

PROFILE Registry and FDA BIA-ALCL Data Comparison

All PROFILE Data (as of 4/8/2019) (n=103)				All MDR Reports (as of 9/30/2018 (n=660)*		All MDR Reports (as of 9/30/2018 (n=457)*	
Age at time of diagnosis (yrs)	Mean	55		Median	53		
	Range	31-84		Range	24-90		
	Not specified	n/a		Not specified (# of reports)	240 (36%)	Not specified (# of reports) 111 (24%)	
Time from the last Implant ("Current implant" for PROFILE) to ALCL Diagnosis (yrs)**	Mean	9.75		Median	8.5		
	Range	.08-27		Range	0-44		
	Not specified	26		Not specified (# of reports)	231 (35%)	Not specified (# of reports) 110 (24%)	
		N	%	N	%	N	%
Implant Surface***	Textured	81	79	425	64	310	68
	Smooth	4	4	39	6	24	5
	Polyurethane	1	1	n/a	n/a	n/a	n/a
	Not specified	17	17	196	30	123	27
Implant Fill	Silicone	55	53	399	60	274	60
	Saline	43	42	260	39	183	40
	Saline/Silicone	1	1	n/a	n/a	n/a	n/a
	Not specified	4	4	1	0	0	0
Reason for Implant	Reconstruction	50	49	119	18	108	24
	Augmentation	51	50	125	19	104	23
	Not specified	1	1	416	63	245	54
	Unknown	1	1	n/a	n/a	n/a	n/a
Clinical Presentation (breast)****	Seroma	83	81	350	53	266	58
	Breast swelling/pain	n/a	n/a	188	28	135	30
	Capsular contracture	33	32	75	11	69	15
	Peri-implant mass/lump (Palpable Mass: PROFILE)	13	13	85	13	82	18
	Rupture/deflated	n/a	n/a	n/a	n/a	54	12
	Other	n/a	n/a	226	34	43	9
	Not specified/uncertain	n/a	n/a	187	28	105	23
Anaplastic lymphoma kinase (ALK)	Positive	0	0	0	0	0	0
	Negative	77	75	239	36	229	50
	Not specified	19	18	421	64	228	50
	Unknown	7	7	n/a	n/a	n/a	n/a
CD30 Status*****	Positive	85	83	239	36	215	47
	Negative	0	0	0	0	0	0
	Not Specified	15	15	421	64	242	53
	Unknown	3	3	n/a	n/a	n/a	n/a

*Of the 660 total BIA-ALCL related MDRs the FDA received, many MDRs were identified as duplicate reports, including additional follow-up reports that were submitted to the FDA. The FDA has carefully reviewed the 660 MDRs to provide a more accurate analysis and to only provide unique BIA-ALCL reports. The resulting data reflected a total of 457 unique MDRs for BIA-ALCL.

**Includes physician-, pathology-, cytology-, or biomarker-confirmed diagnosis

***The 4 "smooth" cases reported to PROFILE had a reported clinical history of a textured device.

****MDRs and PROFILE data sometime list more than one clinical presentation, e.g. seroma and peri-implant mass/lump, in which two presentations were counted.

*****CD30 is a cell membrane protein associated with diagnosis of classic Hodgkin's Lymphoma and BIA-ALCL.