PROFILE and FDA Data Comparison

All PROFILE Data (as of 10/7/2020) (n=179)				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	10		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	46		Not specified (# of reports)	169 (29%)	Not specified (# of reports)	226 (31%)
		N	**%**	**N**	**%**	**N**	**%**
Implant Surface*	Textured	141	**79**	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	**15**	162	**28**	209	**28**
Implant Fill	Silicone	99	**55**	343	**60**	447	**61**
	Saline	64	**36**	197	**34**	248	**34**
	Saline/Silicone	3	**2**	n/a	**n/a**	n/a	**n/a**
	Polyureathane foam	1	**1**	n/a	**n/a**	n/a	**n/a**
	Not specified	12	**7**	33	**6**	38	**5**
Reason for Implant	Reconstruction	73	**41**	115	**20**	127	**17**
	Augmentation	89	**50**	111	**19**	118	**16**
	Not specified	14	**8**	347	**61**	488	**67**
	Unknown	3	**2**	n/a	**n/a**	n/a	**n/a**
Clinical Presentation (breast)**	Seroma	130	**73**	302	**53**	369	**50**
	Breast swelling/pain	n/a	**n/a**	150	**26**	191	**26**
	Capsular contracture	50	**28**	73	**13**	96	**13**
	Peri-implant mass/lump (Palpable Mass: PROFILE)	27	**15**	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	128	**72**	255	**45**	298	**41**
	Not specified	28	**16**	318	**55**	435	**59**
	Unknown	23	**13**	n/a	**n/a**	n/a	**n/a**
CD30 Status****	Positive	152	**85**	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	111	**62**	481	**84**	620	**84**
	Mentor	21	**12**	38	**7**	50	**7**
	Sientra	8	**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	179	**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.