

PROFILE and FDA Data Comparison

All PROFILE Data (as of 9/4/2020) (n=174)				All MDR Reports (as of 7/6/2019 (n=573))		All MDR Reports (as of 1/5/2020 (n=733))	
Age at time of diagnosis (yrs)	Median	55		Median	53	Median	53
	Range	28-84		Range	27-90	Range	24-90
	Not specified	9		Not specified (# of reports)	161 (28%)	Not specified (# of reports)	237 (32%)
Time from the last Implant ("most recent" for PROFILE) to ALCL Diagnosis (yrs)	Median	9		Median	8	Median	8
	Range	.08-27		Range	0-34	Range	0-34
	Not specified	44		Not specified (# of reports)	169 (29%)	Not specified (# of reports)	226 (31%)
		N	%	N	%	N	%
Implant Surface*	Textured	136	78	385	67	496	68
	Smooth*	10	6	26	5	28	4
	Polyurethane	1	1	n/a	n/a	n/a	n/a
	Not specified	27	16	162	28	209	28
Implant Fill	Silicone	96	55	343	60	447	61
	Saline	62	36	197	34	248	34
	Saline/Silicone	3	2	n/a	n/a	n/a	n/a
	Polyurethane foam	1	1	n/a	n/a	n/a	n/a
	Not specified	12	7	33	6	38	5
Reason for Implant	Reconstruction	70	40	115	20	127	17
	Augmentation	88	51	111	19	118	16
	Not specified	13	7	347	61	488	67
	Unknown	3	2	n/a	n/a	n/a	n/a
Clinical Presentation (breast)**	Seroma	129	74	302	53	369	50
	Breast swelling/pain	n/a	N/A	150	26	191	26
	Capsular contracture	47	27	73	13	96	13
	Peri-implant mass/lump (Palpable Mass: PROFILE)	25	14	94	16	103	14
	Other	n/a	N/A	56	10	64	9
	Not specified/uncertain	n/a	N/A	147	26	207	28
Anaplastic lymphoma kinase (ALK)***	Positive	0	0	0	0	0	0
	Negative	124	71	255	45	298	41
	Not specified	28	16	318	55	435	59
	Unknown	22	13	n/a	n/a	n/a	n/a
CD30 Status****	Positive	147	84	246	43	289	39
	Negative	0	0	0	0	0	0
	Not Specified	1	1	327	57	444	61
	Unknown	26	15	n/a	n/a	n/a	n/a
Implant Manufacturer	Allergan includes McGhan, Inamed	107	61	481	84	620	84
	Mentor	21	12	38	7	50	7
	Sientra	7	4	6	1	10	1
	Other*****	3	2	6	1	6	1
	Unknown	1	1	42	7	47	7
	Not Reported	35	20	0	0	0	0
Reporter Country: US or OUS*****	US	174	100	320	56	384	52
	OUS	n/a	N/A	253	44	334	46
	Not Specified	0	0	0	0	15	2

*9 of the 10 "smooth" cases reported to PROFILE had a reported clinical history of a textured device. PROFILE Team in the process of following up with reporting physician to obtain additional information for the remaining "smooth" case. In the 28 cases of smooth implants reported to the FDA, 10 have unknown prior history of implants, 8 have a history of at least one textured implant, 9 have a history of prior implants with unknown texture, and 1 has a history of one smooth implant and no known textured implant. It should be noted that many MDR reports do not contain information, or contain incomplete information, on the prior implant history of the patient. Therefore, this section may be updated as new information emerges. As of January 5, 2020, there are no reports of cases associated with tissue expanders.

**MDRs sometimes list more than one clinical presentation, e.g., seroma and peri-implant mass/lump, and more than one presentation may be counted.

***As the World Health Organization categorizes BIA-ALCL as an ALK- lymphoma, reports of ALCL diagnosis with ALK+ pathology results are not included in this analysis .

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

*****Other Manufacturers include: Bristol Myers Squib, Nagor, Polytech Silimed, Silimed and Sientra/Silimed

*****US/OUS is counted as the recorded reporter's country in the MedWatch form, or if the event was noted to be from a foreign source in box G3 of the MedWatch form. Please note that the reporter country may not reflect the country where the event occurred or the country where the device is marketed.

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