Implantable Medical Device

Summary This Information Bulletin summarises key developments in the area of implantable medical devices and outlines expected practice in NSW Health facilities

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NSW Health
INFORMATION BULLETIN

Implantable Medical Devices

PURPOSE

Implantable medical devices are commonly used as part of clinical practice across a wide range of disciplines. While there are important health benefits that can be derived from implantable devices, there are also important patient safety considerations. High profile safety issues associated with implantable devices have prompted a focus on this issue internationally and in Australia.

This Information Bulletin summarises key developments in this area and outlines expected practice in NSW Health facilities.

KEY INFORMATION

The Therapeutic Goods Administration (TGA) defines implantable and active implantable medical devices according to the *Therapeutic Goods (Medical Devices) Regulations 2002*[1].

An implantable medical device is:

a medical device (other than an active implantable medical device) that is intended by the manufacturer:

(a) to be, by surgical intervention, wholly introduced into the body of a human being, and to remain in place after the procedure; or

(b) to replace, by surgical intervention, an epithelial surface, or the surface of an eye, of a human being, and to remain in place after the procedure; or

(c) to be, by surgical intervention, partially introduced into the body of a human being, and to remain in place for at least 30 days after the procedure[2]*.*

An active implantable medical device is:

an active medical device, other than an implantable medical device, that is intended by the manufacturer:

(a) either:

i. to be, by surgical or medical intervention, introduced wholly, or partially, into the body of a human being; or

ii. to be, by medical intervention, introduced into a natural orifice in the body of a human being; and

(b) to remain in place after the procedure[2]

[1] https://www.legislation.gov.au/Series/F2002B00237
[2] https://www.tga.gov.au/resource/medical-device-patient-information-leaflets-and-implant-cards

The TGA has published an 'Action Plan' in relation to medical devices to better support patient safety. The action plan is available at Therapeutic Goods Administration website.

Key points from the Action Plan most relevant to NSW Health services include:

1. From 1 December 2021, manufacturers are required to provide patient implant cards and patient information leaflets with all implantable medical devices, as part of consumer information requirements.
2. The TGA is also progressing work relating to adverse event reporting and a Unique Device Identification (UDI) system. Further information on these activities can be found on the Therapeutic Goods Administration website.

**note that some implantable devices (e.g. sutures, staples, screws, wires, dental fillings) are exempt. Exempt devices are listed at https://www.tga.gov.au/publication/medical-device-patient-cards-and-leaflets*

Recommended actions by local health districts/networks

1. Routinely include the product name, type, model and batch code, lot number or serial number for all implantable medical devices meeting the above definition in:
   - the electronic procedure record as entered in theatre or other clinical areas implanting medical devices such as interventional radiology or cardiology; and
   - the patient's discharge summary.

   This will support patients and general practitioners having easy access to details about the implanted medical device.
2. Discuss information about the implantable medical device as part of informed consent and provide the patient with a patient information leaflet (produced by manufacturer).
3. Provide the patient with a patient implant card on discharge.
4. Routinely record explantation of devices in the electronic procedure record and discharge summary.
5. Where a relevant device registry exists, support the provision of captured information to the device registry e.g.
   - Australasian Pelvic Floor Procedure Registry
   - Australian Breast Device Registry
   - Australian Orthopaedic National Joint Replacement Registry
   - National Cardiac Registry
6. Report any suspected adverse event from an implantable medical device to the TGA *even if the event is a known complication*. Information provided to the TGA must be timely and complete.
7. Enter implantable medical device related incidents, near misses or complaints in ims+, the NSW Health incident management system, even if the event is a known complication. If the incident is specifically about the device select the principal incident type (PIT) *Device, Gases and Consumables*. Select other PITs as appropriate. Ensure documentation of device product name, type, model and batch code, lot number or serial number is included in the notification.