



## **PATIENT INFORMATION SHEET AND CONSENT FORM**

### Authorisation and Release of an Explanted Medical Device

#### **Health and Safety matters**

Hospital waste including medical devices removed or explanted from the human body usually contains similar levels of bacteria and other micro-organisms to general household waste. We need to manage hospital waste, including explanted medical devices carefully to reduce the risk of disease to the public.

This Information Sheet explains the risks of receiving and/or keeping explanted medical devices. Before you decide whether or not you want to keep your medical device, it is important that you also understand these risks and why information collected about your device could be useful to you and others.

Please take the time to read the information carefully and discuss it with others if you wish. Ask questions of your health professional if anything is unclear or if you would like more information.

#### **1. Why do we need to keep your explanted medical device?**

Information about your device - Bioengineering Division located at Royal Perth Hospital

We would also like to keep your medical device as the device can contain bacteria and micro-organisms which we cannot easily remove. We have the equipment to handle the device safely, but you may not, so we want to protect you and your loved ones from coming into contact with potentially harmful bacteria or micro-organisms. Your explanted device will not be released directly to you from the operating theatre.

Useful information can be collected from looking at how devices have worked in the human body. The Bioengineering Division located at Royal Perth Hospital performs forensic testing on medical devices which not only can provide information about your device, but aids in research in trying to improve medical devices for future patients.

#### **2. What are the risks to me if I take my explanted device home?**

Infections can be acquired from hospital waste in a number of ways. The hospital will not test any explanted medical device for micro-organisms. It will not disinfect it prior to release.

Unfortunately, disease-causing micro-organisms are not the only problem and many of the medical devices have sharp edges or are rough and may cause cuts or scratches. These can become infected if not handled safely.

### **3. I still want to take my implant home. Who should I contact?**

If you are still keen to take your device home, you can apply to the Director of Clinical Services to release the device. The device should be investigated and decontaminated by Bioengineering before release. In some cases, it may be important for the device to remain with the Bioengineering Department. There are also other options that the Bioengineering Division can arrange, including:

- viewing
- receiving a photograph of the device
- 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 WA 6847

If you still want your explanted medical device, please be aware that the safe, secure handling and storage of the device will be your responsibility.


### **4. What should I do if I want to discuss this further before I decide?**

When you have read this information, your treating senior health professional will discuss it with you and answer any queries you may have.

**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.**

**Authorisation and Release of an Explanted Medical Device  
 Consent Form**

[To be used in conjunction with the Patient Information Sheet]

 <p>Government of <b>Western Australia</b>          Department of <b>Health</b></p> <p>Hospital _____</p>	Surname of the Patient	UMRN / MRN	
	Given Name of the Patient	DOB	Sex
	Address	Telephone	Post Code
	Description of Medical Device, including manufacturer, model, serial number.		

**This authorisation relates to the release of a medical device to a patient / senior available next-of-kin or authorised delegate. In signing the form, you indicate that you understand the potential health risks and agree to handle the medical device in a safe way which will not place you or others at risk.**

- The completed form must be retained as part of the patient’s medical record.
- Only the patient /senior available next-of-kin /authorised delegate is able to complete this consent

1. I,.....Of.....  
 .....have received the stated medical device.
2. I acknowledge that I have read the Patient Information Sheet, which explains the infection control risks of releasing a medical device, and the information has been explained to me to my satisfaction and I understand my responsibilities.
3. I understand that the explanted device(s) has not been screened for infectious diseases and has not been decontaminated or sterilised.
4. Before signing this Consent Form, I have been given the opportunity of asking any questions relating to any possible physical harm I or others might suffer as a result of handling an explanted medical device and I have received satisfactory answers.
5. I am/am not aware of any other person with an interest in the 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).
6. I acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet.

Patient/Senior available next-of-kin/authorised delegate:

Please PRINT name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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Senior health professional authorising the release:

Please PRINT name: \_\_\_\_\_

Designation: \_\_\_\_\_

Pager/mobile: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_