**All fields marked with an \* are mandatory fields (for the Final Report)**

**Report Details**

|  |  |  |  |
| --- | --- | --- | --- |
| **Report Type: \***  Final | **Date of Report:**  10/06/2025 | **Sponsor ID:**  42972 | **TGA Report Number:**  Will receive after submittal |
| **Date of Adverse Event:**  4 June 2025 | **Date of Awareness:**  3 December 2013 | **Report Category:**  Death/Serious Injury | **Reporter’s Reference:** |

**Reporter Details**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Title:**  Ms. | **First Name:**  Amelia | **Surname of Contact:**  Boldrick | **Company/Institution:**  Emergo Australia | | |
| **Position/Occupation:**  Global Vigilance Specialist | | | **Address Line 1:**  Level 20, Tower II Darling Park | | |
| **Phone:**  61.2.9006.1662 | | **Fax:**  61.2.9006.1010 | **Address Line 2:**  201 Sussex Street | | |
| **Email:**  [AUNZvigilance@ul.com](mailto:AUNZvigilance@ul.com) | | | **Country:**  Australia | | |
|  | | | **Town/Suburb:**  Sydney | **State/Province:**  NSW | **Postcode:**  2000 |

**Healthcare Facility Details**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Title:**  Dr. | **First Name:**  Harish | **Surname of Contact:**  H | **Company/Institution:**  Fission | | |
| **Position/Occupation:**  Doctor | | | **Address Line 1:**  Jubilee Hills | | |
| **Phone:**  9880963888 | | **Fax:** | **Address Line 2:**  Hyderabad | | |
| **Email:** | | | **Town/Suburb:** | **State/Province**:  Choose an item. | **Postcode:** |

**Device Identification**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Device ARTG Number: \*** | **GMDN Code**  Flows from ARTG listing | **GMDN Text**  Flows from ARTG listing | | |
| **Brand / Trade Name:** **\*** | | | **Software Version (If Relevant):** | |
| **Device Model:** | **Serial Number:** | If the device is an implantable device, indicate the implant date and if relevant the explant date below. | | |
| **Batch Number:** | **Lot Number:** | **Date of Implant:**  Click here to enter a date. | | **Date of Explant:**  Click here to enter a date. |
| **Operator at Time of Event:**  Choose an item. | **Usage of Device:**  Choose an item. | **Place of Implantation:** | | **Current Device Location:**  Choose an item. |

**Manufacturer’s Details**

|  |  |  |  |
| --- | --- | --- | --- |
| **Title:**  Choose | **First Name:** | **Surname of Contact:** | **Company Name**  Flows from ARTG listing |

**Clinical Event Information**

Please **DO NOT** include the names of hospitals or persons involved in the event. Use the section above ‘Healthcare Facility Details’ for this information.

**Description of Event or Problem:** **\***

|  |
| --- |
|  |

**Patient Information**

|  |  |  |
| --- | --- | --- |
| **Sex:**  Choose an item. | **Age (years, months):** | **Weight (Kg):** |

**Corrective Action Taken Relevant to Care of Patient:**

|  |
| --- |
|  |

**Patient History (Co-morbidities & Medication):**

|  |
| --- |
|  |

**Patient Outcome / Consequences:**

|  |
| --- |
|  |

|  |  |
| --- | --- |
| **If Injured:**  Extent of Injury: Choose an item. | If Other, please specify: |
|  | If Temporary Injury: Consequence: Choose an item.  If Other consequence, please specify: |
|  | If Serious Injury: Consequence: Choose an item.  If Other consequence, please specify: |
|  | If Permanent Disability, device directly linked to disability? Choose |
|  | If Death, device directly linked to death?: Choose |

**Other Devices Involved in Event:**

(Add table below for each device)

|  |  |  |
| --- | --- | --- |
| **ARTG No:** | **Brand / Trade Name:\*** | **Manufacturer:** |
| **Model No:** | **Serial No:** | **Sponsor / Supplier:** |

**Results of Manufacturer’s Investigation**

**Manufacturer’s Device Analysis Results: \***

|  |
| --- |
|  |

**Remedial Action / Corrective Action / Preventive Action:**

|  |
| --- |
|  |

**Internal Corrective Action Reference #:**

|  |
| --- |
|  |

**Completed Actions:** **Planned Actions and Proposed Timeline:**

|  |  |  |
| --- | --- | --- |
| action |  | timeline |

**Other Similar Events Manufacturer/Sponsor Aware of: (IMPORTANT: See instruction last page!) \***

Ex: *12 similar events from 3,187 units sold in Australia (0.37%) in the past 3 years. 235 similar events from 68,078 units sold Worldwide (0.34%) in the past 3 years.*

|  |
| --- |
|  |

**Countries Where these Similar Adverse Events Occurred:**

|  |
| --- |
|  |

**Additional Comments:**

|  |
| --- |
|  |

**Guidance on how to complete this form**

**Note:** This form is a representation of the online MDIR form (Web Version 2.1.6) drafted by Emergo Australia to aid in the submittal of each incident.

The following provides some guidance on what information is required in some parts of the form.

**Report Details:** The online form only contains an Initial and Final option for the first submission, however Follow-up may be selected once an Initial report has been submitted. ***Initial:*** The first report that the reporter (sponsor, manufacturer) is submitting about an event. The reporter expects to submit further information about the event at a later date. ***Follow-up:*** TGA requests that status updates for ongoing investigations be provided every 30 days until complete and a Final report has been submitted. As with Initial reports, Follow-up reports are used when the reporter expects to submit further information about the event at a later date. ***Final:*** The last report that the reporter expects to submit about an event. It is possible for the final report to also be the initial report about an event (e.g. Combined). If so, please indicate that no further reports are expected by choosing Final Report.

**Report Category: *Serious Public Health Threat:*** these reports must be submitted within **48 hours** of the manufacturer becoming aware of the event, please refer to the Medical Devices Regulations and Guidance for interpretation on the meaning of this description. ***Death/Serious Injury****:* Choose this category where the event subject of the report resulted in the death or serious injury of a patient, user or other person. ***Trend****:* Under Quality Management System requirements, the manufacturer is expected to monitor trends of significant adverse events. Significant changes in frequency of occurrence or severity of events associated with devices must be reported. These reports are called “trend” reports. ***Other****:* Choose this category where the event subject of the report was a “near miss” or is the result of testing or other analysis and an event or further occurrence could lead to the death or serious injury of a patient, user or other person.

**Reporter’s Reference Number:** The manufacturer reference number assigned to this particular event. While this is not mandatory, it aids in record keeping.

**Reporter Details:** This section is already filled in by Emergo Australia and no editing is needed.

**Device Identification:** Device ARTG #: The number assigned to the device in the ARTG.

**GMDN Code & Text:** Global Medical Device Nomenclature (GMDN) Code and explanatory text, (e.g. 40589 – clamp, surgical tubing, single use). This populates based on the code included on the ARTG listing and can be left blank.

**Place of Implantation:** Name of hospital where the device was implanted.

**Current Location:** Where and in what state the device is at the time of the report – e.g. destroyed/lost or with manufacturer undergoing testing, or with original reporter, etc. Please note that ‘with reporter’ means that it is with Emergo since in terms of these reports Emergo is the reporter, so this option is not available for selection in our form.

**Clinical Event Information:** Patient Information: 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 in regards to orthopedic implants – The reporter should exercise judgment when filling these fields.

**Extent of Injury:** Note: the injury may or may not be due to the device.

**Other devices involved in the event:** Some events are caused by the combined action of two or more devices. List any other device(s) and their ARTG # that were being used at the time of the event if known.

**Other Similar Events Manufacturer/Sponsor Aware of:** Please ensure that the similar event information provided relates to the actual event reported in the “clinical event information” field of this report, *not* the root cause of the event. Any other similar events reported to the sponsor or manufacturer must be provided as both a number and incidence rate % calculated based on the number of devices supplied, and TGA requires that numbers and percentages be provided for Australia and Worldwide separately.

Whenever possible TGA expects that the period captured in similar event data cover a three year period which includes the date in which the reported event occurred for context.

The incidence rate should be provided in the form of a percentage generated using the calculation (# of similar events/number supplied x 100). For example, 12 similar events from 3,187 units sold: 12/3187 x 100 = 0.37%.

A complete example of similar events would be as follows: 12 similar events from 3,187 units sold in Australia (0.37%) in the past 3 years. 235 similar events from 68,078 units sold Worldwide (0.34%) in the past 3 years.

If no events have occurred please write “0” or “Nil”.