Health Canada / Santé Canada

Mandatory Medical Device Problem Reporting Form for Industry

CANADA VIGILANCE - MEDICAL DEVICE PROBLEM REPORTING PROGRAM

If more space is required, please attach additional sheets
Fields required to be completed for updates/final reports are indicated by an *

A. REPORTER INFORMATION

1. i. Reporter Type

○ Manufacturer ◉ Importer

In the case where the reporter is the importer:

ii. Did the importer report the incident to the manufacturer?

◉ Yes ○ No

iii. Is the importer also submitting the report on behalf of the manufacturer?

◉ Yes ○ No

2. Reporter Contact Information *

fc0b18b00c98a4158a51a030f71c3e61

3. Reporter File No. *

1715748

4. Health Canada File No. (if applicable) *

Incident 922487

5. Type of Report *

○ Preliminary ○ Update ◉ Final ○ Preliminary & Final

If "preliminary" only, anticipated date for the final report:

(YYYY-MM-DD)

If "update/final", date the previous report was submitted to Health Canada:

2020-08-06 (YYYY-MM-DD)

6. Date Submitted *

2020-09-15 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	BECTON DICKINSON INFUSION THERAPY SYSTEMS 9450 S. State Street Sandy, UT, US, 84070	Becton Dickinson Canada Inc. 2100 Derry Road, Suite 100, Mississauga, ON L5N 0B3
8. Health Canada assigned company identification number (if known):	101280	101291
9. Establishment License Number (if applicable):		204

B. INCIDENT INFORMATION

1. Classification of Incident *

i. ◉ 10-Day ○ 30-Day

ii. ◉ Canadian ○ Foreign

iii. ○ Investigational testing ○ Special Access Program

○ Radiation emitting device (if applicable)

2. Date of Incident

(YYYY-MM-DD)

3. Reporter's Awareness Date

2020-07-27 (YYYY-MM-DD)

4. Patient Consequences

f033a8c75fb98d9f3a1ef0afd5ad4079

5. Details of Incident

7c11be6078d2be7d407a215627fa9e46

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
BD InSyte Autoguard Shielded I.V. Catheter with Blood Control

2. Control/Lot/Serial No.
9213332

3. Expiration Date
2022-07-31 (YYYY-MM-DD)

4. i. Device Classification
○ I ◉ II ○ III ○ IV

ii. Device License No.
6621

iii. Device Identification No
565424

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
382512

5. Software Version
not applicable

6. Age of Device
unknown

7. How long was the device in use?
unknown

8. Was the device labelled as sterile?
◉ Yes ○ No

9. Availability of device for evaluation
○ Destroyed ○ Returned to Manufacturer/Importer
◉ Neither (with explanation)

Samples were not received.

D. COMPLAINANT INFORMATION

1. Complainant is a:
○ Consumer ◉ Health professional ○ Other

2. Name of Complainant
de3fa332354eefb10192224f0cac6b28

3. Name of Health Care Facility (if applicable)
2586d2d257907ddfc52d00aef6bedb72

4. Address
d41d8cd98f00b204e9800998ecf8427e

5. Telephone No. and/or E-mail Address
5d5d75a3f7b40389addb89663b883a0c

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline
6a71e2291487c73a5c2efd0222d649a9

This section only applies for preliminary & final, and final reports

2. Root Cause of Problem
6a45f8911834d97f6d470047e7c4f59f

3. Corrective Actions taken as a result of the investigation
a1d557964b862c8b46629b9914b411d7