FreeFlex+ Transfer Adapter Set Performance Report

FRESENIUS KABI

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

Incident Date: _____ UDI No.: _____

Product Code: _____ Lot No.: _____

When was the incident detected?

☐ Before Use ☐ Set Up ☐ Prime ☐ During Procedure ☐ After Procedure

Incident Type (*Mark all applicable*)

☐ Discolored ☐ Illegible ☐ Deformed/Damaged ☐ Incorrect Labeling ☐ Foreign Matter ☐ Connection Problems
☐ Kinked ☐ Missing ☐ Misassembly ☐ Leak ☐ Blocked/Restricted ☐ Separated ☐ Other (please specify) _____
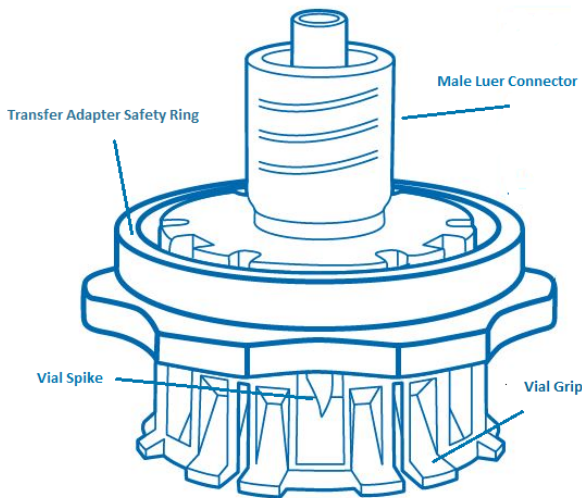
Please answer the following questions:

1. Was there any adverse event or injury? Yes ☐ No ☐
2. Was the infusion stopped before completion? Yes ☐ No ☐ N/A ☐
3. Was the infusion successfully completed? Yes ☐ No ☐ N/A ☐
4. What drug was used for the infusion? _____ Cytotoxic? Yes ☐ No ☐
5. Was a pressure cuff used during administration? Yes ☐ No ☐
6. What company manufactured the container that was spiked? _____ 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 issues occurred

Transfer Adapter Safety Ring

Male Luer Connector

Vial Spike

Vial Grip

Additional Incident 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:

Customer Information (please print)
The following information is required to receive a credit

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

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 set.