

Office of Origin: Hospital Epidemiology & Infection Control.

I. Policy Statement:

UCSF Medical Center has established a process whereby implanted tissue suspected or confirmed to be contaminated with infectious pathogens is identified, surveillance investigation is initiated, and notification is made in accordance with the UCSF Medical Center Product Recall Notices and Procedure, General Administrative Policy 1.01.16
<http://manuals.ucsfmedicalcenter.org/AdminManual/IndividualPolicies/ProductRecallNotices.PDF>

This policy applies to cellular-based (including synthetic) elements, tissues including, but not limited to:

Arteries	Cord blood	Skin
Artificially prepared nonhuman products made from coral.	Corneas	Sperm embryos
Bone	Dura	Stem cells
Bone marrow	Eggs	Tendons
Cartilage	Fascia	Veins
	Heart valves and conduits	

This policy does not apply to synthetic tissue products derived from plastic.

(NOTE: This policy is intended to comply with the JCAHO Standard 17.30 pertaining to implanted tissue suspected or confirmed to be contaminated with infectious pathogens.)

II. Purpose:

1. To identify implantable tissues that are at risk for transmitting communicable diseases to the potential recipients
2. To identify patients who have received implanted tissues that have been identified as contaminated or potentially contaminated, in order to offer early surveillance or treatment as necessary

III. Background:

The U. S. Food and Drug Administration (FDA) published Good Tissue (handling) Practices in late 2004, and the Joint Commission on Accreditation of Hospitals and Healthcare Organizations (JCAHO) published revised tissue standards, effective July 2005. Instances of tissue-borne infection in recipients of donor tissues are well-documented. Examples include HIV, Hepatitis B and C, Creutzfeldt-Jakob disease, rabies and others. Recipients may also contract bacterial or fungal infections through contamination of tissue products during transportation, storage, or handling.

Effective communication of an adverse event directly related to tissue use is critical to patient safety. UCSF may become aware of an adverse event directly related to tissue use through external notification or internal detection. Prompt investigation of

each event provides response and treatment to recipients affected by the infected tissue and prevents further implantation of the infected tissues.

IV. Procedure:

- A. Prevention of handling errors that could lead to pathogen growth in transplantable tissues: Other policies govern appropriate vendor selection, ordering, receiving, storing, issuing tissues, and documentation of holding temperatures of tissues. These policies include verifying packaging integrity, logging the tissue into the facility, handling it according to written instructions, monitoring and recording storage temperatures, providing for alarms and emergency backup, and complying with state and federal regulations. *Please refer to individual tissue bank policies:*
- a. IVF Lab CNC x80187
 - b. Adult BMT Lab CNC x80055
 - c. Pediatric BMT lab CNC x80181
 - d. OR Autografts CNC x80431
 - e. OR Allografts CNC x80252
- B. Surveillance of infections associated with implanted tissues:
1. Surgeons are required to report implanted tissue-related infections to Infection Control.
 2. Surgical site infections (SSI) in recipients of implanted tissue will be analyzed and reported to the Risk Management and the Infection Control Committee.
 3. Unexpected rates or distribution of SSI, or unusual or unexpected organisms cultured from said surgical sites, will be investigated and reported to the appropriate UCSF bodies, and local, state, or federal agencies as required, and to the vendor or source facility.
- C. Recall procedure (see General Administrative policy 1.01.16, Product Recall Notices and Procedures):
1. Upon notification of implanted tissue contamination, the Director of Infection Control (415-353-4343) will be notified.
 2. All remaining tissue will be sequestered by the department in possession of the tissue, along with its accompanying documentation, until notified by the Director of Infection Control or the Director of Material Services.
 3. Infection Control will contact the Director of Perioperative Services (415-353-1657) and the Director of Ambulatory Services (415-353-2242) to provide the following information of all patients who received the implicated tissue(s) for infection surveillance and follow-up:
 - a. Patient name
 - b. MRN
 - c. date of procedure
 - d. surgeon

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4. Infection Control will notify the appropriate surgeons or their offices of tissue contamination, and collect the following information:
 - a. Recipients' overall and surgical wound status
 - b. History of antibiotic use for surgical procedure follow-up.
5. Depending upon the situation, the recipient may be notified of the tissue contamination by their surgeon, primary care physician, letter sent by UCSF or other means of notification as determined appropriate by UCSF.
6. Infection Control will report investigation findings internally to the appropriate bodies, and will follow recall instructions for reporting to external agencies.

Reviewed by	Month Approved
Infection Control Committee	04/07
Quality Improvement Executive Committee	04/07

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