

SURFACE COMPARISON

Surface Type	Traditional Smooth	Advanced Smooth	Microtexture	Macrotexture	Polyurethane (PU)
Surface classification ¹ roughness range ISO-14607:2018	Smooth <10µm	Smooth <10µm	Microtexture 10–50µm	Macrotexture >50µm	
ANSM (France) surface classification ISO-14607:2007	Smooth	Smooth	Microtexture	Macrotexture (banned)	
Manufacturer/Brand Per Surface Type	Allergan NATRELLE® Smooth Mentor Smooth POLYsmooth™ Eurosilicone™ Smooth Impleo™ by Nagor™ Smooth Sebbin Smooth B-Lite® Smooth Silimed Smooth	Motiva SmoothSilk®/ SilkSurface®	Mentor Siltex® Polytech Mesmo® Silimed/Sientra TrueTXT PolyTXT/B-Lite® Sebbin Microtexture/Nano Allergan Microcell®/BRST Arion Micro	Allergan Biocell® Sebbin Texture Eurosilicone™ Micro Nagor™ Nagotex® Arion Textured	Polytech Microthane® Silimed PUREpoly
US FDA approval	Allergan, Mentor, Sientra only	IDE approved — US clinical trial in progress²	Mentor, Sientra only	Allergan, Mentor, Sientra only; Allergan Biocell® recalled ³	No
CE mark status	Yes	Yes	Yes (Allergan Microcell® not renewed)	Yes (Allergan Biocell® recalled) ⁴	Yes
Regulatory restriction	None	None	ANSM ⁴ (banned); TGA ^{5,6} (suspended*)	FDA (Biocell®) ³ / ANSM ⁴ / TGA ⁵ (suspended*) / Health Canada (Biocell®) ⁷	ANSM ⁴ (suspended) /TGA ^{5,6} (suspended*)
Correlation of surface area/ roughness with propensity for bacterial growth Jones et al. 2018 grading ⁹	1 Minimal	1 Minimal	2 – 3 Low - Intermediate	3 Intermediate	4 High
Bacterial adhesion/biofilm ⁹ James et al.	Low	Lowest	Moderate	Highest	High
Manufacturing method	Mandrel (traditional method)	360° 3D nano-imprinted mandrel (single-stage method)	PU secondary process PU imprint (Siltex®) Crystal/salt loss (others)	Secondary process Crystal/salt loss + scrubbing	Secondary process PU foam covered (vulcanised)
Immune response	May promote poor cell attachment ¹⁰ and increased fibroblast planar alignment ¹¹	May optimize fibroblast attachment and promote a lower expression of molecules associated with the inflammatory response^{11,12}	May promote poor cell attachment ¹⁰ and uneven fibroblast attachment	May promote uneven fibroblast attachment and aggregation. Macrophages poorly spread ¹¹	May promote uneven fibroblast attachment and aggregation and granulomatous tissue reaction ¹³
Risk of silicone elastomer breakage/particles	Low		Moderate ¹⁴	Highest ¹⁴	N/A
Complication risk profile perception (Complication severity/ complication incidence)	Low/common (capsular contracture)	Low/uncommon (capsular contracture and chronic inflammation- related complications)	Low/common (chronic inflammation- related complications)	High/uncommon (chronic inflammation-related complications)	
Global BIA-ALCL cases reported to the FDA as Medical Device Reports (MDR) up to July 2019 ^{**15}	No pure smooth cases identified to date ^{***}	None reported to date¹⁶	Mentor Siltex® 38/573= 7% Others 12/573= 2%	Allergan Biocell® 481/573= 84%	None reported in the MDR database
Worldwide BIA-ALCL incidence	Zero¹⁵		The risk of a woman with textured breast implants developing BIA-ALCL ranges from 1:2,207 to 1:86,029		
			Siltex® 1:16,703 ¹⁷ to 1:86,029 ¹⁸	Biocell® 1:2207 ¹⁹ to 1:3565 ¹⁸	Silimed 1:2,832 ¹⁸

*For 6 months from Sept 26, 2019

**42 out of the 573 MDRs (7%) correspond to unknown brand implants¹⁵

***Of the 26 cases of smooth implants where BIA-ALCL has been identified, 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.¹⁵

ANSM = Agence Nationale de Sécurité du Médicament et des Produits de Santé (France). FDA = Food and Drug Administration (USA). HC = Health Canada (Canada). TGA = Therapeutic Goods Administration (Australia).

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