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 *

Zuina Hamit
Olympus Canada Inc.
25 Leek Crescent, Richmond Hill, ON L4B 4B3
OCI-Regulatory@olympus.com
Direct: 289-269-0209, Fax: 905-886-7469

3. Reporter File No. *

C20483483

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:

2020-07-10 (YYYY-MM-DD)

6. Date Submitted *

2020-09-25 (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

(YYYY-MM-DD)

3. Reporter's Awareness Date

2020-06-10 (YYYY-MM-DD)

4. Patient Consequences

No patient injury reported.

5. Details of Incident

Olympus was informed that the distal bending section of the device was covered in a sticky, oily film. The bronchoscope was used for the application of bioglue. Prior to the application, Lipogel was applied to the site. The bronchoscope flushed easily and the film did not seem to be from the bioglue. There was no patient injury reported

Date of Incident: Unknown.

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
EVIS EXERA III BRONCHOVIDEOSCOPE

2. Control/Lot/Serial No.
2824456

3. Expiration Date
(YYYY-MM-DD)

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

ii. Device License No.
88632

iii. Device Identification No

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
BF-1TH190

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)

D. COMPLAINANT INFORMATION

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

2. Name of Complainant
Kevin Coghlan

3. Name of Health Care Facility (if applicable)
University of Alberta Hospital

4. Address
8440 - 112 Street
Edmonton, AB
T6G 2B

5. Telephone No. and/or E-mail Address
Email: Kevin.Coghlan@albertahealthservices.ca

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

From Preliminary:
The device was returned to Olympus for evaluation and the customer's reported issue was confirmed.

During inspection, it was observed that near the distal end, an unidentified material was found while the brush was passed. This material was discovered sticking near the plastic cover. A hole was found in the insertion tube. A leak test was performed and passed.

Investigation is still ongoing and when additional information becomes available, this report will be updated accordingly.

Final: Olympus reported this event based on the observed foreign material. Olympus was able to remove the unidentified material after it was cleaned a third time. It is possible that the biopsy working channel may not have been properly cleaned during the initial attempts due the reported use of lipid-based compounds and/or the observed device damages.

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

2. Root Cause of Problem

Final: The legal manufacturer determined that this reported issue is likely caused by insufficient cleaning of the channel and residual substance since a foreign substance emerged from the channel when a brush was inserted into it during inspection.

3. Corrective Actions taken as a result of the investigation

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

Harnum, Brittany (HC/SC)

From: Zuina Hamit <zuina.hamit@olympus.com> on behalf of OCI-Regulatory <OCI-Regulatory@olympus.com>
Sent: 2020-09-25 12:32 PM
To: mdpr / dimm (HC/SC)
Cc: OCI-Regulatory
Subject: Final MPR_C20483483_Catalogue Number: BF-1TH190
Attachments: C20483483_Final MPR_BF-1TH190_092520.pdf

Dear MPR Reviewer,

Please find attached Final MPR document.

With kind regards,

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

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