# Statement of Purposes

**1. Purpose of Collection**

The personal data that are provided by you in connection with this Report Form or when you are in contact with the Department of Health (DH) in connection with in this Report Form will be used by the DH for medical device adverse event investigation and management.

The provision of personal data is voluntary. If you do not provide sufficient information in the Report Form as specified, we may not be able to provide assistance to you.

**2. Classes of Transferees**

The personal data you provided are mainly for use within the DH but they may also be disclosed to other Government bureaux / departments, or relevant parties for the purpose mentioned in paragraph 1 above, if required. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

**3. Access to Personal Data**

You have a right to request access to and correction of your personal data as provided in accordance with the Personal Data (Privacy) Ordinance (Cap. 486).
Your right of access includes the right to obtain a copy of your personal data provided during the occasion as mentioned in paragraph 1 above. A fee may be imposed for complying with a data access request.

**4. Enquiries**

Enquiries in relation to the personal data, including requests for making access or corrections to the data, should be addressed to:

Executive Officer
Medical Device Division, Department of Health
Room 604, 6/F, 14 Taikoo Wan Road,
Taikoo Shing, Hong Kong
Telephone number: 3107 8453
E-mail address: mdd@dh.gov.hk.

Please quote our file reference number when submitting the request.

# MEDICAL DEVICE DIVISION
# Medical Device Adverse Event Report Form – for Local Responsible Persons

| LRP Report No. |
|---|
| MDD Report No. (Official Use Only) |

## I. ADMINISTRATIVE INFORMATION

1. Report Type (select one):

☐ Initial ☐ Follow-up ☐ Final ☐ Trend

2. Classification:

☐ Serious Public Health Concern ☐ Death

☐ Serious Injury ☐ Other Reportable Event

| | |
|---|---|
| 3. Date of this report (dd-mmm-yyyy) | |
| 4. Date of adverse event (dd-mmm-yyyy) | |
| 5. LRP awareness date (dd-mmm-yyyy) | |
| 6. Expected date of next report (dd-mmm-yyyy) | |

Particulars of the LRP Submitting this Report:

| | |
|---|---|
| 7. Name | |
| 8. Company | |
| 9. Address | |

| | | | |
|---|---|---|---|
| 10. Phone | | 11. Fax. | |
| 12. E-mail | | | |

13. Name(s) of regulatory authorities that this event has also been reported to by the LRP:

## II. CLINICAL EVENT INFORMATION

1. Description:

| | | | |
|---|---|---|---|
| 2. No. of affected people | | 3. No. of devices | |

## III. HEALTHCARE FACILITY INFORMATION

| | |
|---|---|
| 1. Name of the Facility | |
| 2. Name of Contact Person | |
| 3. Facility Report No. | |
| 4. Address | |

| | | | |
|---|---|---|---|
| 5. Phone | | 6. Fax. | |
| 7. E-mail | | | |

## IV. DEVICE INFORMATION

Device Information:

| | |
|---|---|
| 1. MDD Listing No. | |
| 2. Manufacturer | |
| 3. Brand Name | |
| 4. Model | |
| 5. Catalogue No. | |
| 6. Serial No . | |
| 7. Lot/Batch No. | |

Manufacturer Information:

| | |
|---|---|
| 8. Manufacturer Name | |
| 9. Contact Person | |
| 10. Address | |

| | | | |
|---|---|---|---|
| 11. Phone | | 12. Fax | |
| 13. E-mail | | | |

14. Operator of device at the time of the adverse event:

☐ Healthcare Professional ☐ Patient ☐ Other ☐ None

15. Usage of Device:

☐ Initial Use ☐ Reuse of Single-Use Device

☐ Reuse of Reusable Device ☐ Re-serviced / Refurbished

☐ Other, please specify:

16. Device Disposition / Current Location:

## V. RESULT OF MANUFACTURER'S INVESTIGATION

1. Manufacturer's Device Analysis Results:

2. Remedial Action / Corrective Action / Preventive Action:

## VI. INFORMATION OF PATIENT

| | | | |
|---|---|---|---|
| 1. Age at time of the adverse event (months, years) | | | |
| 2. Gender (M/F) | | 3. Weight (kg) | |

4. List of devices involved with the patient (see Section IV):

5. Corrective action taken relevant to the care of the patient:

6. Patient outcome:

## VII. OTHER REPORTING INFORMATION

Any other cases with this device with the same root cause?

☐ Yes, please specify:_____ ☐ No

## VIII. COMMENTS

## IX. SUBMISSION OF REPORT

By Mail: Medical Device Division
Department of Health
Room 604, 6/F,
14 Taikoo Wan Road, Taikoo Shing, Hong Kong.

By E-mail: mdd_air@dh.gov.hk By Fax.: (852) 3157 1286

## X. DISCLAIMER

Submission of this report does not constitute an admission of manufacturer, LRP, user, or patient liability for the adverse event and its consequences. It does not, in itself, represent a conclusion by the LRP that the content of this report is complete or confirmed, that the device(s) listed failed in any manner. It is also not a conclusion that the device(s) caused or contributed to the adverse event.

# GUIDANCE FOR FILLING IN THE ADVERSE EVENT REPORT FORM

## GENERAL

All fields must be completed with appropriate information, or "NA" if not applicable to the event, or "unknown" when the data is not available.

"LRP Report No." on the top right hand corner of the first page is the unique number assigned by the LRP to identify the report in the LRP's internal system.

Reasonable effort must be made to address all elements. However, failure or inability to do so is not a justification for failing to submit a report within the established timeframes.

All GHTF documents referred to in this guidance are available at the GHTF homepage: http://www.ghtf.org.

## I. ADMINISTRATIVE INFORMATION

1. Report Type:

Initial: defined as the first report submitted by the LRP about a reportable event, but the information is incomplete and supplementary information will need to be submitted. This includes immediate submission.

Follow-up: defined as a report that provides supplemental information about a reportable event that was not previously available.

Final: defined as the last report that the LRP expects to submit about the reportable event. A final report may also be the first report.

Trend: defined as information supplied as a result of significant increase in the rate of (i) reportable events, (ii) adverse events exempted from reporting, or (iii) adverse events scheduled for periodic reporting. Please refer to the GHTF guidance document of ref. SG2 N36 R7 for details.

2. Classification:

Please note that the following use errors are also reportable adverse events:

a. Use errors that result in death or serious injury or serious public health concern;
b. When the LRP or manufacturer notes a change in trend or a change in pattern of an issue that can potentially lead to death or serious injury or public health concern;
c. When the LRP or manufacturer initiates corrective action to prevent death or serious injury or serious public health concern.

Other use errors that do not result in death or serious injury or serious public health concern need not be reported.

For details on reportable and non-reportable events, please refer to the Guidance Notes GN-03: Adverse Event Reporting by Local Responsible Persons.

3 - 6. Dates of this report, date of adverse event, LRP awareness date, and expected date of next report:

All dates must be formatted as follows: 2-digit day, 3-letter month, 4-digit year e.g., 01-JAN-2001

Expected date of next report: the date when further information will be provided. This should be "NA" for final report.

7 - 12. Particulars of the LRP Submitting this Report

Please fill in the contact details of the LRP's reporter.

13. Name(s) of regulatory authorities that this event has been reported to by the LRP:

Please identify other regulatory authorities, such as the FDA (US), MHRA (UK), that this event was also reported to.

## II. CLINICAL EVENT INFORMATION

1. Description:

Clarification or relevant information that might impact the understanding or evaluation of the adverse event AND that is not included elsewhere in the report. E.g. "the patient was confused prior to becoming trapped at the bedside"; "the patient was a very low birth weight prematurely delivered baby and had a central line placed three days before onset of cardiac tamponade"; "the X-ray machine was over 20 years old and had been poorly maintained at the time of the adverse event", etc.

2. No. of affected people

Includes any affected individual, e.g. user, patient, or third party.

3. No. of devices

Please state of the number of devices involved in this adverse event.

## III. HEALTHCARE FACILITIY INFORMATION

Please provide information about the place of the adverse event. It could include home care, transport or emergency care site.

## IV. DEVICE INFORMATION

1 - 13. Device Information:

Please provide information on the device involved. Please repeat this section for each device in separate sheets.

14. Operator of device at the time of the adverse event:

Please indicate the type of operator of the device at the time of the adverse event. “None” means that the problem is noted prior to use.

15. Usage of Device:

Please indicate the usage of the device involved.

16. Device Disposition / Current Location:

Please provide information on where and in what state the device is at the time of the report, e.g. “the device has been destroyed”; “the device remains implanted in patient”; “the device was returned to the manufacturer”; “the device remains under investigation”, etc.

## V. RESULT OF MANUFACTURER’S INVESTIGATION

1. Manufacturer’s Device Analysis Results:

Specify, for this adverse event, details of investigation methods, results, and conclusions.

Alternatively, manufacturer’s device analysis report may be submitted.

2. Remedial Action / Corrective Action / Preventive Action:

Specify if action was taken by manufacturer and/or LRP for the reported event or for all similar types of products. Include what action was taken by the manufacturer and/or LRP to prevent recurrence. Clarify the timeframes for completion of various action plans.

## VI. INFORMATION OF PATIENT

Please provide individual patient information (including information of any affected individual, e.g. user, patient, or third party) for each element as appropriate. Please repeat this section for each patient involved in separate sheets.

Please note that in some cases, the patient’s age, gender and weight might be irrelevant. In some cases, they are essential, e.g. the age and weight of the patient in regards to some implants.

Some adverse events are caused by the combined action of two or more devices, medical or non-medical. Please provide a brief list of devices involved.

## VII. OTHER REPORTING INFORMATION

If the manufacturer or the LRP is aware of similar adverse events with this device with the same root cause, please provide the number of such events. The number should be specified in terms of event per unit sold, or the number of event per unit sold / in use in a region, etc.

## VIII. COMMENTS

Please provide any additional details that are relevant and not requested elsewhere in this report.