Form	
Product Incident Report (PIR)	Value Life Confidential

*The **US Food and Drug Administration** requires all medical device manufacturers to promptly report information that reasonably suggests their marketed device may have caused or contributed to a death or serious injury or if the device has malfunctioned and would be likely to cause a death or serious injury if the malfunction were to recur. In order to comply with this reporting mandate, we ask that you review this form, and enter all associated information.*

To submit a PIR, please contact your sales representative / dealer or Vygon USA (800) 473-5414

Please complete one PIR for each incident / failure mode.
If more than one occurrence, please submit ALL devices associated to each occurrence for evaluation.

Date Received by Vygon Quality: *(Vygon Internal Use Only)*	

Section 1: Contact Information

Date Reported	
Dealer / Sales Representative Name	
Contact Name	
Contact Title	
Facility Name	
Facility Address	
Phone	
Email	
Fax	

Section 2: Product Information

Product Code(s)	If unknown, please provide a description of the product:

Lot Numbers	
Is a picture of the sample available?	Yes If yes, please include this image with this report.
Will samples be returned for investigation?	Yes If yes, how many will be returned? All samples should be cleaned, placed in a biohazard bag & returned to the Quality Department at: Vygon Manufacturing 87 Venture Drive, Dover NH, 03820
Have samples contacted chemotherapy drugs?	Yes If yes, Vygon apologies but we cannot accept products which have contacted chemotherapy drugs due to hazardous material restrictions. Please provide photos if available.
Is replacement product requested?	Yes Note: Replacements are only completed if Vygon investigation deems that the incident was related to a manufacturing problem.

Section 3: Incident Information

Date of Incident	
Number of Occurrences	1
Description of Incident	
General Issue Code	Contamination
Patient Affected?	Yes
What actions were taken following the incident?	
Patient Outcome	

Blood Loss	None (0 mL)
Patient Information *Note: Vygon may utilize this information if patient outcome led to serious injury or death.*	Age: years Weight: lbs Gender: Past Medical History:
Additional Information	

Section 4: Catheter Specific Questions

Choose N/A is the incident did not involve a catheter

Site Care Solution	☐ Iodine ☐ Chlorhexidine (tradename) ☐ Alcohol ☐ Other: ☐ Not Applicable
Catheter Dwell Time	
What was being infused?	
Was the infusion being carried out by Pump, Syringe, or Gravity?	Not Applicable
If syringe, what size?	Not Applicable *Note: If the size is not available from the drop down, enter the applicable mL size.*
What size syringe was used to flush the catheter?	Not Applicable *Note: If the size is not available from the drop down, enter the applicable mL size.*