



Product Incident Report

Churchill Medical Systems, Inc., A Vygon Company

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.

Incomplete information may delay and/or prohibit a thorough investigation.

(One Product Incident Report for each failure mode).

*If more than one occurrence, please submit **ALL** devices associated to each occurrence for evaluation)*

Section 1 Contact Information

Date of this Report: _____

Dealer/ Rep: _____

Contact Name: _____

Contact Title: _____

Facility Name: _____

Facility Address: _____

Date received by
Vygon Customer _____
Service: _____ *(for internal use only)*

Phone _____

Email _____

Fax _____



Section 2 Product Information **(THIS INFORMATION IS CRITICAL FOR INVESTIGATION)**

Product Code(s): _____



Lot Number: _____



Will samples be returned for Evaluation? _____

(device is required for proper investigation)

Section 3 Incident Information

Date of Incident: _____

Number of Occurrences: _____

(Inserting "Multiple" or "Many" is not acceptable. Number is required)

Please Describe the Incident in detail:

If a catheter was used, please also fill out Section 4.

Patient Outcome:

Blood Loss (mL): 0 <20 20-100 >100



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Section 4 Catheter Specific Information

How long was the catheter in the Patient prior to the above incident? _____

What was being Infused? _____

Was the Infusion being carried out by pump or syringe? _____

If a syringe, what size? _____

What size syringe was used to flush the catheter? _____

What actions were taken following the Incident?

Section 5 Patient Information *(Vygon to utilize this information if patient outcome led to serious injury or death)*

Patient Past Medical History:

Age: _____

Weight: _____ lbs, or _____ kg

Gender: M or F

Patient ID: _____

(Please use one Product Incident Report per patient)

Site Care: iodine chlorhexidine (tradename) _____
 alcohol other (tradename) _____

Additional Information:

