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:

3. Reporter File No. *

MDPR-2019-00588-02

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:

2020-05-08 (YYYY-MM-DD)

6. Date Submitted *

2020-09-25 (YYYY-MM-DD)

	Manufacturer	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

2019-07-18

3. Reporter's Awareness Date

2019-10-24

4. Patient Consequences

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5. Details of Incident

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C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
DURATA 4POLE CON.ACT-FIX. TRUE BIPOLR SINGLE COIL ST.ELUT.ENDOC.DEFIBRILL LEAD

2. Control/Lot/Serial No.
BKB069230

3. Expiration Date
2022-01-31 (YYYY-MM-DD)

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

ii. Device License No.
77538

iii. Device Identification No
579992

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
7122Q

5. Software Version
N/A

6. Age of Device
2019-02-27

7. How long was the device in use?
308 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
La80326a28b36e2d76ff1f4e818cfa010

3. Name of Health Care Facility (if applicable)
S35aab94f737566390932d9a2a6158b6b

4. Address
5
N
L1ecbdec1265267518276b4ff61ea6db3

5. Telephone No. and/or E-mail Address
9

e68804484423c9dd123c70ea35d3a9c0

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

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

2. Root Cause of Problem

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3. Corrective Actions taken as a result of the investigation

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