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

(•) Importer ( ) Manufacturer

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 *

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3. Reporter File No. *

PC-000492833

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

N/A

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:

2019-07-03 (YYYY-MM-DD)

6. Date Submitted *

2020-10-22 (YYYY-MM-DD)

	turer	Importer
7. Name and Address:	MENTOR MEDICAL SYSTEMS, B.V. Zernikedreef 2 Leiden, NL, 2333 CL	Johnson & Johnson Medical Products, 200 Whitehall Dr., Markham, ON, L3R 0T5
8. Health Canada assigned company identification number (if known):	113303	N/A
9. Establishment Licence Number (if applicable):		321

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

2019-06-25 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-06-26 (YYYY-MM-DD)

4. Patient Consequences

62d9524e02b29e50e3fb4aef96687108

5. Details of Incident

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c4320948ab2b432d8772822bb8951f98

Reco

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *

SMOOTH ROUND MODERATE PLUS PROFILE

2. Control/Lot/Serial No.

(N/A)/7011091/(N/A)

3. Expiration Date

2021-01-08 (YYYY-MM-DD)

4. i. Device Classification

○ I ○ II ○ III ◉ IV

ii. Device License No.

72269

iii. Device Identification No

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

350-3501BC

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

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f9bbe24916a629771dd7ef166144b2bf

d41d8cd98f00b204e9800998ecf8427e

ee7c59ec40a3720e58c61934fbdf062a

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: http://infosource.gc.ca/inst/1476/1476-fedemp00-eng.asp

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

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d41d8cd98f00b204e9800998ecf8427e