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 *

7a748cca746076ebfb233a169f309b46

3. Reporter File No. *

0702999861

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:

2019-05-14 (YYYY-MM-DD)

6. Date Submitted *

2020-08-14 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	MEDTRONIC SOFAMOR DANEK USA, INC. 1800 PYRAMID PLACE, MEMPHIS, TN, US Postcode:38132 Tel:(+1-901)3963133 Fax:(+1-901)3441570	MEDTRONIC CANADA ULC 99 HEREFORD STREET, BRAMPTON, ON, CANADA Postcode:L6Y 0R3 Tel:(800)268-5346 Fax:(905) 460-3992
8. Health Canada assigned company identification number (if	109592	106916
9. Establishment License Number (if applicable):	NA	35

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

2019-02-08

3. Reporter's Awareness Date

2019-02-08

4. Patient Consequences

0f9f4c411ce93750efae9c7b5c81fd55

5. Details of Incident

I

i

i

ee019496f4731333f3f6754020ea156a

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *

STRAIGHT TIP RADIANCE ILLUMINATION SYSTEM

2. Control/Lot/Serial No.

0601680W

3. Expiration Date

2022-10-23

4. i. Device Classification

☐ I ☒ II ☐ III ☐ IV

ii. Device License No.

102086

iii. Device Identification No

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

9560668

5. Software Version

Not Applicable

6. Age of Device

Manufacturing Date:2017-11-14

7. How long was the device in use?

UNKNOWN

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

73ae7894b92ee6a3949460163027b460

3. Name of Health Care Facility (if applicable)

d9e1ba956b69e95d23e34b2a38384142

4. Address

5b73652309d646bfaf1bfa846545d5da

5. Telephone No. and/or E-mail Address

29bb85e886da61c6b5baf294bd5892f2

of the complainant and/or reporter will be protected as personal information under the *Privacy Act*, 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

ce679adcef1da8e29db6db6253eaf67e

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

2. Root Cause of Problem

270b6249ef6fa95c3f222f391add2ced

3. Corrective Actions taken as a result of the investigation

a374688aa91834d9673f5294c0b04dd1