# Standard Operating Procedure

## Quarantine of Implantable Medical Devices Pending Biological Indicator

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### OBJECTIVES

To provide guidelines for Medical Device Reprocessing Department (MDRD) staff for quarantining implantable medical devices pending biological indicator results.

### APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary) working within Medical Device Reprocessing.

**Note:** Site specific procedures shall be developed and followed based on the specific equipment that is used.

### ELEMENTS

1. Biological indicator testing shall be done

   Every load containing implantable devices shall be monitored by a Process Challenge Device (PCD).

   **Note:** Implants include but are not limited to:

   a) All internal fixation devices such as
      I. screws;
      II. slates;
      III. wires.
   b) Cardiac valves

2. Procedure for using BI PCD
   - 2.1 Refer to SOP for Routine Biological Monitoring Of Steam Sterilization.
   - 2.2 Clearly identify the set or package contains an implantable device as per site procedure.

3. Release of loads containing implantable medical devices
   - 3.1 Implantable devices shall be quarantined until the results of the BI have been verified as a negative (pass) or on a passed Class 5 integrator.
   - 3.2 Record results of BI as per site specific documentation requirements.

For more information contact
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4. Early release of implantable medical devices

4.1 Early release of implantable medical devices shall only be used in situations when there is an urgent or unplanned need (e.g. trauma). Early release shall not be used to compensate for inventory shortages or scheduling problems.

4.2 The following steps shall apply when an implantable device needs to be released prior to the BI results being available.

a) The BI test pack shall be opened and the Class 5 integrator checked to confirm the cycle has passed and the BI vial incubated and recorded as per site procedure.

b) Confirm cycle parameters have been met.

c) Complete Section A of the Exception Form for Premature Release of Implantable Medical Device/Set and send form with the prematurely released device/set.

d) Release implantable medical device to the Operating Room with appropriate sterilization records and documentation.

e) Notify OR of the results of the BI; OR will document result on the Premature Release of Implantable Medical Device/Set Release Form.

## DEFINITIONS

None

## REFERENCES

- Non-Alberta Health Services documents
  - *B.I PCD manufacturer's instructions for use*
  - Canadian Medical Device Reprocessing. (Canadian Standards Association) (CAN/CSA Z314-18)

## VERSION HISTORY

| Date | Action taken |
|---|---|
| November 2018 | Initial approval |
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## APPENDIX 1

### EXCEPTION FORM FOR PREMATURE RELEASE OF IMPLANTABLE MEDICAL DEVICE/SET

**Note**: In a documented emergency situation, implantable devices may be released from quarantine from the Medical Device Reprocessing Department without the biological indicator result. This form shall accompany the implantable device/tray to the Operating Room. Operating Room personnel shall complete this form and return it to Medical Device Reprocessing once surgical procedure is completed.

### ALL INFORMATION MUST BE COMPLETED:

*Section A to be completed by MDR personnel and Section B to be completed by OR personnel requesting early release.*

| SECTION A | | |
|---|---|---|
| Date: | | Time: |
| Medical Device Reprocessing Personnel Completing This Report | | |
| Signature: | | |
| Cycle Time | | |
| Cycle Temp | | |
| Cycle Type | | |
| The following implantable medical device was prematurely released to the Operating Room: | | |
| Implant Identification Number: Click here to enter text.Describe the device: | | |
| Result of class 5 chemical indicator located in the B.I PCD (please circle one) | | |
| PASS | | FAIL |
| **SECTION B** | | |
| Name (OR): | | |
| Designation: | | |
| Surgeon: | | |
| Results of internal chemical indicator *(please circle one)* | PASS | FAIL |
| Implant Identification number: | | |
| **SECTION C** | | |
| Result of B.I. *(please circle one)* | PASS | FAIL |
| Patient Identifier: | | |
| Name: | ULI #: | |
| Reason premature release of implantable devices was required: | | |
| What could have prevented premature release of this device/set? | | |

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