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 *

ecc122dda5dadea3e49c4c3ad5d76bda

3. Reporter File No. *

1240844

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

not assigned yet

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:

2019-11-14 (YYYY-MM-DD)

6. Date Submitted *

2020-02-27 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	BECTON DICKINSON AND COMPANY 1 Becton Drive Franklin Lakes, NJ, US, 07417	Becton Dickinson Canada Inc. 2100 Derry Road, Suite 100, Mississauga, ON L5N 0B3
8. Health Canada assigned company identification number (if known):	101288	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

2019-10-16 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-10-18 (YYYY-MM-DD)

4. Patient Consequences

f992c434152bb402cebc4ed827b71db7

5. Details of Incident

2295e0f68bf27305174acd922eee0b6e

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
13x100 mm 6.0 mLBD Vacutainer® SPC Plus plastic tube

2. Control/Lot/Serial No.
8215763

3. Expiration Date
2019-08-31 (YYYY-MM-DD)

4. i. Device Classification
(●) I ( ) II ( ) III ( ) IV

ii. Device License No.
n/a

iii. Device Identification No
n/a

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
368380

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)

D. COMPLAINANT INFORMATION

1. Complainant is a:
( ) Consumer (●) Health professional ( ) Other

2. Name of Complainant
b33716b603812f08ba38330eaf46f08e

3. Name of Health Care Facility (if applicable)
f46fb06e9313dde978b6cd80d76f212d

4. Address
6f17970e92b48c54d8186641160186f6

5. Telephone No. and/or E-mail Address
840097f15c168e673e466d0bd45e4680

Privacy Notice Statement: For the purposes of the Canada Vigilance - Medical Device Problem Reporting Program, information related to the identity of the complainant and/or reporter will be protected as personal information under the *Privacy Act*, and under the *Access to Information Act* in the case of an access to information request. For details with regard to personal information collected under this program, visit the Personal Information Bank; Health Canada; Health Products and Food Branch; Branch Incident Reporting System; HC PPU 088 at: http://infosource.gc.ca/inst/1476/1476-fedemp00-eng.asp

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline
a4ea2800bfedd3a4b8cdf31de77d88a7

2. Root Cause of Problem
9cc232adb3113436058eb73fbf09c4b9

3. Corrective Actions taken as a result of the investigation
e46700e7d85b370898da9c9e5db2eda4