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*

3. Reporter File No.*

CA-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

c916c2212d67c325c145bdb8a6fc850d

te Submitted *

/12/29

	Manufacturer	Importer
7. Name and Address	Abbott Vascular 3200 Lakeside Drive Santa Clara CA 95054-2807 US	Abbott 6975 Creditview Road Unit 1 Mississauga ON L5N 8E9
8. Health Canada assigned company identification number (if known):	100230	107941
9. Establishment License Number (if applicable):	NA	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

2020/10/21

3. Reporter's Awareness Date

2020/10/21

4. Patient Consequences

5. Details of Incident

60d3530e6ab28ddec9a9a6f387a92cc6

406b2749dbc89f999e33b879f5517d1b

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

Privacy Notice Statement: For the purposes of the Canada Vigilance - 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

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