Health Canada Santé Canada

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Medical device problem report form for health care professionals

Canada Vigilance - Medical device problem reporting program

For best results, download and open this form in a PDF reader.

Privacy notice: The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information we need to administer the Medical device problem reporting program authorized by *the Department of Health Act*, Section 4(h), and the *Food and Drugs Act*, Section23 (1) (c) and the *Medical Devices Regulations*, Section(s) 59 (1) (a) (b) (2), 60, 61.1 (1), 62, 63, 64, 65, 77, 81(k) (v) (2) and 88 (c).

Purpose of collection: We require your information to assess the nature of the report and to fulfill the Health Products and Food Branch (HPFB) program's responsibilities for monitoring the use of medical devices in Canada. Personal information regarding the Submitter, collected from the medical device problem reports, may be used to conduct follow-up of a medical device incident; to monitor the safety and efficacy of marketed medical devices; for compliance and enforcement activities; to request safety and efficacy information from the manufacturers, health care professionals / practitioners / facilities and other users of marketed medical devices for the purpose of post-market surveillance of medical devices, to report to senior management, or to complete a trend analysis. Trend and safety data in a de-identified format may be communicated by a variety of risk communication tools (including a monthly Health Canada newsletter – Infowatch – and an incident database/data extracts) and / or responses to inquiries.

Other uses or disclosures: Your personal information may also be provided to the Manufacturer/Importer of the device in the event that they require follow-up of a medical device incident. In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8 (2) of the *Privacy Act*.

Refusal to provide the information: If the report governed under the above sections was not provided when known, in the unlikely event that a situation of non-compliance is not resolved through this cooperative, staged approach, Health Canada could potentially use provisions of the *Food and Drugs Act* and its associated regulations, for example, to seek an injunction under section 21.5 of the Act, to compel a reporter to comply with the regulations.

For more information: This personal information collected is described in Info Source, available online at https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/access-information-privacy/info-source-federal-government-employee-information.html#a26. Refer to the personal information bank, HC PPU 415.

Your rights under the *Privacy Act*: In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact the Privacy Coordinator at 613-946-3179 or hc.privacy-vie.privee.sc@canada.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

Submission methods

Electronic reporting
If you are interested in submitting reports electronically (e.g. secure file transfer protocol - sFTP) to Health Canada, please email the Canada Vigilance Program at hc.canada.vigilance.sc@canada.ca.

Fax
Download, complete and print the Medical device problem report form for health care professionals.
Send by fax at: 1-866-678-6789

Mail it to the Canada Vigilance National Office
Canada Vigilance Program
Health Products Surveillance and Epidemiology Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Address Locator 1908C
Ottawa, Ontario
K1A 0K9

If you have any questions related to mandatory reporting for hospitals, you may contact the Canada Vigilance Program by:
Email: hc.canada.vigilance.sc@canada.ca
Toll-free telephone: 1-866-234-2345

Canada

* = required, if known (if information is in the control of or reasonably accessible by the hospital for mandatory reporting)
** = required (hospital is exempt from mandatory reporting if this information is unavailable)
Specific field instructions can be found at the end of the form. Submission of a report does not constitute an admission that medical personnel or the medical device caused or contributed to the incident.

A. Report and submitter information

1. Type of report* ☐ Initial ☐ Follow-up	2. Health Canada reference no. (for follow-up reports)		
3. Internal submitter file no.	4. Type of event*	5. Date report submitted	6. Documentation / awareness date*
7. a. Submitter first name* b. Submitter last name*	8. a. Contact phone no.* ext. b. Contact email c. Fax		
9. Organization name*	10. a. Report type*	b. ITA authorization no. or SAP reference no.	
11. Profession	12. Department	13. Health Canada institutional ID (If this unique number is provided, address details do not need to be completed)	
14. Address	15. City	16. Province / Territory	17. Postal code

18. Alternate contact

19. Seriousness of the incident

☐ a. Death (yyyy-mm-dd) _____
☐ b. Life-threatening
☐ c. Permanent impairment of a body function
☐ d. Permanent damage to a body structure
☐ e. Unexpected medical or surgical intervention to prevent a. through d.

B. Affected person

1. Person's ID (e.g. initials)	2. Who was affected?	3. Vulnerable population? Other:	
4. Height cm or ft in	5. Weight kg or lbs oz	6. Sex	7. Age

8. Consequences to the affected person* (Describe the outcome of the incident to the affected person).

9. Contributing factors of the affected person* (e.g. family/socioeconomic issues, understanding of the person, medical directive/therapies, or conditions and history of the person).

10. a. Were there other people involved? ☐ Yes ☐ No	b. If so, how many?

c. Please describe the impact on them.

C. Device information

i. Primary device

Box 1 or 3 is required**

1. Device name**	2. Device model	3. Device identifier**

4. Serial no.*	5. Catalogue no.	6. Lot/batch no.*

7. Software and version

8. Unique device identifier (UDI)

9. Start of use date	10. End of use date	11. Duration of use	12. Expiry date	13. Age of device

14. a. Manufacturer name*	15. a. Vendor name (importer/distributer/retailer/supplier)
b. Did you also report to the manufacturer?* ☐ Yes ☐ No c. Date reported d. Reference no.* (if known)	b. Did you also report to the vendor? ☐ Yes ☐ No c. Date reported d. Reference no. (if known)

16. a. Was the device returned to the manufacturer? ☐ Yes ☐ No	b. Date returned	c. If not, is it available for evaluation? ☐ Yes ☐ No

17. a. Was the device implanted? ☐ Yes ☐ No	b. Date implanted	c. Was the device explanted? ☐ Yes ☐ No	d. Date explanted	e. Duration of implant

18. a. Was more than one of this device involved? ☐ Yes ☐ No	b. No. of devices involved	19. Usage of device Other

20. Potential device/use contributing factors* (e.g. design issues, missing component, software errors, incompatible with other devices/accessories, sterility/packaging issues, unclear instructions for use, lack of training (materials or other information), expired devices, issues with operator/reason for use, use/environmental issues, reprocessed devices, or maintenance issues such as condition/last inspection date).

C. Device information

ii. Secondary device , if applicable (if more than two devices are involved, list other devices in Section F)

Box 1 or 3 is required**

1. Device name**	2. Device model	3. Device identifier**

4. Serial no.*	5. Catalogue no.	6. Lot/batch no.*

7. Software and version

8. Unique device identifier (UDI)

9. Start of use date	10. End of use date	11. Duration of use	12. Expiry date	13. Age of device

14. a. Manufacturer name* b. Did you also report to the manufacturer? * ☐ Yes ☐ No c. Date reported d. Reference no.* (if known)	15. a. Vendor name (importer/distributer/retailer/supplier) b. Did you also report to the vendor? ☐ Yes ☐ No c. Date reported d. Reference no. (if known)

16. a. Was the device returned to the manufacturer? ☐ Yes ☐ No	b. Date returned	c. If not, is it available for evaluation? ☐ Yes ☐ No

17. a. Was the device implanted? ☐ Yes ☐ No	b. Date implanted	c. Was the device explanted? ☐ Yes ☐ No	d. Date explanted	e. Duration of implant

18. a. Was more than one of this device involved? ☐ Yes ☐ No	b. No. of devices involved	19. Usage of device Other

20. Potential device/use contributing factors* (e.g. design issues, missing component, software errors, incompatible with other devices/accessories, sterility/packaging issues, unclear instructions for use, lack of training (materials or other information), expired devices, issues with operator/reason for use, use/environmental issues, reprocessed devices, or maintenance issues such as condition/last inspection date).

D. Incident information (continue in section F if necessary)

1. Date of incident	2. Source of report	3. a. Is this a recurring issue? ☐ Yes ☐ No b. If so, how many times?	4. In which country did the incident occur? 5. Location of the incident

6. Incident details** (Please ensure there is no personal information including names of affected persons/patients/staff involved).

E. Actions taken

1. Actions taken by hospital, if applicable (e.g. retested/calibrated device, called for service for device, discontinued use of device, treatment of injured party, education provided to staff or reported elsewhere, or development of new clinical guidelines).

2. Actions taken by manufacturer/vendor, if applicable (e.g. pick up of device for investigation, on site servicing of device/training of the staff, recalling products, or replacement devices provided).

F. Additional details

1. Insert any additional details, including additional affected persons or devices involved. Use the fields in section B, C, and D to guide the content.

Instructions on completing the medical device problem report form for health care professionals

A. Report and submitter information

A1. **Type of report***: Indicate whether the report is the first one submitted for this specific medical device incident (i.e. initial) or a follow-up to a previously submitted report.

A2. **Health Canada reference number**: If the report is identified as a follow-up in A1, provide reference number generated by Health Canada and provided to the submitter further to the initial report submission.

A3. **Internal submitter file number**: Indicate the hospital's identification number for the case. For follow-up reports, the report number should be the same as the number assigned to the initial report.

A4. **Type of event***: Select the highest impact of the incident in the report: Death, serious deterioration of health (this term means a life-threatening disease, disorder or abnormal physical state, the permanent impairment of a body function or permanent damage to a body structure, or a condition that necessitates an unexpected medical or surgical intervention to prevent such a disease, disorder or abnormal physical state or permanent impairment or damage), potential for serious harm (i.e. death or serious deterioration in health; known as near incidents), or other (provide more details in incident narrative D6.).

A5. **Date report submitted**: Indicate the date the report was sent to Health Canada.

A6. **Documentation/awareness date***: For hospitals, indicate the date when the medical device incident was first documented. For all others, indicate the date of awareness.

A7. **Submitter's first and last names***: Enter the submitter's names.

A8. **Contact phone number, email or fax***: Enter the telephone number, email address or facsimile number to contact in the case of follow-up.

A9. **Organization name***: Enter the full name of the reporting organization.

A10. **a. Report type***: Select if the report is being submitted to fulfill obligations for Mandatory reporting for hospitals under sections 62 of the *Medical Devices Regulations* (MDRs), for Investigational testing under section 88 c) of the MDRs, for Special access program under section 77 of the MDRs, or for voluntary participation in the Canadian Medical Devices Sentinel Network (CMDSNet) program.
b. ITA authorization no./SAP reference no.: Enter the Investigational Testing Authorization number or Special Access Program reference number, if applicable.

A11. **Profession**: Select the submitter's profession.

A12. **Department**: Enter the submitter's department.

A13. **Health Canada institutional ID**: Indicate the submitter's unique hospital identifier as assigned by Health Canada. To obtain this identifier, please contact hc.canadavigilance.sc@canada.ca. Address details do not need to be completed if this unique number is provided.

A14. **-17. Address/City/Province-Territory/Postal code**: Enter the submitter's facility/hospital/institution/organizational civic address.

A18. **Alternative contact**: Provide an alternative contact.

A19. **Seriousness of the incident**: Select a criterion that makes the report a serious medical device incident, if applicable. More than one criterion can be selected. Enter date of death if known.

B. Affected person

B1. **Person's ID**: Provide a person identifier in order to readily locate the case for follow-up purposes. This can be the person's initials or the record number. Please do not provide the full name of the person.

B2. **Who was affected?** Select the category of person affected by the incident. N/A should be used when no one was injured; potential for harm should be selected in A4.

B3. **Vulnerable population?** Indicate whether the affected person is part of a vulnerable population. Pediatric is defined as 21 years of age or younger. Geriatric is 65 years of age or older. Select the most relevant vulnerable population. If applicable, indicate other populations in Other field.

B4. **Height**: Enter the person's height.

B5. **Weight**: Enter the person's weight.

B6. **Sex**: Enter the affected person's biological sex. Intersex is a term used for a variety of conditions in which a person is born with a reproductive anatomy that does not fit the typical definitions of female or male.

B7. **Age**: Provide the person's age at the time of the incident.

B8. **Consequences to the affected person***: Detail the outcome of the incident for the affected person.

B9. **Contributing factors of the affected person***: Provide any other pertinent details of the affected person which may have had an impact on the incident.

B10. **a. Were there other people involved?** Select either Yes/No. **b. If so, how many?** Indicate number of people involved in the incident. **c. Describe the impact on other people involved.** Provide any relevant information as per B 1-9 above/use Section F.

C. Device information

C1. **Device name****: Provide the name of the device as per the product label, or information that can uniquely identify the device from others. You must provide either Device name or Device identifier as essential information.

C2. **Device model**: Enter the model of the device as per the product label, or information that can uniquely identify the device from others.

C3. **Device identifier****: Enter the device identifier found on the label or information that can uniquely identify the device from others, such as a bar code or GTIN. You must provide either Device name or Device identifier as essential information.

C4. **Serial no.***: Enter the serial number of the device.

C5. **Catalogue no.**: Provide the catalogue number of the device.

C6. **Lot/batch no.***: Provide the lot, control, or batch number of the device.

C7. **Software and version**: Provide the software and version number.

C8. **Unique device identifier (UDI)**: Provide the UDI assigned to medical devices by the manufacturer of the device.

C9. **-11. Start and end of use dates/duration**: Provide the time frame details for device use.

C12. **Expiry date**: Provide the expiry date of the device per the label.

C13. **Age of device**: Provide the age of the device.

C14. **Manufacturer details***: Indicate the name of the medical device manufacturer and if the incident details were also provided to the manufacturer. If so, please also provide the date that it was reported to the manufacturer and the reference number if known.

C15. **Vendor details**: Indicate the same information as above, but for a report provided to the vendor of the medical device.

C16. **Was the device returned to the manufacturer?** Indicate if the device was returned to the manufacturer and, if so, provide the date returned. If not, indicate if it is available for assessment.

C17. **Implantation details**: Provide implantation details if applicable.

C18. **Was more than one of this device involved?** Select Yes/No if there were multiples of the same device used in this particular incident. I.e. Three out of thirteen pads were used in the procedure (ten were defective, three were suitable for use).

C19. **Usage of device**: Select the most appropriate device usage. If not applicable or more than one usage, enter the details in the Other section.

C20. **Potential device/use contributing factors***: Please provide any pertinent device details that may have had an impact on the incident.

D. Incident information

D1. **Date of incident**: Provide the date of the medical device incident.

D2. **Source of report**: Select the complainant who contacted the submitter to inform them about the incident.

D3. **a. Is this a recurring issue?** Select Yes/No to indicate if this type of incident has occurred previously in your organization. **b. If so, how many times?** Indicate the amount of times it has occurred.

D4. **In which country did the incident occur?** Indicate if the incident occurred in Canada or not. If Other is selected, please describe the circumstances in the narrative D6.

D5. **Location of the incident**: Select from the list the setting of the incident.

D6. **Incident details****: Provide a detailed description of the incident including information on what happened in the incident, the outcome of the affected persons involved if known, device(s) and equipment(s) involved, and other concomitant therapy involved during the incident.

E. Action taken

This section contains information about any actions taken as a result of the medical device incident. These are not legally required but they provide additional information about the incident for Health Canada's consideration.

E1. **Actions taken by hospital**: Includes information on any relevant actions taken by the hospital or the healthcare professionals to correct the problem or any preventive actions, if known.

E2. **Actions taken by manufacturer/vendor**: Includes information on any relevant actions taken by the manufacturer/vendor to investigate or correct the problem, if known.

F. Additional details

F1. This section provides space for additional information about affected persons, other devices involved, or details for the narrative if required.

For more details, refer to the Guidance Document for hospitals at https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting/drugs-devices.html