Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Instructions for searching the DAEN - medical devices

Database of Adverse Event Notifications

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On this page

When searching the database please select:

1. medical devices
2. date range

There is also an advanced search option where you can restrict your search to particular International Organization for Standardization (ISO) event types.

Medical devices

Once you have typed the first three characters from a trade name, sponsor, manufacturer, Global Medical Device Nomenclature (GMDN) term (device descriptor e.g. 'hip', 'pump' etc.), or an ARTG number, a list of options will be displayed showing, in order, manufacturer, trade name and the GMDN term shown in brackets.

Select the medical device/s you want to search for by ticking or unticking the boxes.

More information on medical device searches

Searches on trade names, sponsor, manufacturer, GMDN terms, and ARTG numbers will produce different results in most cases.

- Trade name and ARTG number searches are more suitable for conducting specific medical device searches. If you are unsure of the exact spelling of the trade name, you can enter the first few letters and search through the results.
- Sponsor searches and manufacturer searches can be used for conducting more general searches particularly where you are unsure of the trade name of a medical device.
- GMDN term searches are most suited to conducting searches on types of medical devices (for example 'hip', 'pump') which may be manufactured and/or sponsored by different companies.
- The selection of medical devices is limited to those contained within the Database of Adverse Event Notifications - medical devices.

- For searches using trade name, sponsor name, manufacturer name, GMDN term or ARTG number the list of displayed options will be filtered further as you enter additional characters.

Date range

To select a start date and end date for your search you need to choose a year, month and day. Ensure the '**to**' date is after the '**from**' date.

The Database of Adverse Event Notifications - medical devices includes reports from 1 July 2012 up to three months prior to the date of access. During this time the TGA checks these reports to ensure they are complete and accurate, and undertakes analyses of the data to check for patterns of adverse events that may indicate a safety issue.

The report 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.

Search results

There are two types of results shown in two tabs:

- **Medical device summary**

  The medical device summary provides general details of the reported medical device/s involved.

- **List of reports**

  The list of reports details contains further information on the reported medical device/s involved and a description of the adverse event for each report (de-identified).

Further information about search results is available at DAEN - medical devices: about the search results.

Advanced search

Advanced search fields are optional and allow you to specify particular ISO event type codes of interest. This will result in a narrower search. You must select a medical device and a date range before you can open the advanced search options.

Only the ISO event type codes recorded for your selected medical device/s and date range will be shown.

ISO event type codes

The ISO event type codes are from ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes. This is the international standard for categorising types of medical device adverse events and assists regulators with sharing information.

The ISO event type codes are:

1. Activation, Positioning or Separation
2. Computer Hardware
3. Computer Software

4. Connection or Fitting
5. Electrical/Electronic
6. External Conditions
7. Implantable Device Failure
8. Incompatibility
9. Infusion/Flow
10. Marking, Labelling or Instructions for Use
11. Material
12. Mechanical
13. Non-Mechanical
14. Other
15. Output Issue
16. Packaging/Shipping
17. Protective
18. Temperature
19. Unintended Function
20. Use Error

Topics: Safety