

17. For all new reports of malignant breast disease following breast implantation, please provide the following information for each indication (i.e., augmentation, reconstruction, or revision):

- a. the duration following implantation when breast malignancy was diagnosed;
- b. the tissue type and severity of the malignancy;
- c. the method of diagnosis and the nature of how the diagnosis was made;
- d. whether the diagnosis resulted in breast implant removal, and if so, whether replacement was performed;
- e. the age of the patient at diagnosis;
- f. whether the patient had risk factor(s) for breast malignancy, and if so, their description; and

17 a-f Response:

In the original PMA, we reported that there were two patients with new diagnoses of malignant breast disease. We have since learned that one of these patients was a Reconstruction patient with pre-existing disease, and the database has been corrected to reflect that there was only one patient with a new diagnosis of malignant breast disease. The specific information for this patient is listed below:

Patient                      revision patient, was 46 years of age at the time of diagnosis. Diagnosis came 275 days after implantation (year 1 visit). The one year mammogram indicated a suspicious abnormality for both breasts (i.e., biopsy should be considered). The malignancy was considered severe; tissue type was not specified. The diagnosis did not result in breast implant removal. Inclusion/exclusion criteria indicated no active cancer at time of study entry. Patient had no risk factors: She never smoked, had no current alcohol use, and no family history of cancer. Patient was never pregnant, began menarche at 13 years, and has not gone through menopause. In 1984 patient underwent bilateral augmentation mammoplasty to correct for asymmetry. Patient was 46 years old

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at time of diagnosis, which was made 275 days after implantation (year 1 visit). Diagnosis was made via mammogram which indicated a suspicious abnormality in the left breast. The malignancy was considered severe; tissue type was not specified. A lumpectomy was performed on 12/24/2001. The breast implant was not removed.

- g. for those patients with a diagnosis of malignancy in the breast prior to implantation, indicate whether any reports of breast malignancy (either via patient questioning or via mammography results) following implantation are a recurrence in the same breast and of the same type of breast cancer, or whether this represents malignancy in the contralateral breast or of a different type of cancer than the original.**

17g Response:

The information pertaining to recurrent breast malignancy is included in Attachment C of this Report.