#

# ADVERSE EVENT REPORT – Healthcare Professionals

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

ALL PERSONAL INFORMATION WILL REMAIN CONFIDENTIAL TO MEDSAFE.

## PART ONE: About the person completing this report

|  |  |
| --- | --- |
| **Date of Report:** | Click here to enter a date. |
| **Date of Adverse Event:** | Click here to enter a date. |
| **Reporter’s Name:** | Click here to enter text. |
| **Position/Occupation:** | Click here to enter text. |
| **Reporting Organisation:** | Click here to enter text. |
| **Address:** | Click here to enter text. |
| **Telephone number:** | Click here to enter text. |
| **Email address:** | Click here to enter text. |
| **Consultant in charge (if known):** | Click here to enter text. |

## PART TWO: About the medical device that caused the adverse event

*Please provide as much information as possible.*

|  |  |  |
| --- | --- | --- |
| **Type of Device:** | Choose an item. | If other, please specify |
| **Brand/Trade name:** | Click here to enter text. |
| **Name of the device** (including model/serial/lot or batch number, if known) | Click here to enter text. |
| **Manufacturer’s details:**  | Click here to enter text. |
| **Supplier’s details:** | Click here to enter text. |
| **Expiry date:** | Click here to enter a date. |
| **Is this device supplied sterile?** | Choose an item. |
| **Is the product an implanted medical device?** | Choose an item. | **If so please provide the following:** |
|  | **Type of implant:** | Click here to enter text. |
|  | **Date of implantation:** | Click here to enter a date. | **Date of explantation:** | Click here to enter a date. |
| **Current location of the device:**  | Click here to enter text. |
| **Have you contacted the manufacturer/supplier** | Choose an item. | **If so please provide the following:** |
|  | **Date contacted:** | Click here to enter a date. |
|  | **Name of contact person** (if known) | Click here to enter text. |

##  PART THREE: About the person who had the adverse event

|  |  |
| --- | --- |
| **What was the device used for?** | Click here to enter text. |
| **Name (optional) or initials:** | Click here to enter text. |
| **Age at time of adverse event:** | Click here to enter text. |
|[ ]  **Male** |[ ]  **Female** |  |
| **Weight:** | Click here to enter text. | **Height:** | Click here to enter text. |
| **Is there anything else we should know?** (eg, other medical conditions, consequences, outcomes) | Click here to enter text. |
| **Details of incident/nature of device defect:** | Click here to enter text. |
| **Details of injury to patient, carer or healthcare professional:** | Click here to enter text. |
| **Action taken** (includes any action by patient, carer, healthcare professional, manufacturer/supplier) | Click here to enter text. |

## PART FOUR: Other information

|  |  |
| --- | --- |
| **Can Medsafe contact you to ask for further information if needed?**  | Choose an item. |
| **Preferred contact method:**  | Choose an item. | If other, please specify |

Thank you for taking the time to complete this form.

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

EMAIL TO: devices@health.govt.nz