

+13 Years

of contributions to Women's Health



October, 2023

01

Motiva Implants® Post-Market Surveillance

With over **3.2 million implants sold**, spanning more than **13 years**, in over **85 countries** worldwide, Motiva Implants® have consistently reported superior safety outcomes. This includes **rates of less than 1% of device-related complications** that lead to reoperation, such as capsular contracture and implant rupture.

The low rates of capsular contracture with Motiva Implants® are consistent **across all surgical planes:** *submuscular, subglandular, or subfascial*. The worldwide rate of reoperation due to rupture with Motiva Implants® is **lower than 0.1%**.

Preliminary clinical results from the Motiva® IDE study in the United States, which is still in its follow-up phase, are encouraging and with a high rate of patient follow-up. The 3-year Kaplan-Meier risk of occurrence for capsular contracture and implant rupture are **0.5%** and **0.6%**, respectively.

The strong safety and performance of Motiva Implants® are confirmed by international registry data and independent peer-reviewed publications from around the world.



02

Adverse Events

Motiva Implants® Rate of Adverse Events (as a % of sales)

Rate of Adverse Events

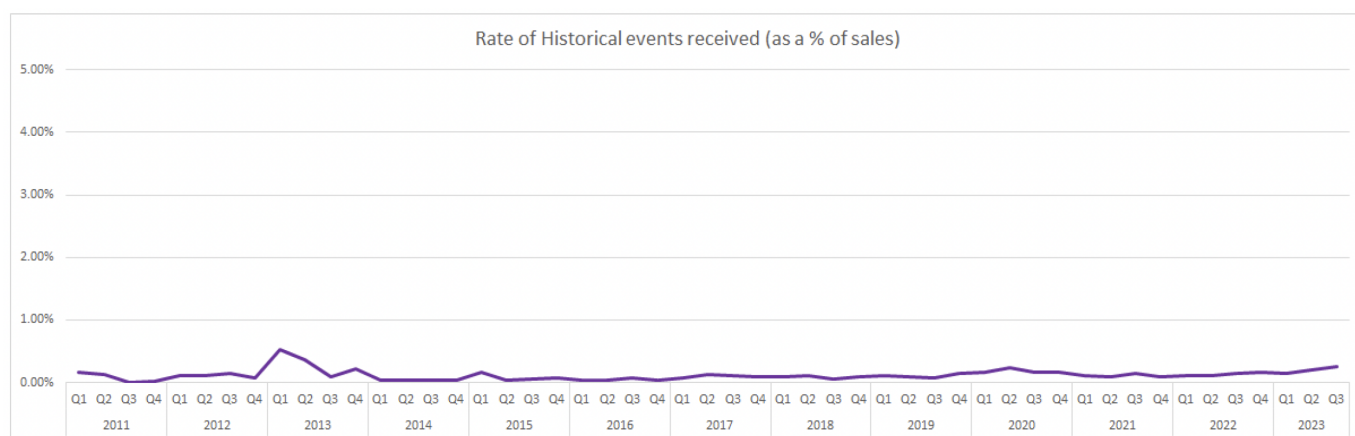
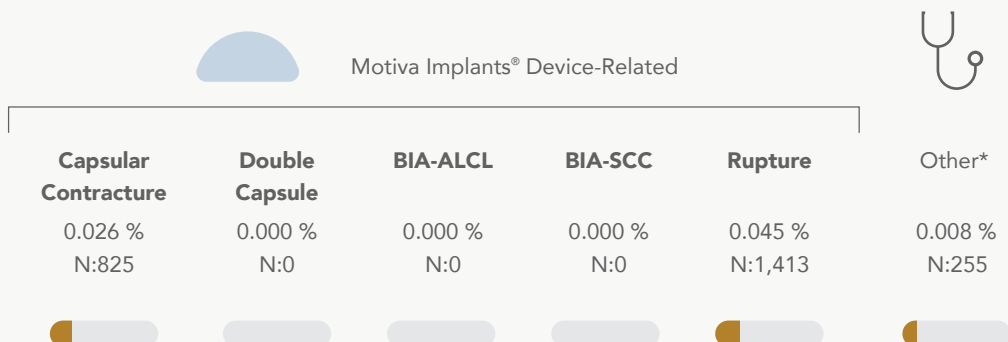


Figure 1: Trend of adverse events – Motiva Implants, January 2011 to September 2023

Source: Establishment Labs®, Post-Market Surveillance Preliminary Results Q3-2023

Adverse Events by Type



Percentages based on the total implants in the market.

* The following were considered technique-dependent complications: implant malposition, implant displacement, asymmetry. Infection, wound dehiscence, hematoma, and seroma.

Figure 2: Adverse events by type – Motiva Implants®, January 2011 to September 2023

Source: Establishment Labs®, Post-Market Surveillance Preliminary Results Q3 2023.

03

Motiva Implants® Patient Registry

From 2010 through September 2023, 354,000 women have registered their implants in the Motiva® Registration App.

Over 28,000 women have purchased the extended warranty that provides financial assistance for re-operation due to capsular contracture Baker grade III/IV or implant rupture.

Less than 1% of the registered patients have reported a device-related complication or redeemed standard and extended warranty coverage.

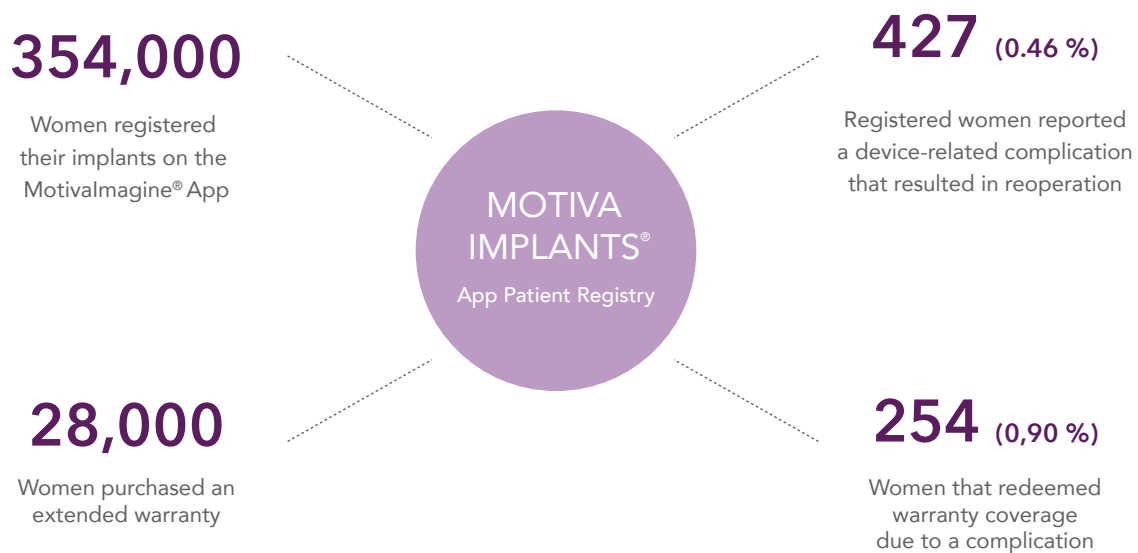


Figure 3: Motiva Implants® - Motiva® Registration App and Extended Warranty Registration

04

International Registry Data

Valuable information about breast implants' long-term safety and performance in a large population is collected in independent registry databases. This data includes the reasons for reoperation in patients previously implanted to monitor the occurrence of events such as capsular contracture and rupture.

Sweden's national breast implant registry demonstrates a reoperation rate of less than 1% due to device-related complications* after studying over 8,000 Motiva Implants® with a follow-up period of 6 years after implantation.¹



In addition, no cases of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) or Breast Implant-Associated Squamous Cell Carcinoma (BIA-SCC) have been registered in patients with a history of only Motiva Implants®.²

*Device-related complications are capsular contracture, rupture and/or BIA-ALCL.

1. The Breast Implant Registry, Sweden. Report to Establishment Labs S.A. Motiva® Implants Industry Report (2014-2020), 2021.

2. Establishment Labs®, Post-Market Surveillance Preliminary Results Q3 2023.

05

Motiva Implants® US IDE Study 3- Year Data

This three-year study follow-up update provides data on 451 primary augmentation patients based on follow-up compliance rate of 92.4%.

The three-year, by-patient, Kaplan-Meier risk rates of first occurrence of complications for patients (95% confidence interval) in the primary augmentation cohort were as follows:

Primary Augmentation	3-year (N=451), 95% CI
Capsular contracture (Baker Grade III/IV)	0.5%
Rupture, suspected or confirmed; MRI cohort ¹	0.6%
Breast pain	0.7%
Infection	0.9%
Implant removal, with or without replacement	1.6%
Any reoperation ²	6.1%
Any complication ³	8.4%

1. MRI cohort N=176

2. Any surgery on the breast or chest area, device or non-device related, including size change

3. Any device or non-device related event, including reoperation

Of special note, two of the main endpoints of the study, capsular contracture and rupture risk rates, were below a 1% incidence, specifically 0.5% and 0.6%, respectively.

This is consistent with rates observed from independent international registries in high-vigilance countries, peer-reviewed publications, and the company's post-market surveillance data.

06

Motiva Implants® Published Clinical Outcomes

Multiple independent peer-reviewed studies, including well-designed case-control, cohort studies, metaanalysis and non-randomized controlled trials with Motiva Implants®, have been published in leading plastic and reconstruction surgery journals.

Motiva Implants® Published Clinical Outcomes - Aesthetic Group

27 independent and peer-reviewed publications report low device-related complications and high-patient satisfaction with a patient follow-up range between six months and six years.

Authors	Journal	Follow-up (years)	Number of cases (#)	Capsular Contracture (%)	Rupture (%)
Sforza M et al.	Aesthetic Surgery Journal, 2018	2	2506	0	0
Chacón M et al.	Aesthetic Surgery Journal, 2018	6	35	0	0
Huemer G et al.	Plastic Reconstructive Journal Global Open, 2018	1	100	1	1
Sim HB	Aesthetic Surgery Journal, 2018	1	76	0	0
D'Onofrio et al.	Aesthetic Plastic Surgery, 2020	1	100	0	NA
Rigo M et al.	Aesthetic Plastic Surgery, 2020	1	387	0.3	0
Yoon S & Chang JH	Plastic Reconstructive Journal Global Open, 2020	1	152	1.3	0
Montemurro P & Kay VTS	Aesthetic Surgery Journal, 2020	2	161	1.2	0
Maximiliano J et al.	Aesthetic Surgery Journal, 2021	1.5	30	0	0
Munhoz AM et al.	Aesthetic Surgery Journal, 2021	1.5	42	2.4	0
Hong P et al.	Aesthetic Plastic Surgery, 2021	1.5	873	1.9	NA
Moon DS et al.	Journal of Plastic and Hand Surgery, 2021	0.33	76	0	NA
Zeplin PH	Handchir Mikrochir Plast Chir, 2021	1	252	0	0
Lam MC et al.	Handchir Mikrochir Plast Chir, 2021	2	103	1.9	NA
Botti et al.	Aesthetic Surgery Journal, 2021	3	356	0.6	0
Han et al.	Medicina, 2022	1	312	0	0
Lee S at al.	Aesthetic Surgery Journal, 2022	1	69	1.4	0
Oh YH et al.	Journal of Plastic, Reconstructive and Aesthetic Surgery, 2022	1.7	251	0.4	0
Trigano E et al.	Gland Surgery, 2022	1	122	0	0
Randquist C et al.	Aesthetic Surgery Journal, 2022	4	1053	0.4	0.2
Aitzetmuller-Kleitz ML et al.	Journal of Clinical Medicine MDPI, 2023	NA	4784	0.54	0.02
Nam SE et al.	PLoS One, 2023	2	73	2.7	0
Lee S et al.	Aesthetic Surgery Journal, 2023	2.5	1324	1.8	NA
Mayo F.	Journal of Plastic, Reconstructive and Aesthetic Surgery, 2023	1	122	0	0
Munhoz AM et al.	Plastic and Reconstructive Surgery Journal, 2023	3	45	0	NA
Moio M et al.	European Journal of Plastic Surgery, 2023	1	325	0	0.307%

See references for additional data on patient satisfaction.

Motiva Implants® Published Clinical Outcomes - Reconstruction Group

Four independent and peer-reviewed publications report low device-related complications in breast reconstruction, with a patient follow-up ranging between 12 months and two years.

Authors	Journal	Follow-up (years)	Number of breasts (#)	Capsular contracture (%)	Malposition (%)	Early seroma (%)
Stillaert F et al.	Plastic Reconstructive Journal Global Open, 2020	2	56	0.0	NA	NA
Patzelt M et al.	Aesthetic Plastic Surgery, 2022	1	128	0.0	1.6	3.1
Adelson D et al.	Aesthetic Surgery Journal, 2023	1	321	0.9*	0.3	0.6
Kaplan HM et al.	Journal of Plastic Reconstructive Aesthetic Surgery, 2023	1.1	269	4.5**	NA	2.2

* All capsular contracture cases were in women with irradiated breasts.

** 2.23% were in women with irradiated breasts and 1.49% were in women with non-irradiated breasts.



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