

**Medical Device Incident Report – For use by industry**

|  |  |
| --- | --- |
| 1. **Administrative Information**
 | If the device is an implantable device indicate both implant date and explant dates: (Known): |
| **Report Category (see definitions on page 3)** |  |
|  |   |  |  | **\* Implant Date:**  | Click here to enter a date. |
|  | [ ]  | **Death/Serious Injury**  | **\* Explant Date:** | Click here to enter a date. |
|  |  |  |  |
|  | * Please submit an initial report as soon as possible, and within 10 calendar days.
* Submit a final report once the investigation has been completed.
 | **3. Healthcare Facility Information** |
|  |  |  |
|  |  | **Name:** Click here to enter text. |
|  |  | **Address:** Click here to enter text. |
|  | [ ]  | **Minor injury** |  |[x]  **Quality issue** | **Tel:** Click here to enter text. |
|  | * Please submit a report within 120 calendar days.
* Where possible, submit only a final report, once the investigation has been completed in full.
* If there could be a market action as a result of this incident, submit within 10 working days.
 | **Contact name at site of the event:**  Click here to enter text. |
|  |  |  |
|  |  |  |
|  |  | **4. Device Information (Primary Device)** |
|  |  | **Generic Device Information** |
|  |  |  |
|  |  | **Sponsor:** Click here to enter text. |
|  |  |  **Device WAND number**: Click here to enter text. |
| **Report Type (select one)**  | **GMDN Code:** Click here to enter text. |
| **Initial:** [ ]  | **Follow up:** [ ]  | **Final:** [ ]  | **GMDN Code Text:** Click here to enter text. |
| **Date of this report:**  | Click here to enter a date. |  |
| **Date of adverse event:** | Click here to enter a date. | **Specific Device Information** |
| **Date manufacturer aware:** | Click here to enter a date. |  |
| **Final report target date:** | Click here to enter a date. | **Brand name**: Click here to enter text. |
|  |  | **Model #**: Click here to enter text. |
| **Person Submitting This report** | **Software version**: Click here to enter text. |
| **Name:** Click here to enter text. | **Serial or Lot #s**: Click here to enter text. |
| **Company:** Click here to enter text. | **Manufacturer:** Click here to enter text. |
| **Address:** Click here to enter text. | **Manufacturer Contact Name** Click here to enter text.  |
| **Tel:**  Click here to enter text. | **Email:**Click here to enter text. | **Address:** Click here to enter text. |
|  |  | **Tel:** Click here to enter text. |
|  |  | **Email:** Click here to enter text. |
| 1. **Description of the clinical Event /Problem**
 |  |
| Provide as much detail about the event as possible, including what happened and what led up to the event (eg, the type of surgery or treatment). See guidance on page 3.  | **Operator of Device at Time of Event** |
|  |  |
|  | **HCP:** [ ]  | **Other Caregiver**: [ ]  | **Patient:** [ ]  | **N/A:** [ ]  |
| Click here to enter text. |  |  |  |  |
|  |  |
|  | **Use of Device** |
|  |  |
|  | **Single use:** [ ]  | **Reuse of single Use:** [ ]  |
|  | **Reuse of Reusable:** [ ]  | **Re-serviced/Refurbished:** [ ]  |
|  |  |
|  | **Device Disposition/Current Location:** Click here to enter text. |
| **5. Results of Manufacturer’s Investigation** | **6. Patient Information** |
| **Manufacturer’s Device Analysis Results** | **Note:** in some cases, the patient’s age gender and/or weight will be irrelevant. In others this information will be essential – e.g. weight of patient regarding orthopaedic implants – The reporter should exercise judgement when filling these fields.) |
| **(**Specify, for this event, details of investigation method, results, and conclusion): |  |
| Click here to enter text. | **\*Age:**Enter age | **\*Wt.(kg):**Enter weight | **\*M/F:**Click to choose |
|  |  |
|  | **Patient focused Resolution of Event and Outcomes** |
|  |  |
|  | **Corrective action taken relevant to the care of the patient:** |
|  | Click here to enter text. |
|  | **Patient history (co-morbidities & medication):**Click here to enter text. |
|  | **Description of harm caused to the patient:** |
|  | Click here to enter text. |
|  | **Patient outcome:** |
|  | Click here to enter text. |
| **Remedial Actions/Corrective Action/Preventive Action** | **List of other devices involved in the event:****If other implants involved – list brand, model & WAND number.** |
| (Specify if/what action was taken for the reported specific event or products. Include what action was taken to prevent recurrence. Clarify the timeframe for completion of action plans):Click here to enter text. | Click here to enter text. |
|  |  |
|  | **Other Reporting Information** |
|  | If there have been other similar events reported to either the sponsor or the manufacturer, enter the number or rate. The rate should preferably be provided in the form of an incidence rate, for example: 0.4%, the number should include the number sold, for example, 12 of 3,000 units sold over two years in New Zealand or 25 of 5 million units sold over 5 years worldwide. If none, write “0” or “nil”. |
|  |  |
|  | **Mfr/sponsor aware of other similar events? (Number or rate):** |
|  | Click here to enter text. |
|  | **Country where these similar adverse events occurred:** |
|  | Click here to enter text. |
|  | **Additional comments:** |
|  | Click here to enter text. |
|  |  **Submitting this report:**Compliance Management Branch, Medsafe, PO Box 5013, Wellington, 6145.Email: devices@health.govt.nz  |

Guidance

## Harm definitions

**Serious injury**

An injury which meets any of the criteria:

* life threatening illness or injury has occurred or is likely to have occurred.
* permanent impairment of a body function or permanent damage to a body structure
* an unexpected condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

**Minor injury**

An injury which does not meet the criteria of serious as defined above occurred or is likely to have occurred.

**Quality issue**

If an issue is related to the quality of a medical device, but no serious injury occurred (i.e. no one was harmed by the device), and it is unlikely that a serious injury could have occurred, you can still report this to us using this form.

## Report types

**Initial*:*** The first report that the reporter (sponsor, manufacturer) submits about the event. Submit this report if the investigation is not yet complete and the final report not available.

**Follow-up*:*** Where required, to provide an update to a previous report.

**Final*:***Submit this report when the investigation is complete. For “minor injury” or “quality issue”, where possible submit a final report only, once the investigation is complete.

if you are referring to an existing corrective action, please quote the Medsafe reference number.

**Clinical event information**

The event description should include sufficient details to allow a clear understanding of the event, this could include:

* What procedure was being undertaken at the time?
* Who was using the device at the time
* Was the device being used according to the IFU

**Manufacturer’s investigation**

This investigation should include details such as:

* Rates of occurrence of similar adverse events, both within New Zealand and worldwide as appropriate.
* Is this potentially a quality issue which would affect other devices?
* Is this event a known issue with the device, and is it described in the IFU?
* Where the device cannot be returned from the healthcare facility, consider other ways to evaluate it, for example photographs, x-rays, visiting the facility, detailed description of the device from the healthcare facility. It’s not acceptable not to investigate only on the basis that the device was not returned.
* The investigation should be completed with technical input from a product specialist who is familiar with the device.
* If the healthcare facility/professional has not provided you with some information, describe the efforts you have made to communicate with them and get info.

**Patient information**

Critical information that should be provided includes:

* Age, weight and gender
* implant and explant date, or estimated duration of the implanted device (ADD FIELD - or, duration of implant.