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 *

e6335a0c4b947068ef7a8a8f56b5c6c3

3. Reporter File No. *

PC-000611608

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:

2020-02-19 (YYYY-MM-DD)

6. Date Submitted *

2020-10-05 (YYYY-MM-DD)

	turer	Importer
7. Name and Address:	Ethicon Inc., P.O. Box 151, Route 22 West, Somerville, USA, 08876-0151	Johnson & Johnson Medical Products, 200 Whitehall Dr., Markham, ON, L3R 0T5
8. Health Canada assigned company identification number (if known):	103689	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

2019-01-01 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-12-02 (YYYY-MM-DD)

4. Patient Consequences

13ec66b52efd7de6cd1c3c67fdfd3016

5. Details of Incident

I

884db1ccbddb03ce64da4ed42ec0b1ea

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *

PRONOVA SUTURE - TAPER POINT

2. Control/Lot/Serial No.

PCQ092

3. Expiration Date

(YYYY-MM-DD)

4. i. Device Classification

○ I ○ II ○ III ◉ IV

ii. Device License No.

401

iii. Device Identification No

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

3706H34

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

5068f9935707795565125f56b85c77ce

fd8897f1eb574c3377c666b4f46230e7

6b2a1a8a72b486aa636c3d0e4a8e3728

3192441830e697e6d46f8ba0e485d044

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

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

2. Root Cause of Problem

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