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

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 *

0079e399c9eefbf729f113f462e044c5

3. Reporter File No. *

PC-000724207

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:

2020-07-08 (YYYY-MM-DD)

6. Date Submitted *

2020-09-11 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address:	MENTOR 3041 Skyway Circle North Irving, TX, US, 75038	Johnson & Johnson Medical Products, 200 Whitehall Dr., Markham, ON, L3R 0T5
8. Health Canada assigned company identification number (if known):	106949	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

2020-02-01 (YYYY-MM-DD)

3. Reporter's Awareness Date

2020-07-01 (YYYY-MM-DD)

4. Patient Consequences

5. Details of Incident

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3ef7ef496c55bb402e6cd5f192dc16c3

3b3d41393a5e85e3565af97f9634fa6f

Reco

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *

SMOOTH ROUND HIGH PROFILE SALINE-FILLED

2. Control/Lot/Serial No.

Unknown

3. Expiration Date

(YYYY-MM-DD)

4. i. Device Classification

○ I ○ II ○ III ◉ IV

ii. Device License No.

12558

iii. Device Identification No

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

350-3270

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

02a4a26a7ca602171f8206de6cf082ac

95fe5b443479d753c9046c97dd404ac9

9889dc5e479b5bba85dc9e9469aafe88

d41d8cd98f00b204e9800998ecf8427e

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

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

817d876419900b1a93b2bc77a141fdf2

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

2. Root Cause of Problem

d41d8cd98f00b204e9800998ecf8427e

c288174b5847368a447f56cf286f2794

capsule, seroma or hematoma, development of postoperative breast dysplasia, unilateral discrepancy in muscle development, deflation of the implant, incorrect choice of implant shape or size, and surgical technique. Asymmetry is a known complication associated with these devices and is referenced in our current Product Insert Data Sheet. Each device is visually inspected during manufacturing to ensure the device meets the required specifications prior to shipment. Deflation and Anisomastia complaint information are- (Refer to attachment for more details)