I. POLICY STATEMENT

To ensure proper handling of all explanted devices.

II. PURPOSE

UMHHC has established a process for the proper handling of explanted devices to ensure patient safety and to comply with federal and state laws governing the use and disposal of these devices.

III. DEFINITIONS

Device: Any instrument, apparatus, or other article that is used to prevent, diagnose, mitigate, or treat a disease or to affect the structure or function of the body, with the exception of drugs. These include but are not limited to ventilators, monitors, dialyzers, and any other electronic equipment, implants, thermometers, patient restraints, syringes, catheters, in vitro diagnostic test kits and reagents, disposables, components, parts, accessories and related software.

Implant/Explant Device Definition: A device that is "placed into/out of a surgically or naturally formed cavity in the human body" is an implant/explant. These devices are totally encased by the human body. Any external component must not form a physical connection to the device.

Trackable Explanted Devices: Explants as indicated by the Food and Drug Administration (FDA) Guidance on Medical Device Tracking.

Non-trackable Explanted Devices: Explants not listed by the FDA Guidance on Medical Device Tracking.

Defective Explanted Device: the failure of a device to perform or function as intended, including any deviations from the device's performance specifications or intended use.

End of Life/Use: The time that a device is no longer in use. If there is elective removal of a device, this is "end of use". If the device has a battery and the battery is dead, this is "end of life".

Recalled Device: Removed upon the request of the manufacturer or the FDA.

Serious Illness or Injury:

1. Is life threatening
2. May result in permanent impairment of a bodily function or permanent damage to a bodily structure.
3. May necessitate immediate medical or surgical intervention to preclude permanent impairment
or a bodily function or permanent damage to a bodily structure.
4. Examples include but are not limited to: burns, temporary brain damage, loss of fingers or damage to organs, deafness, loss of limb, an eye, a kidney or a lung, paraplegia, blindness, or severe brain damage.

Examples of non-biological and non-electrical devices: Orthopaedic hardware (screws, plates, rods, etc.).

Designated Explant Container: A unit specific container designated for the disposal of biohazardous explants. If there is a question regarding which container to use, Biomed should be paged at 2000 or 2001.

IV. POLICY STANDARDS

A. Compliance with FDA Safe Medical Device Act 1990 for trackable explants.
B. Compliance with OSHA Infectious Waste handling laws.
C. Compliance with EPA laws on Disposal of Battery-containing devices.

V. PROCEDURE ACTIONS

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. If an explanted device has caused an injury to the patient, follow the &quot;Device Malfunction Flowchart&quot;. See Exhibit B.</td>
<td></td>
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<tr>
<td>B. Determine if the explant is trackable or non-trackable.</td>
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<tr>
<td>C. Consult with the surgeon to assess if the removal is due to infection, suspected failure/recall, end of life/use or injury.</td>
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<tr>
<td>D. Refer to the &quot;Explanted Device Flowchart&quot; to determine procedure for processing and disposition of explanted devices. See Exhibit A.</td>
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<tr>
<td>E. Trackable/non-trackable explanted devices that are suspected of failure/recall by the surgeon and have a pathological exam request will be handled as follows:</td>
<td></td>
</tr>
<tr>
<td>1. UMHHC staff documents explanted device information via an on-line explant form at <a href="http://www.med.umich.edu/i/riskmgmt/">http://www.med.umich.edu/i/riskmgmt/</a>. (Prior to submitting the form, copies will be printed for medical record, pathology and if applicable for OR coordinators or purchasing staff).</td>
<td></td>
</tr>
<tr>
<td>2. The explanted device is placed in a patient labeled zip-lock specimen bag. A copy of the explant form will be placed in the side pocket of the bag. (If the device does not fit in a zip-lock, it will be placed in a large labeled specimen container with a copy of the explant form affixed to the container with tape.)</td>
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</tr>
<tr>
<td>3. The explanted device is logged in with Pathology. After hours the device will be delivered to Central Distribution.</td>
<td></td>
</tr>
<tr>
<td>4. Pathology will examine the device, generate and fax a</td>
<td></td>
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</tbody>
</table>
| Trackable/non-trackable failure/recall, no request for pathological exam | F. Trackable/non-trackable explanted devices that are suspected of failure/recall by the surgeon that *do not* require a pathological exam will be handled as follows:

1. UMHHC staff documents explanted device information via an on-line explant form at [http://www.med.umich.edu/i/riskmgmt/](http://www.med.umich.edu/i/riskmgmt/). (Prior to submitting the form, copies will be printed for medical record, and if applicable, an OR Service Coordinator or purchasing staff).

2. The explanted device is placed in a patient labeled zip-lock specimen bag. If the device does not fit in a zip-lock, it will be placed in a large labeled specimen container.

3. The explanted device is picked up from the OR front desk by Biomed after they have been paged at #5663. Biomed will coordinate reporting with Risk Management. |
| Trackable, No failure/recall request No infection | G. Trackable devices that are *not* suspected of failure/recall and have not been removed due to infection will be handled as follows:

1. UMHHC staff documents explanted device information via an on-line explant form at [http://www.med.umich.edu/i/riskmgmt/](http://www.med.umich.edu/i/riskmgmt/). (Prior to submitting the form, copies will be printed for medical record, and if applicable, an OR Service Coordinator or purchasing staff).

2. Discard the device in a designated explant container.

| Non-trackable No failure/recall No infection not to patient | H. Non-trackable devices that are *not* suspected of failure/recall and have not been removed due to infection and have not been requested by the patient, will be handled as follows:

1. UMHHC staff documents explanted device description, quantity and disposition on the Perioperative Nursing Care Plan. An explant form is not required.

2. Discard the end of use/life device in a designated explant container. |
| Trackable/non-trackable No failure/recall Infected with request for | I. Trackable/non-trackable explanted devices that are *not* suspected of failure/recall that have been removed due to infection and require a pathological exam will be |
### Pathological Exam

<table>
<thead>
<tr>
<th>Trackable</th>
<th>Non-trackable</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No failure/recall</strong></td>
<td><strong>No failure/recall</strong></td>
</tr>
<tr>
<td><strong>Infected but no need for pathological exam</strong></td>
<td><strong>Infected but no need for pathological exam</strong></td>
</tr>
</tbody>
</table>

**Pathological Exam**

- **UHKHC staff documents explanted device information via an on-line explant form at [http://www.med.umich.edu/i/riskmgmt/](http://www.med.umich.edu/i/riskmgmt/).** (Prior to submitting the form, copies will be printed and distributed as follows: medical record, pathology, and if applicable, an OR Service Coordinator or purchasing staff).

- The explanted device is placed in a patient labeled zip-lock specimen bag. A copy of the explant form will be placed in the side pocket of the bag. (If the device does not fit in a zip-lock, it will be placed in a large labeled specimen container with a copy of the explant form affixed to the container with tape.)

- The explanted device is logged in with Pathology. A Pathology requisition is NOT required. After hours the device will be delivered to Central Distribution.

- Pathology will examine the device, generate and fax a report to Biomed at 936-8989.

- Pathology will place the device in a patient labeled zip-lock specimen bag. (If the device does not fit in a zip-lock, it will be placed in a large labeled specimen container.) Biomed will be paged at #5663 to pick up the device. Biomed will coordinate reporting with Risk Management.

- Risk Management will notify Infection Control.

**Trackable No failure/recall Infected but no need for pathological exam**

- **Trackable explanted devices that are not suspected of failure/recall that have been removed due to infection and do not require a pathological exam will be handled as follows:**

  1. UMHHC staff documents explanted device information via an on-line explant form at [http://www.med.umich.edu/i/riskmgmt/](http://www.med.umich.edu/i/riskmgmt/). (Prior to submitting the form, copies will be for the medical record, and if applicable, an OR Service Coordinator or purchasing staff).

  2. Discard the device in a designated explant container.


**Non-trackable No failure/recall Infected but no need for pathological exam**

- **Non-trackable explanted devices that are not suspected of failure/recall that have been removed due to infection and do not require a pathological exam will be handled as follows:**

  1. UMHHC staff documents explanted device information via an on-line explant form at [http://www.med.umich.edu/i/riskmgmt/](http://www.med.umich.edu/i/riskmgmt/). (Prior to submitting the form, copies will be printed and in medical record, and if applicable, an OR Service Coordinator or purchasing staff).

  2. Discard the device in a designated explant container.

Non-trackable explanted devices that are **not** suspected of failure/recall that have **not** been removed due to infection and the patient requests the device will be handled as follows:

1. End of life/use devices may be returned if they are:
   a. Non-biological
   b. Non-electrical
   c. For all other requests, contact Risk Management at 763-5456.

2. The device must be cleaned of all visible blood and body fluids.

3. Place the device in a peel pack and seal.

4. Place a patient ID label on the package.

5. Label the package as "NOT STERILE".

6. The MD releases the device to the patient.

7. UMHHC staff documents explanted device description, quantity and disposition on the Perioperative Nursing Care Plan. An explant form is not required.

### VI. CONTRAINDICATIONS/PRECAUTIONS

A. Explanted devices are **NOT** to be given directly to the patient by nursing staff.

B. Non-trackable explanted devices removed due to infection may **not** be given to the patient.

C. Explanted devices that are non-trackable, non-electrical, non-biological and have not been involved in an incident may be returned to the patient. For all other requests, contact Risk Management at 763-5456.

D. **DO NOT STERILIZE** an explant.

E. **DO NOT** place explanted devices in formalin.

### VII. Exhibits

A. [Exhibit A](#) - Explanted Device Flowchart

B. [Exhibit B](#) - Device Malfunction Flowchart

### VII. References

A. Safe Medical Device Act 1990

B. UMHHC Safe Medical Device Act Committee
C. Equipment Management Committee

D. Guidance for Industry and FDA Staff: Guidance on Medical Device Tracking, January 24, 2000
http://www.fda.gov/cdrh/modact/tracking.html

E. UMHHC Safe Medical Device Act Hospital Policy:
http://www.med.umich.edu/i/policies/umh/05-02-006.html

Authors: The Safe Medical Device Act Committee

Approved by: Environmental Safety and Security Committee, February, 2003
Approved by: Executive Director, UMHHC, May 30, 2003