Purpose

To provide a method by which specimens collected during surgical procedures are labeled, stored, and delivered to the pathologist in a manner that permits tracking of the specimen from removal to disposal.

Policy

Bone, tissue, cultures, removed implants and foreign objects removed during surgery are sent to Pathology. Specimens are collected, handled and stored to maintain the integrity of the tissue for examination. (184).

Population Covered

Any patient having a surgical or invasive procedure.

Responsible Persons

Registered nurse, scrub technologist/procedure technologist; surgeon or physician.

Definitions

Specimen. Any bone, tissue, body fluids or foreign object (e.g., plates, screws) removed from the patient for pathological, microbiological, or gross examination.

Amputated limbs. A large limb is any leg amputation that includes the ankle, an arm amputation above and including the wrist joint, and revisions of amputations greater than 18 inches in length. A small limb is a foot amputation below and not including the ankle joint, toes, fingers, hand, and partial hand amputations with no wrist joint, and revisions of amputations less than 18 inches in length.

Culture. A sample taken from aerobic or anaerobic investigation.

Explant. A medical device removed from the patient because the device is no longer needed or because it is defective.

Equipment/Supplies

- Labels embossed with the patient information
- Pathology slips with applicable patient information
- Surgical schedule
- Containers and media appropriate to the case
- Specimen log
Supplemental Information

Surgical specimens collected during procedures are used to confirm diagnosis, establish boundaries for excisions, and suggest treatment. Specimen identification, collection, and handling are multidisciplinary tasks that require vigilant attention to detail so that each person in the chain of custody understands the patient’s needs and is aware of information about the specimen. Mishandling or misidentification of specimens can lead to inaccurate or incomplete diagnosis or the need for additional procedures.

Currently, Swedish Medical Center requires that all material removed from the patient’s body in surgery is submitted for pathology examination unless exempted by the medical staff. The decision to send an exempted item for examination is at the discretion of the surgeon. Only the current exempted items below may be discarded:

- Arthroscopic irrigation fluids, including debris within
- Bone fragments (e.g., femoral heads, bunionectomies)
- Cataractous lenses
- Carotid or iliofemoral endarterectomy specimens
- Dental appliances
- Disk material and/or lamina
- Extraocular muscle
- Facial skin removed for cosmetic surgery
- Fat from liposuction
- Fingernails and toenails
- Foreign bodies (unless needed for legal purposes)
- Foreskin under age 15
- Hernia sacs
- Hydrocele sacs
- Intrauterine devices
- Loose bodies removed from joints
- Medical devices removed
- Menisci
- Myringotomy tubes
- Orthopedic hardware and implants removed (must go to Pathology for disposal)
- Panniculectomy specimens
- Penile implants
- Placentas that do not meet criteria for examination
- Portions of ribs removed for exposure provided the patient does not have a history of malignancy
- Saphenous veins
- Subcutaneous tissue removed for exposure
- Surgical scars
- Teeth
- Therapeutic radioactive sources
- Thrombus from vascular repairs
- Tonsils or adenoids under age 15
A pathologist examines specimens and results are reported to the surgeon and attending physician.

It is the registered nurse’s responsibility to label and document any and all specimens collected during the surgical procedure. It is the responsibility of the pathology laboratory to notify the operating/procedure room if there are discrepancies or missing samples, according to the information on the log or requisition.

Any item identified as evidence or that is connected with a criminal investigation is handled in a manner that maintains the integrity of the specimen and chain of custody.

Medical devices removed due to apparent failure of the device must be retained by the hospital; all portions of the device are retained together, as well as the packaging if available. The device is sent for pathologic examination for identification purposes; the device is not decontaminated or sterilized before being transported from surgery. A Quality Variance Report is completed, including the reason for removal if known. The defective device must be reported to the manufacturer. [“Medical device tracking requirements.” 21 CFR (April 1, 2005), U.S. Food and Drug Administration.].

This does not include normal end of useful life items (e.g. batteries).

### Steps

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The surgical specimen is removed and identified by the surgeon.</td>
</tr>
<tr>
<td>2</td>
<td>The scrub person verifies the specimen.</td>
</tr>
<tr>
<td></td>
<td>→ The scrub person confirms with the surgeon on the name of the specimen.</td>
</tr>
<tr>
<td></td>
<td>→ The scrub person inquires which tests are to be performed by pathology (e.g. frozen section, permanent, boundaries, or margins to be checked).</td>
</tr>
<tr>
<td></td>
<td>→ The scrub person checks with the surgeon before passing the specimen to the circulating nurse.</td>
</tr>
<tr>
<td>3</td>
<td>The specimen is placed in an appropriate specimen container and delivered from the surgical field and placed in the appropriate media. The type of test to be performed determines the media in which the specimen is placed.</td>
</tr>
<tr>
<td></td>
<td>→ Telfa sheets used to collect specimens are moistened with normal saline in the specimen container; the specimen is not to be submerged or floating in saline solution.</td>
</tr>
<tr>
<td></td>
<td>→ The scrub person labels the specimen in writing on the sterile field, unless the specimen is being placed directly into a labeled container off the field.</td>
</tr>
<tr>
<td></td>
<td>→ Normal saline is used to moisten fresh specimen to prevent it from drying; the specimen is not to be submerged or floating in saline solution.</td>
</tr>
</tbody>
</table>
4. The circulating nurse is handed the specimen by the scrub person, verifies the specimen name and the tests the surgeon wants performed; if the circulator is not readily available to receive the specimen, the container is placed in a designated place off the sterile field (e.g., rolling Mayo stand).

   a. The circulating nurse labels the specimen with a patient label naming the contents of the container; specimens are labeled A, B, C, . . . to indicate the order of harvesting.

   b. A patient label is legibly marked with the name of the specimen using approved abbreviations; side-specific information must be written “right” or “left.”

   c. The circulating nurse reads back the patient’s name, name of the specimen and test to be done.

   d. The name and number of the specimen is documented on a specimen slip with any special instructions for the pathologist and other requested information (e.g., ICD-9 code, surgery date and preoperative diagnosis as determined by the surgeon, name of the circulating nurse).

   e. Specimens for disposal are labeled “FOR DISPOSAL;” the specimen is placed in the specialized bin for disposal of pathologic material.

   f. The circulating nurse documents the name of the specimen, tests to be run, destination, and transporter into the intraoperative record.

   g. During the procedure all specimen containers are placed in a common location in the operating room until they are transferred to the pathology refrigerator or taken by the pathologist.

   h. The specimen requisition form or pathology slip should accompany the specimen in a manner that protects the form and keeps it secured with the specimen.

   i. With the exception of amputated limbs, large specimens are covered in clear plastic and delivered to the pathology room.

   j. Specimens for disposal are placed in a separate container marked “For Disposal Only.” These specimens do not need to be logged into the pathology log. The charge nurse or supervisor in the OR reviews specimens for disposal before they are actually disposed of.

5. The surgeon checks the specimen record for accuracy at the end of the procedure prior to leaving the room.

6. When transported to the pathology refrigerator, a patient label is placed in the log along with the number of specimens and the name of the person placing them in the refrigerator.

**AMPUTATED LIMBS**

1. The amputated limb is securely wrapped.

   a. The exposed bone of the limb is covered with a surgical towel to prevent penetration of the plastic bag.

   b. Use two opaque plastic bags to contain the large limb; small limbs may be placed in a regular specimen bag.

   c. A patient label is placed on each bag.

   d. Place the distal end of the amputated limb in the bag first.

   e. Express air out of the inner bag and secure the top with tape; close and secure the outer bag.

2. The limb is transported and stored properly.

   a. Small limbs are placed with the routine specimens.

   b. For large limbs, call the operator for a transporter to take the limb to the morgue.

3. The circulating nurse documents the disposition of the specimen in the intraoperative record and in the log book.
CULTURES

1. When the tissue for culturing is exposed, the circulating nurse opens the package containing the sterile swab and presents the swab to the scrub person in a sterile manner.

   If aerobes and anaerobes are requested, two specimen tubes are necessary.

2. The scrub person accepts the sterile swab grasping it by the proximal end avoiding any contact with the swab or stem to any surface other than the tissue to be cultured.

   Care must be taken so that the cotton tip and stem touch only the tissue to be cultured, does not touch any other surface, and has limited exposure to the open air.

3. Once the culture is obtained, the circulating nurse removes the cap from the culture tube and presents the tube in such a manner that the scrub person can insert the swab into the tube.

4. The circulating nurse writes the source of the culture on a patient label and affixes it to the tube; a laboratory slip is completed by the circulating nurse to accompany the specimen.

5. The culture tube is placed in a plastic bag or wrapped in protective material prior to sending it to the laboratory with separate requisition.

CYTOLOGY

1. When there is fluid in addition to tissues on a case and cytology is requested on the fluid, document cytology order on the tissues requisition. Submit a copy of the requisition with the fluid specimen to Pathology.

2. If a culture is also requested on the fluid or the tissue, submit a separate sample for the culture. If that is not possible, note on the cytology requisition that a culture is needed on same sample.

CHROMOSOME ANALYSIS

1. When chromosome analysis is ordered on a tissue in addition to a tissue work-up, submit a separate piece of tissue for the chromosome analysis and a requisition for chromosome analysis.

2. If separate pieces of tissue cannot be provided, submit both tissue and chromosome analysis requisitions with tissue, noting that there is a single tissue to be used for both.

3. If culture is ordered as well, submit a separate sample for culture and separate requisition. If only one tissue is possible for all testing, submit a requisition for each test, noting on each requisition there is only one tissue being submitted for the tests being requested.

EXPLANTS

Requested by the Patient

No explant may be released to a patient if it is considered a defective medical device or if it cannot be properly decontaminated (unable to remove all visible bioburden or unable to sterilize without destroying the explant).

1. If a patient or surgeon requests to have an explant returned to them and the explant is not defective, the circulating nurse requests trained support staff to decontaminate the device in an appropriate area.

   No explant may be released to the patient unless it can be appropriately decontaminated.

2. The support staff returns the decontaminated explant to the circulating nurse.
3. The circulating nurse autoclaves the device for 10 minutes.
4. When cool, the device is placed in a specimen bag and given to the surgeon or the patient.
5. The circulating nurse documents the disposition of the explant in the intraoperative record and on a pathology slip.
6. Explanted tissue requested by the patient is considered hazardous waste and is regulated by the Department of Health. For special considerations of patient requests for this tissue, please call Epidemiology for guidance.

**Defective Implants**

1. Medical devices removed due to apparent failure of the device must be retained by the hospital; all portions of the device should be retained together, as well as the packaging when applicable or if available.
2. A **Quality Variance Report** is completed including the reason for the removal, if known.
3. **DO NOT RELEASE** the defective item to a vendor or outside source. See administrative policy **Devices or Products Suspected of Causing Patient Harm** for additional instructions on who is to receive the defective item after it leaves the OR.
4. All of this is in accordance with “Medical device tracking requirements.” CFR [April 1, 2005], US Food and Drug Administration.

**End of Life Batteries**

1. When a battery is removed for end-of-life purposes it is to be wiped down with antiseptic wipe and placed in a biohazard bag.
2. The batteries are disposed of in a designated box provided by EVS for explanted batteries with bioburden on them.

---

**Expert Consultant**

Pathology Laboratory Supervisor  
Surgery & Anesthesia Services Administration

**Author**

Renae Battie, RN, MN, Director, Intraoperative Services  
Dorothy Canavan, Manager Dynacare Laboratories/SMC Liaison  
Niki Ellington, RN, Charge Nurse, Neurosurgery  
Ruth Flint, RN MN Surgical Services

**References**