POLICY FOR THE RELEASE OF HUMAN TISSUE
AND EXPLANTED MEDICAL DEVICES

INTRODUCTION

The release of human tissue, including surgically excised tissue, organs and amputated limbs, may be sought by individuals for a wide range of reasons. In addition, requests may be received by health professionals for the release of explanted medical devices such as prostheses, heart valves, pacemakers and orthopaedic implants.

Under Western Australian regulation, the disposal of human tissue and explanted medical devices is dealt with as clinical waste. As outlined in the Department of Health (DoH) Clinical and Related Waste Policy, the healthcare sector has 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 human tissue and explanted devices.

Due to the potential public health risks associated with uncontrolled transport, storage and disposal of clinical waste, the Department of Health does not support the release of human tissue or explanted medical devices.

However, under certain circumstances, consideration may be given to requests for the release of human tissue or explanted medical devices.
DEFINITIONS

Authorised delegate: the individual or senior available next-of-kin may authorise another person, in writing, to exercise their function.

Explanted medical device: a medical or surgical device previously implanted and subsequently removed.

Human fetus (Non registrable birth): a fetus less than 20 weeks gestation of pregnancy, or where the gestation of the pregnancy is unknown and the fetus weighs less than 400grams. Included in this definition is an intact or complete fetus and the remains of conception expelled from the mother’s body, or involving surgical intervention to be removed (i.e. dilation and curettage).

Individual: the person from whom the human tissue or medical device was removed. Where applicable, 'individual' may also refer to the person’s senior available next-of-kin, authorised delegate, carer or guardian.

Public health risk: includes the risk of infection to persons outside the healthcare facility and contamination of streams, wells, or other water sources affecting safe drinking water.

Senior health professional: Senior Medical Officer (preferably medical practitioner involved with care of the patient), Midwife or Senior Registered Nurse level 1-10.


Clinical Waste: Waste that has the potential to cause disease, sharps injury or public offence including sharps, human tissue waste, laboratory waste and animal waste resulting from medical or veterinary research or treatment or any other waste as specified by the WA Health facility.

Related Waste: Other wastes generated within healthcare settings which are contaminated with cytotoxic drugs or other pharmaceuticals, chemicals and radioactive materials.

SCOPE

- The policy for the Release of Human Tissue and Explanted Medical Devices applies to all public hospitals and those private healthcare facilities contracted to provide services to public patients.

- The scope of this policy includes requests for the release of tissue or devices removed from an individual’s body, to that individual. The policy does not cover tissue or organs intended for donation either during the lifetime of a person or following their death, as regulated by the Human Tissue and Transplant Act 1982.

- As teeth, hair and nails are excluded from the definition of human tissue waste in the Standards Australia AS/NZ 3816:1998 Management of clinical and related wastes, this policy does not apply to these tissues. Individuals requesting their teeth, hair and nails do not need to complete the Authorisation and Release of Human Tissue and Explanted Medical Device Consent Form (Appendix 1). However, health professionals may wish to consider the broader public health impact with regard to the release of these tissues.
<table>
<thead>
<tr>
<th>TYPE OF TISSUE / MEDICAL DEVICE</th>
<th>SOURCE: HOSPITAL / HEALTH SERVICE</th>
<th>AUTHORITY PROVIDER FOR RELEASE</th>
<th>OPTION OTHER THAN TO RELEASE TO AN INDIVIDUAL</th>
<th>LEGISLATION / REGULATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teeth, hair and nails</td>
<td>Hospital/Health Service</td>
<td>Exempt from Operational Directive (no form required)</td>
<td>View / Photograph Health Service Disposal</td>
<td>AS 1998</td>
</tr>
<tr>
<td>Tissue and organs other than products of conceptions</td>
<td>Hospital/Health Service</td>
<td>Senior Health Professional</td>
<td>View / Photograph Health Service Disposal</td>
<td>EPR 2004 HTTA 1982 OD 0259/09</td>
</tr>
<tr>
<td>Products of conception</td>
<td>Hospital/Health Service</td>
<td>Senior Health Professional</td>
<td>View / Photograph Health Service Disposal Cremation</td>
<td>EPR 2004 HTTA 1982 OP 0713/96 OP 1743/04</td>
</tr>
<tr>
<td>Explanted Devices</td>
<td>Hospital/Health Service</td>
<td>Senior Health Professional</td>
<td>View / Photograph Health Service Disposal Send to RPH Bioengineering Return to TGA / manufacturer</td>
<td>EPR 2004 TGA 1989 TGA Guidelines 2011 OP 0259/09</td>
</tr>
<tr>
<td>Explanted Devices</td>
<td>RPH Bioengineering Division</td>
<td>Director of Clinical Services, Royal Perth Hospital</td>
<td>View / Photograph Archive Return to TGA / manufacturer</td>
<td>EPR 2004 TGA 1989 TGA Guidelines 2011 OP 0259/09</td>
</tr>
</tbody>
</table>

1. THE RELEASE OF HUMAN TISSUE

1.1 Legislation and regulation covering the release of human tissue

Neither State nor Commonwealth legislation explicitly authorises or prohibits the release of human tissue to an individual. However, legislation does exist to regulate the manner in which human tissue should be dealt with, including regulation of:

- the advertisement and sale of human tissue. This is an offence under Part V of the Human Tissue and Transplant Act 1982 (WA) (HTT Act)
- excised or removed human tissue. This is dealt with as clinical waste. Clinical waste falls under the Environmental Protection (Controlled Waste) Regulations 2004 (WA) of the Environmental Protection Act 1986 (WA).

There are also a number of DoH Operational Directives setting out requirements for the management of waste, including


Any decision by a senior health professional to release human tissue to an individual must therefore consider the following.

1.2 Release of human tissue other than products of conception

1.2.1 General Considerations/ Hazards and Risks

- All requests are to be assessed by a senior health professional, preferably the senior medical practitioner, who has been involved in the care of the individual.
- Where there may be issues of grief or adjustment, any request made for the release of tissue is to be assessed in conjunction with a social worker or counsellor. Note: this clause does not relate to the considerations given to the risks, or granting of release.
- A senior health professional is only to release tissue to an individual if they are satisfied that the arrangements for transport, storage and disposal will not constitute a public health risk.
- Human tissue that is a component of laboratory waste (such as a biopsy or tissue culture) must not be released.
- Human tissue that may include a related waste component such as cytotoxic, pharmaceutical, chemical or radioactive waste must not be released.
- Human tissue that may pose a risk of infectious disease risk: including but not limited to tissue from patients suspected or known to carry Human immunodeficiency virus (HIV), Hepatitis B, Hepatitis C, or multi-resistant bacteria must not be released. See Clinical and Related Waste Management Policy - Clinical Wastes: 5.1.1 Infectious Agents.
- The storage and/or disposal methods planned by the individual are to be in accordance with DoH OD 0259/09 Clinical and Related Waste Management - Clinical Wastes except where this policy specifies minor alterations that do not adversely affect the risk mitigation process or procedure. For example, the use of sealed clear plastic bags for the transport and storage of human tissue, rather than yellow bag/container with black biological hazard marking, may be acceptable.
• If unsure, the health professional may obtain advice from infection prevention and control personnel in their Health Service.
• The outcome of any discussion must be documented in the individual’s health record with the decision clearly recorded.
• The Executive Director, or equivalent, of the facility is responsible for resolving any disputes.

1.2.2 Information for individuals requesting release of human tissue

Following a request *not ruled out* by the above hazards or risks, staff assessing the release of human tissue are to ensure that the individual is informed:

- of the associated risks to personal and public health
- of the options other than the release of human tissue to an individual, including viewing or photographing the tissue (see Appendix 2)
- of the public health obligations and (if the individual continues with the request) the appropriate means of storage and disposal of the item
- that the individual who signs the *Authorisation and Release of Human Tissue and Explanted Medical Device Consent Form* (Appendix 1) is responsible for the safe, secure storage and future disposal of the human tissue
- that the human tissue will not have been tested for pathogens, decontaminated, disinfected or preserved
- that the advertisement and sale of human tissue is an offence under the HTT Act.

The Information Sheet: Handling and Disposal of Human Tissue (Appendix 4) may support the provision of this information.

1.2.3 Preparation for the release of human tissue

If satisfied that the arrangements for released tissue will not constitute a public health risk, it is the responsibility of staff releasing the tissue to ensure:

- the human tissue is double bagged and sealed to prevent leakage
- the bagged human tissue is placed in a rigid walled leak-proof container for the purpose of storage and transport
- the container is dated and labelled “Human tissue for collection by <insert name of individual>”
- the contained human tissue is refrigerated as soon as possible in a non-food storage fridge until collection by the individual
- the container is not re-opened on hospital premises unless further clinical examination is required
- the individual has received information about the safe disposal of the human tissue, and completed the *Authorisation and Release of Human Tissue and Explanted Medical Device Consent Form*
- this consent form must be signed by the individual and the senior health professional. The original form is to be retained in the patient health record of the person to whom the human tissue pertains.
1.3 Release of products of conception

It is recognised that products of conception including placental tissue may be of special significance to an individual following a birth. While any public health risk must still be taken into account as set out in 1.2.1 General Considerations/ Hazards and Risks, a request for the release of placenta may be regarded as a special circumstance under which the release of human tissue may be considered.

Similarly, the death of a human fetus (see Definitions) may be regarded as a special circumstance under which the release of the body from a healthcare facility to an individual may be considered.

1.3.1 Preparation for the release of a placenta

Requests to release a placenta should be discussed with the midwife, obstetrician and operating room staff prior to the birth or operative procedure when possible.

Patient information should still be provided as per 1.2.2

If the senior health professional is satisfied that the arrangements for released tissue will not constitute a public health risk it is the responsibility of the midwife/nurse to ensure:

- the placenta and birth products are double-bagged and sealed in clear plastic waste bags
- the bagged placenta is placed in a rigid walled leak-proof container for the purpose of storage and transport
- the container is dated and labelled “Human tissue for collection by <insert name of individual>”
- the contained placenta is refrigerated as soon as practicable in a non-food storage fridge until collection by the individual
- the container is not re-opened on the premises unless further clinical examination is required
- the individual has received information about the safe disposal of the placenta, and completed the Authorisation and Release of Human Tissue and Explanted Medical Device Consent Form, and
- this consent form must be signed by the individual and the midwife/nurse. The original form is to be retained in the patient health record.
1.3.2 Release of a body following a perinatal death

See Operational Instruction OP 0713/96 and Operational Circular OP 1743/04.

For a human fetus of fewer than 20 weeks gestation

- There are no statutory requirements dealing with funeral arrangements following the death of a human fetus of fewer than 20 weeks gestation or of unknown gestation under 400g body weight. Nor is the birth required to be registered.
- Where hospital policy exists, funeral and cremation options should be dealt with as per hospital policy. Where facilities exist, cremation should be offered as the preferred option.
- In the event of a request for the release of the body, the senior health professional is to discuss the request with the individual and, if applicable, their partner.
- The senior health professional is to ensure the individual has received information about the safe disposal of the body, and completed the Authorisation and Release of Human Tissue and Explanted Medical Device Consent Form (Appendix 1).

For a human fetus of greater than 20 weeks gestation

- Cremation or funeral arrangements must be made. See Operational Instruction OP 0713/96.
2. THE RELEASE OF EXPLANTED MEDICAL DEVICES

Individuals are to be discouraged from taking home explanted medical or surgical devices. Explanted medical devices may be hazardous to the individual or to the wider public due to biological, radiological, biomechanical 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 may have health implications for other patients with similar implants. For these reasons, an explanted medical device is never to be released directly to an individual from an operating theatre.

2.1 Legislation and regulation 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)*. In general, medical devices used routinely in the hospital will be registered on the Australian Register of Therapeutic Goods (ARTG).
- Explanted medical devices are dealt with as clinical waste under the *Environmental Protection (Controlled Waste) Regulations 2004 (WA)* of the *Environmental Protection Act 1986 (WA)*.
- The predominant view in respect of explanted medical devices supplied and implanted by public hospitals and those private healthcare facilities contracted to provide services to public patients is that the patient owns the device (once implanted) by way of a gift, but that ownership re-vests to the Hospital once the device is explanted. Where it is determined that the patient (or the patient's estate) may take ownership of the device, once explanted, it does not necessarily follow that the patient has a right to take possession or custody of the device if the patient's interest is at odds with clinical waste regulation, requirements for WA Health medical device analysis or the TGA regarding testing or disposal.
- Adverse events related to use of a medical device should be reported to the TGA via its Medical Device Incident Reporting & Investigation Scheme (IRIS).
- Devices approved under a Special Access Scheme or in an approved clinical trial may not have ARTG registration. However, devices accessed under these schemes must still comply with adverse event reporting requirements.
2.2 Bioengineering Division of the Department of Medical Engineering and Physics at Royal Perth Hospital

- The Biomaterials and Implant Technology Section of the Bioengineering Division at RPH (RPH Bioengineering Division) provides a medical device analysis service to assess, investigate, record and archive explanted medical devices.
- This 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.
- All devices (not only those associated with fault or adverse events) are sought for assessment to provide an overview of device performance.
- An initial examination is conducted and devices are triaged for priority. Devices not marked for investigation will be archived to allow future investigation if indicated.
- The RPH Bioengineering Division reports to the responsible surgeon following assessment.
- The RPH Bioengineering Division reports to the TGA following assessment if this or patient clinical history indicates a possible reportable finding under IRIS (see TGA Guidelines 2011).
- Explanted devices are routinely reported to approved State or National Registries (eg. National Joint Replacement Registry) in accord with DoH procedures.

2.2.1 Referral to RPH Bioengineering Division

- It is a recommendation that all medical devices removed in public hospital operating theatres and from patients being cared for in the public system, be sent to the RPH Bioengineering Division for examination and, where required, failure analysis.
- Where an explanted medical device is sent to RPH Bioengineering Division:
  - explanted medical devices should not be cleaned for transport
  - theatre management system procedures should be followed with regard to the preparation for the transport of explanted devices
  - the internal health courier system can be utilised for transport of devices to the RPH Bioengineering Division.
- Certain medical devices (including heart pacemakers, defibrillators) are required to be returned to the manufacturer for testing in accordance with post-market surveillance arrangements agreed at the hospital level.
- Following assessment and failure analysis, release of explanted medical devices can be sought from the Director of Clinical Services, Royal Perth Hospital following written application. This includes:
  - a medical device sought by the TGA or the sponsor
  - a medical device sought by an individual
  - in the event of intended legal action in relation to an explanted device. 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.
2.3 Other disposal options

In the event that the surgeon elects to **not** send an explanted medical device to the RPH Bioengineering Division:

- devices can be dealt with by appropriate health service clinical waste disposal methods
  or
- in certain circumstances, a senior health professional may consider a request to release an explanted medical device to an individual. In this case, the following hazards and risks must be considered.

2.3.1 General Considerations - hazards and risks of release

- All requests for the release of medical devices by an individual are to be assessed by a senior health professional, preferably the medical practitioner who has been involved in the care of the patient during the patient’s stay in the hospital.
- A senior health professional is only to release an explanted device to an individual if they are satisfied that
  - the device is not defective or
  - associated with an adverse event or near adverse event (see below) and
  - the arrangements for transport, storage and disposal will not constitute a public health risk.
- Consideration should be given to any sharps hazard.
- An explanted device that may include a related waste component such as cytotoxic, pharmaceutical, chemical waste or radioactive waste must not be released.
- An explanted device that may pose an infectious disease risk: including but not limited to tissue from patients suspected or known to carry Human Immunodeficiency Virus (HIV), Hepatitis B, Hepatitis C or multi-resistant bacteria must not be released. See Clinical Waste Policy: 5.1.1 Infectious Agents.
- Storage and/or disposal methods planned by the individual are to be in accordance with the DoH OD 0259/09 Clinical and Related Waste Management - Clinical Wastes except where this policy specifies minor alterations that do not adversely affect the risk mitigation process or procedure. For example, the use of sealed clear plastic bags and container, rather than yellow bag/container with black biological hazard marking, may be acceptable for the transport and storage of an explanted medical device.
- If unsure, the health professional may obtain advice from infection prevention and control personnel in their Health Service.
- RPH Bioengineering staff are also available to offer advice in respect to these matters.
- The outcome of any discussion must be documented in the health record of the person from whom the device was explanted with the decision clearly recorded.
- The Executive Director, or equivalent, of the healthcare facility is responsible for resolving any disputes.
2.3.2 Information for individuals requesting release of medical devices

Following a request not ruled out by the above hazards or risks, staff are to ensure that the individual is informed:

- about the option to have the device investigated by the RPH Bioengineering Division Biomaterials and Implant Technology service
- about options other than the release of an explanted medical device to an individual, including viewing or photographing the device, or (where feasible) provision of a similar non-contaminated device (see Appendix 3)
- about associated risks to personal and public health
- about public health obligations and (if the individual continues with the request) the appropriate means of storage and disposal of the item
- that the recipient who signs the Authorisation and Release of Human Tissue and Explanted Medical Device Consent Form (Appendix 1) is responsible for the safe, secure storage and future disposal of the explanted medical device
- that the recipient is advised that the medical device will not be tested for pathogens, decontaminated, disinfected or preserved.

The Information Sheet: Handling and Disposal Explanted Devices (Appendix 5) may support the provision of this information.

2.3.3 Preparation for the release of an explanted device

If satisfied that the arrangements for the released explanted medical device will not constitute a public health risk or circumvent reporting requirements, it is the responsibility of staff releasing the explanted device to ensure:

- the device is double bagged and sealed to prevent leakage
- the bagged device is placed in a rigid walled leak-proof container for the purpose of storage and transport
- the container is dated and labelled “Explanted Medical Device for collection by <insert name of individual>”
- the contained device is refrigerated as soon as possible in a non-food storage fridge until collection by the individual
- the container is not re-opened on the premises unless further clinical examination is required
- the individual has received information about the safe disposal of the explanted device and completed the Authorisation and Release of Human Tissue and Explanted Medical Device Consent Form.
- This consent form must be signed by the individual and the senior health professional. The original form is to be retained in the patient health record of the person from whom the device was explanted.
2.4 Explanted devices associated with a known adverse or near adverse event

- The TGA operates the incident reporting scheme, IRIS. Reporting timeframes for health professionals to report sentinel, adverse or near adverse events associated with a medical device to the TGA are set out in the TGA Guidelines 2011.
- Explanted devices associated with a known adverse or near adverse event should be sent to the RPH Bioengineering Division for failure analysis.
- RPH Bioengineering Division 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.
- RPH Bioengineering Division will liaise with the TGA regarding return of the device to the TGA or the manufacturer if required.
- Reporting of an adverse event to the DoH Clinical Incident Management System (CIMS) remains the responsibility of the health professional/surgeon.

APPENDICES

**Appendix 1**: Authorisation and Release of Human Tissue or Medical Device Form

**Appendix 2**: Flowchart - Request for the Release of Human Tissue

**Appendix 3**: Flowchart - Request for the Release of an Explanted Medical Device

**Appendix 4**: Information Sheet: Handling and Disposal of Human Tissue

**Appendix 5**: Information Sheet: Handling and Disposal of Explanted Medical Devices

BIBLIOGRAPHY

**Authorisation and Release of Human Tissue and Explanted Medical Device Consent Form**

This authorisation relates to the release of human tissue or an explanted medical device to a patient, senior available next of kin, or authorised delegate.

- The completed form must be retained as part of the Medical Records.
- This hospital / health service bears no responsibility for any use or misuse of human tissue or explanted medical devices once released to an individual from the hospital / health service premises.
- The human tissue or explanted device(s) have not been screened for infectious diseases and have not been decontaminated or sterilised.
- Where the tissue is to be buried or cremated under the management of a contracted funeral director, the funeral director is to verify the identity of the patient, senior available next of kin or authorised delegate and authorise the release of the tissue.

**A. Person authorising the release of the human tissue or explanted medical device(s)**

<table>
<thead>
<tr>
<th>Surname</th>
<th>UMRN / MRN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Given Name</td>
<td>DOB</td>
</tr>
<tr>
<td>Address</td>
<td>Post Code</td>
</tr>
<tr>
<td>Telephone</td>
<td></td>
</tr>
</tbody>
</table>

Please select if applicable:

- Funeral Director arranging funeral services on behalf of the patient / senior available next of kin or authorised delegate.

**B. Details of the patient and human tissue / explanted medical device(s)**

<table>
<thead>
<tr>
<th>Surname</th>
<th>Given Name(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Birth:</td>
<td></td>
</tr>
<tr>
<td>Description of the human tissue or explanted medical device(s):</td>
<td></td>
</tr>
</tbody>
</table>

**C. Designated senior available next of kin or authorised delegate**

*(Only complete if tissue / device is to be released to the senior available next of kin or authorised delegate)*

<table>
<thead>
<tr>
<th>Surname</th>
<th>Given Name(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>Relationship with Patient:</td>
<td></td>
</tr>
</tbody>
</table>

This is to confirm that I / we: (Please select if applicable)

- have received the stated human tissue / explanted medical device(s)
- have had the infection control risks explained to me / us and understand my / our responsibilities.
- are not aware of any other person with an interest in the human tissue or explanted medical device who does not agree with this decision, or reasons why others should be consulted (as in the case of joint custody or guardianship).

**Signature of person taking receipt of human tissue or medical device:**

_________________________________ Date: __________

**Signature of Authorising Person:**

_________________________________ Date: __________
Appendix 2: Flowchart- Request for the Release of Human Tissue

Tissue, prepared and sealed as per infection control guidelines, to be released to the individual (or where applicable the funeral director).

Consent form to be signed by individual and senior staff member.

Discuss information about the risks and responsibilities with the individual.

Funeral Director (where applicable)

Request not approved

Decision disputed - Executive Director or equivalent to make the final decision

Dispose of tissue in accordance with Department of Health Clinical Waste Management Policy

Nurse/midwife or doctor reports request to senior health professional

Senior health professional to clarify the reason of the request. If request is considered, discuss suitable options (see below) with the individual.

Arrange for counselling if required

Options

Executive Director or equivalent

Process end point

Medical
Appendix 3: Flowchart - Request for the Release of an Explanted Medical Device

Request for the release of an explanted medical device

Nurse / doctor reports to senior health professional / surgeon

Arrange counselling if required

Surgical Removal

Return to manufacturer for post-market surveillance as per hospital agreement

*Recommended option*

RPH Bioengineering Division (for investigation and reporting)

Device archived or disposed of in accordance with DoH Clinical Waste Policy

Device prepared and released to the TGA or manufacturer

Not Approved

Decision disputed - Executive Director or equivalent to make final decision

Not Approved

Device archived or disposed of in accordance with DoH Clinical Waste Policy

Approved

*Recommended option*

Surgical Removal

Not Approved

Decision disputed - Executive Director or equivalent to make final decision

Not Approved

Device archived or disposed of in accordance with DoH Clinical Waste Policy

Approved

*Recommended option*

Discuss information about risks and responsibilities with the individual.

Consent form is to be signed by the individual and senior health professional

Prepared device is released to the individual

Key / Legend

- Reporting staff
- Senior Health Professional (Registered Nurse or Midwife, Senior Medical Officer) to oversee
- Options
- Executive Director or equivalent
- Process end point
Information Sheet: Handling and Disposal of Human Tissue

Health and Safety matters
Hospital waste usually contains similar levels of bacteria and other micro-organisms to general household waste. Careful management of clinical waste including human tissue is necessary to reduce the risk of disease to the public.

Infections from hospital waste can be caused by exposure to disease-causing micro-organisms in a number of ways. These include direct contact, through the air or from a water source. The sight of human tissue may also be distressing to some people.

For these reasons, it is preferable that human tissue is not released from a healthcare facility. You may wish to discuss options other than taking home the tissue with nursing or medical staff. These options include viewing or taking a photograph of the tissue.

If you still wish to take tissue home from the healthcare facility, there are precautions to follow. These are for your health and safety as well as for others in your household and the wider public.

It is important to note that the healthcare facility will not test any human tissue for micro-organisms, disinfect the tissue or preserve it prior to release. Please also note that it is illegal to advertise and sell human tissue.

Handling and Disposing of your tissue
The tissue will be given to you in a labelled container. The container may also contain normal saline (salty water). Normal saline does not harm the skin or human tissue. It is not a preservative.

As your tissue will not be preserved, it should be:
- stored in a cool place such as a non-food refrigerator or in an esky containing ice
- disposed of, such as by burial or cremation, within seven (7) days of taking it from the healthcare facility.

You may also need to check with your local government about safe disposal of the tissue and container.

For tissue intended for burial, please make sure that:
- the tissue is to be buried with permission of the property owner
- burial is in a location not likely to contaminate a domestic or drinking water supply
- accidental excavation or removal by animals is avoided by burying the tissue at least one metre below the surface of the soil
- protective gloves are worn when handling the tissue
- the tissue is only removed from the transport container just before burial.

For disposal of the saline and the container:
- handle the container wearing protective gloves and safety glasses
- remove the lid of the container, drain the fluid into a toilet bowl and flush the toilet
- place the lid on the container and seal the container in a plastic bag for disposal.

If the circumstances for safe disposal of the tissue change, you may return the human tissue to the healthcare facility for safe disposal. Tissue presented to a healthcare facility for disposal should be double bagged and in a labelled container.

In signing the attached form you indicate that you understand the potential health risks and agree to handle the human tissue in a safe way which will not place you or others at risk.

Please consider this information carefully and keep it with the tissue to help keep you and your family safe.
Appendix 5

Information Sheet: Handling and Disposal of Explanted Medical Devices

Health and Safety matters
Hospital waste usually contains similar levels of bacteria and other micro-organisms to general household waste. Careful management of hospital waste including medical devices explanted (removed) from the human body is necessary to reduce the risk of disease to the public.

Infections from hospital waste can be caused by exposure to disease-causing micro-organisms in a number of ways. These include direct contact, through the air or from a water source. Explanted devices can pose an additional risk by causing injury such as cuts, abrasions and punctures. Wound infection is a particular concern. Devices that pose a serious ‘sharps’ or infectious risk, or contain pharmaceutical, chemical or radioactive material cannot be released.

Information about your device - Bioengineering Division of Royal Perth Hospital
Important information can be gathered from looking at how devices have worked in the human body. The Bioengineering Division of the Department of Medical Engineering and Physics at Royal Perth Hospital (RPH Bioengineering Division) runs a medical device investigation service that collects and researches information about explanted devices. This service may also be able to provide information about your device. The medical team managing your case may wish to send your device to the RPH Bioengineering Division for specific information about your device and to also help with research about how such devices work in the human body.

For these reasons, your explanted device will not be released directly to you from the operating theatre. In addition, as the healthcare facility will not test a device for micro-organisms, disinfect or preserve a device prior to its release, it is strongly preferred that explanted medical devices are not released to individuals direct from a healthcare facility.

If you are still keen to take your device home you can apply to the RPH Bioengineering Division to release the device following its investigation and decontamination. In some cases it may be important for the device to remain with the Bioengineering Department. However, there are also other options that the RPH Bioengineering Division can arrange. You can discuss these options with nursing or medical staff before your surgery or apply to the Bioengineering Division.

Options other than taking home your explanted device are:

- viewing
- receiving a photograph
- receiving a similar non-contaminated device (when available).

Requests to the Bioengineering Division can be made through the Director of Clinical Services at this address.

Director of Clinical Services
Royal Perth Hospital
GPO Box X2213
Perth, Western Australia, 6001

Release of a medical device from a healthcare facility:
If you still request the release of an explanted medical device that has not been assessed or decontaminated through the RPH Bioengineering process, please be aware that the safe, secure handling and storage of the device will be your responsibility.

In signing the attached form you indicate that you understand the potential health risks from the explanted medical device, including infection and injury, and agree to handle the medical device in a safe way which will not place you or others at risk.