Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

About the search results: DAEN - medical devices

Database of Adverse Event Notifications

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There are two types of search results:

- Medical device summary (#medical-device-summary)
- List of reports (#list-of-reports)

Medical device summary

The medical device summary provides general details of the reported medical device/s involved in each report in the order of report date.

Heading	Description
Report number	A unique number that provides a reference to a particular report.
Report date	The date that TGA received the finalised report. This date does not necessarily reflect the date of the adverse event. Although reports are often received soon after an adverse event has occurred, there are occasions, often in response to the publicising of a particular adverse event, that the TGA continues to receive reports of adverse events many years after they occurred.
Trade name	The trade name is the name under which the medical device is sold. This is also known as the brand name.
Sponsor	The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.
Manufacturer	The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

ARTG number	The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.
GMDN term	A description of the medical device as defined by the Global Medical Device Nomenclature system.

List of reports

The list of reports details provides further details of the reported medical device/s and a description of the adverse event for each report (de-identified) in the order of report date.

Heading	**Description**
Report number	A unique number that provides a reference to a particular report
Report date	The date that TGA received the finalised report. This date does not necessarily reflect the date of the adverse event. Although reports are often received soon after an adverse event occurred, there are occasions, often in response to the publicising of a particular adverse event, that the TGA continues to receive reports of adverse events many years after they occurred.
Trade name	The trade name is the name under which the medical device is sold. This is also known as the brand name.
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Manufacturer	The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.
ARTG number	The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.
GMDN term	A description of the medical device as defined by the Global Medical Device Nomenclature (https://www.tga.gov.au/node/282893) system.
Device classification	The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

	For medical devices, see the Australian Regulatory Guidelines for Medical Devices (https://www.tga.gov.au/node/289305) (ARGMD) Part 1 – Section 4 for more information. For IVD medical devices, see Classification of IVD medical devices (https://www.tga.gov.au/node/285099) for more information.
Sterile	The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.
Single use	The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.
Model number	The alphanumeric code assigned by the manufacturer to identify a specific product type. The presented identification number may represent a model, catalogue or part number.
Software version	The alphanumeric code assigned by the manufacturer to identify a specific release of a program.
Event description	A description of the adverse event.
Reported event outcome	A description of the outcome reported to have been caused by the adverse event.
Report source category	A general category describing the type of person who made the report.
Event type	General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 (https://www.tga.gov.au/node/289292) - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.
Other medical devices reported as being used	A list of other medical devices reported to be associated with the adverse event.

The Database of Adverse Event Notifications - medical devices is updated monthly and the search page reflects the date of the most recent update. Reports generated on different days may be different, even if the same date range is searched, because the TGA receives follow-up information from reporters that leads to reports being updated in the database.

Topics:

Safety (https://www.tga.gov.au/safety/safety)