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 *

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F:

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3. Reporter File No. *

MDPR-2019-00400-01

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

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:

2019-08-07 (YYYY-MM-DD)

6. Date Submitted *

2020-07-30 (YYYY-MM-DD)

		Importer
7. Name and Address	St. Jude Medical, CRMD 15900 Valley View Court Sylmar, CA 91342	Abbott Medical Canada, Co. 6975 Creditview Rd Unit #1 Mississauga, ON, Canada L5N 8E9
8. Health Canada assigned company identification number (if known):	107942	107941
9. Establishment License Number (if applicable):		19

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

2019-04-25

3. Reporter's Awareness Date

2019-07-19

4. Patient Consequences

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903e89118b29a0082b72c6e270dd6fc2

5. Details of Incident

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306debb8b6ce4e3dabe6874ceed6a4e7

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
FORTIFY ASSURA VR

2. Control/Lot/Serial No.
1093721

3. Expiration Date
2015-09-30 (YYYY-MM-DD)

4. i. Device Classification
☐ I ☐ II ☐ III ☑ IV

ii. Device License No.
84623

iii. Device Identification No
573137

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
CD1359-40C

5. Software Version
N/A

6. Age of Device
2013-10-01

7. How long was the device in use?
1788 days

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
P692c8930a8de28886fcd4597aac67d14

3. Name of Health Care Facility (if applicable)
C8d4a0da78e1b68a8760e920e16820204

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69f26b3c62971576053e531c35501d15

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

c80020861bd27b661be227cc0a44625d

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

2. Root Cause of Problem

4acd6010d0c04ecacf73ed13bff64f15

3. Corrective Actions taken as a result of the investigation

2bcd33a1fd7c10e358a5acf3c2ff7f5e