MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Medical Device Incident Report – For use by industry

1. Administrative Information

Report Category (see definitions on page 3)

☒ **Death/Serious Injury**

- Please submit an initial report as soon as possible, and within 10 calendar days.
- Submit a final report once the investigation has been completed.

☒ **Minor injury** ☐ **Quality issue**

- 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.

Report Type (select one)

Initial: ☐ **Follow up:** ☒ **Final:** ☐

Date of this report: 11/06/2025
Date of adverse event: 10/06/2025

Date manufacturer aware: 2/06/2025
Final report target date: 8/06/2025

Person Submitting This report

Name: Staff
Company: Medlife
Address: Delhi

Tel: 123987457
Email: staff@medlife.com

2. 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.

Feeling Discomfort in Chest. Getting Tired Quickly

If the device is an implantable device indicate both implant date and explant dates: (Known):

* **Implant Date:** 25/06/2025
* **Explant Date:** 9/06/2025

3. Healthcare Facility Information

Name: Fission
Address: Hyderabad

Tel: 1122334455
Contact name at site of the event: Fission

4. Device Information (Primary Device)

Generic Device Information

Sponsor: NewSonsor
Device WAND number: 123456
GMDN Code: AFGHT
GMDN Code Text: Hyderabad

Specific Device Information

Brand name: Samsung
Model #: S24
Software version: Win7
Serial or Lot #s: 123456

Manufacturer: Japan
Manufacturer Contact Name John
Address: Singapore
Tel: 1231231234
Email: john@gmail.com

Operator of Device at Time of Event

HCP: ☒ **Other Caregiver:** ☐ **Patient:** ☒ **N/A:** ☐

Use of Device

Single use: ☒ **Reuse of single Use:** ☐
Reuse of Reusable: ☐ **Re-serviced/Refurbished:** ☐

Device Disposition/Current Location: Hyderabad

5. Results of Manufacturer's Investigation

Manufacturer's Device Analysis Results

(Specify, for this event, details of investigation method, results, and conclusion):

Prescribed Some tests to be done

Remedial Actions/Corrective Action/Preventive Action

(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):

Take Medicines on Timely. Take proper Rest and Healty Food

6. 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 regarding orthopaedic implants – The reporter should exercise judgement when filling these fields.)

*Age:	*Wt.(kg):	*M/F:
25	70	Male

Patient focused Resolution of Event and Outcomes

Corrective action taken relevant to the care of the patient:
Healthy Food

Patient history (co-morbidities & medication):
No

Description of harm caused to the patient:
Chest Pain

Patient outcome:
Recovering

List of other devices involved in the event:
If other implants involved – list brand, model & WAND number.
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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):
N/A

Country where these similar adverse events occurred:
N/A

Additional comments:
N/a

Submitting this report:

Compliance Management Branch, Medsafe, PO Box 5013, Wellington, 6145.

Email: devices@health.govt.nz

Send this form to devices@health.govt.nz.

Guidance

Harm definitions

Serious injury
An injury which meets any of the criteria:

- life threatening illness or injury has occurred or is likely to have occurred.
- permanent impairment of a body function or permanent damage to a body structure
- an unexpected condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

Minor injury
An injury which does not meet the criteria of serious as defined above occurred or is likely to have occurred.

Quality issue
If an issue is related to the quality of a medical device, but no serious injury occurred (i.e. no one was harmed by the device), and it is unlikely that a serious injury could have occurred, you can still report this to us using this form.

Report types

Initial*:* The first report that the reporter (sponsor, manufacturer) submits about the event. Submit this report if the investigation is not yet complete and the final report not available.

Follow-up*:* Where required, to provide an update to a previous report.

Final*:* Submit this report when the investigation is complete. For "minor injury" or "quality issue", where possible submit a final report only, once the investigation is complete.

if you are referring to an existing corrective action, please quote the Medsafe reference number.

Clinical event information
The event description should include sufficient details to allow a clear understanding of the event, this could include:

- What procedure was being undertaken at the time?
- Who was using the device at the time
- Was the device being used according to the IFU

Manufacturer's investigation
This investigation should include details such as:

- Rates of occurrence of similar adverse events, both within New Zealand and worldwide as appropriate.
- Is this potentially a quality issue which would affect other devices?
    - Is this event a known issue with the device, and is it described in the IFU?
    - Where the device cannot be returned from the healthcare facility, consider other ways to evaluate it, for example photographs, x-rays, visiting the facility, detailed description of the device from the healthcare facility. It's not acceptable not to investigate only on the basis that the device was not returned.
    - The investigation should be completed with technical input from a product specialist who is familiar with the device.
    - If the healthcare facility/professional has not provided you with some information, describe the efforts you have made to communicate with them and get info.

Patient information
Critical information that should be provided includes:

Send this form to devices@health.govt.nz.

- Age, weight and gender
- implant and explant date, or estimated duration of the implanted device (ADD FIELD - or, duration of implant.

Send this form to devices@health.govt.nz.