

Gravity and Extension Set Performance Report



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) _____

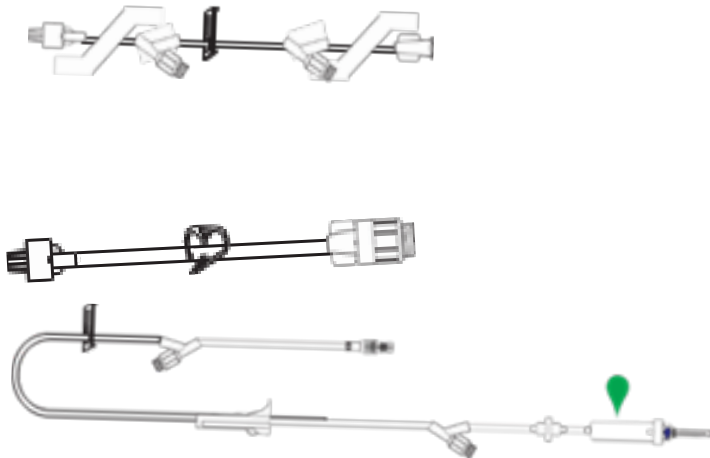
Please answer the following questions:

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



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.

REFERENCE DOCUMENTS (S): NONE