




## Provincial Safety Management System Medical Device Incident Form

*Please be advised that Medical Device incidents are required/mandatory reporting to Health Canada.*

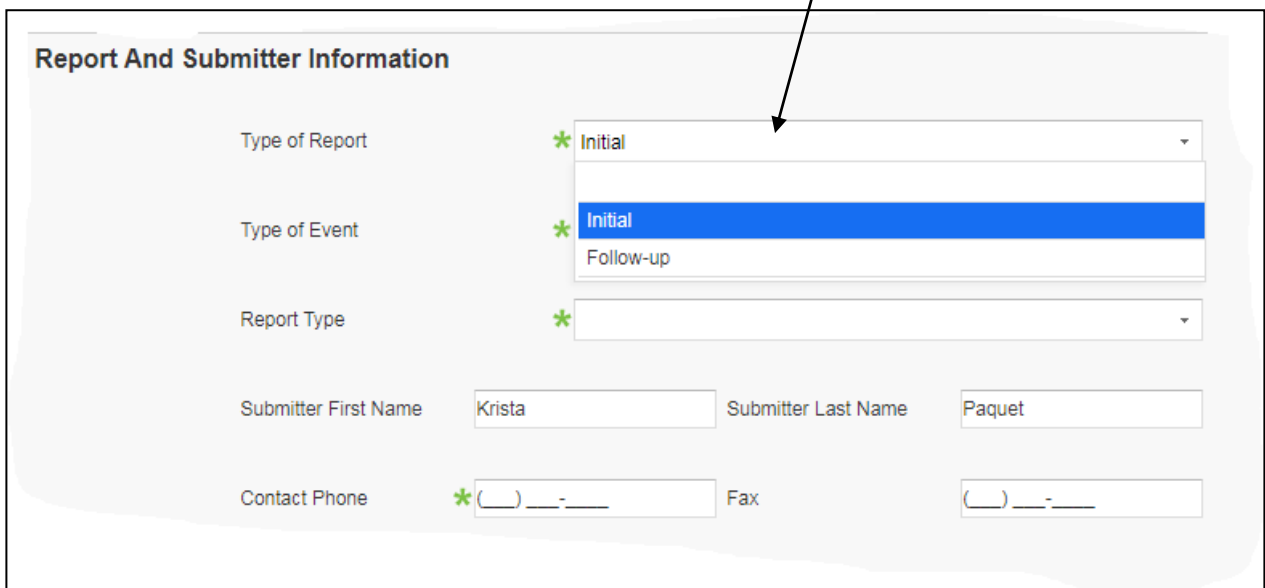
### Step 1



When reporting an **Medical Device incident**, please select the Medical Device Form . You must complete all mandatory fields marked with a green asterisk ( \* ).

### Step 2

Under the **Type of Report**: Select if this is the “Initial” report OR “Follow-up” report on a defective medical device.



**Report And Submitter Information**

Type of Report	* Initial		
Type of Event	* Initial Follow-up		
Report Type	* [ ]		
Submitter First Name	Krista	Submitter Last Name	Paquet
Contact Phone	* ( ) - -	Fax	( ) - -

### Step 3

Under **Affected Person**: Please note: If more than one person affected, please put in the **most serious affected** from the drop down list provided (**Health Care Professional, No Patient affected, Other or Patient**).

#### Affected Person

If more than one person was affected, describe the most serious here.

Who was Affected \*

First Name \*  Last Name \*

DOB  Sex

Age  Age Unit

Consequences to the Affected Person \*

Describe the outcome of the incident to the affected person.

### Step 4

Under **Device Information** please select the word **ADD** and complete the following mandatory fields shown below. If field value is unknown, type **“Unknown”** OR **“N/A”**.

#### Device Involved

[Basic Information (If field value is is unknown, type "unknown" or "N/A")]

Please provide information for both Device Name and Device ID if it is available.

Device Name \*  Device Identifier \*

However, only 1 of the fields is required in order to submit the form.

Serial No. \*  Lot/Batch No. \*

Manufacturer and Vendor

Manufacturer Name \*

Did you also report to the manufacturer? \*