+14 Years

of contributions to Women's Health

October, 2024

01 Motiva Implants® Post-Market Surveillance

With nearly **4 million implants placed in the market**, spanning more than +**14 years**, in over **90 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 0.2%**.

Over 2.2 million Motiva Implants® featuring RFID enablement (microtransponder) have been successfully placed worldwide since 2014. Of these, almost 15,000 devices with the state of the art Zen microtransponder, are now in the market as the company shifts gradually to this latest technology globally.

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 89% rate of patient follow-up. The 4-year Kaplan-Meier risk of occurrence for capsular contracture and suspected implant rupture in an MRI cohort 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.

Source: Establishment Labs Notes Presentation of 4-Year Results from Motiva U.S. IDE Study at The Aesthetic Meeting 2024

02 Adverse Events

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

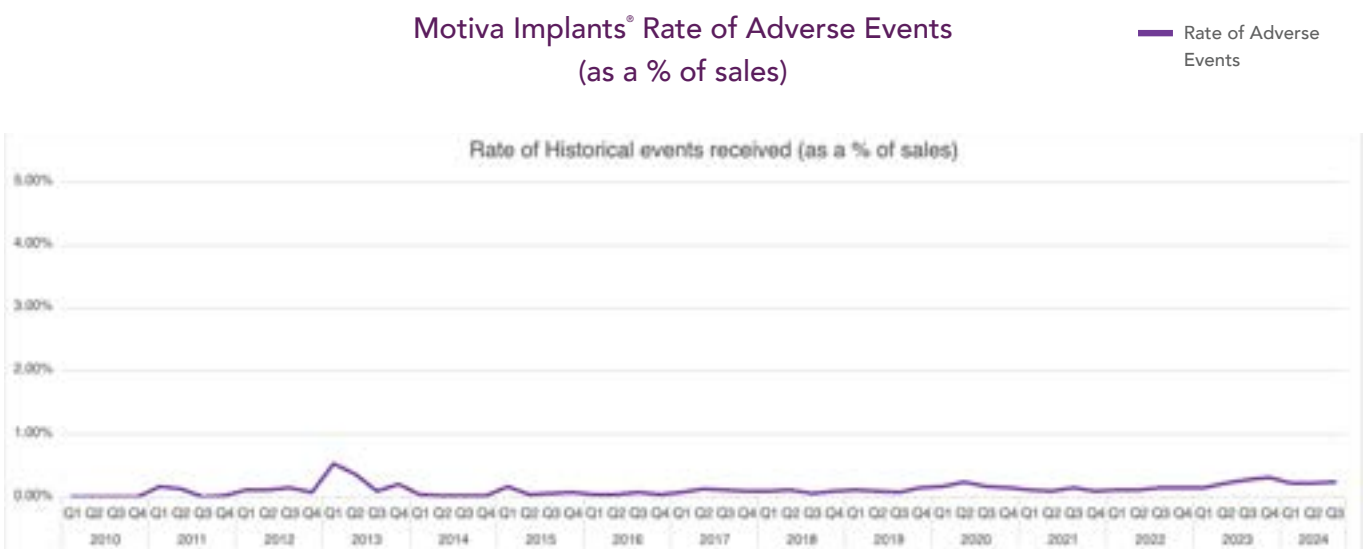

Figure 1:Trend of adverse events – Motiva Implants , October 2010 to September 2024.

Source: Establishment Labs®, Post-Market Surveillance Preliminary Results Q3-2024.

Adverse Events by Type

Motiva Implants® Device-Related

Capsular Contracture III/IV	Double Capsule	Primary BIA-ALCL	BIA-SCC	Rupture	Other*
0.029 % N:1070	0.000 % N:0	0.000 % N:0	0.000 % N:0	0.048 % N:1,791	0.010 % N:359

Percentages based on the total implants in the market.

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

Figure 2: Adverse events by type – Motiva Implants®, October 2010 to September 2024.

Source: Establishment Labs®, Post-Market Surveillance Preliminary Results Q3-2024.

03 Motiva Implants® Patient Registry

From 2010 through September 2024, 418,222 women have registered their implants in the Motiva® Registration App.

Over 37,254 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.

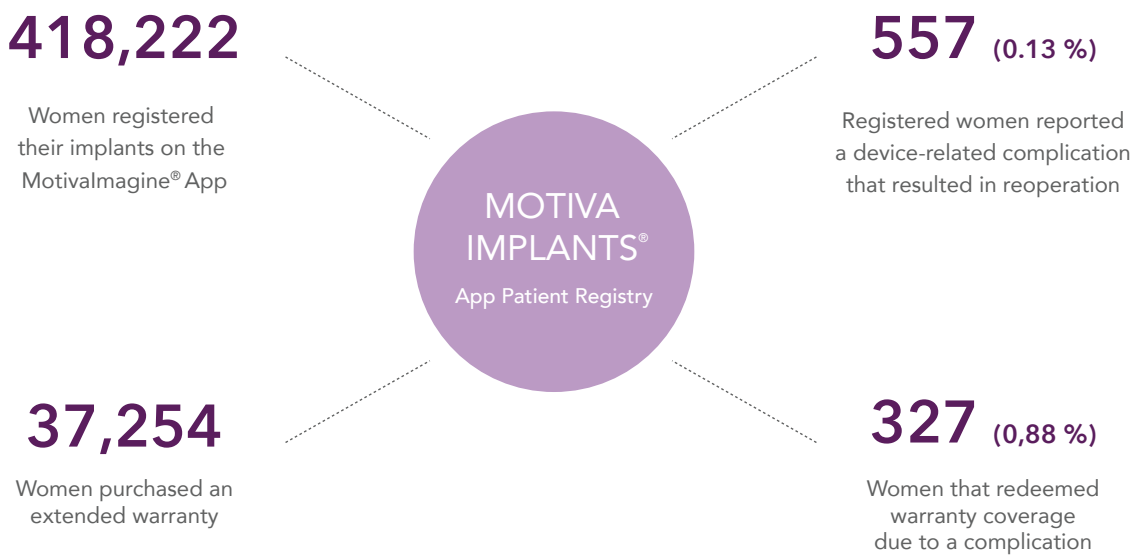

Figure 3: Motiva Implants® - Motiva® Registration App and Extended Warranty Registration

Source: Establishment Labs®. Registrations via the Motiva® website and MotivaImagine® digital mobile application.

04 International Registry Data

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

For instance, 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), Breast Implant-Associated Squamous Cell Carcinoma (BIA-SCC) or B-Cell Lymphomas have been registered 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 (2014-2021), 2022.
2. Establishment Labs®, Post-Market Surveillance Preliminary Results Q2 2024.

05

Motiva Implants®
US IDE Study 4– Year Data

This four-year study follow-up update provides data on 451 primary augmentation patients based on follow-up compliance rate of 89%.

The four-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	4-year (N=451), 95% CI
Capsular contracture (Baker Grade III/IV)	0.5%
Rupture, suspected or confirmed; MRI cohort[1]	0.6%
Breast pain	0.9%
Infection	0.9%
Implant removal, with or without replacement	1.8%
Any reoperation[2]	6.8%
Any complication[3]	9.6%

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.

Source: Establishment Labs® Notes Presentation of 4-Year Results from Motiva U.S. IDE Study at The Aesthetic Meeting 2024.

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

29 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
Munhoz AM et al.	Plastic and Reconstructive Surgery Journal, 2023	2.4	93	0.30	NA
Hubaide M et al.	Plastic and Reconstructive Surgery Journal, 2024	1.5	129	0	0
P Szychta.	Aesthetic Plastic Surgery Journal	NA	31	0	0

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.*

Motiva®

Medical Affairs
by Establishment Labs®