

was reported that after the cyclone hit, the device would not

Medical Device Incident Report – For use by industry 1. Administrative Information If the device is an implantable device indicate both implant date Report Category (see definitions on page 3) and explant dates: (Known): * Implant Date: 25/06/2025 * Explant Date: 09/06/2025 **Death/Serious Injury** |X|Please submit an initial report as soon as possible, 3. Healthcare Facility Information and within 10 calendar days. Submit a final report once the investigation has Name: Fission been completed. Address: Hyderabad Tel: 1122334455 Minor injury X Quality issue Contact name at site of the event: Fission Please submit a report within 120 calendar days. Where possible, submit only a final report, once the investigation has been completed in full. 4. Device Information (Primary Device) If there could be a market action as a result of this **Generic Device Information** incident, submit within 10 working days. Sponsor: NewSonsor **Device WAND number: 123456 GMDN Code: AFGHT** Report Type (select one) **GMDN Code Text: Hyderabad** Final: □ Initial: Follow up:⊠ Date of this report: 11/06/2025 Date of adverse event: 10/06/2025 **Specific Device Information** Date manufacturer aware: 02/06/2025 Final report target date: 08/06/2025 Brand name: Samsung Model #: S24 **Person Submitting This report** Software version: Win7 Serial or Lot #s: 123456 Name: Staff Company: Medlife Manufacturer: Japan Address: Delhi Manufacturer Contact Name John Address: Singapore Tel: Email: Tel: 123456789 1231231234 staff@medlife.com Email: john@gmail.com 2. Description of the clinical Event / Problem Operator of Device at Time of Event 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. HCP: ⊠ N/A: □ Other Caregiver: Patient: ⊠ It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the **Use of Device** device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported Single use: ⊠ Reuse of single Use: \Box that after the cyclone hit, the device would not power on.It

Reuse of Reusable: \Box

Re-serviced/Refurbished:

power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on.It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on.It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on.It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on.It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the de

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):

Type of investigation is not yet determined. Type of investigation is not yet

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: 30 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

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

determined. Type of investigation is not yet determined. Type

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

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