SUNY DOWNSTATE MEDICAL CENTER
UNIVERSITY HOSPITAL OF BROOKLYN
POLICY AND PROCEDURE

	No. LAB-5
Subject: **HANDLING OF PROSTHETIC BREAST IMPLANTS**	**Page 1 of 4**
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Approved by: Peter J. Howanitz, M.D. Anny Yeung, RN, MPA Margaret Jackson, MA, RN David Conley, MBA Michael Lucchesi, M.D. Debra D. Carey, MS	**The JC Standards:** EC.7.10,PC.17.10,PC.17.20, PC.17.30 **Issued by: Regulatory Affairs**

I. PURPOSE

To ensure proper handling of prosthetic breast implants according to rules and regulations.

II. POLICY

The departments/persons responsible for handling prosthetic breast implants removed from patients must follow the procedures below for their proper handling, storage and disposal/return. Unless litigation is pending, patients should be informed that, following the pathological examination, the explanted devices will be stored for thirty (30) days or returned to the patient upon receipt of a completed and signed hospital release form within that period. If the patient has not requested their return or if the Surgical Pathology Office (A2-467) is not otherwise notified, the explanted devices will be discarded. Notification will be accomplished, before surgery, through the University Hospital's informed consent process.

III. DEFINITION(s)

Prosthesis- Replacement or addition of a part by an artificial substitute.

IV. RESPONSIBILITIES

Surgical Pathology, Department of Surgery, Nursing.

V. PROCEDURES/GUIDELINES

A written pathology report will be produced for all explanted prosthetic breast implants. The report will include:

I.A. Pathology Report
I.A.1 Gross Examination
I.A.1.a Implant
I.A.1.a (1) Weight in grams
I.A.1.a (2) Type of external surface, e.g. smooth or textured
I.A.1.a (3) Type of implant; e.g. single lumen or double lumen
I.A.1.a (4) Contents of the implant e.g. clear viscus gel, oil, or watery fluid.
I.A.1.a (5) Condition of the implant. The report will include an indication as to the status of the outer shell: intact & dry.
- Intact but covered by slippery material.
- Focally ruptured (to include size of rupture and whether gel extrudes significantly when squeezed.
- Completely disrupted with fragmentation of the outer shell.
- Completely deflated and flat (for saline-filled devices)

NOTE: When only gel is received, a careful search should be made for small, in apparent shell fragments before concluding that the shell is missing.

I.A.1.b. (6) Presence of inscriptions to be noted on the Pathology Report, including:
- Brand name
- Size
- Serial number

NOTE: In the absence of inscriptions, a photograph or description of the back patch is recommended.

I.A.1.b. Tissue capsule
Gross examination of the tissue capsule will follow standard practice and will include:
I.A.1.b (1) Weight and/or diameter, (aggregate diameter if submitted in multiple pieces)
I.A.1.b (2) Thickness of the capsule
I.A.1.b (3) Description of the inner surface (e.g. smoothes, focally calcified, or extensively calcified)
I.A.1.b (4) Any other significant findings.
I.A.1.c Photography
Specimen photography is strongly recommended, especially for any implant that is grossly ruptured and for implants that will be returned to the patient. This may be accomplished in the Operating Room at the time of explanation or in the pathology laboratory.

I.A.2 Microscopic Examination

The tissue capsule should be sampled for histologic study. If there are no unusual findings at the time of gross examination, one (1) or two (2) cassettes from each capsule is sufficient for routine microscopic examination. Specialized techniques such as electron microscopy, energy dispersive x-ray microanalysis, and Fourier transform infrared spectroscopy to identify the exact composition of foreign materials are not routinely necessary but may be useful in selected cases. The microscopic report should include a description of the following:

I.A.2.a Breast capsule

I.A.2.b Presence and character of inflammatory reaction

I.A.2.c Description of foreign material if present

(E.g. silicone appears as refractile, non-birefringent, colorless material often found within Macrophages)

I.B. Storage of Removed Implants

All breast implants, regardless of whether they will be returned to the patient, will be handled in accordance with standard procedures for ensuring specimen identification. All explanted devices will be stored according to written institutional policies and retained for thirty (30) days.

Patients will be fully informed prior to surgery that their implants will be discarded after the period of thirty (30) days, as per institutional policy, if the patient has not requested their return. For those cases in which notification has been given that there is impending litigation, the implants will be stored indefinitely.

II.A. Return of Non-Litigation Specimens to Patients

For those implants that can be returned to the patient, a release form (see attached form) must be completed and signed by the patient. The release form must then be filed with the Surgical Pathology Report. Only after the completed & signed form is delivered to the Surgical Pathology Office (A2-467) will the implants be released to the patient or patient's representative.

The specimen will be prepared as follows:

- If there is tissue is attached to the implant, the specimen will be fixed in 10% Neutral Buffered Formalin, washed and placed in a sealed container.
- If there is no tissue attached to the implant, the specimen will be disinfected and placed in a sealed container.
- If the implant is not intact, the specimen will be placed in a sealed container.

Risks related to biohazardous materials (e.g. Formalin-fixed material, unsterilized devices) will be explained to the patient and documented on the Release Form. A fee of $10 will be charged to cover the costs associated with packaging and handling.

VI. ATTACHMENTS

None

VII. REFERENCES

Rules and Regulations of the Medical/Dental Staff

UHB-SUNY HSCB (including Amendments through Aug. 13, 1998)

Date Reviewed	Revision Required (Circle One)		Responsible Staff Name and Title
09/03	**Yes**	**No**	Alix Laguerre, Clinical Lab Administrator
11/04	**Yes**	**No**	Alix Laguerre, Clinical Lab Administrator
11/05	**Yes**	**No**	Alix Laguerre, Clinical Lab Administrator
11/06	**Yes**	**No**	Alix Laguerre, Clinical Lab Administrator
6/07	**Yes**	**No**	Alix Laguerre, Clinical Lab Administrator