+10 Years

of contributions to Women's Health

October, 2022

01 Motiva Implants® Post-Market Surveillance

After more than a decade on the market, from 2010 to October 15, 2022, with presence in more than 80 countries and more than **2.5 million implants** sold, Motiva Implants® have consistently reported superior safety outcomes. This includes rates of **less than 1% device-related complications** leading 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 rate of reoperation due to rupture with Motiva Implants® is **lower than 0.1%.**

The Motiva® IDE study is still in its follow-up phase, but the high rate of patient follow-up and preliminary clinical results are encouraging. The 2-year Kaplan-Meier risk rates of occurrence for rupture and capsular contracture are **lower than 1%.**

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)

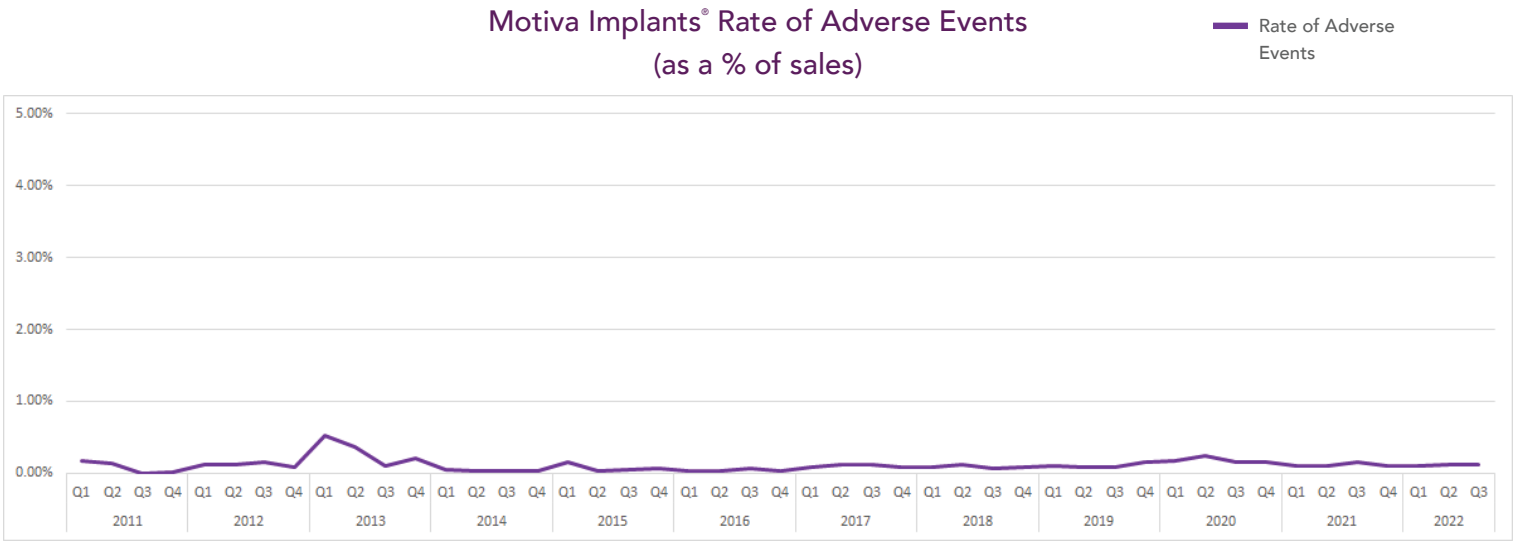


Figure 1: Trend of adverse events – Motiva Implants®, January 2011 to September 2022.

Source: Establishment Labs®, Post-Market Surveillance Preliminary Results Q3-2022.

Adverse Events by Type

Device-Related

Capsular Contracture	Double Capsule	BIA-ALCL	BIA-SCC	Rupture	Iatrogenic Rupture	Technique-Dependent Complications*	Other**
0.022 % N:535	0.000 % N:0	0.000 % N:0	0.000 % N:0	0.000 % N:0	0.037 % N:918	0.003 % N:71	0.004 % N:71

Percentages based in the total implants in the market.

* The following were considered technique-dependent complications: implant malposition, implant displacement, asymmetry.

** Infection, wound dehiscense, hematoma, seroma.

Figure 2: Adverse events by type – Motiva Implants®, January 2011 to September 2022.

Source:
Establishment Labs®, Post-Market Surveillance Preliminary Results Q3 2022.

03 Motiva Implants® Patient Registry

From 2010 through September 2022, 290,000 women have registered their implants in the Motiva® Registration App.

Over 21,000 women paid an additional fee for the extended warranty that provides financial assistance for reoperation due to capsular contracture Baker grade III/IV or implant rupture.

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

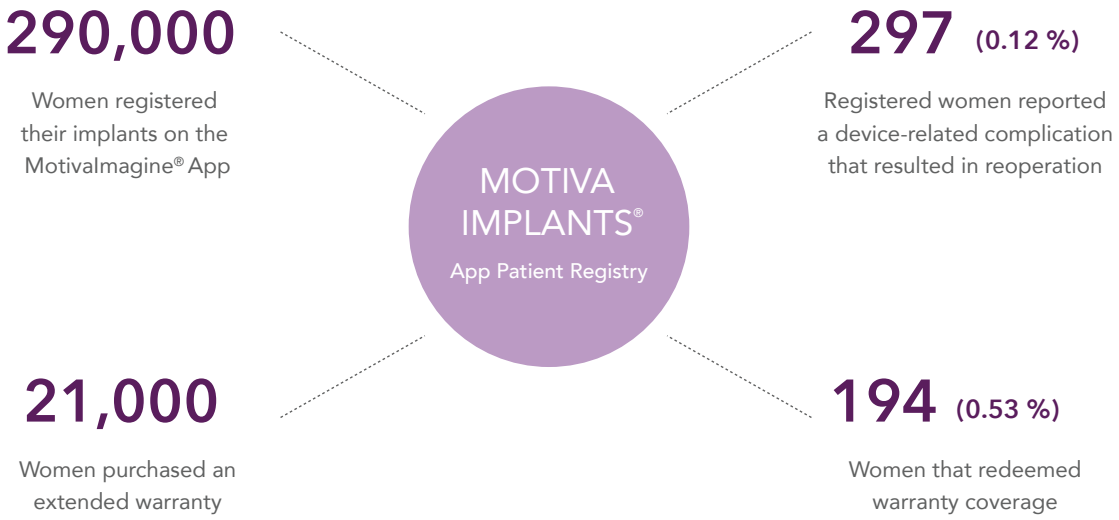


Figure 3: Motiva Implants® - MotivaImagine® App Registry and Extended Warranty Registration

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. The reasons for reoperation are collected and analyzed to report the occurrence of events such as capsular contracture or rupture.

Registry data from three independent registries with over 45,000 Motiva Implants® reported rates of reoperation due to capsular contracture, rupture, and device malposition are less than 1% in the augmentation procedures and less than 1.3% in the reconstruction indications.

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 history of Motiva Implants®.

INTERNATIONAL INDEPENDENT REGISTRIES

SWEDEN[1]

8598 MOTIVA IMPLANTS® REGISTERED

re-op rate due to malposition within 6 years after primary operation

0.46 % Motiva®*

re-op rate due to implant rupture within 6 years after primary operation

0.06 % Motiva®

re-op rate due to capsular contracture within 5.5 years after primary operation[2]

0.34 % Motiva®*

*Statistically significantly lower than other manufacturers in the registry.

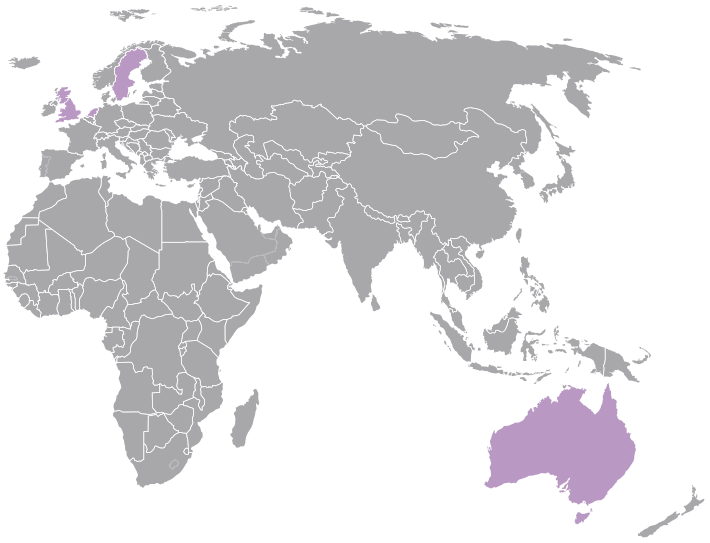


Figure 4: BRIMP international registry findings – Motiva Implants®.
Figure 5: Countries that develop independent implant registries: Sweden, Australia, Netherlands, England and Scotland.

Sources:
1. Breast Implant Register Annual Report 2020, 2021.
2. Breast Implant Register Annual Report 2019, 2020.

AUSTRALIA[3]

33,244 MOTIVA IMPLANTS® REGISTERED

Augmentation		Reconstruction
28,536	MOTIVA IMPLANTS® REGISTERED	**4,708**
0.5 %	re-op rate due to capsular contracture**	**1 %**
0.1 %	re-op rate due to implant rupture**	**0.3 %**

NETHERLANDS[4]

3954 MOTIVA IMPLANTS® REGISTERED

Augmentation		Reconstruction
3717	MOTIVA IMPLANTS® REGISTERED	**237**
0.43 %	re-op rate due to capsular contracture**	**1.27 %**
0.51 %	re-op rate due to device malposition**	**1.27 %**
0.03 %	re-op rate due to implant rupture**	**0.42 %**

** Percentages include the complication revision incidence rates for all Motiva Implants® within 5 years after insertion dates as an observational proportion.

Figure 6: ABDR and DBIR international registry findings – Motiva Implants®

Sources:
3. Monash University Australian Breast Device Registry: Report to the Establishment Labs S.A. Motiva Implants® Industry Report (2016-2021), 2022.
4. Dutch Institute for Clinical Auditing. Dutch Breast Implant Registry. Establishment Labs (Motiva) Post-Market Surveillance Report (2015-2020), 2022Z

05

Motiva Implants®
US IDE Study

This update includes follow-up data of 451 primary augmentation patients enrolled in the Motiva® US IDE Study, through the two-year follow-up visit. Patient compliance in the cohort was 94.9%[5].

The two-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	2-year (N=451), 95% CI
1. Capsular Contracture (Baker III/IV)	0.5%
2. Rupture, suspected or confirmed	0.3%
3. Breast Pain	0.5%
4. Infection	0.9%
5. Implant removal, with or without replacement	1.6%
6. Any reoperation*	5.7%
7. Any complication**	7.5%

*Any surgery on the breast or chest area, device or non-device related, including size change.
**Any device or non-device related event, including reoperation.
The Motiva® Core pivotal study is an ongoing US clinical trial of an investigational medical device under an FDA-approved Investigational Device Exemption. The Motiva® device has not been approved by the Food and Drug Administration and is not commercially available in the United States.

Of special note, the main safety endpoints of the study, which are capsular contracture and rupture, were below 1% event rate (0.5% and 0.3% respectively), which is consistent with independent international registries from high vigilance countries, peer-reviewed publications, and our internal post-market surveillance data.

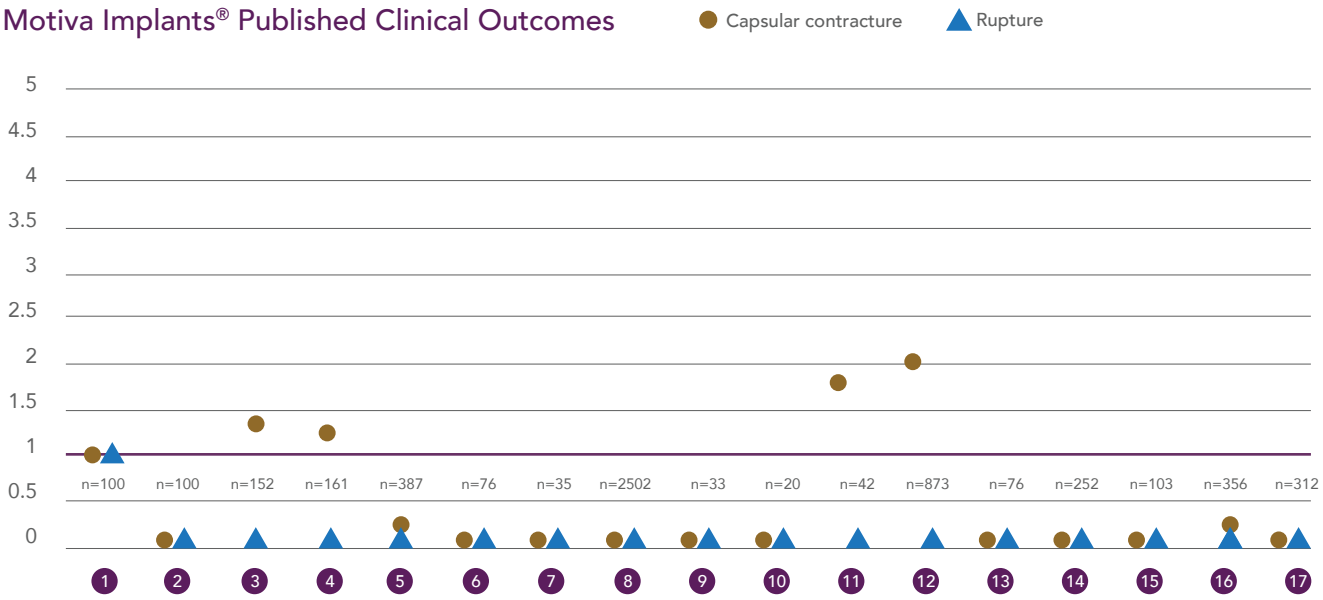
Source:
5. Establishment Labs Notes Presentation of 2-Year Results from Motiva US IDE Study, 2022.
Available at: https://investors.establishmentlabs.com/news-releases/newsrelease-details/establishment-labs-notes-presentation-2-year-results-motiva-us

06

Motiva Implants®
Published Clinical Outcomes

Multiple independent peer-reviewed studies, including well-designed case-control, cohort studies, and non-randomized controlled trials with Motiva Implants®, have been published in leading plastic surgery journals. These studies report low device-related complications (0 % - 2 %), and high patient satisfaction, with patient follow-up ranging from six months to six years.

Motiva Implants® Published Clinical Outcomes



n= number of patients

Author(s)	Peer-review Journal	Mean Follow-up
1. Huemer GM, Wenny R, Aitzetmüller MM, Duscher D	Plastic Reconstructive Surgery, 2018	1 Year
2. D' Onofrio C	Aesthetic Plastic Surgery, 2020	6-12 Months
3. Yoon S, Chang JH	PRS-Global Open, 2020	1 Year
4. Montemurro P, Tay VKS	Aesthetic Surgery Journal, 2020	2 Years
5. Rigo M, Piccinini PS, Sartori LDP, de Caravelho LAR, Uebel CO	Aesthetic Plastic Surgery, 2020	1 Year
6. Sim HB	Aesthetic Surgery Journal, 2018	1 Year
7. Chacón M, Chacón M, Fassero JJ	Aesthetic Surgery Journal, 2018	6 Years
8. Sforza M, Zaccheddu R, Alleruzzo A, et al	Aesthetic Surgery Journal, 2017	2 Years
9. Stillaert F, Lannau B, Van Landuyt K, Blondeel P	Plastic Reconstructive Surgery Global Open, 2020	2 Years
10. Maximiliano J, Marques AA, Munhoz AM	Aesthetic Surgery Journal, 2021	1.5 Years
11. Munhoz AM, Maximiliano J, Marques AA	Aesthetic Surgery Journal, 2021	1.5 Years
12. Hong P, Kim SS, Jeong C, et al	Aesthetic Plastic Surgery, 2021	1.5 Years
13. Moon DS, Choi WS, Kim HC, et al	Journal of Plastic Surgery and Hand Surgery, 2021	4 Months
14. Zeplin PH	Handchirurgie Mikrochirurgie Plastiche Chirurgie, 2021	1 Year
15. Lam MC, Vorhold J, Pech T, et al	Handchirurgie Mikrochirurgie Plastiche Chirurgie, 2021	2 Years
16. Botti G, Botti C, Ciancio F	Aesthetic Surgery Journal, 2021	3 Years
17. Han S, Kim R, Kim TS, et al	Medicina, MDPI Journals, 2021	1 Year

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