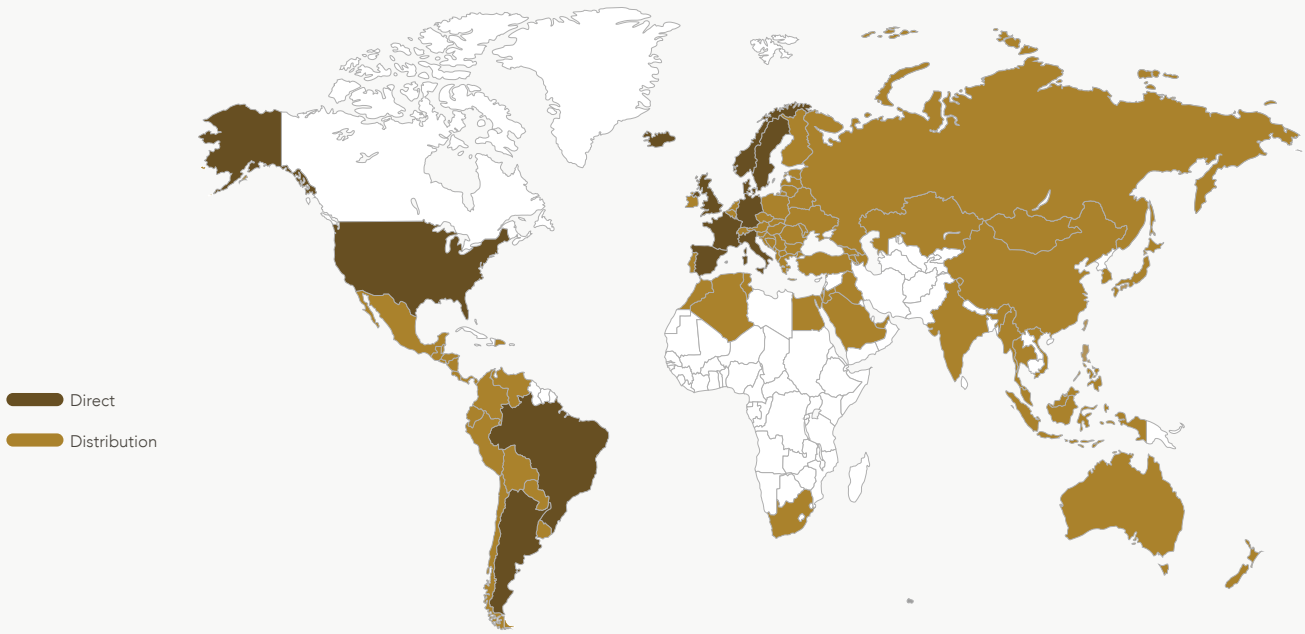
+15 *Years*

of Motiva® Data

Motiva Implants®
Post-Market Surveillance



Background

With over **4.5 million implants placed across more than 90 countries**, Motiva® implantable devices have consistently demonstrated superior safety outcomes. Establishment Labs® conducts Post-Market Surveillance (PMS) activities within a robust global regulatory framework, aligned with the standards of high-vigilance authorities such as the U.S. Food and Drug Administration (FDA), the European Union Medical Device Regulation (EU MDR), the Australian Therapeutic Goods Administration (TGA), and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA).

This **15-year abstract** encompasses data collected from the launch of Motiva Implants® in 2010 through September 2025, covering global regions, including the Americas, with the recent addition of the United States and our largest market, Brazil, followed by EMEA, featuring key areas such as Central Europe and APAC, which now includes our newly launched market in China, and Japan.

The analysis includes the **full Motiva Implants Matrix®** for aesthetic and reconstructive indications.

Overall, device-related complications requiring reoperation, such as capsular contracture (Baker grade III/IV) and implant rupture, occur at rates below 1%. The low incidence of capsular contracture remains consistent across surgical planes (submuscular, subglandular, and subfascial) and incision sites (inframammary, transaxillary, and periareolar). The reoperation rate due to implant rupture is less than 0.2%.

01 Adverse Events

Post-Market Surveillance consistently demonstrates a low incidence of device-related complications over the entire evaluation period. Adverse events, measured as a percentage of total device sales, have remained **below 1%.**

The adverse events reported for Motiva Implants® include capsular contracture (Baker Grade III/IV) and implant rupture. To date, no primary cases of Breast Implant-Associated Anaplastic Large-Cell Lymphoma (BIA-ALCL) have been identified through Post-Market Surveillance activities.

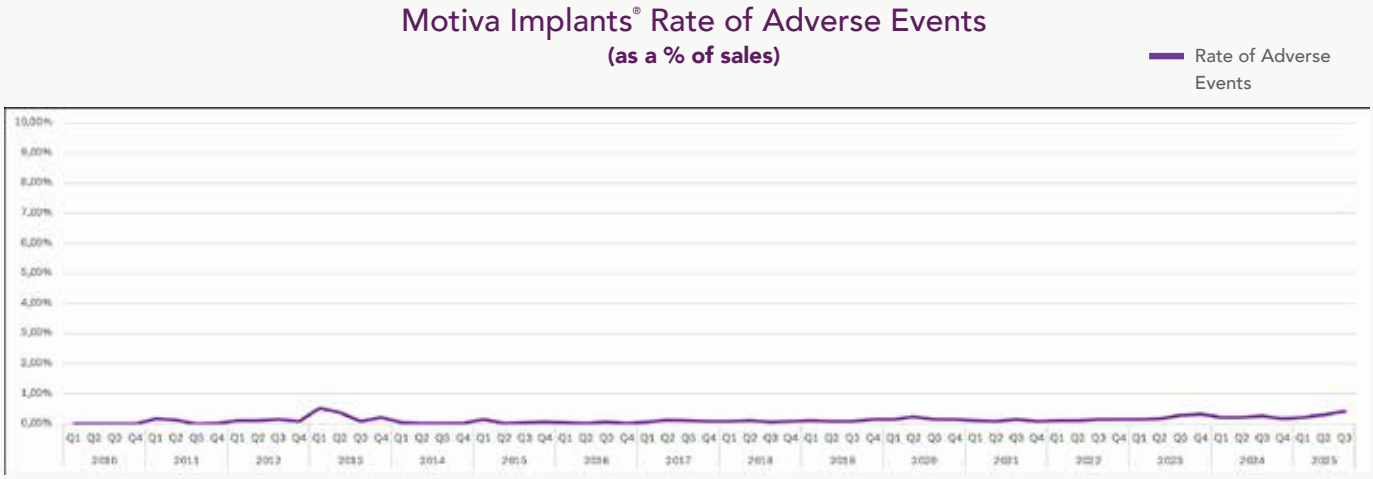
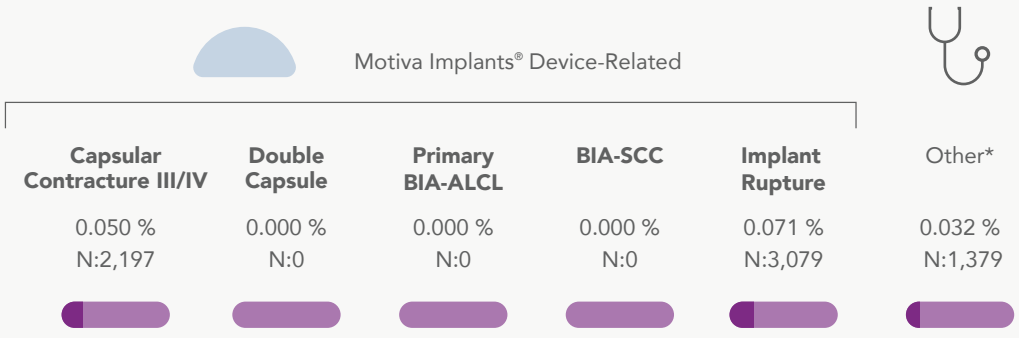


Figure 1: Trend of adverse events – Motiva Implants , October 2010 to September 2025.

Adverse Events by Type



* 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®, October 2010 to September 2025.

Source: Establishment Labs®, Post-Market Surveillance Results 15-Year Report

01 Adverse Events

Post-market surveillance data reports regional rates of adverse events as follows:

Complication	Rate by Region		
	AMERICAS	APAC	EMEA
Capsular Contracture	0.06%	0.05%	0.04%
Rupture	0.12%	0.04%	0.06%
All Complications	0.25%	0.11%	0.13%

Motiva Implants® with RFID Technology

To date, **2,443,553** Motiva® breast implants equipped with **the first-generation RFID microtransponder** have been distributed globally. Clinical data demonstrate no statistically significant difference in complication rates compared to Motiva Implants® without RFID technology.[1]

First-generation RFID technology includes ferrite components that may cause imaging artifacts during MRI scans, potentially requiring a dual-modality approach to ensure full breast tissue assessment. Establishment Labs has not received **any reports of delayed or missed cancer diagnoses** attributable to the presence of RFID microtransponders. Since 2014, only eight complaints worldwide (0.00032%) have been reported regarding imaging artifacts during routine MRI evaluations.[1]

Regulatory authorities in high-vigilance countries, including the United States FDA, have recently approved implants containing RFID technology, with no adverse reports to date.[2]

Establishment Labs is now implementing a **global transition to our second-generation RFID platform, Zen®**, integrated into Motiva Implants®. This state-of-the-art technology eliminates ferrite, thereby resolving its-related imaging artifact issues during MRI procedures. Additionally, it introduces a Biosensor Platform capable of temperature measurement, which is presently undergoing clinical trials.

The transition to Motiva Implants® with Zen® technology has been successfully adopted in collaboration with health authorities, as evidenced by our latest CE mark certification. Zen®-enabled implants are **now available in 76 countries**, with regulatory processes ongoing in many more.

Source:
1. Establishment Labs, Compliance Quest Complaints Report October 2025. Data in File.
2. Motiva USA LLC. Summary of Safety and Effectiveness Data (SSED), PMA P230005: Motiva SmoothSilk / Round / Ergonomix Silicone Gel–Filled Breast Implants. FDA; September 26, 2024. Accessed October 16, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230005B.pdf

02

Motiva Implants®
Patient Registry

From 2010 through September 2025, a total of 487,376 women have registered their implants in the Motiva® Registration App.

Over 49,487 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 all the registered patients have reported a device-related complication and **0.76%** of those who have purchased an extended warranty have redeemed coverage.

606 (0.13%)
Registered women reported a device-related complication that resulted in reoperation.

377 (0.76%)
Women that redeemed warranty coverage due to a complication

49,487
Women purchased an extended warranty

487,376
Women registered their implants on the MotivaImagine® App

MOTIVA IMPLANTS®

App Patient Registry

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

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

03 International Registry Data

Valuable information on the long-term safety and performance of breast implants in large populations is collected through independent registry databases. This data includes reasons for reoperation in previously implanted patients, allowing monitoring of events such as capsular contracture and rupture.

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

*Device-related complications are capsular contracture, implant rupture and/or BIA-ALCL.
Source: 1. The Breast Implant Registry, Sweden. Report to Establishment Labs S.A. Motiva Implants® Industry Report (2014-2021), 2022.

04 Clinical Evaluation and Global Evidence Generation

The Clinical Evaluation process at Establishment Labs is a systematic and ongoing approach to generate, collect, analyze, and assess clinical data related to Motiva® devices. Its purpose is to verify the safety, performance, and clinical benefits of the devices when used as intended.

This process is conducted in accordance with the European Medical Device Regulation (EU) 2017/745 (MDR), a globally recognized framework that strengthens the scientific and regulatory basis of our clinical evidence.

As part of this framework, Establishment Labs has developed a Clinical Investigation Program, where Post-Market Clinical Follow-up (PMCF) studies play a pivotal role. These studies proactively collect real-world data to confirm the continued safety and performance of our devices throughout their lifecycle.

Together, these clinical activities reinforce our evidence generation strategy and support the ongoing assessment of the benefit–risk profile of Motiva® devices.

The map below illustrates Establishment Labs' global clinical footprint, demonstrating our commitment to continuous clinical validation and patient safety worldwide.

05

Motiva Implants®
US IDE Study 5–Year Data

This five-year study follow-up update provides data on 451 primary augmentation patients based on follow-up compliance rate of **88.5%.**

The five-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[1]:

Primary Augmentation	5-year (N=451), 95% CI
Capsular contracture (Baker Grade III/IV)	0.5%
Rupture, suspected or confirmed; MRI cohort[1]	0.6%
Breast pain	1.2%
Infection	0.9%
Implant removal, with or without replacement	3.1%
Any reoperation[2]	8.8%
Any complication[3]	12.0%

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 key study endpoints, capsular contracture and implant rupture, each remained below 1%, specifically **0.5% and 0.6%**, respectively. Additionally, 17 (3.8%) of the patients in the primary augmentation cohort (451) were reported with implant malposition, with only 7 (1.5%) of the cases classified as inferior malposition.[2]

Physician and patient satisfaction remained high through year five, with BREAST-Q data showing satisfaction rates ranging from 91.9 - 96.6% in the Primary Augmentation Cohort.

In this ongoing study, 154 subjects have received RFID-enabled implants. Among the MRI cohort—who undergo scheduled imaging at 1, 2, 3, and 5 years—33 participants (representing 66 implants) contain RFID microtransponders. To date, **no issues have been reported** related to impaired detection of silent rupture or other MRI-related complications.[3]

Sources:
1.Establishment Labs® Notes Presentation of 5-Year Results From Motiva U.S IDE Study At the Aesthetic MEET 2025.
2.Establishment Labs, Core Clinical Study. Data on File.
3. Motiva USA LLC. Summary of Safety and Effectiveness Data (SSED), PMA P230005: Motiva SmoothSilk / Round / Ergonomix Silicone Gel–Filled Breast Implants. FDA; September 26, 2024. Accessed October 16, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230005B.pdf

06

Motiva Implants®
Published Clinical Outcomes

Multiple independent peer-reviewed studies, including well-designed case-control and cohort studies, meta-analysis, 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

37 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
Montemurro P.	Aesthetic Surgery Journal, 2024	0.6	144	2.1	0
Szychta P.	Aesthetic Plastic Surgery Journal, 2024	NA	31	0	0
Montemurro & Pietruski .	Plastic & Reconstructive Surgery Global Open, 2024	1.5	288	1.04	0
Szychta P.	Aesthetic Surgery Journal, 2024	1	1000	0	0.3
Antonino A.	Aesthetic Surgery Journal, 2024	1	200	0	0
Torres-Arciniegas SC.	Science and Art Plastic Surgery Journal, 2024	1	138	0	0
Elfieshawy H.	American Journal of Cosmetic Surgery, 2024	1	6	0	0
Glicksman C et al.	Aesthetic Surgery Journal, 2024	3	451	0.5	0.6
Kul Z.	Journal of Medical Research & Surgery, 2025	N/A	30	0	0

06

Motiva Implants®
Published Clinical Outcomes

Motiva Implants® Published Clinical Outcomes - Implant Based Reconstruction Group

Eight 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, 2022	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
Kaplan & Rysin.	Aesthetic Surgery Journal, 2024	1.5	410	4.14***	2.92	2.1
Doyle B et al.	Annals of Breast Surgery, 2024	1.2	64	NA	NA	1.6
Oranges C et al.	Journal of Plastic, Reconstructive & Aesthetic Surgery, 2024	NA	206	NA	NA	4.37
Caddia G et al.	Cereus, 2025	1.4	100	3	NA	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.
***Non irradiated N=4 (1.11%) / Irradiated adjuvant N=9 (18%) / Irradiated neoadjuvant N=4 (8%).

Takeaways: Bench-to-bedside

The transparency demonstrated in this report underscores the alignment of Establishment Labs' bench-to-bedside approach. This is supported by comprehensive post-market surveillance activities, clinical evaluation reports, international registry data, regulatory-guided prospective Investigational Device Exemption (IDE) studies, as well as more than 45 scientific publications and 140 clinical articles.

These findings emphasize the importance of Motiva's controlled and patented surface architecture, shown to enhance biocompatibility and reduce pro-fibrotic inflammatory responses[1]. This scientific breakthrough has led to a significant reduction in serious long-term adverse events, including capsular contracture, late seroma, and lymphoproliferative disorders.

Motiva Implants have consistently demonstrated exceptional safety outcomes—most notably, zero reported cases of primary BIA-ALCL over 15 years on the market[2], with the latest FDA data indicating a median interval of 8 years from last implant placement to diagnosis.[3]

Regarding implant stability and the impact of low periprosthetic tissue formation, PMS data reports an inferior malposition rate of 0.005%.[2] At the five-year follow-up of the FDA trial, the primary augmentation cohort exhibited an overall malposition rate of 3.8%, including a 1.5% incidence of inferior malposition.[4] Peer-reviewed literature further documents how surgeons who initially reported higher rates, of up to 14%, with surgical techniques designed for textured implants, were able to significantly reduce the incidence to 1.5% through refined approaches, improved device handling protocols, and by clinically treating these implants as smooth-surfaced devices.[5,6]

Sources:
1. Doloff JC, Veiseh O, de Mezerville R, et al. The Surface Topography Of Silicone Breast Implants Mediates The Foreign Body Response In Mice, Rabbits And Humans. Nat Biomed Eng. 2021;5(10):1115-1130. doi:10.1038/s41551-021-00739-4
2. Establishment Labs, Post-Market Surveillance Results, 15-Year Report
3. Food and Drug Administration. Medical Device Reports of Breast-Implant Associated Anaplastic Large Cell Lymphoma https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma Current as of June 2025.
4. Establishment Labs, Core Clinical Study. Data on File.
5. Montemurro P, Tay VKS. Transitioning from conventional textured to nanotextured breast implants: Our early experience and modifications for optimal breast augmentation outcomes. Aesthetic Surg J. 2020. doi:10.1093/asj/sjaa169
6. Randquist C, Jaeger M, Stavrou D. Six-year evaluation of Motiva round and ergonomix SmoothSilk surface silicone breast implants: A two-center, two-surgeon outcome analysis of 1053 primary and secondary breast augmentations and augmentation mastopexy. Aesthet Surg J. 2023;43(3):295-307. doi:10.1093/asj/sjac276


Motiva®
Medical Affairs
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