



Clinical Staff Executive Committee

MEDICAL CENTER POLICY NO. 0275

A. SUBJECT: Management of Surgically Removed Body Parts and/or Implants

B. EFFECTIVE DATE: April 1, 2011 (Rvd)

C. POLICY:

The University of Virginia Medical Center disposes of explanted devices/items, explanted tissues and/or removed body parts as regulated medical waste. The Medical Center recognizes, however, that special situations and events may occur which require exceptions to general disposal practice. Examples of such situations include removal of implanted devices/items suspected of malfunctioning and requests made by a patient, the patient's guardian, or other third party for release and return of body part(s), explanted tissue, or explanted devices/items. The Medical Center has established procedures to be followed for situations that present and require exceptions to general disposal practice.

D. PROCEDURES:

A. Monitoring of Removed Implanted Devices/Items:

1. If an implanted device/item is being removed due to a malfunction or is suspected of causing injury to a patient, secure the device/item and notify Supply Chain Management and the Office of Patient Safety and Risk Management immediately by completion of a quality report via the Quality Track System. The Office of Patient Safety and Risk Management shall determine if the removal requires reporting under the federal Safe Medical Devices Act and shall coordinate such reporting as described in [Medical Center Policy No. 0165, Safe Medical Devices Act Reporting](#).
2. It is the responsibility of the Department/Clinical Service explanting any device/item that requires tracking under the federal Safe Medical Devices Act to record the available device tracking information and report the information to the manufacturer, if known. (See [Medical Center Policy No. 0165](#).)

B. Releasing of Explanted Devices/Items, Explanted Tissue and/or Removed Body Part(s):


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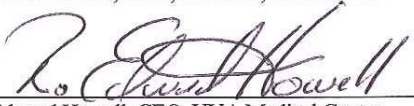
1. Explanted devices/items that are to be returned to a vendor or other third party as part of a written agreement for exchange, legal settlement, or other reason, shall be handled as specified in the written agreement. The Department/Service shall consult with the Office of Patient Safety and Risk Management prior to releasing any such item.
2. Requests made by a patient (or patient's legal guardian) to his/her physician/surgical team representative for release and return of explanted tissue/removed body part(s) **routinely** (clinically indicated) or **not-routinely** (not clinically indicated) sent to Surgical Pathology shall be managed as follows:
 - a. The physician removing the tissue/body part shall be responsible for submitting the tissue/body part to Surgical Pathology and indicating the patient's request on the Surgical Pathology Request Form that is submitted with the tissue/body part. The patient shall be informed of his/her ability to make arrangements to retrieve the tissue/body part from Surgical Pathology after a minimum 30-day waiting period from the date that the Surgical Pathology surgical case has been signed out (per College of American Pathology guidelines).
 - b. To maintain patient safety and privacy, Surgical Pathology shall process, package, and monitor all tissue/body part(s) to be returned to the patient. Any tissue/body part(s) that are returned to a patient in formalin (or other caustic agent) shall have a label attached to the container outlining the precautions to be followed for handling. Instructions shall include precautions related to formalin or other agent. Surgical Pathology shall require an **Authorization to Release Form** (see [Attachment A](#)) to be completed and signed by the patient (or legally authorized representative) to indicate his/her understanding of the information. Surgical Pathology shall send the signed release form to Medical Laboratory Administration for faxing to UVA Health Information Services and shall retain a file copy.
 - c. If the tissue/body part(s) have not been picked-up by the patient on the date agreed upon, Surgical Pathology shall keep the tissue/body part(s) up to 90 days from the date the case has been signed out. When this time expires, the tissue/body part(s) will be discarded according to general disposal practice.
3. Requests made by a patient to his/her physician/surgical team representative for release and return of an explanted device/item **routinely** sent to Surgical Pathology shall be managed as outlined in the procedure steps outlined in B.2. Above.
4. Requests made by a patient to his/her physician/surgical team representative for release and return of an explanted device/item **not-routinely** sent to Surgical Pathology shall be managed by the Department/Clinical Service as follows:
 - a. The explanted device/item shall be handled according to the policy of the Department/Clinical Service that explanted the device/item and shall include an accepted method to render the item safe (e.g. decontamination, sterilization). The Department/Clinical Service shall package the item to assure all materials that may represent a health risk to anyone coming in contact with the item have been removed and that the item is safe for handling.

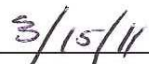
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- b. The Department/Clinical Service shall require that an **Authorization to Release Form** (see Attachment A) be completed and signed by the patient (or legally authorized representative) to indicate his/her understanding of the information. The Department/Clinical Service shall forward a copy of the signed release form to UVA Health Information Services and retain a copy for Department files.

SIGNATURE:


Robert S. Gibson, M.D., President, Clinical Staff


R. Edward Howell, CEO, UVA Medical Center


3/15/11

DATE:

Medical Center Policy No. 0275 (Rvd)
Approved January 2008
Reviewed March 2011
Approved by Operating Room Committee
Approved by Clinical Staff Executive Committee

Attachment A

UNIVERSITY OF VIRGINIA HEALTH SYSTEM



1500000

Place Label Here

If Label Not Available Write In PT Name and MR#

AUTHORIZATION TO RELEASE EXPLANTED TISSUE, DEVICE/ITEM OR BODY PART

COMPLETE THE FOLLOWING:

1. Patient Name _____

2. Medical Record # _____

3. Date of Birth _____

4. Name of Person to Receive _____

5. Address of Person to Receive _____

6. Type of Release

Tissue/Body Part (Identify) _____

Device/Item (Identify) _____

7. Handling Precautions (if applicable) _____

8. Lab Accession Number (if applicable) _____

9. Releasing Department/Clinical Service _____

10. Released By _____ Date _____

(Signature)

(Print Name)

11. Received By _____ Date _____

(Signature of Patient or Legally Authorized Representative)

Internal Use:

Provide Signed Copy to Person to Receive

Mail or Fax White Copy to: UVA Health Information Services

FAX # 924-2432

Box # 800476

Retain Copy for Department/Clinical Service File

Refer to Medical Center Policy 0275 for additional information