

ANNEXE / ANNEX III

Nom de l'implant :

Si applicable (rachat) : nom de la marque originale.

Name of the implant: Mentor Gel® Breast ImplantsIf applicable (repurchase of a brand): name of the original brand. Mentor LLC Texas USA

Années Years		Monde / Worldwide			Dont France / For France		
		Implants lisses <i>Smooth implants</i>	Implants texturés <i>Textured implants</i>	Total	Implants lisses <i>Smooth implants</i>	Implants texturés <i>Textured implants</i>	Total
2004	Nombre d'unités mises sur le marché <i>Number of units marketed</i>						
	Nombre de cas de LAGC signalés <i>Number of ALCL cases reported</i>	0	0	0	0	0	0
2005	Nombre d'unités mises sur le marché <i>Number of units marketed</i>						
	Nombre de cas de LAGC signalés <i>Number of ALCL cases reported</i>	0	0	0	0	0	0
2006	Nombre d'unités mises sur le marché <i>Number of units marketed</i>						
	Nombre de cas de LAGC signalés <i>Number of ALCL cases reported</i>	0	0	0	0	0	0
2007	Nombre d'unités mises sur le marché <i>Number of units marketed</i>						
	Nombre de cas de LAGC signalés <i>Number of ALCL cases reported</i>	0	0	0	0	0	0
2008	Nombre d'unités mises sur le marché <i>Number of units marketed</i>						
	Nombre de cas de LAGC signalés <i>Number of ALCL cases reported</i>	0	0	0	0	0	0
2009	Nombre d'unités mises sur le marché <i>Number of units marketed</i>						
	Nombre de cas de LAGC signalés <i>Number of ALCL cases reported</i>	0	0	0	0	0	0
2010	Nombre d'unités mises sur le marché <i>Number of units marketed</i>						
	Nombre de cas de LAGC signalés <i>Number of ALCL cases reported</i>	1 ¹	0	1 ¹	0	0	0

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Années Years		Monde / Worldwide			Dont France / For France		
		Implants lisses Smooth implants	Implants textures Textured implants	Total	Implants lisses Smooth implants	Implants texturés Textured implants	Total
2011	Nombre d'unités mises sur le marché <i>Number of units marketed</i>						
	Nombre de cas de LAGC signalés <i>Number of ALCL cases reported</i>	1 ²	0	1 ²	0	0	0
2012	Nombre d'unités mises sur le marché <i>Number of units marketed</i>						
	Nombre de cas de LAGC signalés <i>Number of ALCL cases reported</i>	1 ¹	0	1 ¹	0	0	0
2013	Nombre d'unités mises sur le marché <i>Number of units marketed</i>						
	Nombre de cas de LAGC signalés <i>Number of ALCL cases reported</i>	0	1 ¹	1 ¹	0	0	0
2014	Nombre d'unités mises sur le marché <i>Number of units marketed</i>						
	Nombre de cas de LAGC signalés <i>Number of ALCL cases reported</i>	0	1	1	0	0	0
2015	Nombre d'unités mises sur le marché <i>Number of units marketed</i>						
	Nombre de cas de LAGC signalés <i>Number of ALCL cases reported</i>	0	1 1 ¹	2	0	0	0

¹ Important Note: Based on currently available information, most cases of ALCL have involved primarily patients whose implant history has included at least one device with a particular textured shell type that has never been manufactured by Mentor

² Note: To date, Mentor is aware of only 6 cases of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) in women whose device history has only included Mentor breast implants. The diagnostic criteria for BIA-ALCL were presented by Drs. Clemens and Miranda from the University of Texas MD Anderson Cancer Center in a recent publication (Aesthetic Surgery Journal, 2015, 35(5):545-547), and are as follows:

1. A tumor with adequate pathological specimen for analysis, involving an effusion either surrounding a breast implant or lining a breast implant capsule.
2. Neoplasm with large lymphoid cells with abundant cytoplasm and pleomorphic nuclei.
3. Tumor demonstrates T-cell markers with uniform expression of CD30 by immunohistochemistry or flow cytometry.
4. Negative for anaplastic lymphoma kinase (ALK) protein or translocations involving the ALK gene at chromosome 2q23.

A seventh case of ALCL (in a patient that only had Mentor implants) does not meet the definition of BIA-ALCL. It is included among the 19 total cases of ALCL in women whose device history included at least one Mentor implant. In that seventh case (ALCL but not BIA-ALCL), the ALCL was diagnosed in a right axillary lymph node. The lymphoma was "remote from the breast implant,"; there was no effusion and no capsular involvement (not meeting diagnostic criteria #1) and the lymphoma was positive for anaplastic lymphoma kinase (not meeting diagnostic criteria #4). The lymphoma was successfully treated without removal of the implant. Therefore, this case would seem to represent the very rare background occurrence of ALCL in the breast that occurs in women with or without breast implants. For these reasons, this case should not be considered in the number of pathology-confirmed, Mentor-only cases of BIA-ALCL.

Additionally: two cases reported in 2013 and 2015 respectively with insufficient information to determine the type of implant and shell surface; and one case reported in 2015 with non-confirmed pathology; these three cases are already included in the total 19 cases of the reported ALCL.