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-042539

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:
2020/08/26

06a8b56087dcb813d6bab270cbbea649

te Submitted *
/10/30

	Manufacturer	Importer
7. Name and Address	ABBOTT VASCULAR 3200 Lakeside Drive Santa Clara, CA, US, 95054-2807	Abbott 6975 Creditview Road Unit 1 Mississauga ON L5N 8E9
8. Health Canada assigned company identification number (if known):		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
2020/08/20

3. Reporter's Awareness Date
2020/08/20

4. Patient Consequences

5. Details of Incident

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i 292d5003d917436adf72bebc4adecf6b

d8636f4a95bee2ed6a56047158e329a4

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
MITRACLIP G4 SYSTEM

2. Control/Lot/Serial No
00618U149/N/A

3. Expiration Date
2021/06/18

4. i. Device Classification

( ) I ( ) II ( ) III (•) IV

ii. Device License No.
103207

iii. Device Identification No
CDS0701-NTW

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

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)

Reportedly Discarded

D. COMPLAINANT INFORMATION

1. Complainant is a:

( ) Consumer (•) Health Professional ( ) Other

2. Name of Complainant

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c3cdbf6d835df50966d9c97603130056

68a82de4ba3e352cb4a1bde571cfc68e

1c86d516db809d309e1c9cd17f589be1

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E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

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

2. Root Cause of Problem

903d4eb2278dbb2f4dc71c5c0bd0aa65

3. Corrective Actions taken as a result of the investigation

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