

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

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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:** | | {{description\_of\_the\_clinical\_event\_implant\_date}} | | | | |
|  | {{rtd}} | | **Death/Serious Injury** | | | | | | | | **\* Explant Date:** | | {{description\_of\_the\_clinical\_event\_explant\_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:** {{healthcare\_facility\_information\_facility\_name}} | | | | | | |
| **Address:** {{healthcare\_facility\_information\_facility\_address}} | | | | | | |
|  | {{rtm}} | | **Minor injury** | | | |  | **{{rtq}}** | **Quality issue** | | **Tel:** {{healthcare\_facility\_information\_facility\_telephone}} | | | | | | |
|  | | * 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:** {{healthcare\_facility\_information\_facility\_contact\_name}} | | | | | | |
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| **4. Device Information (Primary Device)** | | | | | | |
| **Generic Device Information** | | | | | | |
|  | | | | | | |
| **Sponsor:** {{generic\_device\_information\_sponsor}} | | | | | | |
| **Device WAND number**: {{generic\_device\_information\_wand\_number}} | | | | | | |
| **Report Type (select one)** | | | | | | | | | | | **GMDN Code:** {{generic\_device\_information\_gmdn\_code}} | | | | | | |
| **Initial:** {{rti}} | | | | | **Follow up:** {{rtfu}} | | | | | **Final:** {{rtf}} | **GMDN Code Text: {{generic\_device\_information\_gmdn\_code\_text}}** | | | | | | |
| **Date of this report:** | | | | | | {{report\_type\_date\_of\_this\_report}} | | | | |  | | | | | | |
| **Date of adverse event:** | | | | | | {{report\_type\_date\_of\_adverse\_event}} | | | | | **Specific Device Information** | | | | | | |
| **Date manufacturer aware:** | | | | | | {{report\_type\_manufacturer\_aware\_date}} | | | | |  | | | | | | |
| **Final report target date:** | | | | | | {{report\_type\_final\_report\_target\_date}} | | | | | **Brand name**: {{specific\_device\_information\_brand\_name}} | | | | | | |
|  | | | | | |  | | | | | **Model #**: {{specific\_device\_information\_model\_number}} | | | | | | |
| **Person Submitting This report** | | | | | | | | | | | **Software version**: {{specific\_device\_information\_software\_version}} | | | | | | |
| **Name:** {{person\_submitting\_this\_report\_name}} | | | | | | | | | | | **Serial or Lot #s**: {{specific\_device\_information\_serial\_or\_lot\_numbers}} | | | | | | |
| **Company:** {{person\_submitting\_this\_report\_company}} | | | | | | | | | | | **Manufacturer:** {{specific\_device\_information\_manufacturer}} | | | | | | |
| **Address:** {{person\_submitting\_this\_report\_address}} | | | | | | | | | | | **Manufacturer Contact Name** {{specific\_device\_information\_manufacturer\_contact\_name}} | | | | | | |
| **Tel:**  {{person\_submitting\_this\_report\_telephone}} | | | | | | **Email:**  {{person\_submitting\_this\_report\_email}} | | | | | **Address:** {{specific\_device\_information\_address}} | | | | | | |
| **Tel:** {{specific\_device\_information\_telephone}} | | | | | | |
| **Email:** {{specific\_device\_information\_email}} | | | | | | |
| 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:** {{ohc}} | **Other Caregiver**: {{ooc}} | | | | **Patient:** {{op}} | **N/A:** {{ona}} |
| {{description\_of\_the\_clinical\_event\_details}} | | | | | | | | | | |
|  | | | | | | |
| **Use of Device** | | | | | | |
|  | | | | | | |
| **Single use:** {{usu}} | | | | **Reuse of single Use:** {{ursu}} | | |
| **Reuse of Reusable:** {{urr}} | | | | **Re-serviced/Refurbished:** {{ursr}} | | |
|  | | | | | | |
| **Device Disposition/Current Location:** {{ uod\_location}} | | | | | | |
| **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): | | | | | | | | | | |
| {{manufacturer\_device\_analysis\_results\_details}} | | | | | | | | | | | **\*Age:**  **{{patient\_information\_age}}** | | | **\*Wt.(kg):**  **{{patient\_information\_weight}}** | | | **\*M/F:**  **{{patient\_information\_gender}}** |
|  | | | | | | |
| **Patient focused Resolution of Event and Outcomes** | | | | | | |
|  | | | | | | |
| **Corrective action taken relevant to the care of the patient:** | | | | | | |
| {{patient\_focused\_resolution\_of\_event\_and\_outcomes\_corrective\_action}} | | | | | | |
| **Patient history (co-morbidities & medication):**  {{patient\_focused\_resolution\_of\_event\_and\_outcomes\_history}} | | | | | | |
| **Description of harm caused to the patient:** | | | | | | |
| {{patient\_focused\_resolution\_of\_event\_and\_outcomes\_description\_of\_harm\_caused\_to\_the\_patient}} | | | | | | |
| **Patient outcome:** | | | | | | |
| {{patient\_focused\_resolution\_of\_event\_and\_outcomes\_patient\_outcome}} | | | | | | |
| **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):  {{remedial\_corrective\_preventive\_action\_action}} | | | | | | | | | | | {{patient\_focused\_resolution\_of\_event\_and\_outcomes\_list\_of\_other\_devices\_involved}} | | | | | | |
|  | | | | | | |
| **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):** | | | | | | |
|  | | | | | | | | | | | {{other\_reporting\_information\_manufacturer\_or\_sponsor\_aware}} | | | | | | |
| **Country where these similar adverse events occurred:** | | | | | | |
|  | | | | | | | | | | | {{other\_reporting\_information\_country\_similar\_adverse\_events\_occurred}} | | | | | | |
| **Additional comments:** | | | | | | |
|  | | | | | | | | | | | {{other\_reporting\_information\_additional\_comments}} | | | | | | |
| **Submitting this report:**  Compliance Management Branch, Medsafe, PO Box 5013, Wellington, 6145.  Email: [devices@health.govt.nz](mailto:devices@health.govt.nz) | | | | | | |