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.*

CN-049064

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

f240d120955b3a21ce113512a79253cc

te Submitted *

/12/21

	Manufacturer	Importer
7. Name and Address	ABBOTT VASCULAR 3200 Lakeside Drive Santa Clara, CA, US, 95054-2807	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

5. Details of Incident

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96eeb1cc78ce40998b5feb919c44cc6c

63c386b91a389c0733e2a2f84a5dcd90

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
TRICLIP DELIVERY SYSTEM

2. Control/Lot/Serial No
00303U2008/N/A

3. Expiration Date
2021/03/05

4. i. Device Classification

( ) I ( ) II ( ) III (•) IV

ii. Device License No.
104546

iii. Device Identification No
TCDS0203-XT

iv. Manufacturer's Medical Device Identifier(catalogue/model no.)
TCDS0203-XT

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

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1326f8d06baaaed5ff7acffb3c890b78

d23ac719ac8644c69f99eea7c0dcfe43

81effcb055d006b97d58182c437a1c65

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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

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3. Corrective Actions taken as a result of the investigation

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