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*

2489040

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:

2021-03-16 (YYYY-MM-DD)

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

2020-09-16 (YYYY-MM-DD)

6. Date Submitted *

2021-01-15 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	Stryker Orthopaedics-Mahwah 325 Corporate Drive Mahwah NJ 07430 US StrykerReconVigilance@stryker.com	Stryker Canada 2 Medicorum Place Ontario Waterdown CAN L8B 1W2 CARAQA@stryker.com
8. Health Canada assigned company identification number (if known):	116713	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

2020-09-08 (YYYY-MM-DD)

3. Reporter's Awareness Date:

2020-09-10 (YYYY-MM-DD)

4. Patient Consequences

5. Details of Incident

It
h
n
p

78fc035ab625f7c4fe9bd1fcddc2006c

ea3dfe638f8d12badae70419b40ae3ed

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
ACCOLADE (127 DEG) SIZE 3.5 ACCOLADE (127 DEG) SIZE 3.5

2. Control/Lot/Serial No.
31389802

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

4. i. Device Classification
☐ I ☐ II ☒ III ☐ IV

ii. Device License No.
23615

iii. Device Identification No
401443

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
6021-3535

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
☐ Neither (with explanation)
N/A

D. COMPLAINANT INFORMATION

1. Complainant is a:
☐ Consumer ☒ Health Professional ☐ Other

2. Name of Complainant
ccb740aee3175ced999cdb9c18ae0e47

3. Name of Health Care Facility (if applicable)
5306ac48cc89bf1ea6078dc54e877b6e

4. Address
6e2f3128c3d8393769137a95e9fb0a6e

5. Telephone No. and/or E-mail Address
ee09aa924fa0bf9876b6c9b676e1c04e

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 Prod 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
e40bb21428dea2f8b2d83dcf6127e438

2. Root Cause of Problem
731f80ed7719307ba563b939dc7bc722

3. Corrective Actions taken as a result of the investigation
46820a36f14cdd304148b67f46141c6e