

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

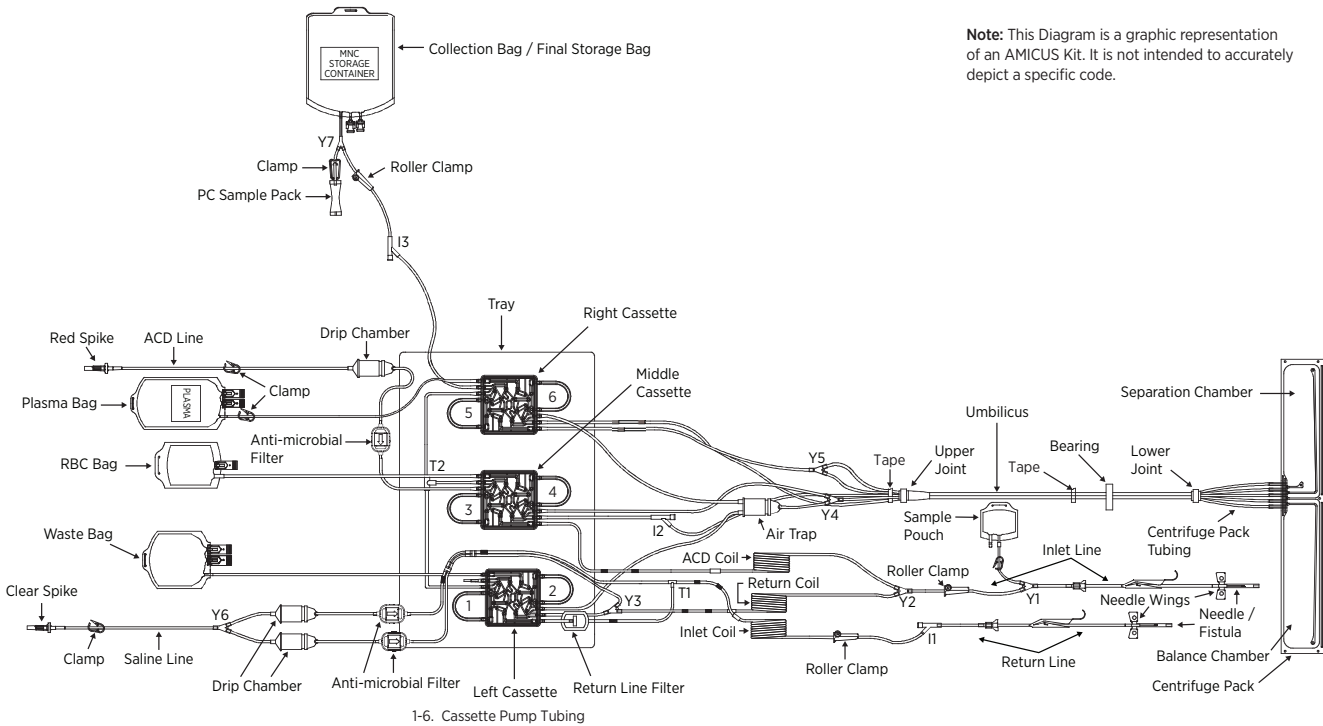
- Problem Type (Mark all applicable)** Cut/Slice Kink Particulate Matter Restriction/No Flow
 Alarms (Specify) _____ Leak Separated Blood Leak
 Cracked Excess Air Missing RBC Contamination Other (Specify Below)

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
 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: _____