FDA/ASPS/PSF August 2021 BIA-ALCL Report

PROFILE Registry

372 Total Suspected/Confirmed Cases Reported to PROFILE Registry to Date
223 Total Suspected/Confirmed cases with detailed clinical history submitted

PROFILE Case Summary: A total of 372 distinct, suspected/confirmed cases of BIA-ALCL in the United States alone were reported to PROFILE from October 2011 to September 1, 2021. As of September 1, 2021, complete case report forms have been submitted for 223 (60%) of these cases. Of this subset, 35% had a history of cosmetic breast augmentation; 28% had a history of post-mastectomy reconstruction. Median time from implantation of current implant to BIA-ALCL diagnosis was 8 years. 25% had saline implants and 40% involved silicone implants. Acellular dermal matrices were reported in 9% percent of cases. Presenting symptoms included 74% peri-prosthetic seroma, 15% palpable breast mass; and 26% capsular contracture. For additional details, please refer to Table 1.

BIA-ALCL Global Network

Global Network Findings Summary: The ASPS BIA-ALCL Global Network is a collaboration of experts from 29 countries and meets by teleconference every 3-4 months.

We are currently gathering updated case counts from across the globe, but as of May 26, 2021, the following countries have reported unique confirmed cases to the BIA-ALCL Global Network:

Argentina: 15 Cases, 1 Death
Australia: 112 Cases, 4 Deaths
Austria: 6 Cases
Belgium: 14 Cases
Brazil: 31 Cases, 1 Death
Canada: 38 Cases, 1 Death
Chile: 2 Cases
China: 1 Case
Colombia: 17 Cases, 1 Death
Croatia: 1 Case
Czech Republic: 1 Case
Denmark: 10 Cases
Egypt: 1 Case
Finland: 13 Cases
France: 86 Cases, 5 Deaths
Germany: 27 Cases
Ireland: 1 Case
Israel: 9 Cases
Italy: 72 Cases, 2 Deaths
Japan: 1 Case
Mexico: 14 Cases
Netherlands: 70 Cases, 2 Deaths
New Zealand: 17 Cases, 1 Deaths
Norway: 6 Cases
Panama: 1 Case
Romania: 1 Case
Russia: 4 Cases
Singapore: 1 Case
South Africa: 3 Cases
South Korea: 3 Cases
Spain: 40 Cases
Sweden: 8 Cases, 2 Deaths
Switzerland: 7 Cases
Taiwan: 1 Case
Thailand: 1 Case
Venezuela: 2 Cases
United Kingdom: 78 Cases, 1 Death
United States: 363 Cases*, 7 Deaths

PROFILE Findings:

Nearly all cases reported to date that have a detailed clinical history have included a textured device at some point in the patient's history. Those few cases that do not have a report of a textured device are being reviewed by the PROFILE PI and Reporting Physician to determine if there is any history of a textured device. The disease tends to be indolent, with rare advanced disease cases most commonly with significant delay in diagnosis and/or no surgical intervention. Surgery is curative in the majority of patients. Diagnosis and treatment follows the National Comprehensive Cancer Network Guidelines for BIA-ALCL www.nccn.org.

Table 1

PROFILE and FDA Data Comparison

All PROFILE Data (as of 9/1/2021) (n=223)				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	15 (7%)		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	8		Median	8	Median	8
	Range	.02-25		Range	0-34	Range	0-34
	Not specified	55 (25%)		Not specified (# of reports)	169 (29%)	Not specified (# of reports)	226 (31%)
		N	**%**	**N**	**%**	**N**	**%**
Implant Surface*	Textured	192	**86**	385	**67**	496	**68**
	Smooth*	11	**5**	26	**5**	28	**4**
	Polyurethane	1	**0**	n/a	**n/a**	n/a	**n/a**
	Not specified	19	**9**	162	**28**	209	**28**
Implant Fill	Silicone	89	**40**	343	**60**	447	**61**
	Saline	56	**25**	197	**34**	248	**34**
	Saline/Silicone	7	**3**	n/a	**n/a**	n/a	**n/a**
	Polyureathane foam	1	**0**	n/a	**n/a**	n/a	**n/a**
	Not specified	70	**31**	33	**6**	38	**5**
Reason for Implant	Reconstruction	62	**28**	115	**20**	127	**17**
	Augmentation	79	**35**	111	**19**	118	**16**
	Not specified	82	**37**	347	**61**	488	**67**
	Unknown	0	**0**	n/a	**n/a**	n/a	**n/a**
Clinical Presentation (breast)**	Seroma	166	**74**	302	**53**	369	**50**
	Breast swelling/pain (PROFILE: Pain)	79	**35**	150	**26**	191	**26**
	Capsular contracture	57	**26**	73	**13**	96	**13**
	Peri-implant mass/lump (Palpable Mass: PROFILE)	33	**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	171	**77**	255	**45**	298	**41**
	Not specified	21	**9**	318	**55**	435	**59**
	Unknown	31	**14**	n/a	**n/a**	n/a	**n/a**
CD30 Status****	Positive	208	**93**	246	**43**	289	**39**
	Negative	0	**0**	0	**0**	0	**0**
	Not Specified	15	**7**	327	**57**	444	**61**
	Unknown	0	**0**	n/a	**n/a**	n/a	**n/a**
Implant Manufacturer	Allergan includes McGhan, Inamed	162	**73**	481	**84**	620	**84**
	Mentor	20	**9**	38	**7**	50	**7**

	Sientra includes Silimed	10	**4**	6	**1**	10	**1**
	Other*****	3	**1**	6	**1**	6	**1**
	Unknown	0	**0**	42	**7**	47	**7**
	Not Reported	28	**13**	0	**0**	0	**0**
Reporter Country: US or OUS******	US	223	**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.