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 reported 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 Infomation*

23c0ce28aa63be955406ec17521654b7

3. Reporter File No*

2479375

4. Health Canada File No (if applicable)*

N/A

5. Type of Report*

☐ Preliminary ☐ Update ☒ Final ☐ Preliminary & Final

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

2021-03-09 (YYYY-MM-DD)

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

2020-09-09 (YYYY-MM-DD)

6. Date Submitted *

2020-12-18 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	Stryker Medical-Kalamazoo 3800 EAST CENTRE AVENUE PORTAGE MI 49002 US medical.kalamazoo_vigilance@stryker.com	Stryker Canada 2 Medicorum Place Ontario Waterdown CAN L8B 1W2 CARAQA@stryker.com
8. Health Canada assigned company identification number (if known):	124796	104767
9. Establishment License Number (if applicable):	N/A	130

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 (YYYY-MM-DD)

3. Reporter's Awareness Date:

2020-08-31 (YYYY-MM-DD)

4. Patient Consequences

5. Details of Incident

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b1ed46e6dd36bf0239703e98aef0fb6d

ea3dfe638f8d12badae70419b40ae3ed

Canada

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
PRIME TC SWING-AWAY MODEL

2. Control/Lot/Serial No.
1909030010

3. Expiration Date:
(YYYY-MM-DD)

4. i. Device Classification
[X] I [ ] II [ ] III [ ] IV

ii. Device License No.
N/A

iii. Device Identification No
N/A

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
1460000000

5. Software Version

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
[X] Neither (with explanation)
Device assessed in the field

D. COMPLAINANT INFORMATION

1. Complainant is a:
[ ] Consumer [ ] Health Professional [X] Other

2. Name of Complainant
Stewart McNeil

d41d8cd98f00b204e9800998ecf8427e

3. Name of Health Care Facility (if applicable)

f1aac95c8ff9b5e8df6d3ee2e47a7b85

4. Address

866069f0ad2758c2b0f7bea947857f28

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

bad858a81dcc35bda56795f78b09bc1a

collected under this program, visit the Personal Information Bank; Health Canada; Health Proc and Food Branch; Branch Incident Reporting System; HC PPU 088 at: https://www.canada.ca /health-canada/corporate/about-health-canada/activities-responsibilities/access-information-privacy/info-source-federal-government-employee-information.html#a25

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

11d95bea675475bbf042ea83253c7d75

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

2. Root Cause of Problem

f32b5631fd234fa146b54797af497f46

3. Corrective Actions taken as a result of the investigation

e390202cd78db9fa7d3413b8d4a55487