

+10 Years

of contributions to Women's Health



October, 2021

01

Motiva Implants® Post-Market Surveillance

After more than a decade on the market, from 2010 to 2021, with presence in over 80 countries and nearly **1.8 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 safety and performance of Motiva Implants® are confirmed by international registry data and independent peer-reviewed publications from around the world.



02

Adverse Events

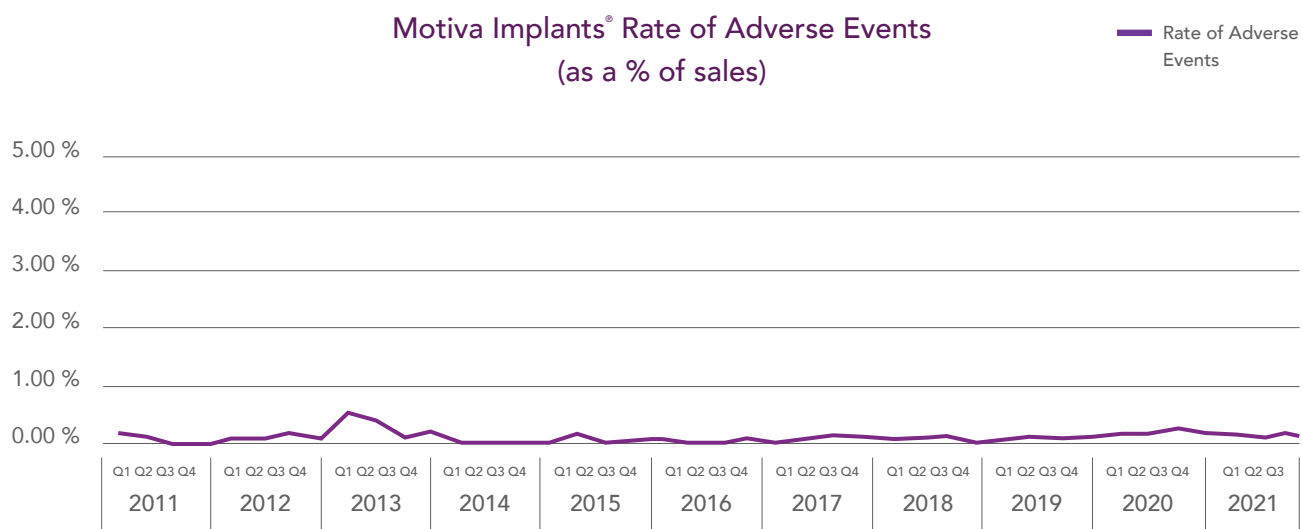
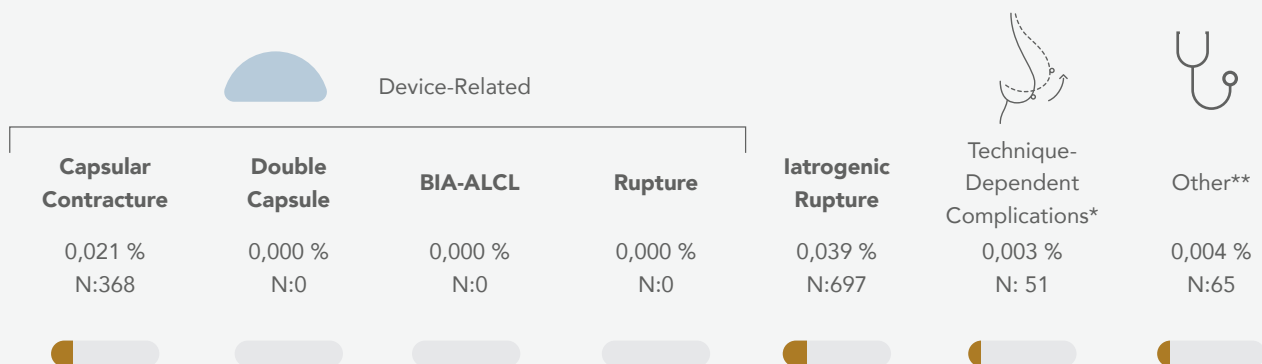


Figure 1: Trend of adverse events – Motiva Implants®, January 2011 to September 2021

Source: Establishment Labs®, Post-Market Surveillance Q3 2021

Adverse Events by Type



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

** Infection, wound dehiscence, hematoma, seroma.

Figure 2: Adverse events by type – Motiva Implants®, January 2011 to September 2021

Source: Establishment Labs®, Post-Market Surveillance Q3 2021.

03

Motiva Implants® Patient Registry

From 2010 through 2021, 207,000 women have registered their implants in the Motiva® Registration App.

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

Over 16,000 women paid an additional fee for the extended warranty that provides financial assistance coverage for reoperation due to capsular contracture Baker grade III/IV or implant rupture, as shown in figure 3.

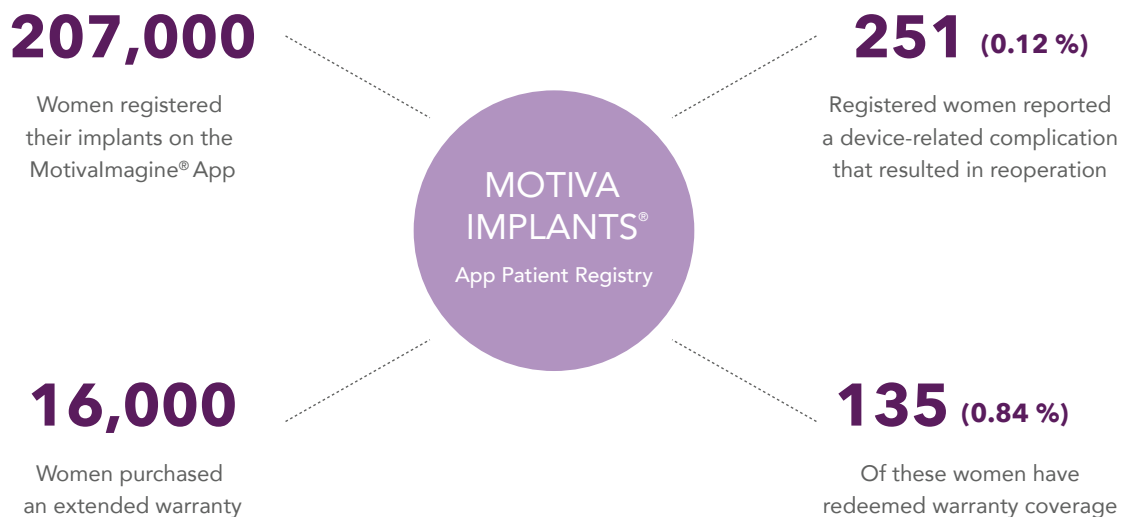


Figure 3: Motiva Implants® - Motivalmagine® App Registry and Extended Warranty Registration

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 report the occurrence of events such as capsular contracture or rupture.

Registry data reported rates of reoperation due to rupture and capsular contracture in over 20,000 Motiva Implants® are less than 1 % in both the augmentation and reconstruction indications (Figure 4 below).

INTERNATIONAL INDEPENDENT REGISTRIES

SWEDEN¹

6,225 Total Operations with Motiva Implants® as of 2020

6-year re-op rate
due to capsular contracture

↓ 0.46 % Motiva**

6-year re-op rate
due to implant rupture

↓ 0.06 % Motiva®

AUSTRALIA²

Aesthetic

12,109

0.03 %

0.06 %

Recon

1,509

0.50 %

0.38 %

**MOTIVA
IMPLANTS®
REGISTERED**

2-year re-op rate
due to capsular
contracture

2-year re-op
rate due to
implant rupture

*Statistically significantly lower than other manufacturers in the registry.

Figure 4: BRIMP and ABDR international registry figures – Motiva Implants®

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

2. Monash University Australian Breast Device Registry: Report to the Establishment Labs S.A. Motiva Implants® Industry Report (2016 – 2019), 2020.

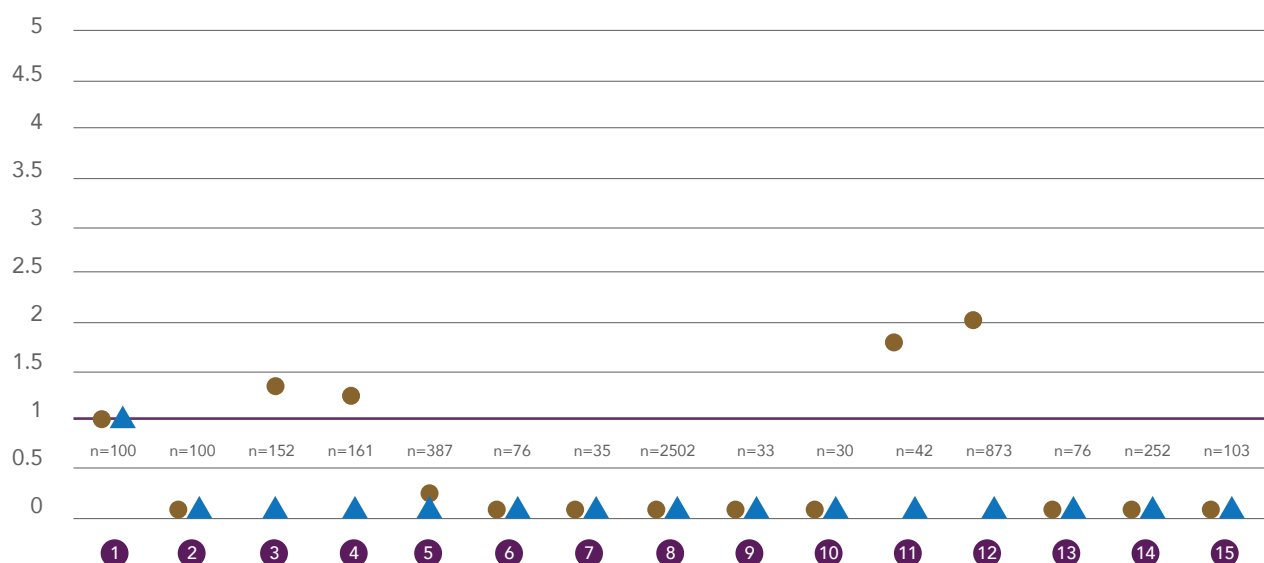
05

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

● Capsular contracture ▲ Rupture



n= number of patients

Article Authors	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, 2021	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 et al.	Plastic Reconstructive Surgery Global Open, 2018	2 Years
10. Maximiliano et al.	Aesthetic Surgery Journal, 2021	1.5 Years
11. Munhoz AM et al.	Aesthetic Surgery Journal, 2021	1.5 Years
12. Hong P et al.	Aesthetic Plastic Surgery, 2021	1.5 Years
13. Moon DS 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 et al.	Handchirurgie Mikrochirurgie Plastische Chirurgie, 2021	2 Years

