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 *

Laura Aziken
Integra Canada ULC
2590 Bristol Circle, Unit 1
Oakville ON, Canada L6H 6Z7
laura.aziken@integralife.com

3. Reporter File No. *

PR 224908 (C20-117)

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:

2020-05-11 (YYYY-MM-DD)

6. Date Submitted *

2020-11-18 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	INTEGRA LIFESCIENCES PRODUCTION CORPORATION 11 Cabot Blvd. Mansfield, MA, US 02048	Integra Canada ULC 2590 Bristol Circle, Unit 1 Oakville ON, Canada L6H 6Z7
8. Health Canada assigned company identification number (if known):	152033	
9. Establishment License Number (if applicable):	N/A	594

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

Unknown (YYYY-MM-DD)

3. Reporter's Awareness Date

2020-04-22 (YYYY-MM-DD)

4. Patient Consequences

Bleeding

5. Details of Incident

Customer states - "Problem : When the surgeon releases the crankset the pliers of the forceps remain glued to the tissue - When the neurosurgeon removes his forceps this creates bleeding."

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
Bipolar Forceps

2. Control/Lot/Serial No.
961197

3. Expiration Date
(YYYY-MM-DD)

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

ii. Device License No.
13279

iii. Device Identification No
80-2901

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
80-2901

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)

Awaiting product return

D. COMPLAINANT INFORMATION

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

2. Name of Complainant
Georges Ayoub

3. Name of Health Care Facility (if applicable)
CHUS - HOPITAL FLEURIMONT

4. Address
3001 12TH AVE N, SHERBROOKE, QC J1H 5N4

5. Telephone No. and/or E-mail Address
819 346-1110, poste 21235 /
georges.ayoub.ciussse-chus@ssss.gouv.qc.ca

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

A DHR review was conducted and all test results passed procedural specifications. There was no indication that the production process may have contributed to this complaint

A 1 year look back found that the product family did not exceed its upper control limit. There was no trend determined for the complaint failure mode.

Failure analysis could not be confirmed

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

2. Root Cause of Problem
Root cause not determined per above evaluation

3. Corrective Actions taken as a result of the investigation
No CAPA required per the above evaluation

Perras, Eryn (HC/SC)

From: AZIKEN, LAURA <laura.aziken@integralife.com>
Sent: 2021-01-25 5:31 PM
To: mdpr / dimm (HC/SC)
Cc: Nelson, Vivian
Subject: RE: PR 224908 Final MDPR Report -25JAN2021 Investigation Updated
Attachments: PR 224908 Final Report-Updated.pdf

Hi,

Please see attached updated final report for PR 224908. Investigation section has been updated to state “Failure analysis could not be confirmed”

Thanks,

Laura Aziken
Quality Specialist

Integra Canada ULC
2590 Bristol Circle, Unit 1
Oakville ON, Canada L6H 6Z7
Phone: (905) 618-1602

Laura.aziken@integralife.com
www.integralife.com

From: AZIKEN, LAURA
Sent: Wednesday, November 18, 2020 7:06 PM
To: hc.mdpr-dimm.sc@canada.ca
Cc: Nelson, Vivian
Subject: RE: PR 224908 Final MDPR Report -18NOV2020

Hi,

Please see attached final report for PR 224908.

Thanks,

Laura Aziken
Quality Specialist

Integra Canada ULC
2590 Bristol Circle, Unit 1
Oakville ON, Canada L6H 6Z7
Phone: (905) 618-1602

Laura.aziken@integralife.com
www.integralife.com

From: AZIKEN, LAURA
Sent: Monday, May 11, 2020 12:03 PM
To: hc.mdpr-dimm.sc@canada.ca
Cc: Nelson, Vivian <vivian.nelson@integralife.com>
Subject: PR 224908 Preliminary TPP Report -11MAY2020

Hi,

Please see attached preliminary report for PR 224908.

Thanks,

Laura Aziken
Quality Specialist

Integra Canada ULC
2590 Bristol Circle, Unit 1
Oakville ON, Canada L6H 6Z7
Phone: (905) 618-1602

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