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. *

1286506

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:

2019-12-13 (YYYY-MM-DD)

6. Date Submitted *

2020-04-14 (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

2019-11-13 (YYYY-MM-DD)

3. Reporter's Awareness Date

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

4. Patient Consequences

a78bd7d99e2579c63656fac0e743a82f

5. Details of Incident

1e5b1647820d0a0c2ca9543493efdcbd

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
BD UltraFine Nano Pen Needle, 4 mm, 32G

2. Control/Lot/Serial No.
8352658

3. Expiration Date
2023-12-31 (YYYY-MM-DD)

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

ii. Device License No.
8388

iii. Device Identification No
163366

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
320144

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
316e26b50a582e9c98988c14e76b0291

3. Name of Health Care Facility (if applicable)
d41d8cd98f00b204e9800998ecf8427e

4. Address
e9e2c045c81e864c09b2f1c057783978

5. Telephone No. and/or E-mail Address
98baaa3d7246a249370ebb77e61d54ee

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E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline
e4c4b0c6483013eea9f83cfc252dcfbd

2. Root Cause of Problem
ad977c8bcaab18e23e69302be661f71b

3. Corrective Actions taken as a result of the investigation
916b5a9a6d0db2eb3ea5d14ec8dae15c