

# +12 Years

of contributions to Women's Health



March, 2023

# 01

## Motiva Implants® Post-Market Surveillance

With over **3 million implants sold**, spanning more than **12 years**, in **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 rate of occurrence for capsular contracture and implant rupture 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)

Rate of Adverse Events

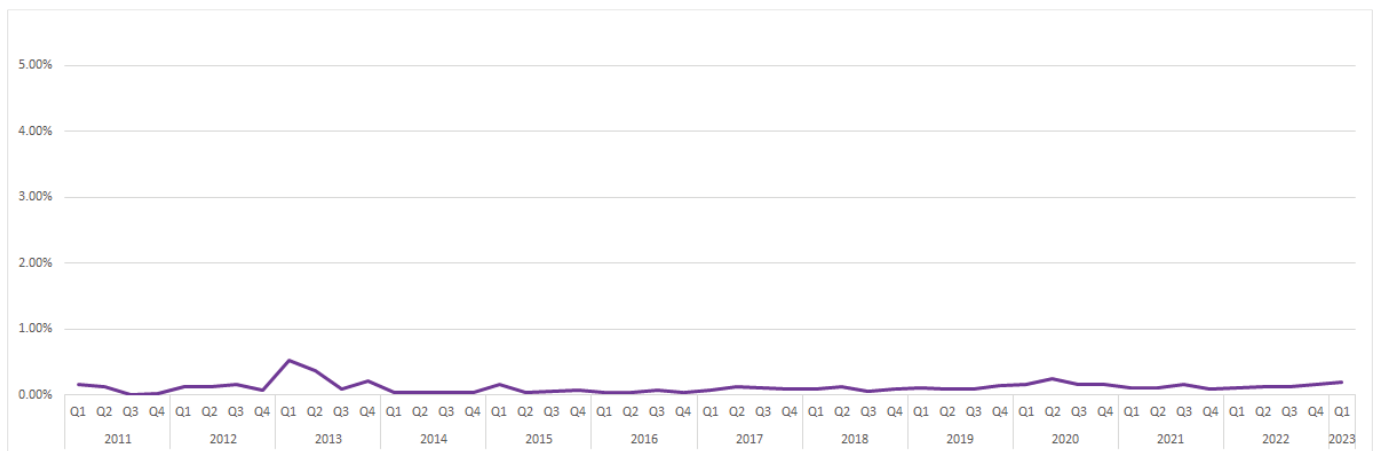
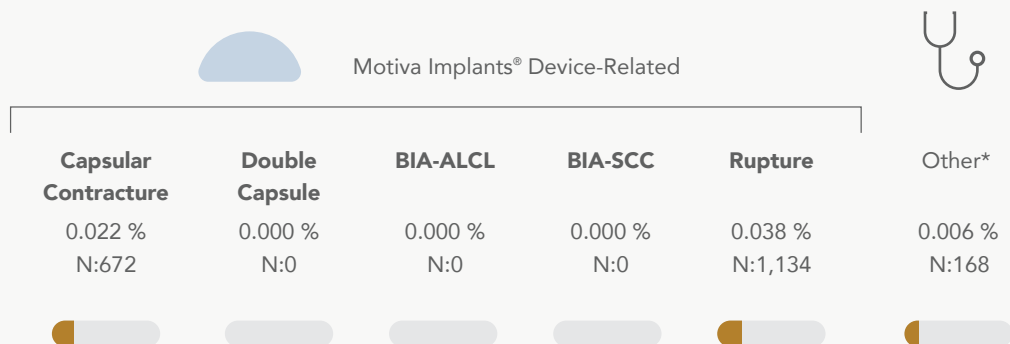


Figure 1: Trend of adverse events – Motiva Implants , January 2011 to March 2023

Source: Establishment Labs®, Post-Market Surveillance Preliminary Results Q1-2023

### 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 March 2023

Source: Establishment Labs®, Post-Market Surveillance Preliminary Results Q1 2023.

# 03

## Motiva Implants® Patient Registry

From 2010 through March 2023, 318,000 women have registered their implants in the Motiva® Registration App.

Over 24,500 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% have reported a device-related complication or redeemed standard and extended warranty coverage.

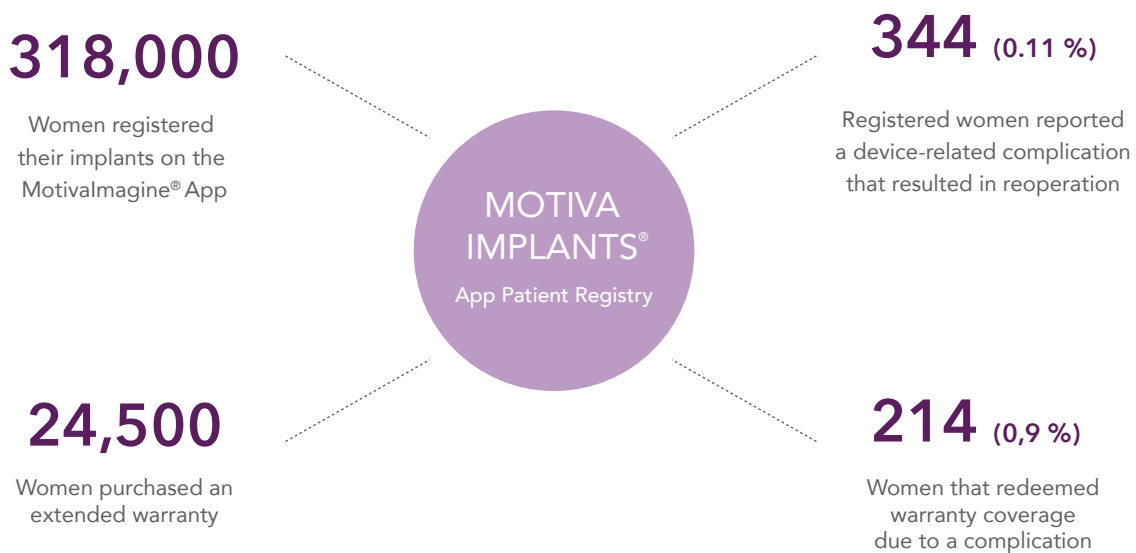


Figure 3: Motiva Implants® - Motiva® Registration App and Extended Warranty Registration

# 04

## International Registry Data

Valuable information about breast implants' long-term safety and performance in a large population is collected in independent registry databases. The reasons for reoperation are collected and analyzed to monitor the occurrence of events such as capsular contracture or rupture.

Registry data from two independent registries with over 41,841 Motiva Implants® registered have reported rates of reoperations due to capsular contracture, rupture, and device malposition to be less than 1% for augmentation procedures and less than 1.3% for 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 a history of only Motiva Implants®.

### INTERNATIONAL INDEPENDENT REGISTRIES

#### SWEDEN<sup>1</sup>

**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<sup>2</sup>

↓ 0.34 % Motiva®\*



\*Statistically significantly lower than other manufacturers in the registry.

Figure 4: BRIMP international registry findings – Motiva Implants®.

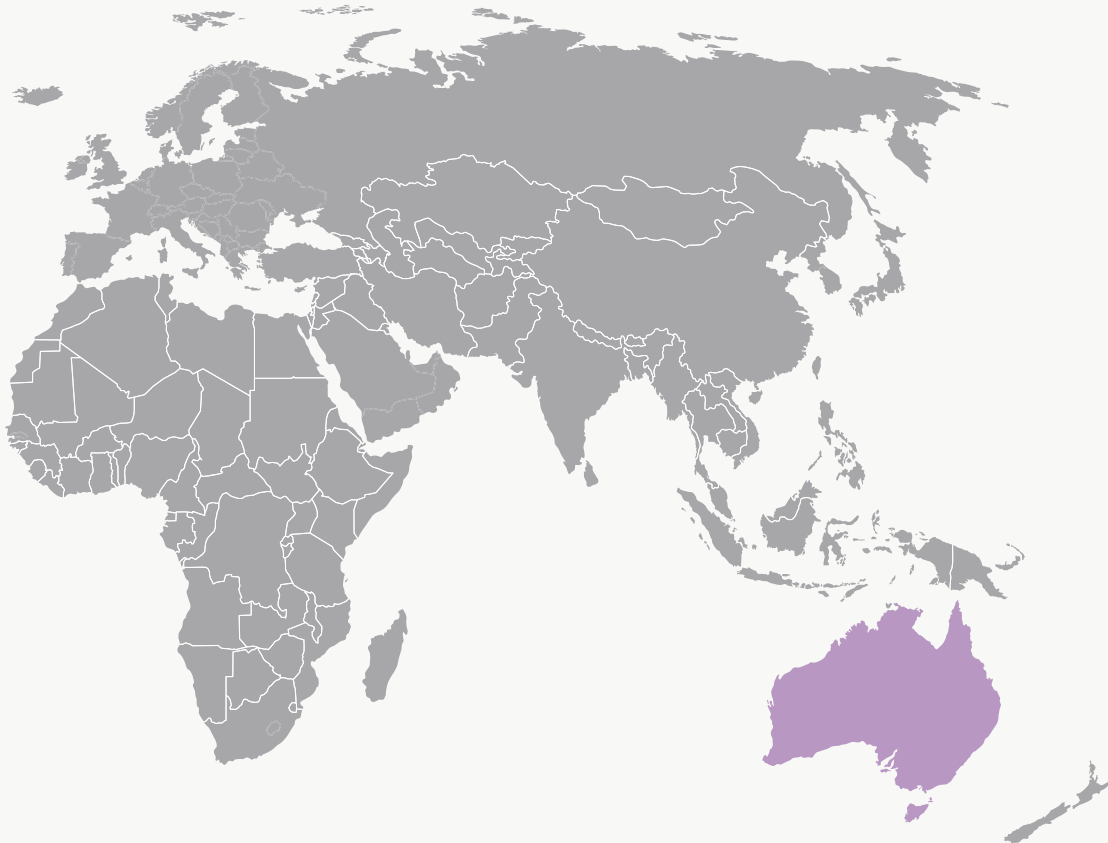
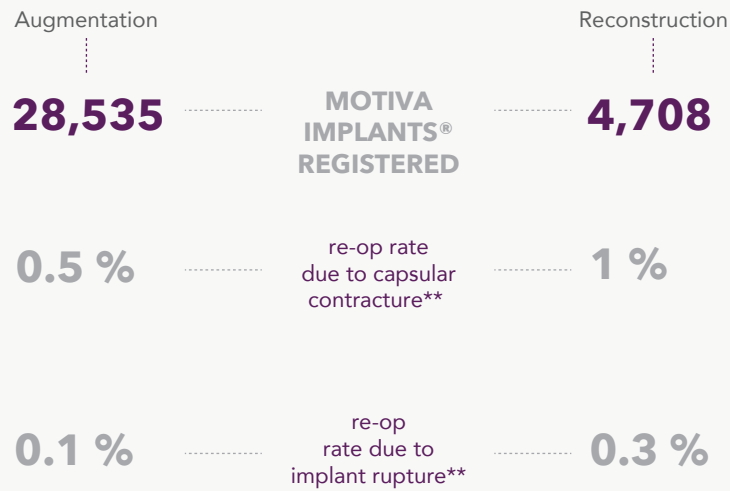
Figure 5: Countries that develop independent implant registries: Sweden, Australia, England and Scotland.

Sources:

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

# AUSTRALIA<sup>3</sup>

**33,243** MOTIVA IMPLANTS® REGISTERED



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

Figure 6: ABDR international registry findings – Motiva Implants®

# 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 95%.<sup>4</sup>

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 <sup>1</sup>	0.6%
Breast pain	0.7%
Infection	0.9%
Implant removal, with or without replacement	1.6%
Any reoperation <sup>2</sup>	6.1%
Any complication <sup>3</sup>	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 key study endpoints, capsular contracture and MRI suspected or confirmed rupture were below 1%, 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.

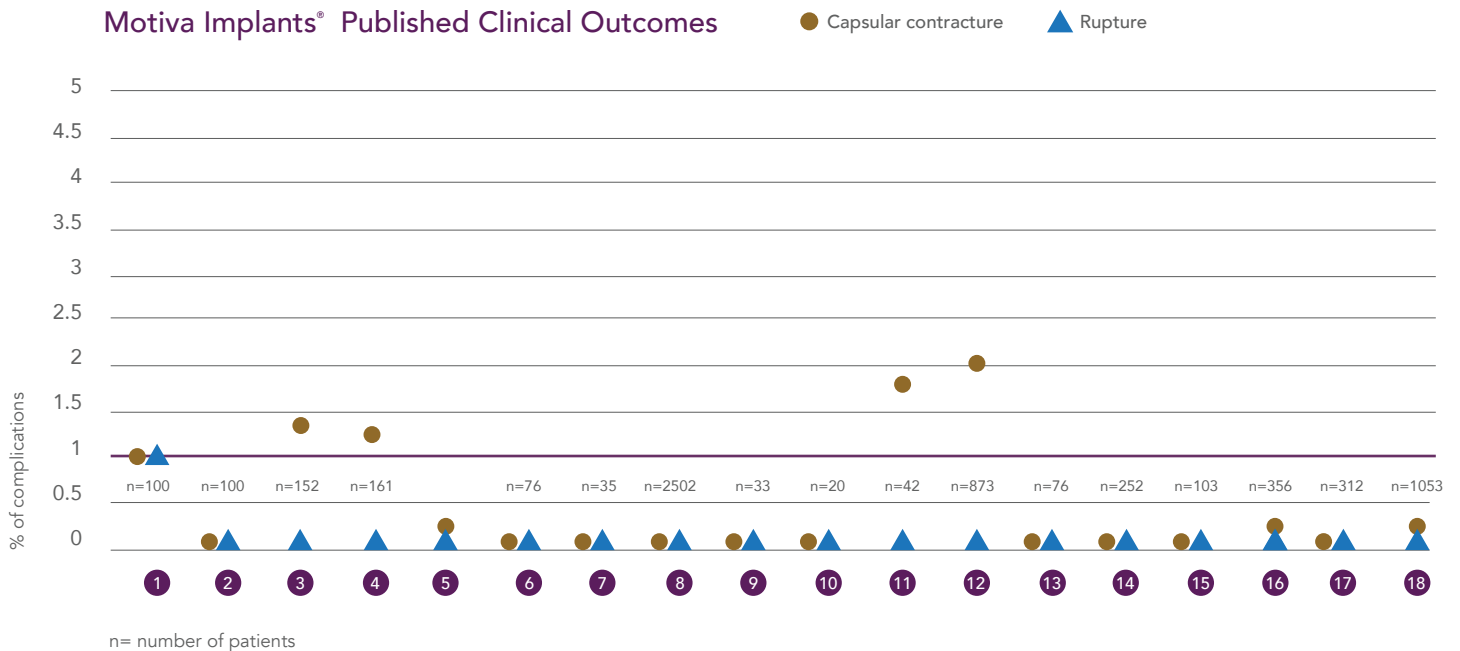
Source:

4. Establishment Labs Notes Presentation of 3-Year Results from Motiva U.S. IDE Study at The Aesthetic Meeting 2023.

# 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.



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 Plastische Chirurgie, 2021	1 Year
15. Lam MC, Vorhold J, Pech T, et al	Handchirurgie Mikrochirurgie Plastische 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
18. Randquist.C, Jaeger.M, Stavrou	Aesthetic Surgery Journal, 2022	4 Years





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