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|  | HEALTH SCIENCES AUTHORITY**Clinical Trials Branch****MEDICAL DEVICE ADVERSE EVENT REPORT****(FOR CLINICAL RESEARCH)** |

**Instructions:**

1. This form may take you 15 minutes to fill in. You will need to prepare some information to fill in the form.
2. This form and any attachment are to be submitted to **Clinical Trials Branch** via email to HSA\_CT\_SAE@hsa.gov.sg.
3. This form is to be completed by dealers (i.e., local manufacturers, importers, suppliers, sponsors) of medical device for clinical research purposes, for the reporting of an adverse event (AE) associated with a medical device and to be submitted according to the stipulated timeframe in the regulations.
4. Each field must be completed with the requested information, “NA” if not applicable, or “unknown” when the data is not available. All date fields are to be completed in the following format : **DD/MM/YYYY**
5. If the space provided in the form is insufficient, please provide the information as an attachment.
6. Use the “Other Information” section at the end of the form to provide any additional details that are relevant and not requested elsewhere.

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| HSA Adverse Event Reference No. *(for official use only)* |       |
| **1. ADMINISTRATIVE INFORMATION** |
| Product Owner Reference No.  |       |
| Report Type *(please select one)* | [ ]  Initial / [ ]  Follow-up #   / [ ]  Final / [ ]  Trend |
| Report Category | Serious Health Threat  | [ ]  Serious Health Threat (Public / Study Group) |
| Death | [ ]  Death (Date:       ) |
| Serious Injury | [ ]  Life-threatening[ ]  Disability or Permanent Damage[ ]  Congenital Anomaly / Birth Defect / Foetal Death/Distress[ ]  Required Intervention to Prevent Permanent Impairment/ Damage[ ]  Inpatient / Prolonged Hospitalisation  |
| Others | [ ]  Device Deficiency/Defect that might have led to Serious Injury[ ]  Others, please specify:       |
| Expectedness | [ ]  Anticipated [ ]  Unanticipated |
| Relatedness of AE/Device Deficiency | For Principal Investigator[ ]  Device-related[ ]  Procedure-related[ ]  Unknown[ ]  Unrelated | For Product Owner[ ]  Device-related[ ]  Procedure-related[ ]  Unknown[ ]  Unrelated |
| If “Unrelated”, please specify reasons: |       |       |
| Did the adverse event occur in Singapore? *(please select one)* | [ ]  Yes [ ]  No, **AE not required to be reported to HSA** |
| Date of occurrence of AE/Device Deficiency |       |
| Date of awareness by Principal Investigator |       |
| Date of awareness by Company |       |
| Date of awareness by Product Owner |       |
| Date of next report *(within 30 days from date of this report)* |       |
| Regulatory/Competent Authority / Others that this report was also sent to |       |

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| **2. CLINICAL RESEARCH INFORMATION** |
| Clinical Research Material Notification No. |       |
| Title of Clinical Research |       |
| Protocol Number |       |
| Local Clinical Research Sponsor Name |       |
| Local Clinical Research Centre/Institution Name |       |
| Local Clinical Research Centre/Institution Address |       |
| Name of Principal Investigator |       |
| Job Title |       |
| Tel no. |       | Fax no. |       |
| Email address |       |
| **3. COMPANY INFORMATION** |
| Company Name |       |
| Company Address |       |
| Contact Person |       |
| Job Title |       |
| Tel no. |       | Fax no. |       |
| Email address |       |
| **4. DEVICE DETAILS** |
| Device Name |       |
| Intended purpose/use of device |       |
| SMDR Listing No. *(if applicable)* |       |
| Model No.  |       |
| Catalogue No. |       |
| Serial No. |       |
| Lot/Batch No. |       |
| Software version *(if applicable)* |       |
| Accessories / Associated Devices affected |       |
| ***Product Owner Details*** |
| *Company Name* |       |
| *Address* |       |
| *Contact Person* |       |
| *Job Title* |       |
| *Tel no.* |       |
| *Email address* |       |
| **5. CLINICAL EVENT INFORMATION** |
| Operator of device at the time of the event*(please select one)* | [ ]  Healthcare Professional[ ]  Patient[ ]  Other Caregiver **[ ]** None / Problem noted prior to use |
| Usage of device (please select one) | [ ]  Initial use[ ]  Reuse of Single Use Device[ ]  Reuse of Reusable Device [ ]  Re-serviced/Refurbished[ ]  Other (Please specify:       ) |
| Device disposition / current location |       |
| Description of event or problem |       |
|  | If the device is an implantable device, please indicate –Implant Date:       Explant Date:       |
| Investigation arm for comparative investigations, if known |        |
| No. of patients enrolled at site |        |
| No. of patients treated in the study |        |
| No. of patients involved in this incident | Death |        |
| Serious Injury |        |
| Others |        |
| **Total** |       |
| No. of devices involved | Death |        |
| Serious Injury |        |
| Others |        |
| **Total** |       |
| No. of patients exposed to this device*(for reusable device only)* |       |
| **6. INFORMATION ON AFFECTED PERSON(S) (Repeat this section for each person involved)** |
| Age at time of event *(years, months)* |       |
| Gender |       |
| Weight (kg) |       |
| List of other device(s) involved in this AE |       |
| Corrective Action(s) taken by Investigator |       |
| Outcome  | [ ]  Recovered (Date:       )[ ]  Not yet recovered [ ]  Death (Date:       )[ ]  Others (Please specify:       ) |
| Patient ID code *(if applicable)* |       |
| Patient history *(co-morbidities & medication)* |       |
| **7. RESULTS OF PRODUCT OWNER INVESTIGATION** |
| Product Owner/ Device Analysis Results*(For Final Report, please include all investigations done and their results)* |       |
| Course of Action / Remedial/ Corrective/ Preventive Action, including timeline |       |
| Is Product Owner aware of other similar events in treatment group? *(please select one)* | [ ]  Yes [ ]  No |
| If Yes, please specify the no. of event and or rate:       |
| Is Product Owner aware of other similar events in comparator groups? *(please select one)* | [ ]  Yes [ ]  No |
| If Yes, please specify the no. of event and or rate:       |
| Opinion of the Product Owner on the acceptability of the AE and of its current frequency in this clinical trial with rationale*(For Final Report only)* |       |
| Actions to be taken for the clinical investigation (e.g. suspension, termination, none)*(For Final Report only)* |       |
| **8. OTHER INFORMATION** |
|       |

**Note: Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, importer, supplier, manufacturer or product caused or contributed to the event.**

I attest that the information submitted is true and correct.

Signature : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Reporting Person :

Date of this notification :

Company stamp : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Guidance on how to fill this form**

The following provides some guidance on what information is required in some parts of the form. It is envisaged that the fields not mentioned in this explanatory note are self-explanatory.

*\* Please also refer to* [*GN-05-R2 Guidance on Reporting of Adverse Events for Medical Devices*](http://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Overview_Framework_Policies/Guidances_for_Medical_Device_Registration/GN-05-R2_Guidance%20on%20the%20Reporting%20of%20Adverse%20Events%20for%20Medical%20Devices.pdf)*.*

**Definitions**

Sponsor: A person who takes responsibility for the initiation, management or financing of any clinical research. (as defined in Health Products (Medical Devices) Regulations)

**Reference Number**

HSA Adverse Event Reference No.: The reference number given by HSA upon receipt of the adverse event. It is used as a reference for future correspondence with HSA. This reference no. would only become available after the initial report has been submitted.

Product Owner Reference No.: The reference number assigned by the product owner to this adverse event.

**Report Type**

Initial: The first report that the reporter (dealers) is submitting about an event. The reporter is expected to submit further information about the event within 30 days.

Follow-up: Additional information to a previous (initial, follow-up or final) report.

Final: The last report that the reporter expects to submit about an event. The initial report can be a final report if the reporter has all the information about the event.

Trend: Significant changes in frequency of occurrence or severity of events associated with devices must be reported. These reports are called trend reports. Under the quality management system requirements, the product owner is expected to monitor trends of significant serious adverse events.

**Report Category**

Serious health threat: Select this category when the event represents a serious threat to public. The initial report for this category of adverse events must be submitted not later than 48 hours after the reporter becomes aware of the event.

Death/Serious injury: Select this category when the adverse event results in the death or serious injuries of a patient, user or other person. The initial report for this category must be submitted not later than 10 days after the reporter becomes aware of the event.

Device Deficiency: Inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. Includes malfunction, misuse or use error and inadequate labeling.

Others: Select this category when the adverse event was a near incident or is the result of testing or other analysis and event or further occurrence could lead to death or serious injury or a patient, user or other person. The initial report for this category must be submitted not later than 30 days after the reporter becoming aware of the event.

**Expectedness**

Anticipated: An anticipated adverse event is an event which by its nature, incidence, severity or outcome has been identified in the risk analysis report or investigator’s brochure.

**Device Details**

SMDR Listing No.: The number assigned to the device in the Singapore Medical Device Register, in the format of DEXXXXXXX. ‘X’ referring to the numeric number assigned to the device listing.

**Clinical Event Information**

Device disposition / 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 sponsor, investigator etc.

Description of event or problem:

For an adverse event: Describe the adverse event in detail, including a description of what happened and a summary of all the relevant clinical information (medical status prior to the event; signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.) and results of relevant tests and laboratory data.

For a product problem: Describe the problem (quality, performance, or safety concern) in sufficient detail so that the circumstances surrounding the deficiency/defect or malfunction of the medical device can be understood. If available, the results of any evaluation by the Investigator and/or Sponsor of a malfunctioning device and, if known, any relevant maintenance/service information should be included.

No. of patients enrolled at site: The number of subjects/patients who have enrolled for the clinical trial at the site where the adverse event occurred.

No. of patients treated in the study: The number of subjects/patients who have undergone the treatment plan involving the investigational device as outlined in the clinical trial protocol.

**Patient Information**

Weight and Gender: 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 orthopaedic implants. The reporter should exercise judgement when filling this field.

List of other device(s) involved in this AE: Provide the device name and also if any, a brief list of other device(s) involved in the event. Some events are caused by the combined action of two or more medical or other devices.

Patient ID code: Provide the patient’s initials or some other type of identifier that will allow both the submitter and the reporter to locate the case if contacted for follow-up. Do not use the patient’s name or NRIC number.

Patient history (co-morbidities & medication): Provide information on other known conditions in the patient e.g. Hypertension, diabetes mellitus, renal/hepatic dysfunction and significant history e.g. Race, allergies, pregnancy history, smoking and alcohol abuse, drug abuse etc.

**Results of Product Owner’s Investigation**

Product Owner’s Device Analysis Results: Specify, for this event, details of investigation methods, results and conclusions.

Course of Action / Remedial/ Corrective/ Preventive Action: Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken by the product owner to prevent recurrence. Clarify the timeframes for completion of various action plans.

Is Product Owner aware of other similar events and its number or rate and countries: If there have been other similar events reported to the product owner, provide the countries and the number. The number should preferably be provided in the form of an incidence rate, e.g. 8 of 3000 units undergoing clinical investigation over two years worldwide. If none, indicate “0”.