



# THE MOTIVA® STANDARD



THREE-YEAR  
DATA FROM US  
FDA STUDY



THREE MILLION  
MOTIVA IMPLANTS  
@12 YEARS



CONSISTENT <1%  
DEVICE-RELATED  
COMPLICATIONS

## MOTIVA® US IDE STUDY UPDATE

The by-patient, Kaplan-Meier risk rates of first occurrence of complications for patients in the primary augmentation:



CONSISTENT, LESS  
THAN 1%  
DEVICE-RELATED  
COMPLICATIONS  
SUPPORT  
BEST-IN-CLASS  
SAFETY STANDARD.

Primary Augmentation	2-Year (N=451), 95% CI	3-Year (N=451), 95% CI
Capsular contracture (Baker Grade III/IV)	0.5% (n=2)	0.5% (n=2)
Rupture, suspected or confirmed (MRI Cohort) <sup>1</sup>	0.6% (n=1)	0.6% (n=1)
Breast pain	0.5%	0.7%
Infection	0.9%	0.9%
Implant removal, with or without replacement	1.6%	1.6%
Any reoperation <sup>2</sup>	5.7%	6.1%
Any complication <sup>3</sup>	7.5%	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

All data presented is preliminary 3-year follow-up data and does not reflect the final study results nor establish the ultimate safety or effectiveness of the device.

## POST-MARKET SURVEILLANCE



MORE THAN 12-PLUS  
YEARS ON THE  
MARKET (FROM 2010  
TO MARCH 2023)

PRESENCE IN  
85-PLUS COUNTRIES

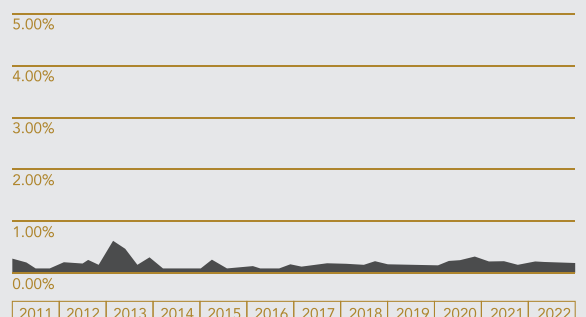
OVER THREE MILLION  
IMPLANTS IN THE  
MARKET

### Rate of Adverse Events Motiva® Implants Device-Related

Capsular Contracture	0.022%
Rupture	0.038%
Double Capsule	0.000%
BIA-ALCL (Primary)	0.000%
BIA-SCC (Primary)	0.000%
Other*	0.006%

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

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





## 80-PLUS PUBLICATIONS ON THE MOTIVA LITERARY SHELF

17 independent and peer-reviewed publications report low device-related complications and high patient satisfaction and patient follow-up range: six months to six years

Authors	Journal	Follow-up (years)	Number of cases	Capsular contracture (%)	Rupture (%)	Malposition (%)	Infection (%)
Sforza M et al.	Aesthetic Surgery Journal, 2018	2	2506	0	0	0	0.04
Chacón M et al.	Aesthetic Surgery Journal, 2018	6	35	0	0	0	0
Huemer G et al.	Plastic Reconstructive Journal Global Open, 2018	1 (n=71)	100	1	1	4	0
Sim HB	Aesthetic Surgery Journal, 2018	1	76	0	0	0	0
D'Onofrio et al.	Aesthetic Plastic Surgery, 2020	1	100	0	NA	NA	NA
Rigo M et al.	Aesthetic Plastic Surgery, 2020	1	387	0.3	0	0.8	0
Yoon S & Chang JH	Plastic Reconstructive Journal Global Open, 2020	1	152	1.3	0	2	0.6
Montemurro P & Kay VTS	Aesthetic Surgery Journal, 2020	2	161	1.2	0	0	0
Maximiliano J et al.	Aesthetic Surgery Journal, 2021	1.5	30	0	0	0	0
Munhoz AM et al.	Aesthetic Surgery Journal, 2021	1.5	42	2.4	0	0	0
Hong P et al.	Aesthetic Plastic Surgery, 2021	1.5	873	1.9	NA	1	0.7
Moon DS et al.	Journal of Plastic and Hand Surgery, 2021	0.33	76	0	NA	1.3	0
Zeplin PH	Handchir Mikrochir Plast Chir, 2021	1	252	0	0	NA	0
Lam MC et al.	Handchir Mikrochir Plast Chir, 2021	2	103	1.9	NA	1.9	NA
Botti et al.	Aesthetic Surgery Journal, 2021	3	356	0.6	0	0.3	0
Han et al.	Medicina, 2022	1	312	0	0	3.85	0
Randquist et al.	Aesthetic Surgery Journal, 2022	4	1053	0.4	0.2	2.9	0

See references for additional data on patient satisfaction

Four independent and peer-reviewed publications report low device-related complications in breast reconstruction, with a patient follow-up range of 14 months to 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, 1.49% were in women with non-irradiated breasts

## INTERNATIONAL REGISTRIES

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.<sup>1</sup>

\*Device-related complications are capsular contracture, device rupture, and/or BIA-ALCL.

1. The Breast Implant Registry, Sweden. Report to the Establishment Labs S.A. Motiva® Implants Industry Report (2014-2020), 2021.