

PROFILE Data Compared to FDA Data September 2019

All PROFILE Data (as of 9/17/2019) (n=105)				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)	Mean	55		Median	53		
	Range	31-84		Range	24-90		
	Not specified	n/a		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)	Mean	9.56		Median	9		
	Range	.08-27		Range	0-34		
	Not specified	27		Not specified (# of reports)	110 (24%)	Not specified (# of reports) 169 (29%)	
		N	%	N	%	N	%
Implant Surface *	Textured	83	79	310	68	385	67
	Smooth	4	4	24	5	26	5
	Polyurethane	1	1	n/a	n/a	n/a	n/a
	Not specified	17	16	123	27	162	28
Implant Fill	Silicone	56	53	274	60	343	60
	Saline	44	42	183	40	197	34
	Saline/Silicone	1	1	n/a	n/a	n/a	n/a
	Not specified	4	4	0	0	33	6
Reason for Implant	Reconstruction	50	48	108	24	115	20
	Augmentation	53	50	104	23	111	19
	Not specified	1	1	245	54	347	61
	Unknown	1	1	n/a	n/a	n/a	n/a
Clinical Presentation (breast)**	Seroma	84	80	266	58	302	53
	Breast swelling/pain	n/a	n/a	135	30	150	26
	Capsular contracture	36	34	69	15	73	13
	Peri-implant mass/lump (Palpable Mass: PROFILE)	15	14	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	78	74	229	50	255	45
	Not specified	20	19	228	50	318	55
	Unknown	7	7	n/a	n/a	n/a	n/a
CD30 Status***	Positive	86	82	215	47	246	43
	Negative	0	0	0	0	0	0
	Not Specified	16	15	242	53	327	57
	Unknown	3	3	n/a	n/a	n/a	n/a
Implant Manufacturer	Allergan includes McGhan, Inamed	70	67	386	84	481	84
	Mentor	12	11	36	8	38	7
	Sientra	0	0	2	0.4	6	1
	Other****	2	2	5	1	6	1
	Unknown	2	2	28	6	42	7
	Not Reported	19	18	0	0	0	0
Reporter Country: US or OUS*****	US	105	100	276	48	320	56
	OUS	n/a	n/a	181	32	253	44
	Not Specified	0	0	0	0	0	0

*The 4 "smooth" cases reported to PROFILE had a reported clinical history of a textured device. In the 26 cases of smooth implants, 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.