

Multiple Levels of Clinical Evidence Indicate Superior Safety

Prospective Study: 10-year Follow-up with MRI, 35 cases with Motiva Implants[®] after 6 years of implantation.

Safety

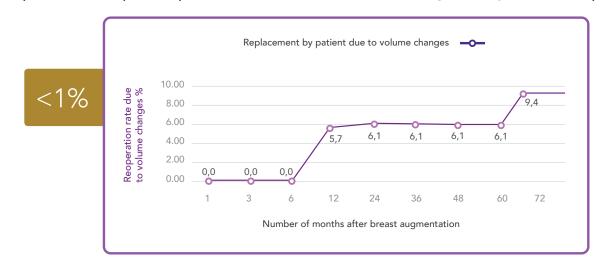
No reported rupture, capsular contracture, double capsule or late seromas. No implant replacement due to clinical reasons.

100% of MRI cohort showed no evidence of implant rupture or capsular contracture *MRI cohort 62% of the patients (N=20)

	Complication	MRI cohort results 6-years follow-up (N=20)	6-years follow-up results (N=35)
<1%	Capsular contracture III/IV	0%	0%
	Rupture after implantation	0%	0%
	Late seroma	0%	0%
	Double capsule	*N/A	0%
	ALCL	*N/A	0%

*Not applicable.

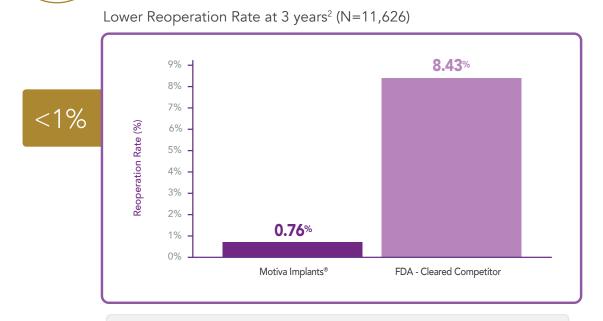
Kaplan-Meier implant replacement rate due to volume changes at 6-year follow-up visit (N=35)



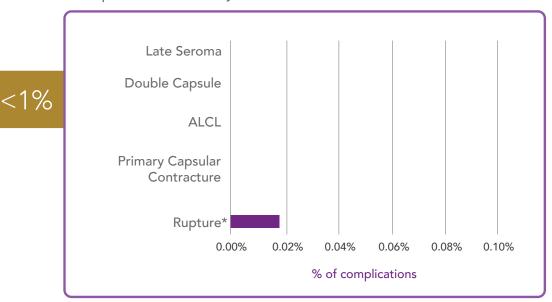
Clinical Evidence



Retrospective Study: 3-year follow-up of 5,813 consecutive cases with Motiva Implants[®] and competitor experience at Dolan Park Hospital in the United Kingdom performed by 16 Plastic Surgeons.



11 times less likely to require revision operations



Complication rates at 3 years²

*Implant ruptures related to contact with metal instruments.

No reports of implant rupture due to device failure.

Clinical Evidence



Motiva Implants[®] Post Market Vigilance Report.

Since the commercial launch of Motiva Implants[®] in October 2010, Establishment Labs has placed a total of 302,124 breast implants in the international market, with a total of 78 clinical related events reported, which represent 0.025% of the total units placed in the market.

Complication rates³ (N=302,124)

	Complication	Number of cases	Risk rates %
<1%	Capsular contracture III/IV	33	<1%
	Rupture after implantation*	12	<1%
	Late seroma	0	0%
	Double capsule	0	0%
	ALCL	0	0%

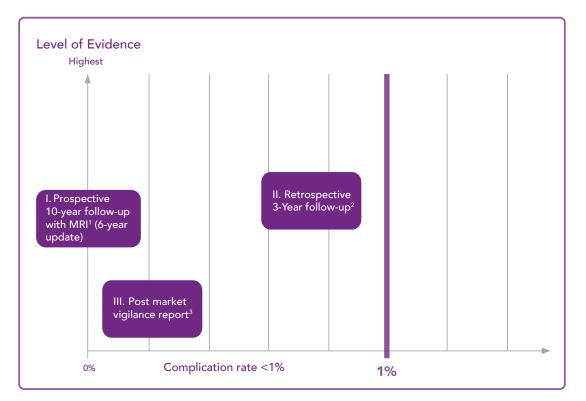
*No cases of implant rupture due to device failure.



Clinical Evidence







Motiva Implants[®] real world data suggests superior clinical results according to the level of evidence provided by each report.



Low complication rates in comparison to those reported in published literature regarding silicone gel-filled breast implants.

References: 1. Motiva Implants[®] Silicone Breast Implants: Summary of Clinical Data- 6-Year Follow Up. February 2017. Establishments Labs Alajuela, Costa Rica. **2.** Sforza, MD., Zaccheddu, MD, MSc., Alleruzzo, MD., Seno, MD., Mileto, MD., Paganelli, MD., Sulaiman, MD., Payne, MD., Maurovich-Horvat, PhD Preliminar. 3-year Evaluation of Experience With SilkSurface[®] and Velvet Surface[®] Motiva[®] Silicone Breast Implants: a Single Center Experience with 5813 Consecutive Breast Augmentation Cases. Aesthetic Surgery Journal 2017, 1–12. **3.** Motiva Implants[®] Complaint Data Report October 2010 - June 2017.