

CATS Disposable Set Performance Report

Important: If reaction or injury has occurred call Fresenius Kabi Product Complaint and Support at 1-800-933-6925.

Incident Date: _____ S/N: _____ UDI No.: _____
 Product Code: _____ Lot No: _____ Customer Reference No.: _____

When Was the Problem Detected?

- Before Use Set Up Prime During Procedure After Procedure
 Clinical Use Other (specify) _____

Problem Type (Mark all applicable) Hole Blood Leak Detached/Separated Illegible Label Solution Leak
 Alarm (Specify) _____ Kinked Cut/Slice Missing (not in box) Other (Specify) _____

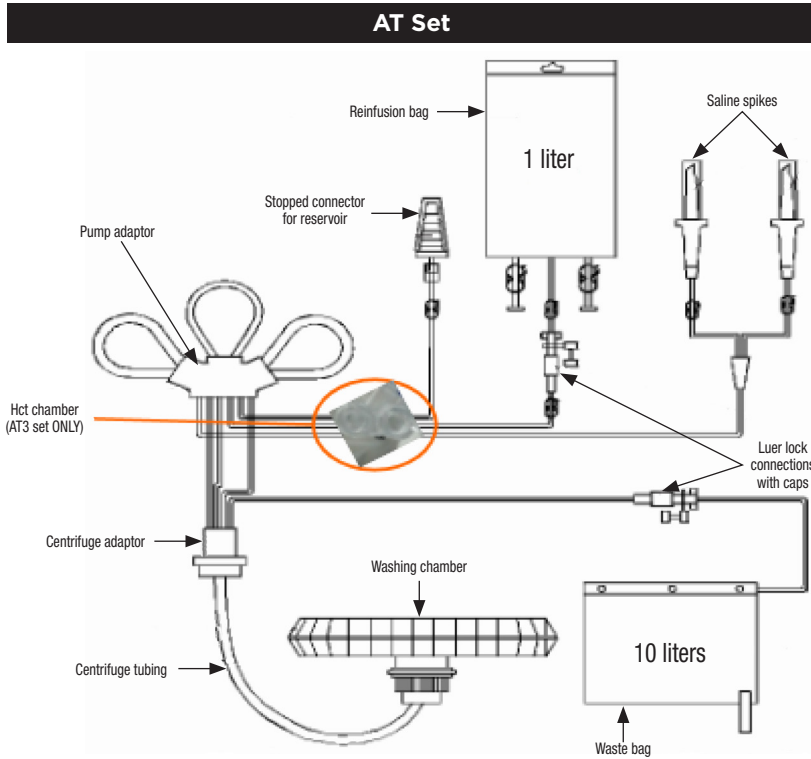
Please answer following questions:

1. Was there any adverse event or injury? Yes No
2. Did the alleged deficiency result in delay in the beginning or continuing the medical procedure? Yes No N/A
3. Was the surgery successfully completed? Yes No N/A
4. Was there blood loss as a result of the reported issue? Yes No N/A

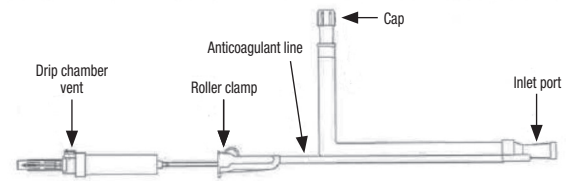
Check box if you do **NOT** wish to receive response letters.

_____ E-mail address for letter recipient (if applicable)

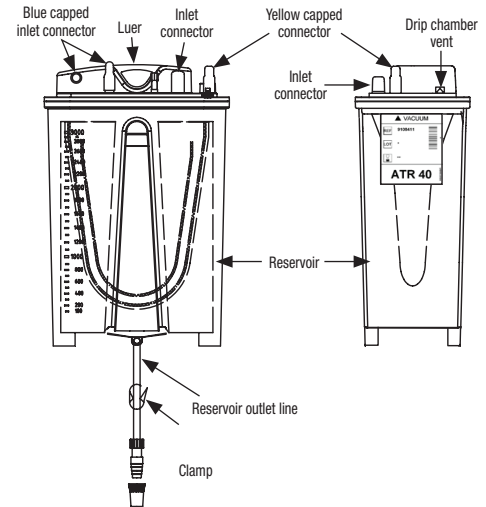
Please circle specific components on the diagram where incident occurred



ATS Set



ATR 40-120 Reservoir



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
MDComplaintSupport@Fresenius-kabi.com

Center Authorized Signature/Date:

**Fax this report to 1-888-858-2983 or E-mail to
 MDComplaintSupport@Fresenius-kabi.com
 and include a copy of this form when returning a kit.**

Customer Information (please print)

Facility Name: _____
 Contact Person: _____
 Account Number (if known): _____
 Operator Name: _____
 Street Address: _____
 City/State/Zip: _____
 Phone Number: _____
 Contact Person's E-mail: _____