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 *

c6561edd1710da76dfdafdde6bcdf83c

3. Reporter File No. *

5947-2019-00018

4. Health Canada File No. (if applicable) *

5. Type of Report *

( ) Preliminary ( ) Update (●) Final ( ) Preliminary & Final

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

(YYYY-MM-DD)

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

2019-11-07 (YYYY-MM-DD)

6. Date Submitted *

2020-12-02 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	Umano Medical Inc. 230, boulevard Nilus-Leclerc L'Islet, Qc G0R 2C0 téléphone: 418-247-3986 télécopieur: 418-247-7925	
8. Health Canada assigned company identification number (if known):	137428	
9. Establishment License Number (if applicable):	5947	

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

2019-10-09 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-10-09 (YYYY-MM-DD)

4. Patient Consequences

6ba53351de983667a8b30a19fed38b3f

5. Details of Incident

00a79ff33cbabfaa0f738628f41124bb

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
ook snow

2. Control/Lot/Serial No.
F13601 656A

3. Expiration Date
(YYYY-MM-DD)

4. i. Device Classification
(●) I ( ) II ( ) III ( ) IV

ii. Device License No.

iii. Device Identification No

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
FL36

5. Software Version
1.3

6. Age of Device
3 years

7. How long was the device in use?
about 3 years

8. Was the device labelled as sterile?
( ) Yes (●) No

9. Availability of device for evaluation
( ) Destroyed ( ) Returned to Manufacturer/Importer
(●) Neither (with explanation)

In use at customer site

D. COMPLAINANT INFORMATION

1. Complainant is a:
( ) Consumer (●) Health professional ( ) Other

2. Name of Complainant
f4017dcd087178e9d6fe44783b53de4f

3. Name of Health Care Facility (if applicable)
7e67c1afec822cab159c0208003b3362

4. Address
fe541b2d44cad2ccbc9042732417e852

5. Telephone No. and/or E-mail Address
d3c37ebe83a313e3d5d6cd73dad6ce29

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: https://www.canada.ca/en/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

d50d9f8be2166313d9a326ba6183ac49

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

2. Root Cause of Problem

5783eb99c0af3caae9348714643acba5

3. Corrective Actions taken as a result of the investigation

b8b63c033ea1935a5542cbbd43daab47