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 *

30aa611c991cc316858fa75e14f7f37d

3. Reporter File No. *

1248621

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:

2019-11-20 (YYYY-MM-DD)

6. Date Submitted *

2020-03-03 (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

2019-10-23 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-10-24 (YYYY-MM-DD)

4. Patient Consequences

d4c6d5eb293e0614632edf568267af57

5. Details of Incident

8c6c808094f58b8457a9b992603a0c22

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
BD NEEDLE SFTYGLD 25X5/8

2. Control/Lot/Serial No.
8187585

3. Expiration Date
2023-06-30 (YYYY-MM-DD)

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

ii. Device License No.
4347

iii. Device Identification No
180046

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
305901

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)

Photos were provided for evaluation.

D. COMPLAINANT INFORMATION

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

2. Name of Complainant
30ac6f7b7a03c1606551eb42c5c90de8

3. Name of Health Care Facility (if applicable)
c7f332a9b68fba6dc189947bdcc67085

4. Address
df29e05affb33a3ccd25dedaf493b17f

5. Telephone No. and/or E-mail Address
1e96108de8706080eea8c5a33df429ac

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

3cf0540881f5856a9d7c99388159d0db

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

2. Root Cause of Problem

5d25c788a106249ff0bd6c360f2a6b7b

3. Corrective Actions taken as a result of the investigation

916b5a9a6d0db2eb3ea5d14ec8dae15c