

## **Policy Applies To:**

All Mercy Hospital staff associated with the return of explantable medical devices or implants.  
External healthcare practices who utilise sterilising services at Mercy Hospital.

## **Related Standards:**

NZS4304:2002 – Management of Healthcare Waste.

AS/NZS4187:2014 – Reprocessing of Reusable Medical Devices in Healthcare Organisations.

NZS 8134.3:2008– Health & Disability Services (Infection Control)

EQUIP Standards 1.3.1 – Healthcare and services are appropriate; 1.5.2 – The infection control system supports safe practice and ensures a safe environment for consumers/patients and healthcare workers. 1.6.2 – Consumers are informed of their rights and responsibilities.

## **Purpose:**

To ensure there is an effective process to evaluate requests from patients, clinicians and medical companies for the viewing or return of explanted metalware and surgical implants.

## **Definitions:**

### ***Explanted Medical Device / Metalware Removal***

Single Use medical device such as screws, plates, nails & rods etc. which are required to be removed from the patient by a surgical procedure. This is usually performed when the metalware has “done its job” or if it is causing pain or irritation for the patient. Less commonly, metalware can be removed from the patient because there may be an infection in the bone.

### ***Faulty Medical Device or Implant including Company Product Recall***

A medical device which is intended to be implanted in a patient at the time of surgery is not functioning correctly and is not in a suitable condition to be used on a patient.

A product recall is initiated by the company and is required to be returned to the company for investigation.

### ***Patient Specific Single Use Device***

3D scanning technology allows for the creation of patient specific surgical alignment guides to be used intraoperatively at Mercy Hospital.

## **Objectives:**

- To minimise risk where metalware is being released to patients.
- To identify situations where explanted medical devices if requested can be reprocessed and returned safely to patients, clinicians and companies.
- To ensure the process for return of explanted medical devices is clear to all staff associated with this practice.
- To ensure the process for return of explanted medical devices is clear to all relevant patients

### Criteria:

All metalware items that are processed for return to a patient will be reported by the CSSD Coordinator to the Infection Prevention and Control Committee.

Explanted metalware will only be returned when:

- Sufficient surface cleaning can occur with the removal of excess bioburden of bone, blood, tissue fragments & cement. This can sometimes be difficult to achieve with complex tibial or femoral rod removal as there is a lot of bone and tissue internally within the rod. Final decision will be made by CSSD Coordinator.
- There are no safety issues identified for staff or the patient. E.g. sharp tips, handling and disposal of medical waste.
- There is no pathogen or infectious disease exposure which could pose an increased risk to the community such as but not limited to MDRO, Hepatitis, HIV, and Staphylococcus lugdunensis etc. This is also applicable to patients who have been exposed to cytotoxic materials.

If the return of explanted metalware does not meet release criteria a photo will be provided to the patient free of charge in lieu of explanted metalware.

### Evaluation:

- Company documentation associated with a recall of a product.
- Increased community infection risk or pathogen exposure including cytotoxic material by releasing the explanted metalware to the patient.
- Monthly data collection by CSSD Coordinator of photo and metalware returns to patients.
- Copies of CSSD decontamination certificates that are held at Mercy Hospital.
- Infection Prevention and Control committee report.
- Incident process
- Patient feedback
- Complaints

### Common Situations Where Requests will occur:

- The surgeon may request metalware to be returned to them if they suspect a fault with the product.
- The Surgeon or Theatre Educator may request metalware to be returned to them for teaching or patient demonstration purposes, this more commonly happens when new techniques are introduced e.g. 3D Patient Specific Devices.
- The company may initiate a product recall of an instrument or implant. This is usually due to a fault or technical issue e.g. cannot be cleaned effectively.
- The patient may request to retain possession of their metalware in lieu of a photograph. This will be identified by the patient at the time of completing the Preadmission Form (PAF) and confirmed during the preadmission phone call providing the request meets the policy criteria. This service can be offered if the risk to staff and the patient is low and will incur a \$75.00 handling and cleaning fee which is payable upon admission to main reception.

**Associated Documents:**

**External**

NZS4304:2002 – Management of Healthcare Waste.

AS/NZS4187:2014 – Reprocessing of Reusable Medical Devices in Healthcare Organisations.

NZS 8134.3:2008 – Health & Disability Services (Infection Control)

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**Internal**

Return or disposal of Koiwi Tangata/Body Parts and tissue policy

Waste Management Policy

Infectious Diseases - Patient Management

Standard Precautions

Cytotoxic Safe Handling and Disposal

Credentialing Process