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

(O) Manufacturer (●) Importer

In the case where the reporter is the importer:

ii. Did the importer report the incident to the manufacturer?

(●) Yes (O) No

iii. Is the importer also submitting the report on behalf of the manufacturer?

(●) Yes (O) No

2. Reporter Contact Information *

[redacted]

3. Reporter File No. *

C19094859

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

5. Type of Report *

(O) Preliminary (O) Update (●) Final (O) 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. (O) 10-Day (●) 30-Day

ii. (●) Canadian (O) Foreign

iii. (O) Investigational testing (O) Special Access Program

(O) Radiation emitting device (if applicable)

2. Date of Incident

[redacted]

3. Reporter's Awareness Date

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

4. Patient Consequences

No patient injury.

5. Details of Incident

Olympus was informed that during a therapeutic Colonoscopy/Gastroscopy procedure, the spring fell out of the applicator of the clip device and became a foreign body in the patients bowel. The spring and prongs were retrieved from the patient. The intended procedure was completed. There was no patient injury reported.

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
Myra Bertrand

3. Name of Health Care Facility (if applicable)
East Kootenay Regional Hospital

4. Address
13 24 Ave N
Cranbrook, BC
V1C 3H9

5. Telephone No. and/or E-mail Address
Email: myra.bertrand@interiorhealth.ca

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

Final: The device was not returned to the manufacturer. However, if additional information becomes available or if the device is returned at a later date, this report will be updated accordingly.

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

2. Root Cause of Problem

Final: The exact cause of the reported event could not be determined at this time.

3. Corrective Actions taken as a result of the investigation

None. This report will be updated if Olympus Canada receives additional information.

Aijaz, Naeem (HC/SC)

From: Zuina Hamit <zuina.hamit@olympus.com> on behalf of OCI-Regulatory <OCI-Regulatory@olympus.com>
Sent: 2021-01-13 5:01 PM
To: mdpr / dimm (HC/SC)
Cc: OCI-Regulatory
Subject: RE: Final MPR_C19094859_Catalogue Number: HX-202UR
Attachments: Preliminary MPR_C19094859_Catalogue Number: HX-202UR; C19094859_Final MPR_HX-202UR_091019.pdf

Dear MPR Reviewer,

This is an update for complaint reporter file # C19094859. After further evaluation and investigation, the legal manufacturer has determined that this complaint is non-reportable.
For reference, below is the final report email and attached is preliminary report email.

Kind Regards,

Zuina Hamit
Associate, Market Quality
Medical Systems Group
Olympus Canada Inc.
25 Leek Crescent
Richmond Hill, ON L4B 4B3

Phone: (289) 269-0209
Main: 1-800-387-0437 x 700209
zuina.hamit@olympus.com
www.olympuscanada.com

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www.truetolife.com

From: Zuina Hamit **On Behalf Of** OCI-Regulatory
Sent: Tuesday, September 10, 2019 11:41 AM
To: hc.mdpr-dimm.sc@canada.ca
Cc: OCI-Regulatory
Subject: Final MPR_C19094859_Catalogue Number: HX-202UR

Dear MPR Reviewer,

Please find attached Final MPR document.

With kind regards,

Zuina Hamit
Associate, Market Quality
Medical Systems Group
Olympus Canada Inc.
25 Leek Crescent
Richmond Hill, ON L4B 4B3

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