

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 \*

			Page <u>'</u> of <u></u>
A. REPORTER INFORM	IATION		
1. i. Reporter Type		3. Reporter File No.	*
OManufacturer   ● Importer		C20483483	
In the case where the reporter is the importer:		4. Health Canada File No. (if applicable) *	
ii. Did the importer report the incident to the manufacturer?			
O Yes No		5. Type of Report *	
iii. Is the importer also submitting the	e report on behalf of the	OPreliminary OUpdate OFinal OPreliminary & Final	
manufacturer?  O Yes  O No			
		If "preliminary" only, anticipated date for the final report:  (YYYY-MM-DD)  If "update/final", date the previous report was submitted to Health	
2. Reporter Contact Information *			
Zuina Hamit		Canada: 2020-07-10 (YYYY-MM-DD)	
Olympus Canada Inc. 25 Leek Crescent, Richmond Hill, ON L4B 4B3			
OCI-Regulatory@olympus.com		6. Date Submitted *	
Direct: 289-269-0209, Fax: 905-886-7469		2020-09-25 (YYYY-MM-DD)	
	Manufactu	irer	Importer
7. Name and Address	OLYMPUS MEDICAL SYSTEM CORPORATION		OLYMPUS CANADA INC.
	2951 Ishikawa-cho, Hachioji-shi, T		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 INFORMA	ATION		
	ATTON		
1. Classification of Incident *		5. Details of Inciden	t
i.  10-Day  30-Day ii.  Canadian  Foreign		Olympus was informed that the distal bending section of the device was	
iii. O Investigational testing O Special	Access Program	covered in a sticky, oily film. The bronchoscope was used for the	
ORadiation emitting device (if applic	_		Prior to the application, Lipogel was applied to cope flushed easily and the film did not seem to
2. Date of Incident			nere was no patient injury reported
2. Date of incident	(VVVV MM DD)		, , , ,
3 Papartor's Awaroness Data	(YYYY-MM-DD)	Date of Incident: Unkn	own.
3. Reporter's Awareness Date 2020-06-10			
4. Patient Consequences	(YYYY-MM-DD)		
No patient injury reported.			
110 patient injury reported.			



A program of  $MedEffect^{TM}$ Canada HC Pub.: 110180 (April 2018)

	of Medical Device Into Minarion
	Trade/Brand Name * /IS EXERA III BRONCHOVIDEOSCOPE
	Control/Lot/Serial No. 24456
3.	Expiration Date  (YYYY-MM-DD)
4.	i. Device Classification  I I II III III III IIII IIII IIIIIIII
	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)
Ī	D. COMPLAINANT INFORMATION
1.	Complainant is a:  O Consumer O Health professional O Other
	Name of Complainant evin Coghlan
	Name of Health Care Facility (if applicable) niversity of Alberta Hospital
84 Ec	Address 40 - 112 Street Imonton, AB 6G 2B Telephone No. and/or E-mail Address
J.	relephone No. and/or L-mail Address

Email: Kevin.Coghlan@albertahealthservices.ca

government-employee-information.html#a25

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-

MEDICAL DEVICE INFORMATIO

#### **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 Olympus Canada Inc. 25 Leek Crescent Richmond Hill, ON L4B 4B3

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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

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