Product Incident Report

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: _____ Phone _____

Contact Title: _____ Email _____

Facility Name: _____ Fax _____

Facility Address: _____

_____

Date received by Quality Assurance Department: _____ *(for internal use only)*

All samples should be cleaned & returned to the Quality Department at Vygon Manufacturing
87 Venture Drive, Dover NH, 03820

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

Product Code(s): _____ Lot Number: _____

Will samples be returned for Evaluation? Yes or No. _____ *(device is required for proper investigation)*

If Yes, how many? _____

All samples must be de-contaminated before return to Vygon. Contaminated samples received in Dover will be disposed of without 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:

_____

_____

_____

(Please use one Product Incident Report per patient)

Age: _____

Weight: _____ lbs, or _____ kg

Gender: M or F

Patient ID: _____

Site Care: ☐ iodine ☐ chlorhexidine (tradename) _____

☐ alcohol ☐ other (tradename) _____

Additional Information:

_____

_____

_____