

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.: _____
 Lot No.: _____ Video Jet No.: _____

When Was the Problem Detected?

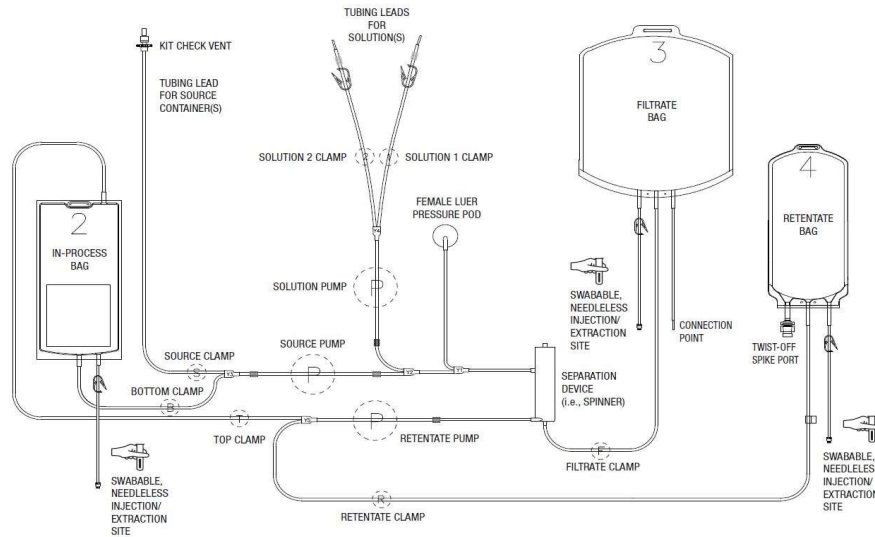
- Before Use Kit Installation Disposable Kit Check Disposable Kit Prime During Procedure After Procedure

Problem Type (Mark all applicable)

- Packaging:** Packaging Open Mispacked Illegible Label Discolored Missing or Separated Component (e.g. keeper)
Tubing: Flattened Kinked Hole Cut/Sliced Blocked/Occluded Discolored
Separation Device: Cracked Leaking Fluid Noise
Pressure Pod: Cracked Leaking Fluid Poor Fit on Pressure Sensor Port
Container: Leaking Fluid Improper Seal around Container Port Discolored
 Other: _____ Associated Alert Name/Code (if applicable): _____

Additional Problem Description/Explanation

Please circle specific components on the diagram where incident occurred



Picture available for evaluation? Yes No

If a picture is available, please e-mail a clear picture along with this report to mdpmqa.usa@fresenius-kabi.com

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
 5. Did the procedure involve clinical or patient material? Yes No N/A
- Check box if you do **NOT** wish to receive response letters.

E-mail address for letter recipient (if applicable)

<p>Kit Return to Fresenius Kabi</p> <p>1. Sample available for evaluation? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>2. Return label needed? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>3. Sample return box needed? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <hr/> <p>Center Authorized Signature/Date:</p> <div style="border: 1px solid black; height: 40px; width: 100%;"></div> <p>Fax this report to 1-888-858-2983 or E-mail this report to mdpmqa.usa@fresenius-kabi.com and include a copy of this form when returning a kit.</p>	<p>Customer Information (please print)</p> <p>The following information is required to receive a credit</p> <p>Facility Name: _____</p> <p>Contact Name: _____</p> <p>Account Number (if known): _____</p> <p>Operator Name: _____</p> <p>Street Address: _____</p> <p>City/State/Zip: _____</p> <p>Phone Number: _____</p> <p>Contact Person's E-mail: _____</p>
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