28 Medical Devices and Foreign Material

All foreign material removed from humans, whether of medical origin or not, is generally sent to pathology for documentation (with the exception of temporary medical devices such as IV catheters). Some of these specimens will be of legal significance (e.g., silicone implants, bullets) and others will be subject to legislation that requires the tracing of certain medical devices.

THE SAFE MEDICAL DEVICES ACT OF 1990

The Federal Safe Medical Devices Act of 1990 (PL 101-629) went into effect in August of 1993. This act requires manufacturers of medical devices, healthcare personnel who use or install them, and hospitals to keep records of patients and the history of specific medical device ("tracking"). This will allow manufacturers to remove devices from the market and/or notify patients should problems arise. The subsequent Food and Drug Administration Modernization Act (FDAMA) in 1997 eliminated automatic mandatory tracking for certain devices. Additional information can be found at www.fda.gov/medwatch.

The types of devices tracked include those with the following features (Box 28-1):

- If the device failed it would be reasonably likely to have serious adverse health consequences.
- The device is intended to be implanted in the human body for more than one year.
- The device is intended to be life-sustaining or life-supporting.

BOX 28–1. Current devices subject to tracking under the Safe Medical Devices Act

Permanently implantable devices:
- Vascular graft prostheses (see Chapter 16)
- Vascular bypass (assist) devices (see Chapter 16)
- Implantable pacemaker pulse generator
- Cardiovascular permanent pacemaker electrode
- Annuloplasty ring
- Replacement heart valve (see Chapter 16)
- Automatic implantable cardioverter/defibrillator
- Tracheal prosthesis
- Implanted cerebellar stimulator
- Implanted diaphragmatic/phrenic nerve stimulator
- Implantable infusion devices

Life-sustaining or life-supporting devices:
- Breathing frequency monitors (apnea monitors)
- Continuous ventilator
- CD-defibrillator and paddles

FDA-designated devices:
- Silicone inflatable breast prosthesis
- Silicone gel-filled breast prosthesis
- Silicone gel-filled testicular prosthesis
- Silicone gel-filled chin prosthesis
- Silicone gel-filled Angelchik reflux valve
- Electromechanical infusion pumps

The patient with a tracked device is allowed to refuse to release personal information for the purpose of tracking.

Pathologists play an important role in recognizing medical device-associated complications. Reports of problems with medical devices can be made on forms available at the MEDWATCH home page at www.fda.gov/medwatch. The medical device should be saved.

ORTHOPEDIC HARDWARE

All orthopedic hardware (joint prosthesis, screws, plates, etc.) is usually sent to the pathology department for documentation. The gross description includes the number, color, composition (plastic, metal), and any identifying numbers on the hardware. Any obvious cracks or worn areas should be noted. There is no need to photograph these specimens unless there is a history of trauma or there is obvious damage to the hardware. Some patients will request the return of their orthopedic hardware. The specimen will, preferably, be washed clean of blood and placed in a leakproof permanently-sealed bag before return.

FOREIGN BODIES

Foreign bodies are defined as nonmedical objects within the human body. Photographs are frequently useful because of the potential for lawsuits in some cases.

Information about illegal substances taken from a patient and submitted as pathology specimens (e.g., a bag of heroin extracted from a smuggler's GI tract) may be protected by medical confidentiality. This information should not be released to outside parties without consultation with the hospital's legal department. The legal department should also be consulted before disposal or return of such objects to patients.

BULLETS

The most important principle of handling bullets (or other specimens likely to be used as evidence in a legal case) is to establish an "unbroken chain of evidence" identifying the bullet from the time it is removed by the surgeon to the time that the bullet is released to the police. Any lapse in this procedure could be legal grounds to have the bullet removed as evidence in a trial.

DOCUMENTING THE SPECIMEN

A doctor or nurse should transfer the bullet from the operating room directly to a pathologist. The name of the people delivering and receiving the bullet and the time of transfer is documented in the report.

Do **not** touch bullets or bullet fragments with metal tools (e.g., forceps) because scratches will obscure rifling marks used to identify the gun of origin. The gross description should be detailed enough (including accurate measurements, color, size, and shape) to allow identification of the bullet at a future date, including numbers and letters if present. Descriptive terms (e.g., "conical silver metallic fragment") are preferred unless the prosector is a ballistics expert and can positively identify the specimen as a bullet (e.g., "bullet from a .32 automatic pistol"). The description could potentially become evidence in a trial.

Three photographs including the surgical number and ruler are useful for documentation. Multiple pictures may be useful if there is more information to be gained by different angles. Include any tissue submitted with the bullet. If there is soft tissue or bone present, it is submitted as a surgical specimen, up to one cassette for soft tissue and one cassette for bone.

The bullet should be kept in a locked secure storage compartment until requested by the police.

The name of the policeman or policewoman, his or her badge number, and the name of the person releasing the bullet should be documented as well as the day and time of transfer. Bullets should not otherwise be released. If a question about releasing a bullet arises, legal advice should be sought.