Government of Western Australia
Department of Health

Guideline for the release of an explanted medical device

This Guideline supports the *Release of Human Tissue and Explanted Medical Devices Policy*. The Department of Health (DOH) does not generally support the release of explanted medical devices, such as prostheses, heart valves, pacemakers and orthopaedic implants due to the associated potential public health risks. Explanted medical devices may be hazardous to the individual or to the wider public due to biological, radiological, biomedical or similar hazards. Such devices require processing for disposal in accordance with criteria appropriate to the particular device. In addition, issues associated with medical device failure or suspected adverse events may have health implications for other patients with similar implants; however, consideration may be given to specific requests, subject to the conditions at 3.4 of the Policy being met.

Scope

In scope:

- request for release of a medical device that has been removed (explanted) from an individual patient's body, to that patient, or to the requestor.

Out of scope:

- sutures, staples, dental fillings, dental braces, tooth crowns.

Note: It is not uncommon for explanted medical devices to contain some human tissue.

1. General considerations

Under Western Australian regulation, the disposal of explanted medical devices is dealt with as clinical waste. Health Service Providers (HSPs) have a duty of care to protect public health and the environment in relation to wastes. It is important that the sector ensures that there are no adverse health and environmental consequences of activities associated with waste handling, treatment and disposal. This extends to the safe disposal of explanted medical devices. In addition, medical devices that may be associated with a suspected adverse event or device failure may be required to be examined and analysed.

If unsure of an infection risk of a device, the health professional may obtain advice from infection prevention and control personnel in their Health Service. Bioengineering staff (see below) are also available to offer advice about these matters.

HSPs should ensure that appropriate records are kept for medical devices that are explanted within their facilities, including whether the device was released, disposed of, or sent to Bioengineering for examination and analysis. The additional details to be provided for an explanted medical device include:

- Device name

- Manufacturer name
- Device model
- Device batch code (if available)
- Device lot number or serial number (if available)
- Unique device identifier (if any)

2. Legislation and regulations covering the release of explanted medical devices

Neither State nor Commonwealth legislation explicitly authorises or prohibits the release of explanted medical devices to an individual; however, legislation does exist to regulate the manner in which explanted medical devices should be dealt with.

- Medical devices supplied in Australia are regulated by the Therapeutic Goods Administration (TGA) under the *Therapeutic Goods Act 1989* (Cth) which requires post-market surveillance of all medical devices. In general, medical devices used routinely in the hospital will be registered on the Australian Register of Therapeutic Goods (ARTG).
- Medical devices approved under a Special Access Scheme or for an approved clinical trial may not have ARTG registration.
- The patient does not automatically have the right to take possession or custody of the medical device if the patient's interests are at odds with clinical waste regulation, the requirements for WA Health medical device analysis, or the TGA requirements for testing.

3. Assessment of explanted medical devices

The Biomaterials and Implant Technology Section of the Bioengineering Division, located at Royal Perth Hospital (Bioengineering) provides a state-wide medical device analysis service to all HSPs to assess, investigate, record and archive explanted medical devices. It is a recommendation that all medical devices removed from patients being cared for within Health Service Provider (HSP) facilities be sent to Bioengineering for examination and, where required, investigation and analysis. The internal health courier system can be utilised for transport of devices to Bioengineering.

The Bioengineering service provides analysis of individual explanted medical devices as well as a state-wide collation of data to facilitate the identification of systemic medical device issues or failure. An explanted medical device may require examination and/or testing by Bioengineering because of a failure, potential defect or reported adverse event, with reporting to the TGA as appropriate.

- It is recommended that all explanted medical devices (not only those associated with fault or adverse events) are sent for assessment to provide an overview of device performance.
- An initial examination is conducted and medical devices are triaged for priority. Devices not marked for investigation are archived to allow future investigation if indicated.
- Bioengineering will advise the responsible surgeon, the TGA, and the manufacturer of the outcome of medical device analysis in the event of an adverse or sentinel event, or where a device failure is identified.
- Reporting of an adverse event involving an explanted medical device to the DOH Clinical Incident Management System (CIMS) remains the responsibility of the health professional, pursuant to the *Clinical Incident Management Policy*.
- Bioengineering will liaise with the manufacturer regarding return of the device if required.
- Explanted medical devices are routinely reported to approved State or National Registries (e.g. the Australian Orthopaedic Association National Joint Replacement Registry) by the

surgeon or theatre staff at the time the device is explanted, in accordance with national DOH procedures.

4. Release of an explanted medical device

Following investigation and analysis, release of an explanted medical device can be sought, by written application, from the requestor to the Director of Clinical Services at the hospital in which the patient was treated; the Director can then liaise with Bioengineering for the release of the device. This includes:

- an explanted medical device sought by the sponsor (as defined by the TGA)
- an explanted medical device sought by a requestor
- an explanted medical device sought in relation to intended legal action. In this case, the device will be documented and secured pending further investigation. The device may be released by the hospital to the responsible parties at the request of those parties.

Every device received by Bioengineering is logged into their database. All clinical data, images, component identification, communications and final report are kept in electronic records.

If an implant is released to a patient, surgeon or lawyers, this information is also saved in the implant record in the database.

Prior to release of an explanted medical device, application may be made to Bioengineering for decontamination. Any decontamination process is only surface treatment; internal components of the device may still pose an infection risk.

5. Other disposal options

In the event that the surgeon elects not to send an explanted medical device to Bioengineering, devices can be dealt with by appropriate health service clinical waste disposal methods, pursuant to the *Clinical and Related Waste Management Policy* and HSP associated local practices.

In such instances, HSPs are responsible for ensuring the appropriate recording of the disposal of the explanted device.

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