

PROFILE and FDA Data Comparison

All PROFILE Data (as of 2/21/2020) (n=134)				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	54		Median	53		Median	53	
	Range	28-84		Range	24-90		Range	24-90	
	Not specified	3		Not specified (# of reports)	111 (24%)		Not specified (# of reports)	161 (28%)	
Time from the last Implant ("Current implant" for PROFILE) to ALCL Diagnosis (yrs)	Median	9		Median	9		Median	8	
	Range	.08-27		Range	0-34		Range	0-34	
	Not specified	25		Not specified (# of reports)	110 (24%)		Not specified (# of reports)	169 (29%)	
		N	%	N	%	N	%		
Implant Surface*	Textured	101	75	310	68	385	67		
	Smooth	10	7	24	5	26	5		
	Polyurethane	1	1	n/a	n/a	n/a	n/a		
	Not specified	22	16	123	27	162	28		
Implant Fill	Silicone	72	54	274	60	343	60		
	Saline	52	39	183	40	197	34		
	Saline/Silicone	2	1	n/a	n/a	n/a	n/a		
	Polyurethane foam	1	1	n/a	n/a	n/a	n/a		
	Not specified	7	5	0	0	33	6		
Reason for Implant	Reconstruction	56	42	108	24	115	20		
	Augmentation	71	53	104	23	111	19		
	Not specified	6	4	245	54	347	61		
	Unknown	1	1	n/a	n/a	n/a	n/a		
Clinical Presentation (breast)**	Seroma	106	79	266	58	302	53		
	Breast swelling/pain	n/a	n/a	135	30	150	26		
	Capsular contracture	41	31	69	15	73	13		
	Peri-implant mass/lump (Palpable Mass: PROFILE)	18	13	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	99	74	229	50	255	45		
	Not specified	21	16	228	50	318	55		
	Unknown	14	10	n/a	n/a	n/a	n/a		
CD30 Status***	Positive	110	82	215	47	246	43		
	Negative	0	0	0	0	0	0		
	Not Specified	1	1	242	53	327	57		
	Unknown	23	17	n/a	n/a	n/a	n/a		
Implant Manufacturer	Allergan includes McGhan, Inamed	84	63	386	84	481	84		
	Mentor	17	13	36	8	38	7		
	Sientra	4	3	2	0.4	6	1		
	Other****	2	1	5	1	6	1		
	Unknown	1	1	28	6	42	7		
	Not Reported	26	19	0	0	0	0		
Reporter Country: US or OUS*****	US	134	100	276	48	320	56		
	OUS	n/a	n/a	181	32	253	44		
	Not Specified	0	0	0	0	0	0		

*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 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, 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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