How to submit your medical device adverse event (AE) report?

You can report all suspected medical device AE to HSA at:

Tel : 6866 1111
Fax : 6478 9069
Email : HSA_productsafety@hsa.gov.sg

The medical device AE reporting form is available at: http://www.hsa.gov.sg/ae_online

For further information on medical device AE reporting, please contact HSA at:
HSA_MD_info@hsa.gov.sg

At HSA, what happens to your submitted report?

Adverse event reports associated with medical devices are reviewed by HSA for potential medical device safety, performance and quality issues. Your adverse event reports will be captured in the national database for aggregate analysis. Investigations of adverse events can lead to regulatory actions such as updating of instructions for use with additional warnings, revision to the intended use, issuance of advisories or product recall. When a hazard is considered unacceptable, a medical device may be withdrawn from the market.
**What is a medical device?**

A medical device is any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent, calibrator, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific purposes of:

a) Diagnosis, prevention, monitoring, treatment or alleviation of any disease;

b) Diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

c) Investigation, replacement, modification, or support of the anatomy or of a physiological process;

d) Supporting or sustaining life;

e) Control of conception;

f) Disinfection of medical devices; or

g) Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Some examples of medical devices include: dressings, thermometer, syringe, blood pressure monitor, in-vitro diagnostic / screening kit, surgical sutures, contact lenses, implantable defibrillators, prosthetic heart valves, dental laser surgical device and diagnostic imaging systems.

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**Your report contributes to safety surveillance of medical devices**

As a healthcare professional, you are best positioned to detect and identify safety and quality issues related to the use of medical devices.

Healthcare professionals are encouraged to report adverse events relating to the use of medical device, including use errors and device product problems. In particular, please report if the event has led to the following:

- Death of a patient, user or other person
- Life-threatening illness or injury
- Permanent impairment of body function or structure
- A condition necessitating medical or surgical intervention
- No death or injury occurred but it might lead to death or serious injury of a patient, user or other person if the adverse event recurs.

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**What details should be reported in an adverse event?**

A good quality report is essential for HSA’s investigation

Each report should include the following if possible:

<table>
<thead>
<tr>
<th>Device details (this information should be present on the device label or product information leaflet that comes along with the device)</th>
<th>• Brand name, model number, serial number, batch number, software version (if applicable) • Intended use • Date of manufacture and expiry • How long was the device used by patient? • Manufacturer and/or supplier of the device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of event</td>
<td>• A description of the circumstances and sequence of events leading to the adverse event • Patient outcome attributed to incident</td>
</tr>
<tr>
<td>Patient information (this is required to help in identifying duplicate reporting)</td>
<td>• Name, identification number, age, gender, weight (if available)</td>
</tr>
<tr>
<td>Particulars of reporting person</td>
<td>• Name, profession / designation, telephone and facsimile numbers, email address, place of practice</td>
</tr>
</tbody>
</table>

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**You don’t have to be certain – Just suspicious**