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*

8156936b8ff740cc601f8e791edcf1f1

3. Reporter File No.*

CN-049189

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

5. Type of Report*

○ Preliminary ○ Update ● Final ○ Preliminary and Final

If "preliminary" only, anticipated date for the final report:

If "update/final", date the previous report was submitted to Health Canada:

2020/10/27

te Submitted *

/12/29

	Manufacturer	Importer
7. Name and Address	Abbott Vascular 3200 Lakeside Drive Santa Clara CA 95054-2807 US	NA
8. Health Canada assigned company identification number (if known):	100230	NA
9. Establishment License Number (if applicable):	NA	NA

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

2020/10/21

3. Reporter's Awareness Date

2020/10/21

4. Patient Consequences

406b2749dbc89f999e33b879f5517d1b

5. Details of Incident

60d3530e6ab28ddec9a9a6f387a92cc6

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
MITRACLIP G4 SYSTEM

2. Control/Lot/Serial No
00701U278/N/A

3. Expiration Date
2021/07/06

4. i. Device Classification

(•) IV ( ) I ( ) II ( ) III

ii. Device License No.
103207

iii. Device Identification No
CDS0701-XTW

iv. Manufacturer's Medical Device Identifier(catalogue/model no.)
CDS0701-XTW

5. Software Version
NA

6. Age of Device
NA

7. How long was the device in use?
UNK

8. Was the device labelled as sterile?

(•) Yes ( ) No

9. Availability of device for evaluation

( ) Destroyed ( ) Returned to Manufacturer/Importer (•) Neither (with explanation)

Implanted

D. COMPLAINANT INFORMATION

1. Complainant is a:

( ) Consumer (•) Health Professional ( ) Other

2. Name of Complainant

0ba1ce93a4a1ccb5e89d74dd9151ee56

c3cdbf6d835df50966d9c97603130056

283226987ae988fccbc4472f4b83a898

7581413ad25cc69b12159930d1a0a5d7

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E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

d775dbddff5778c462ef4c5ff861e4a6

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

2. Root Cause of Problem

9141cf7aa264bf47843ffb9028722951

3. Corrective Actions taken as a result of the investigation

3d04a8605fefafdb0fa56b1621fd9104