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 *

06a5a8b26285288df42edf7d575d5a9f

3. Reporter File No. *

PR-2065783-2069927

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

S-2295

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:

2020-01-02 (YYYY-MM-DD)

6. Date Submitted *

2021-01-06 (YYYY-MM-DD)

	er	Importer
7. Name and Address	Baxter Healthcare Corporation, 1 Baxter Parkway, Deerfield, IL, 60015	Baxter Corporation, 7125 Mississauga Road, Mississauga, ON, L5N 0C2
8. Health Canada assigned company identification number (if known):	101215	101173
9. Establishment License Number (if applicable):	N/A	191

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

2019-10-21 (YYYY-MM-DD)

3. Reporter's Awareness Date

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

4. Patient Consequences

cd70cc389e0c6d689fe09d16dc3ad959

5. Details of Incident

4a3d4ec3b4e9b06be655f5c3ec7feafc

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
SECONDARY MEDICATION SET

2. Control/Lot/Serial No.
Unknown

3. Expiration Date
(YYYY-MM-DD)

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

ii. Device License No.
73151

iii. Device Identification No
2C7461

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
2C7461

5. Software Version
Not Applicable

6. Age of Device

7. How long was the device in use?

8. Was the device labelled as sterile?
● Yes ○ No

9. Availability of device for evaluation
○ Destroyed ○ Returned to Manufacturer/Importer
● Neither (with explanation)

The sample wsa not returned to Baxter for evaluation

D. COMPLAINANT INFORMATION

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

2. Name of Complainant
43ee4d8cca624455f94ea2ed0a5dbbca

3. Name of Health Care Facility (if applicable)
7acaec47add78968a0103e30bae99263

4. Address
27bcb26019bf03279b20a59c06df5b43

5. Telephone No. and/or E-mail Address
a0e0c584c2e8e1df973109ba81f18de1

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

Canada reference number from 22915 to 2295.

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

683baac3927f16ec6d18b09b003247f8

2. Root Cause of Problem

0e8738c9d1cb80470ff1891ac838cfad

3. Corrective Actions taken as a result of the investigation

68308ea017b91b572a1cac91ca48cd76