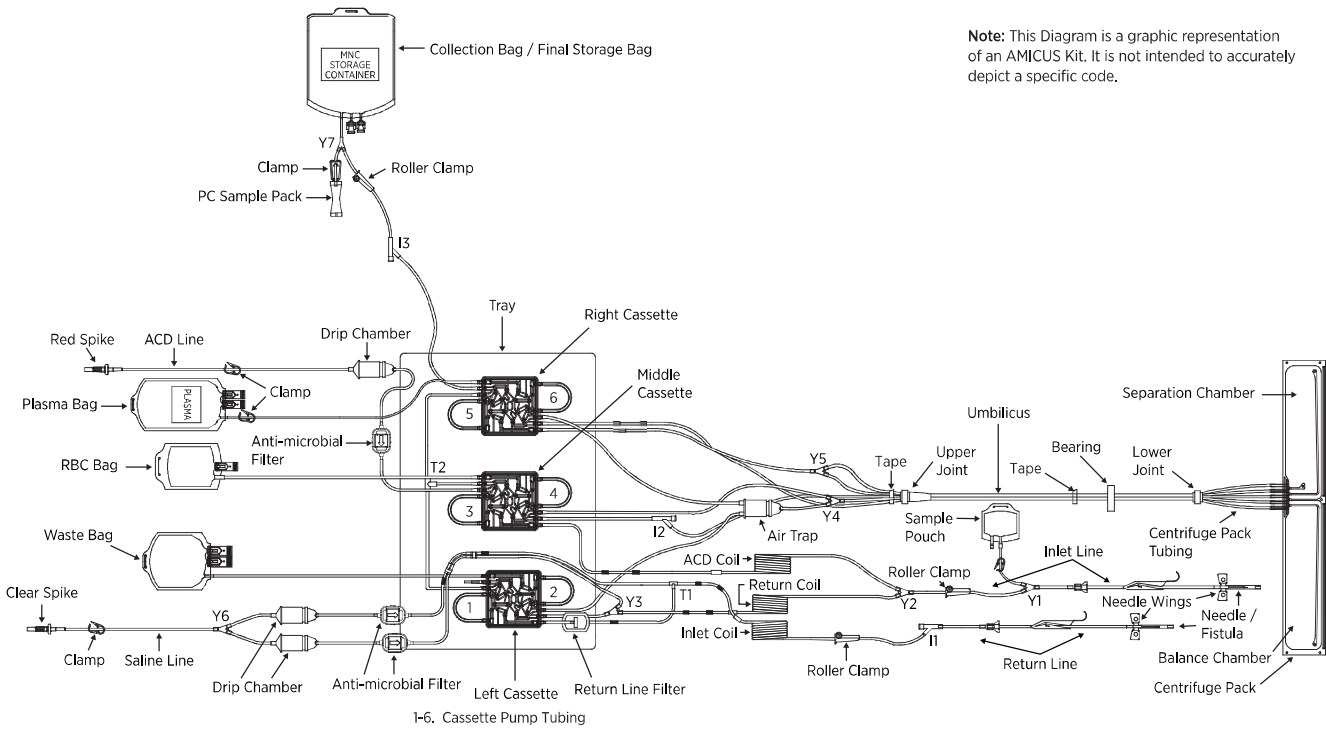
- Problem Type (Mark all applicable)** Cut/Slice Kink Particulate Matter Restriction/No Flow
 Alarms (Specify) _____ Leak Separated Blood Leak
 Cracked Excess Air Missing RBC Contamination Other (Specify Below)

Please answer the following questions:

1. Was there any adverse event or injury? Yes No
 2. If applicable, list name of any drug administered: _____
 3. Was the procedure successfully completed? Yes No N/A
 4. If no, was the procedure stopped due to a soft goods incident? Yes No N/A
 5. 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 Not Required
 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: _____