

UK adverse incident reports associated with breast implants and tissue expanders broken down by health effect (IMDRF coding)

Time Period: 01/01/2021 to 31/12/2021 (Data lock point 12/08/2022)

Table 1 – Health Effects

Annex E – Health Effects	Number of reports for breast implants	Number of reports for tissue expanders
E19 – Infections	<5	
E23 - Generalized Disorders	15	
E24 – Others / E2402 - Appropriate Term / Code Not Available	45	<5
E0110 - Decreased Sensitivity	<5	
E0116 - Headache	<5	
E0127 - Numbness	<5	
E0134 - Tactile Disorders	<5	
E0202 - Emotional Changes	78	
E0204 - Lethargy	<5	
E0307 - Seroma	36	
E0308 - Swollen Lymph Nodes/Glands	29	
E0401 - Autoimmune Disorder	26	
E0402 - Hypersensitivity/Allergic reaction	5	
E040202 - Anaphylactoid	<5	
E0404 - Positive antinuclear antibodies (ANA)	<5	
E0505 - Hematoma	<5	<5
E0701 - Adult Respiratory Distress Syndrome	<5	
E0743 - Respiratory Insufficiency	<5	
E1402 - Breast Discomfort/Pain	30	
E1403 - Breast Mass	27	<5
E1409 - Nipple Sensation Changes	<5	
E1601 - Arthralgia	<5	
E1602 - Arthritis	<5	
E1708 - Itching Sensation	<5	
E1714 - Rash	<5	
E1723 - Wrinkling	16	
E1801 - Cancer (these were further coded as either: E180101-Breast Cancer, E180102-Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA ALCL) or E180104-Lymphoma)*	21	
E1802 - Cyst(s)	<5	
E1901 - Bacterial Infection	<5	
E1906 - Unspecified Infection	15	
E1907 - Viral Infection	<5	
E2013 - Rupture	11	
E2101 - Adhesion(s)	<5	
E2107 - Failure of Implant	138	
E2109 - Implant Pain	27	
E2303 - Capsular Contracture	231	
E2308 - Deformity/ Disfigurement	53	<5
E2309 - Deposits	<5	
E2312 - Fatigue	14	
E2316 - Foreign Body Reaction	<5	
E2317 - Granuloma	9	
E2326 - Inflammation	9	
E2330 - Pain	102	
E2332 - Physical Asymmetry	<5	
E2338 - Swelling/ Edema	30	
E2340 - Wound Dehiscence	<5	
E2401 - Insufficient Information	41	<5
E2403 - No Clinical Signs, Symptoms or Conditions	26	

\* Further information on BIA-ALCL can be found here: <https://www.gov.uk/guidance/breast-implants-and-anaplastic-large-cell-lymphoma-ald>