**ADVERSE EVENT REPORT. (Consumers)**

Use this form to report an Adverse Event associated with the use of a medical device.

Fill in as much of this form as you can and don’t worry if you don’t know everything. If you give permission at the end of the form, Medsafe will be able to contact the healthcare provider to request the additional information.

**If you need assistance to complete this report please contact + 64 4 819 6800 to speak to a Medical Device Advisor.**

* Today’s Date: Click here to enter a date.
* Are you the person that suffered the adverse event? [ ]  Yes [ ]  No
* If no: what is your relationship to the person that experienced the adverse event?

Click here to enter text.

ALL PERSONAL INFORMATION WILL REMAIN CONFIDENTIAL TO MEDSAFE.

**PART ONE: About the medical device that might have caused the adverse event**

*Please provide as much information in this section as you can. If you still have the medical device please keep it safe as it may be required for further testing.*

**1. Name of the device:** Click here to enter text.

Brand: Click here to enter text.

Description: Click here to enter text.

Catalogue Number: Click here to enter text.

Lot Number: Click here to enter text.

**2. Where did the device come from?**

[ ] Surgeon [ ] Nurse [ ]  Pharmacy [ ] DHB [ ] Private Hospital [ ]  Retailer [ ]  GP surgery [ ] Clinic [ ]  Other (e.g., mail order/ internet) Click here to enter text.

**3. What illness or medical problem was the device being used for?**

Click here to enter text.

**4. Date the person first started using the medical device** (approximate date if actual date not known)**:** Click here to enter text.

**5. Are you reporting an adverse event for an implantable device?** [ ]  Yes [ ]  No

Was the implantable device intended to be a permanent implant? [ ]  Yes [ ]  No

Complete the table below if you are reporting an adverse event which may have been caused by an **implantable device**. It is important to give us as much detail as possible about the device.

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of implant** | **Place/facility where the implantation was done** | **Date of implantation*****(dd/mm/yyyy)*** | **Date of explantation (if applicable)*****(dd/mm/yyyy)*** |
|  |  |  |  |
|  |  |  |  |

**6. Has anyone else been notified about the adverse event?** [ ]  Yes [ ]  No [ ]  Don’t know

If YES please provide the name and contact details of the person advised:

Click here to enter text.

**PART TWO: About the Adverse Event.**

**1. When did the Adverse event occur:** Click here to enter a date.(approximate date if unknown)

**Tell us what happened:**

Click here to enter text.

**2. Please provide information on the severity of the adverse event and how the patient’s life has been affected?**

Click here to enter text.

**3. Has anything changed since the adverse event occurred (**e.g. revision surgery)?

Click here to enter text.

**4. Is there anything else you would like to tell us?**

Click here to enter text. (If completing this form as hard copy, continue on separate sheet if required).

**PART THREE: About the Person that had the Adverse Event.**

ALL PERSONAL INFORMATION WILL REMAIN CONFIDENTIAL TO MEDSAFE.

**1. Name (optional) or Initials:** Click here to enter text.

**2. Age at time of adverse event:** Click here to enter text.

**3.** [ ]  **Male** [ ]  **Female**

**4. Weight:** Click here to enter text. **Height:** Click here to enter text.

**5. Is there anything else we should know?** (eg, other medical conditions/ consequences/ outcome)

Click here to enter text.

**PART FOUR: About the person that used the Medical Device or implant. (Optional)**

**1. Doctors / health professional/surgeon’s name:**Click here to enter text.

**2. Practice or Hospital name:**

Click here to enter text.

**3. If we need more medical information, do we have the patient’s permission to contact the doctor/hospital/clinic directly?**

[ ]  Yes [ ]  No

**PART FIVE: About the person completing this report.**

**1. Title:** Click here to enter text. **Full name:** Click here to enter text.

**2. Postal Address:**

Click here to enter text.

**3. Phone:** Click here to enter text.

**4**. **Email:** Click here to enter text.

**5. Can Medsafe contact you to ask for further information if needed?** [ ]  Yes [ ]  No
**Preferred contact method:** [ ]  Phone [ ]  Email [ ]  Post

POST TO: Compliance Management Branch, Medsafe, PO Box 5013, Wellington, 6145.

EMAIL TO: devices@moh.govt.nz