

PROFILE and FDA Data Comparison

All PROFILE Data (as of 6/4/2020) (n=157)				All MDR Reports (as of 9/30/2018) (n=457)		All MDR Reports (as of 7/6/2019) (n=573)	
Age at time of diagnosis (yrs)	Median	55		Median	53	Median	53
	Range	28-84		Range	24-90	Range	24-90
	Not specified	4		Not specified (# of reports)	111 (24%)	Not specified (# of reports)	161 (28%)
Time from the last Implant ("most recent" for PROFILE) to ALCL Diagnosis (yrs)	Median	9		Median	9	Median	8
	Range	.08-27		Range	0-34	Range	0-34
	Not specified	35		Not specified (# of reports)	110 (24%)	Not specified (# of reports)	169 (29%)
		N	%	N	%	N	%
Implant Surface*	Textured	123	78	310	68	385	67
	Smooth	9	6	24	5	26	5
	Polyurethane	1	1	n/a	n/a	n/a	n/a
	Not specified	24	15	123	27	162	28
Implant Fill	Silicone	86	55	274	60	343	60
	Saline	58	37	183	40	197	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	9	6	0	0	33	6
Reason for Implant	Reconstruction	64	41	108	24	115	20
	Augmentation	83	53	104	23	111	19
	Not specified	8	5	245	54	347	61
	Unknown	2	1	n/a	n/a	n/a	n/a
Clinical Presentation (breast)**	Seroma	122	78	266	58	302	53
	Breast swelling/pain	n/a	n/a	135	30	150	26
	Capsular contracture	45	29	69	15	73	13
	Peri-implant mass/lump (Palpable Mass: PROFILE)	23	15	82	18	94	16
	Other	n/a	n/a	43	9	56	10
	Not specified/uncertain	n/a	n/a	105	23	147	26
Anaplastic lymphoma kinase (ALK)	Positive	0	0	0	0	0	0
	Negative	114	73	229	50	255	45
	Not specified	28	18	228	50	318	55
	Unknown	15	10	n/a	n/a	n/a	n/a
CD30 Status***	Positive	130	83	215	47	246	43
	Negative	0	0	0	0	0	0
	Not Specified	1	1	242	53	327	57
	Unknown	26	17	n/a	n/a	n/a	n/a
Implant Manufacturer	Allergan includes McGhan, Inamed	98	62	386	84	481	84
	Mentor	19	12	36	8	38	7
	Sientra	6	4	2	0.4	6	1
	Other****	3	2	5	1	6	1
	Unknown	1	1	28	6	42	7
	Not Reported	30	19	0	0	0	0
Reporter Country: US or OUS*****	US	157	100	276	48	320	56
	OUS	n/a	n/a	181	32	253	44
	Not Specified	0	0	0	0	0	0

*8 of the 9 "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 26 cases of smooth implants reported to FDA, 12 have unknown prior history of implants, 7 have a history of textured implants, and 7 have a history of prior implants with an unknown texture. There are no reports of cases associated with tissue expanders.

**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.

****Other Manufacturers include: Bristol Myers Squibb, Eurosilicone, 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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