

Please refer to the definitions below when completing the Adverse Events Case Report Form.

Device Relationship: 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite

Radiation Dermatitis:

* GRADE I A=FAINT ERYTHEMA B=DRY DESQUAMATION
 ** GRADE II A=BRISK ERYTHEMA B=MOIST DESQUAMATION C=MODERATE EDEMA
 *** GRADE III A=MOIST DESQUAMATION OTHER THAN SKIN FOLDS B=BLEEDING FROM ABRASION
 **** GRADE IV A=NECROSIS OR ULCERATION OF FULL THICKNESS DERMIS B=SPONTANEOUS BLEEDING FROM INVOLVED SPOT

Seroma Cavity:

* SEROMA TYPE (SELECT ONLY ONE) 1=TRANSIENT 2=PERSISTENT 3=SYMPTOMATIC
 ** SEROMA TREATMENT (SELECT ONLY ONE) 1=DRAINAGE 2=OBSERVATION 3=OTHER, SPECIFY

Subcutaneous Tissue Change:

* GRADE I SLIGHT INDURATION / FIBROSIS / LOSS OF SUBCUTANEOUS FAT
 ** GRADE II MODERATE ASYMPTOMATIC FIBROSIS / SLIGHT FIELD CONTRACTURE <10% LINEAR REDUCTION
 *** GRADE III SEVERE INDURATION / LOSS OF SUBCUTANEOUS TISSUE
 **** GRADE IV NECROSIS

Abscess/Infection:

INFECTION LOCATION (SELECT ONLY ONE) 1=BREAST 2=AXILLA 3=OTHER, SPECIFY
 INFECTION TREATMENT (SELECT ALL THAT APPLY) 1=NONE 2=PROPHYLACTIC ANTIBIOTICS 3=ORAL ANTIBIOTICS
 4=IV ANTIBIOTICS 5=HOSPITALIZATION REQUIRED 6=SURGICAL DEBRIDEMENT
 7=FLAP COVERAGE

Skin - Late RT Changes:

* GRADE I ATROPHY / PIGMENTATION CHANGE / SOME HAIR LOSS
 ** GRADE II PATCHY ATROPHY / MODERATE TELANGIECTASIS
 *** GRADE III MARKED ATROPHY / GROSS TELANGIECTASIS
 **** GRADE IV ULCERATION