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 *

905b362d241cc5745ddfd4d0a228bb46

3. Reporter File No. *

PC-000471938

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:

(YYYY-MM-DD)

6. Date Submitted *

2020-11-23 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address:	DEPUY ORTHOPAEDICS, INC. 700 Orthopaedic Drive, P.O. Box 988 Warsaw, IN, US, 46582	Johnson & Johnson Medical Products, 200 Whitehall Dr., Markham, ON, L3R 0T5
8. Health Canada assigned company identification number (if known):	103025	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

2019-05-28 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-05-28 (YYYY-MM-DD)

4. Patient Consequences

4ec9183dcaf1907b757988647d0f8cf9

5. Details of Incident

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13eb7e0a519fbe2d9ecfe410ed7907a7

Reco

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *

TRI-LOCK POR. COATED HIP PRO. STEMS

2. Control/Lot/Serial No.

(N/A)/HR3366/(N/A)

3. Expiration Date

(YYYY-MM-DD)

4. i. Device Classification

○ I ○ II ◉ III ○ IV

ii. Device License No.

11031

iii. Device Identification No

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

1012-04-040

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

b2e94f2a9f68281955b1dfac01f94dc3

3. Name of Health Care Facility (if applicable)

dccc6eb2baa1b0d1db6ede0591d3878c

4. Address

a57947ef34781f462138d7c370661615

bb82670f59f93334aff0cd306e76afdb

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

7d2ff55733c12730762860cdc3b81698

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

2. Root Cause of Problem

ec8853697883091af77b60a53368bbe1

6ec21b8fc6fce281f06a66496c708e29