

## PROFILE and FDA Data Comparison

All PROFILE Data (as of 12/6/2019) (n=124)				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	1		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	12.4		Median	9		
	Range	.08-27		Range	0-34		
	Not specified	37		Not specified (# of reports)	110 (24%)	Not specified (# of reports) 169 (29%)	
		<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>
Implant Surface*	Textured	98	<b>79</b>	310	<b>68</b>	385	<b>67</b>
	Smooth	4	<b>3</b>	24	<b>5</b>	26	<b>5</b>
	Polyurethane	1	<b>1</b>	n/a	<b>n/a</b>	n/a	<b>n/a</b>
	Not specified	21	<b>17</b>	123	<b>27</b>	162	<b>28</b>
Implant Fill	Silicone	67	<b>54</b>	274	<b>60</b>	343	<b>60</b>
	Saline	48	<b>39</b>	183	<b>40</b>	197	<b>34</b>
	Saline/Silicone	2	<b>2</b>	n/a	<b>n/a</b>	n/a	<b>n/a</b>
	Not specified	7	<b>6</b>	0	<b>0</b>	33	<b>6</b>
Reason for Implant	Reconstruction	57	<b>46</b>	108	<b>24</b>	115	<b>20</b>
	Augmentation	61	<b>49</b>	104	<b>23</b>	111	<b>19</b>
	Not specified	5	<b>4</b>	245	<b>54</b>	347	<b>61</b>
	Unknown	1	<b>1</b>	n/a	<b>n/a</b>	n/a	<b>n/a</b>
Clinical Presentation (breast)**	Seroma	97	<b>78</b>	266	<b>58</b>	302	<b>53</b>
	Breast swelling/pain	n/a	<b>n/a</b>	135	<b>30</b>	150	<b>26</b>
	Capsular contracture	39	<b>31</b>	69	<b>15</b>	73	<b>13</b>
	Peri-implant mass/lump (Palpable Mass: PROFILE)	18	<b>15</b>	82	<b>18</b>	94	<b>16</b>
	Other	n/a	<b>n/a</b>	43	<b>9</b>	56	<b>10</b>
	Not specified/uncertain	n/a	<b>n/a</b>	105	<b>23</b>	147	<b>26</b>
Anaplastic lymphoma kinase (ALK)	Positive	0	<b>0</b>	0	<b>0</b>	0	<b>0</b>
	Negative	87	<b>70</b>	229	<b>50</b>	255	<b>45</b>
	Not specified	24	<b>19</b>	228	<b>50</b>	318	<b>55</b>
	Unknown	13	<b>10</b>	n/a	<b>n/a</b>	n/a	<b>n/a</b>
CD30 Status***	Positive	100	<b>81</b>	215	<b>47</b>	246	<b>43</b>
	Negative	0	<b>0</b>	0	<b>0</b>	0	<b>0</b>
	Not Specified	20	<b>16</b>	242	<b>53</b>	327	<b>57</b>
	Unknown	4	<b>3</b>	n/a	<b>n/a</b>	n/a	<b>n/a</b>
Implant Manufacturer	Allergan includes McGhan, Inamed	79	<b>64</b>	386	<b>84</b>	481	<b>84</b>
	Mentor	13	<b>10</b>	36	<b>8</b>	38	<b>7</b>
	Sientra	2	<b>2</b>	2	<b>0.4</b>	6	<b>1</b>
	Other****	2	<b>2</b>	5	<b>1</b>	6	<b>1</b>
	Unknown	2	<b>2</b>	28	<b>6</b>	42	<b>7</b>
	Not Reported	26	<b>21</b>	0	<b>0</b>	0	<b>0</b>
Reporter Country: US or OUS*****	US	124	<b>100</b>	276	<b>48</b>	320	<b>56</b>
	OUS	n/a	<b>n/a</b>	181	<b>32</b>	253	<b>44</b>
	Not Specified	0	<b>0</b>	0	<b>0</b>	0	<b>0</b>

\*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 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.

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