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 *

88d39b527d4703f36c580588c56d9279

3. Reporter File No. *

C19094859

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:

2019-06-11 (YYYY-MM-DD)

6. Date Submitted *

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

	Manufacturer	Importer
7. Name and Address	OLYMPUS MEDICAL SYSTEM CORPORATION 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan	OLYMPUS CANADA INC. 25 Leek Crescent Richmond Hill, ON L4B 4B3
8. Health Canada assigned company identification number (if known):	113585	124441
9. Establishment License Number (if applicable):		2525

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

2019-04-18 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-05-13 (YYYY-MM-DD)

4. Patient Consequences

35838fcb01f525dfbd34f9ca71a550a2

5. Details of Incident

fd5f6a6edd4438e2839542a0fd182980

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
Single Use Repositionable Clip

2. Control/Lot/Serial No.
8XK

3. Expiration Date
(YYYY-MM-DD)

4. i. Device Classification
○ I ◉ II ○ III ○ IV

ii. Device License No.
61998

iii. Device Identification No

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
HX-202UR

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)

Device not returned.

D. COMPLAINANT INFORMATION

1. Complainant is a:
○ Consumer ○ Health professional ◉ Other

2. Name of Complainant
a26c5870a98e1e8a5c73487ac61b585b

3. Name of Health Care Facility (if applicable)
ab7b3d2878db6b9ba95def98cb811bd7

4. Address
9a1fef71eb3929658338ef48a58c3d12

5. Telephone No. and/or E-mail Address
86cc36fd55ef1c35046c4c1947713983

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

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

2. Root Cause of Problem

2d4cfb104b148657a1a003424cd08654

3. Corrective Actions taken as a result of the investigation

b62f226944f7353b44936e133f558596