The National Breast Implant Registry

Annual Report 2025

Allergan Aesthetics an AbbVie company

MENTOR

sientra a Tiger Aesthetics brand

Motiva by Establishment Labs

INTEGRA

The data contained in this report was captured during the NBIR Phase II Pilot and the first seven years of registry operations (November 2017 – September 30, 2025).

THE PLASTIC SURGERY FOUNDATION

This publication was produced by the National Breast Implant Registry (NBIR).

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During this year of registry operations, support was provided by The Plastic Surgery Foundation, Allergan Aesthetics, Establishment Labs, Mentor Worldwide LLC, Sientra/Tiger Aesthetics, and Integra.

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Thank You!

The National Breast Implant Registry (NBIR) Steering Committee has played a crucial role in the development, launch, and growth of the NBIR. We would like to thank all NBIR Steering Committee representatives for their time, effort, and participation in this very important initiative.

NBIR Steering Committee Representatives (October 1, 2024-September 30, 2025):

Colleen McCarthy, MD, MS (Chair) | **The PSF**

Amy K. Alderman, MD, MPH (co-Chair)

Andrea Pusic, MD, MS | **ASPS/PSF**

Joshua Der | **Mentor**

Rosalyn d'Incelli | **Establishment Labs**

Samira Lavingia | **Integra**

Melissa Pathmajeyan | **Allergan Aesthetics**

Sara Saul | **Sientra/Tiger Aesthetics**

Danica Marinac-Dabic, MD | **FDA**

Sung Yoon, MD | **FDA**

Myles Cockburn, PhD | **Epidemiologist**

Holly Adams| **Patient Representative**

Ashley Libby Diaz | **Patient Representative**

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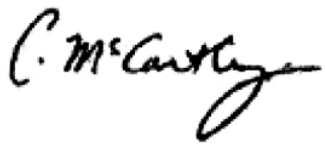
Letter From the Chairs

We are very excited to present this Annual Report of The Plastic Surgery Foundation's (PSF) National Breast Implant Registry (NBIR). The NBIR is a collaborative effort between The PSF, the United States Food and Drug Administration (FDA), patients and breast implant manufacturers to strengthen the post-market surveillance infrastructure for current and future breast implants in the United States. This report includes data submitted to the NBIR during Phase II of our NBIR Pilot (November 2017 – May 2018), as well as the first seven years of registry operations (October 3, 2018 – September 30, 2025). During this timeframe, the NBIR captured data on over 137,000 breast implant procedures reported by physicians across the United States.

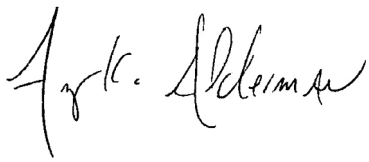
This report includes a detailed summary of data pertaining to patient demographics, risk/co-morbidity, procedural, and complication/adverse event data related to breast implants. The PSF continues to work with surgeons, patients, the FDA, breast implant manufacturers and other stakeholders to effectively utilize this data in strengthening national quality surveillance efforts. We are happy to share the substantial growth we saw in registry participation and case collection. We appreciate the commitment to patient safety from our NBIR participants, and we look forward to their continued participation in this very important initiative.

We hope that this report will not only serve as a guide to current progress and data highlights but will also serve as a call for future participants to join this national quality improvement effort. We look forward to NBIR continuing to evolve to further benefit patients and physicians.

Sincerely,



Colleen McCarthy, MD, FRCS(C)
Chair
NBIR Steering Committee



Amy K. Alderman, MD, MPH
Co-Chair
NBIR Steering Committee

Background

Registries are a powerful means to understand real-world patient outcomes and identify safety signals through systematic data collection and ongoing surveillance. Registries are particularly important for learning more about the safety of breast implants because the majority of these devices are placed for cosmetic reasons in healthy women who may not be seen regularly by a physician. The time between when the implant is placed and the development of an adverse event may be many years, further complicating efforts to collect accurate implant data. Due to the great volume of breast implant procedures that are performed, there is a need to further study these devices to ensure patient safety.

The ASPS and The PSF are committed to patient safety. Through the Plastic Surgery Registries Network (PSRN), ASPS/PSF have been fully invested in clinical data registries for over 20 years. The PSRN provides value to participants by allowing benchmarking of their performance to the registry aggregate, to improve their patient satisfaction, and decrease complications. Data from registries can also be used to inform performance measures and clinical practice guidelines.

The NBIR is a prospective, non-interventional, population-based, outcomes and safety surveillance registry and quality improvement initiative that collects clinical, procedural and outcomes data at the time of an implant operation and any subsequent reoperations (requiring and implant removal or exchange) for all patients receiving breast implants in the United States. The NBIR, a collaboration that The PSF started with FDA and the breast implant manufacturers in 2012, also provides an infrastructure for device manufacturers to facilitate the post-implant component of their device tracking data collection.

Registry Design

The NBIR is an all-comers, opt-out registry for both reconstructive and cosmetic procedures involving breast implants. The registry collects patient demographics, risk/co-morbidity, procedural, and complication/adverse event data related to breast implants. Data is entered into the NBIR at the time of implant placement and at the time of reoperation. The NBIR is designed to link an operation case to the initial implant procedure using minimal patient identifiable information. Collecting this information at these two timepoints, across reporting physicians, allows for a better understanding of the frequency and reasons for reoperation.

The NBIR case report form (CRF) is designed to include data required for device tracking, a federally mandated requirement of manufacturers of breast implants. In 2019, the NBIR launched a technology which allows the NBIR to serve as an infrastructure for the breast implant manufacturers to collect their device tracking data. This allows NBIR Participants to simultaneously register their implants with the manufacturers while also submitting their data to the registry.

Data Collection Model

Data is collected by physicians or their designated staff and entered directly into the NBIR web portal via manual data entry and the use of a mobile barcode scanning application.

The following data elements are entered manually:

- Physician/Reporter Information
- Patient Information
- Procedure Information
- Explanted Device Information
- Reasons for Reoperation

It is important to note that the data pertaining to the physician/reporter is populated automatically by the NBIR, since this data was previously entered by the physician during their NBIR registration. However, the data that was automatically populated can be edited if needed. The data pertaining to the implanted device is electronically captured using one of the NBIR mobile barcode scanning applications; HIPAA-compliant apps available for all Apple and Android devices. The apps connect to the FDA's Global Unique Device Identifier Database (GUDID), allowing it to scan and decode the Unique Device Identifier (UDI) barcode/QR code for all breast implants, and push this data to the NBIR CRF. This technology was implemented to allow for more accurate and complete data entry. It also allows physicians to enter the device information right from the operating room!

Governance

The NBIR Steering Committee is the governing body that oversees all registry operations, including the successful implementation, monitoring and management of resources and activities. Responsibilities include:

- Develop and implement the strategic goals of the NBIR
- Establish and prioritize the objectives and goals of the NBIR
- Provide input into NBIR operations and processes
- Provide strategic direction for the NBIR
- Monitor quality improvement, research and other clinical objectives
- View recommendations for data analysis that come from the Data Access and Publications Committee (DAPC)

The NBIR Steering Committee is comprised of representatives from ASPS, The PSF, the FDA, patients, researchers, and industry.

Data Access and Publications Committee

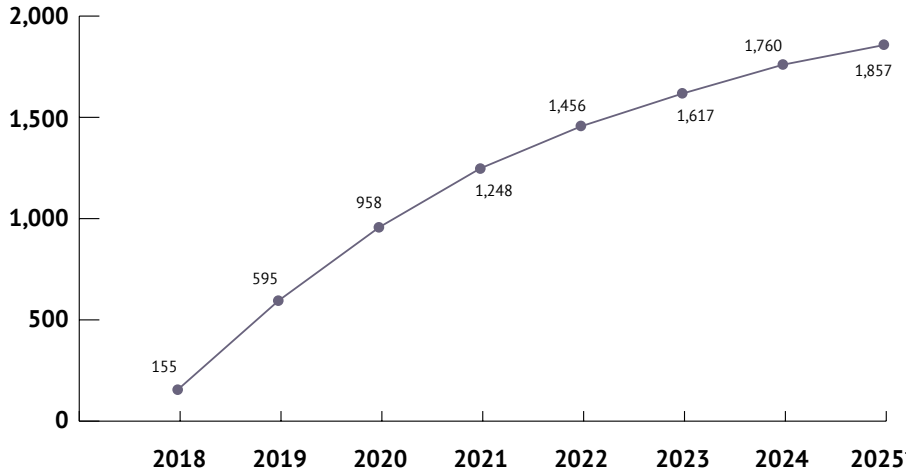
The DAPC is responsible for overseeing all activities related to data reporting, research and publications on aggregate NBIR data, and will address issues of access to NBIR data for analysis and potential research.

The DAPC is comprised of three representatives from The PSF, one representative from each breast implant manufacturer sponsoring the NBIR, and one epidemiologist/statistician/health services researcher.

Registry Participation

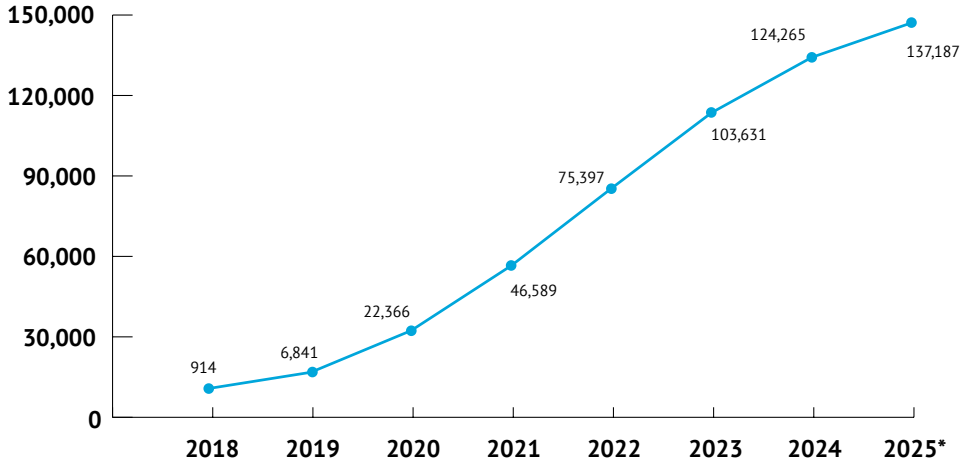
The NBIR has completed seven full years of data collection, which has included an overwhelming push of registration from surgeons across a wide variety of practice types and locations.

Figure 1: ***NBIR Registrants by Year***



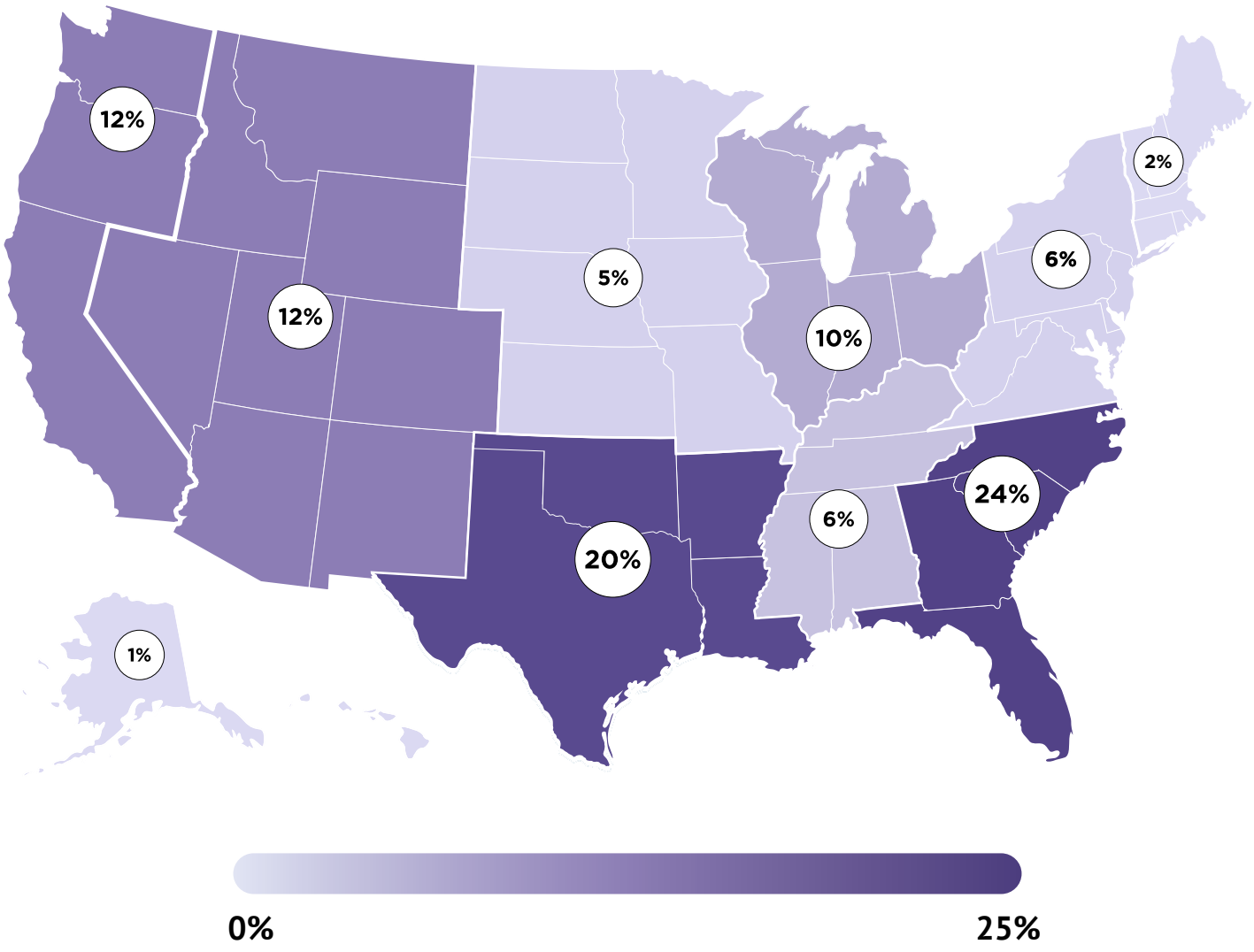
** Data up to September 30, 2025*

Figure 2: ***NBIR Cases Entered***



** Data up to September 30, 2025*

Figure 3. ***Geographic Breakdown by Region***



** Percent total volume of NBIR data contributed by each region (2% not reported)*

Registry Findings

Clinical Demographics

The average patient age is 43.8 years old, with a range of 15 to 100 years old. (Table 1). The median patient age was 42 years old. Aesthetic patients tended to be younger (median: 39 years old) than reconstructive patients (median: 54 years old). Figure 4 shows the age distribution of NBIR patients, indicating that patients undergoing reconstructive procedures tended to be older than the aesthetic patients.

Of the participants with race and ethnicity reported, over 92% were White/Caucasian race, and over 87.7% reported an ethnicity of non-Hispanic [Fig. 5,6]. African American and Asian patients made up 3.7% and 3.2%, respectively. The majority of cases entered involved female patients (99%), and less than 1% involved male or transgender patients, combined [Fig. 7]. Race was only reported in 27% of patients, while ethnicity was only reported in 24% of patients. Gender was reported in 37% of patients.

Table 1 – *Age of NBIR participants variables*

		NBIR	AEST	RECON
Age (years)	Range	15 - 100	15 - 100	15 - 92
	Average	43.8	40.8	54.0
	Median	42.0	39.0	54.0
	N	136,876	105,461	28,149

Figure 4 – *Age Range*

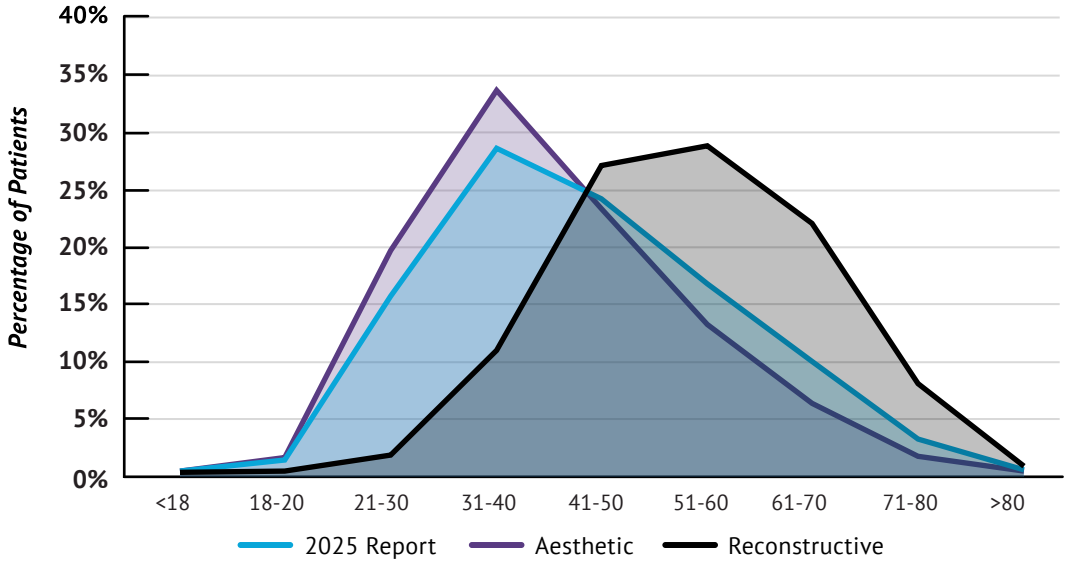
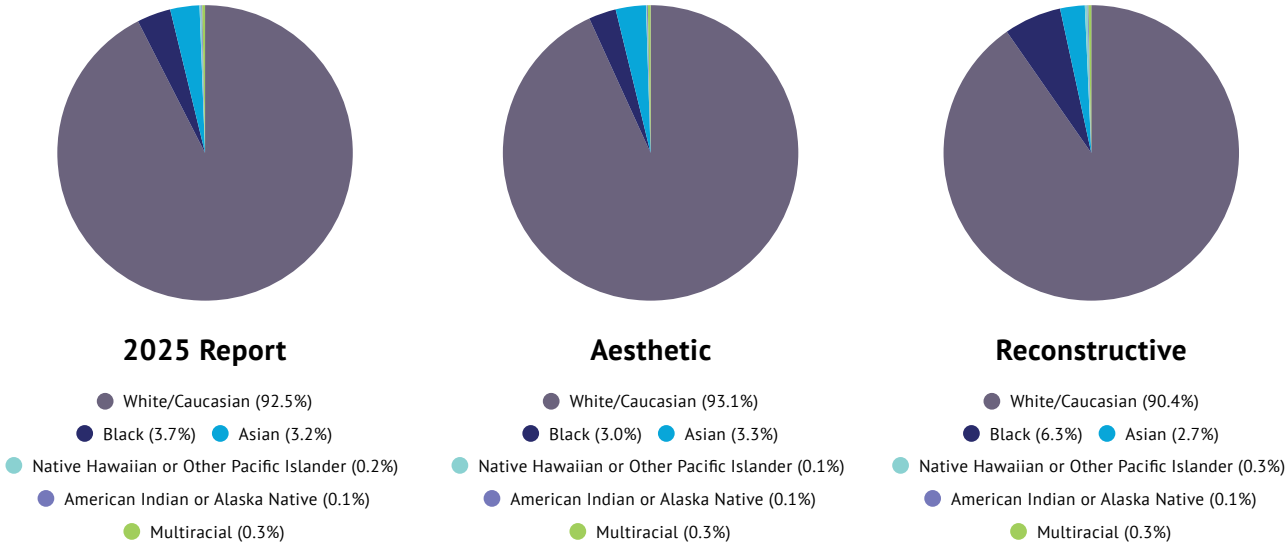
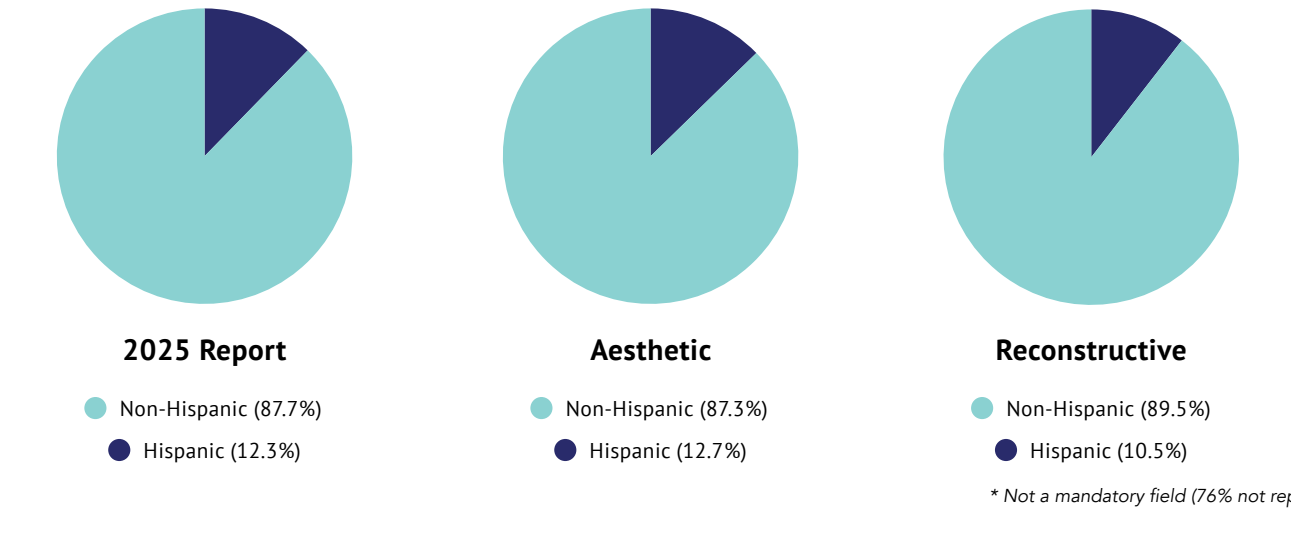


Figure 5 – *Race*



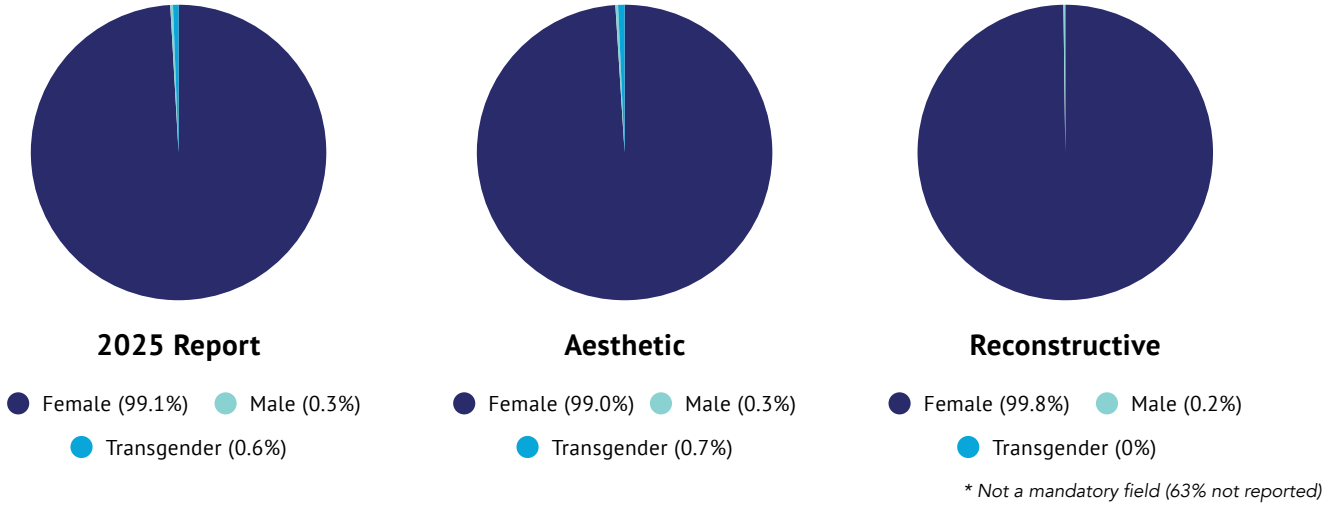
** Multiple values can be selected; not a mandatory field (73% not reported)*

Figure 6 – *Ethnicity*



** Not a mandatory field (76% not reported)*

Figure 7 – *Gender*

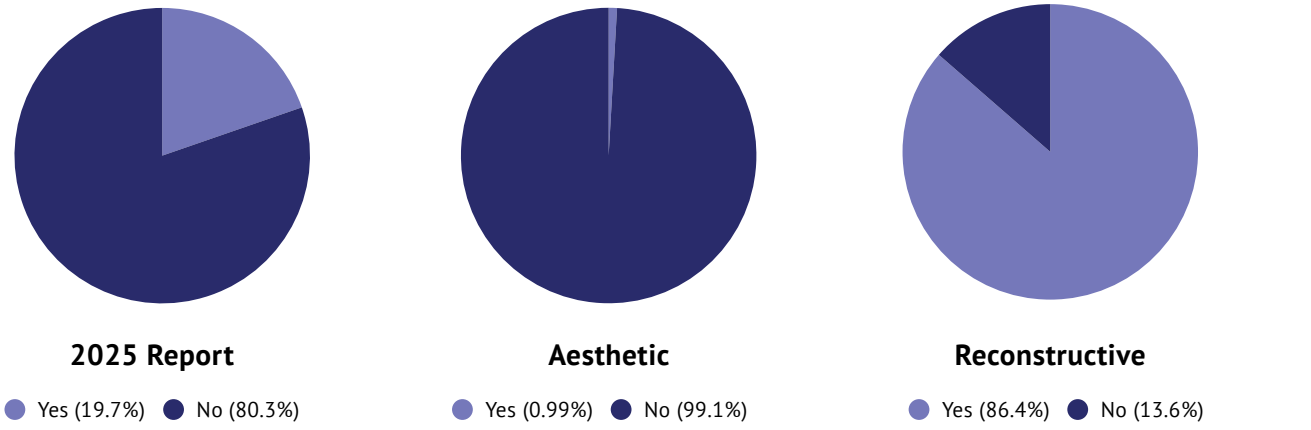


** Not a mandatory field (63% not reported)*

Patient Medical History

One of the greatest strengths of the NBIR is that it not only collects procedural information, but it also collects data on patients' medical history. A 19.7% of total cases reported a prior diagnosis of breast cancer [Fig. 8]. Patients often had a history of more than one medical condition. Twenty-two percent of cases reported a history of at least one medical issue [Fig. 9, Table 2]. Only six percent of NBIR cases are reported as current smokers [Fig. 10].

Figure 8 – *History of Breast Cancer*



** Not a mandatory field (67% not reported)*

Figure 9 – *Presence of Prior Medical Issues*

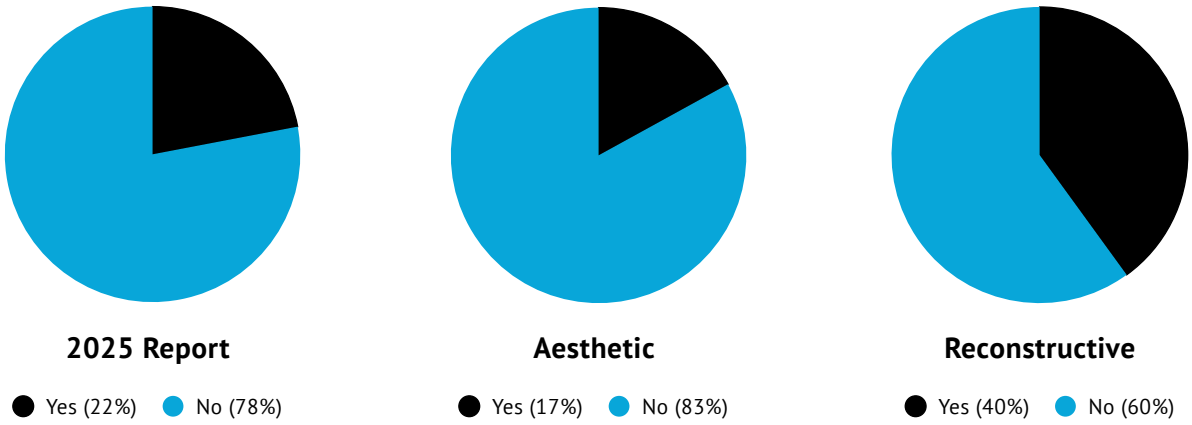
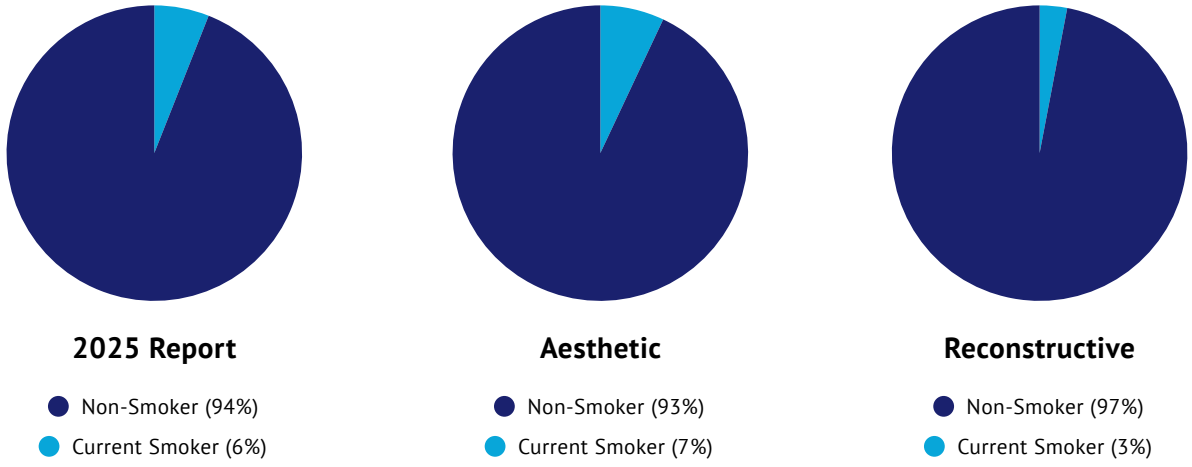


Table 2 – *Medical Issues Identified*

Medical Issues Reported	NBIR	%
Diabetes	871	2%
Renal Disease	122	0%
Cardiac Disease	429	1%
Lung Cancer	39	0%
Hypertension	3008	7%
RA	190	0%
Other	6593	15%

** Multiple values can be selected.*

Figure 10 – *Smoking Status*



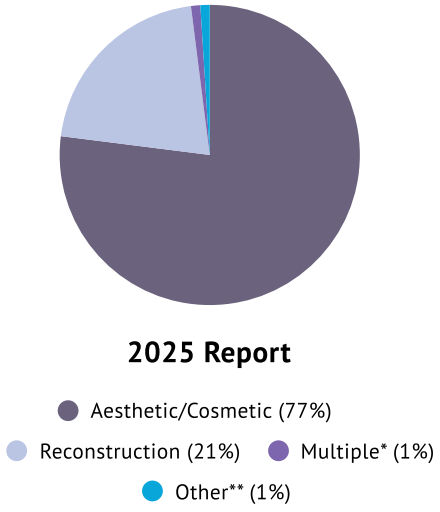
** Not a mandatory field (68% not reported)*

Procedure Information

It is important to note that results for procedure information are calculated using the total number of implants documented, as opposed to the total number of cases collected, since one case often collects data on more than one device. This is why data provided for procedure type appears inflated in comparison to raw case counts, as these figures include the left and/or right breast for each case.

There are two main categories for procedure type reported in the NBIR: Aesthetic/Reconstruction and Operation/Reoperation. Aesthetic procedures represented 77% of all reported indications [Fig. 11]. Approximately 27% of the total procedures are reoperation cases, and 72% involved an initial operation. [Fig. 12]. Figure 13 highlights that 64% of all procedures were implant insertions and 8% were expander removal and implant insertions. The most common reoperation is the implant replacement, occurring in 25% of all procedures. Implant removal without replacement, revision of breast and other reoperations constitutes 1% each of the remaining procedures in the registry [Fig. 13]. About 7% of all reoperation procedures also had capsulotomy or capsulectomy performed.

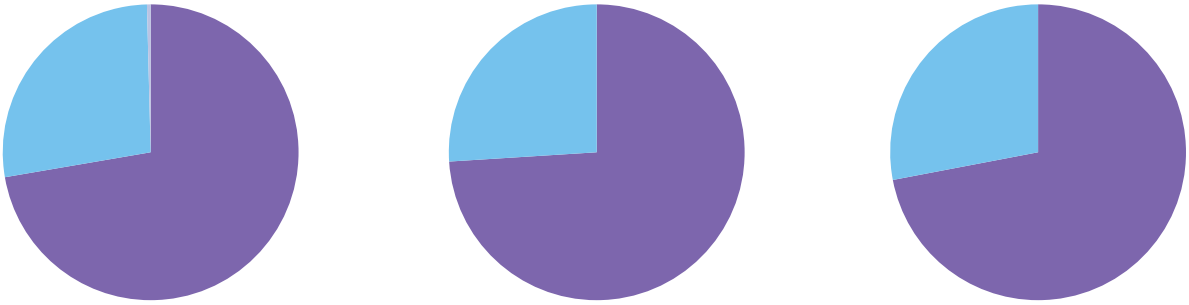
Figure 11 – *Procedure Indication*



*Different indication on left and right side
**Other Reoperation

The NBIR gathers additional procedural techniques regarding drains, fat grafting, surgical mesh, and acellular dermal matrices. Figures 14-17 show the use of these techniques involved in these reported procedures: drains (12%), acellular dermal matrix (ADM) (5%), surgical mesh (4%), or fat grafting (5%). Drain usage is much less common in aesthetic patients than in reconstructive patients [Fig. 14]. This is the case for ADM Usage and Fat Grafting as well [Fig. 15, 17]. Inframammary incisions made up close to 80% of incision types used, and submuscular/pectoral implant location made up 82% of implant location reports [Fig. 18, 19]. No other individual incision method or implant location exceeds 9% utilization by NBIR reporting surgeons.

Figure 12 – *Operation Indication*†



2025 Report

- Primary Operation (72.3%)
- Reoperation (27.3%)
- Both* (0.4%)

Aesthetic

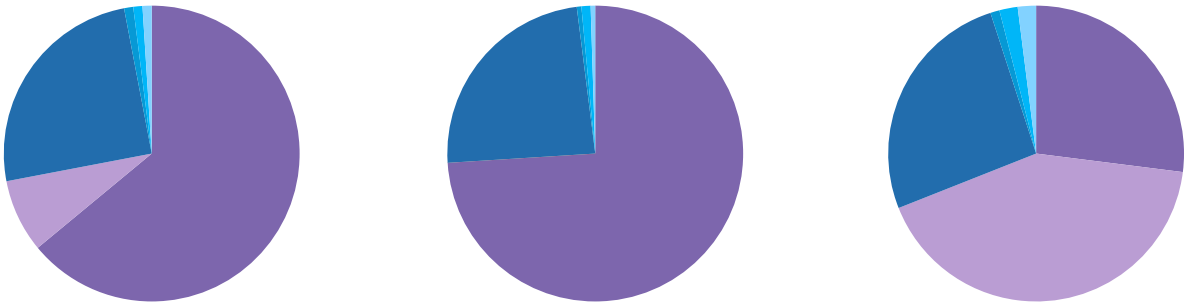
- Primary Operation (74%)
- Reoperation (26%)

Reconstructive

- Primary Operation (72%)
- Reoperation (28%)

** "Operation" on one side and "Reoperation" on other side.*
† Percentage calculated based on total number of cases

Figure 13 – *Operation Types*‡



2025 Report

Total Initial Implant Insertion (72%)
- Implant Insertion (64%)
- Expander Removal, Implant Insertion (8%)

Total Reoperation (28%)
- Implant Replacement (25%)
- Implant Removal without Replacement (1%)
- Breast Revision (1%)
- Other Reoperation (1%)

Aesthetic

Total Initial Implant Insertion (74%)
- Implant Insertion (74%)
- Expander Removal, Implant Insertion (0%)

Total Reoperation (26%)
- Implant Replacement (24%)
- Implant Removal without Replacement (0.5%)
- Breast Revision (1%)
- Other Reoperation (0.5%)

Reconstructive

Total Initial Implant Insertion (69%)
- Implant Insertion (27%)
- Expander Removal, Implant Insertion (42%)

Total Reoperation (31%)
- Implant Replacement (26%)
- Implant Removal without Replacement (1%)
- Breast Revision (2%)
- Other Reoperation (2%)

‡ Percentage calculated based on total counts of operation. More than one value may be selected for each case and each side

Figure 14 – *Drain Usage*

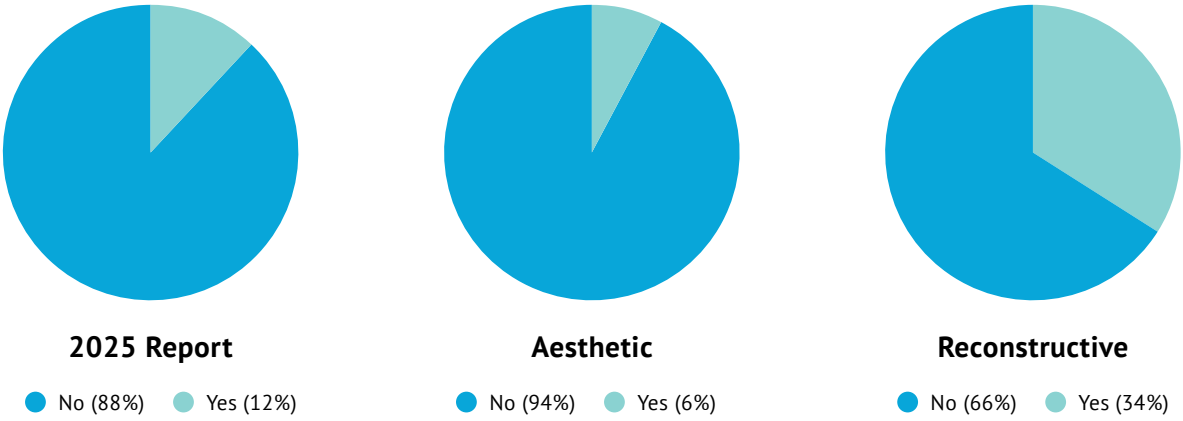
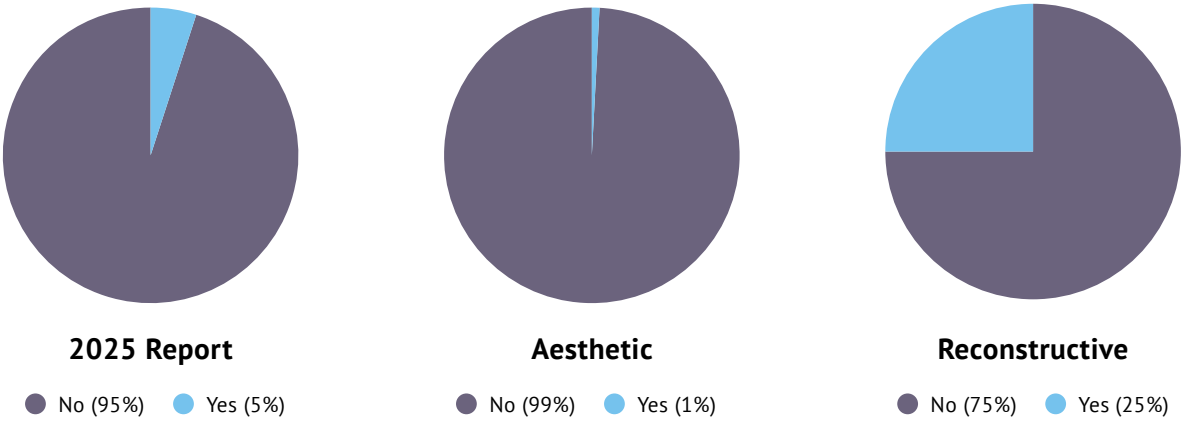
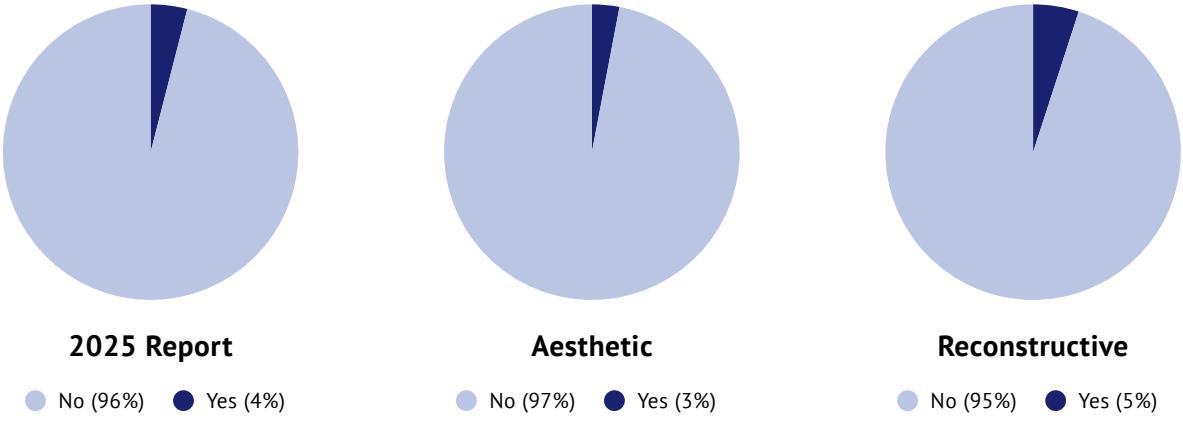


Figure 15 – *Acellular Dermal Matrix (ADM)*



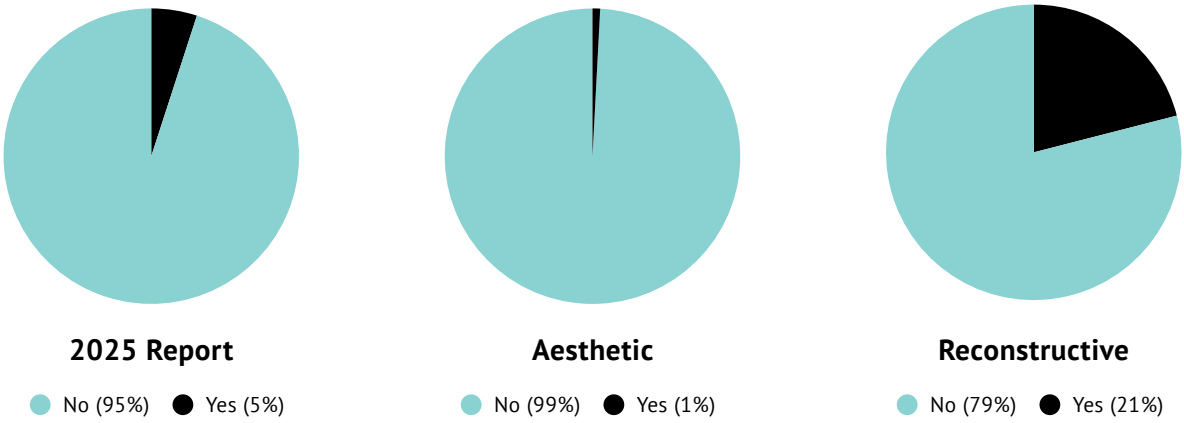
** Not reported 40%*

Figure 16 – *Surgical Mesh*



** Not reported 40%*

Figure 17 – *Fat Grafting*



** Not reported 40%*

Figure 18 – *Incision Type*

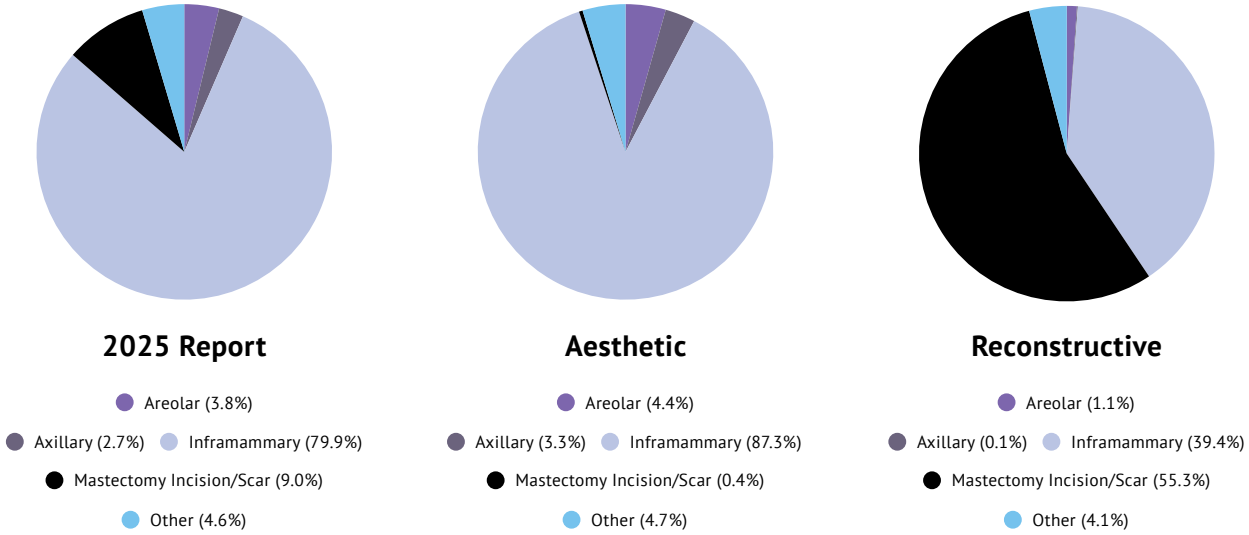
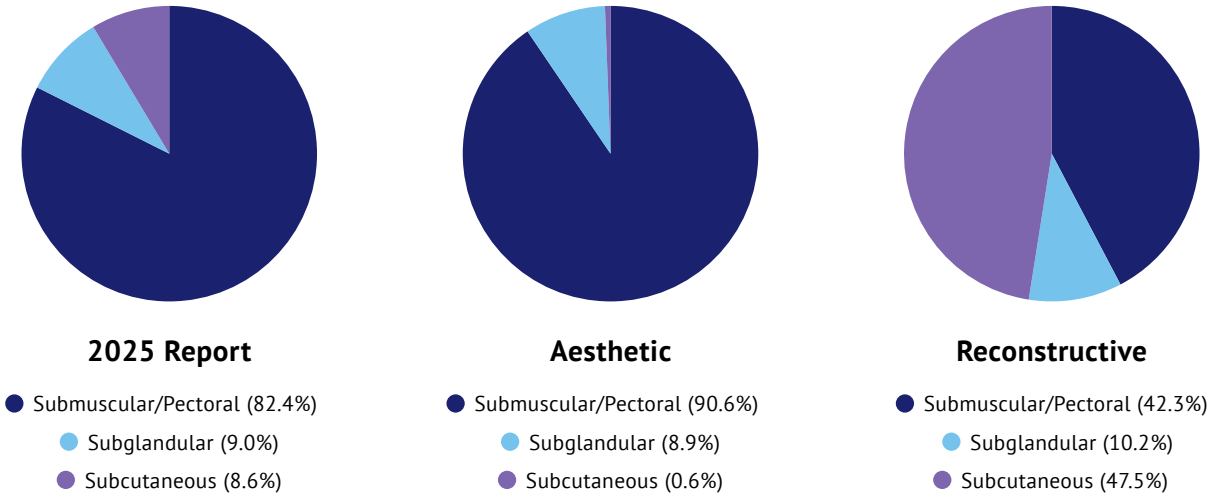


Figure 19 – *Implant Placement Location*



Device Information

A variety of implant types have been reported in the registry, with certain devices predominating. Surgeons reported the use of smooth implants in over 99% and round implants in over 99% of the cases [Fig. 20, 21]. Silicone is the typical implant fill (89%), followed by 9% filled with saline [Fig. 22].

Figure 20 – *Device Texture*

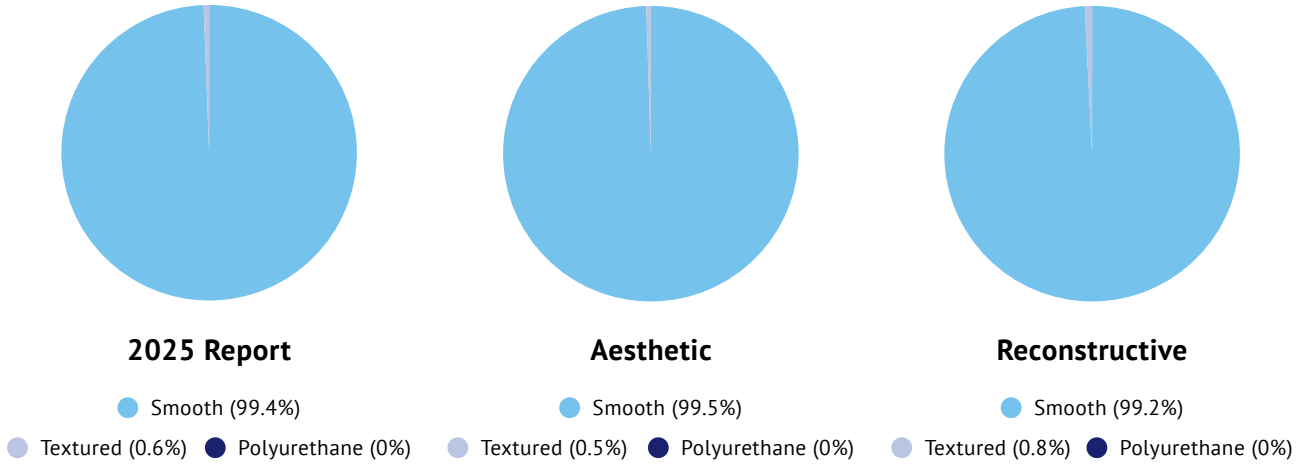


Figure 21 – *Device Shape*

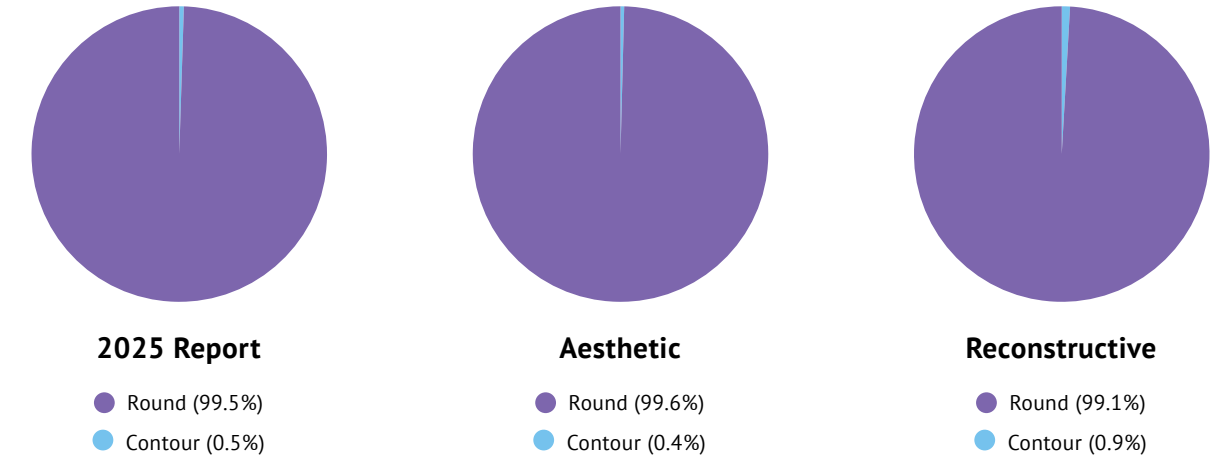
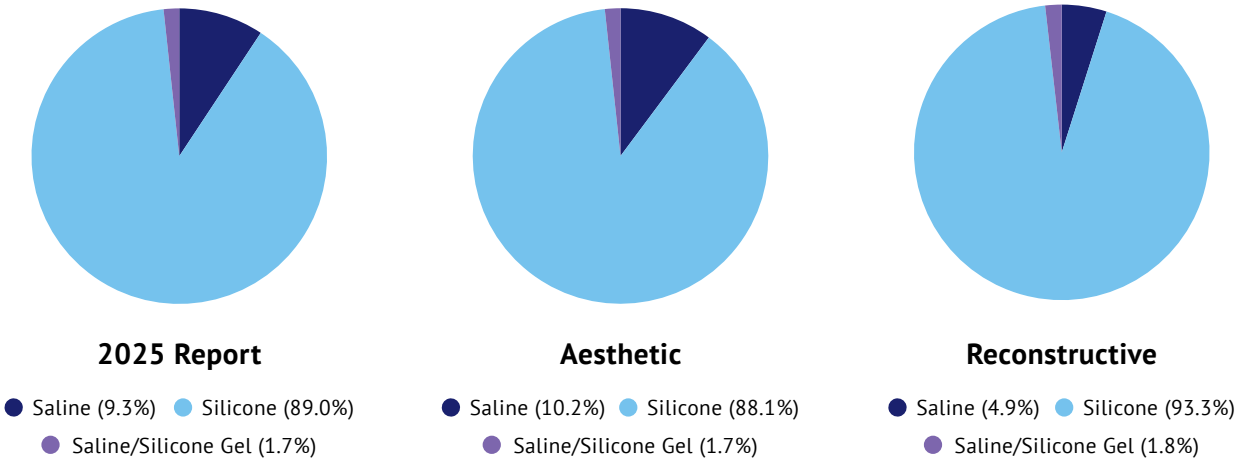


Figure 22 – *Device Fill*



Reoperation

Reoperations are the primary endpoint for the NBIR. As reported in Figure 12, reoperations account for 27% of procedures reported to the NBIR. This includes data for both the left and right implants within each case. It is important to note that each case can have multiple reasons for reoperation reported.

Reoperations are done for a wide variety of reasons, including complications associated with the surgery and device problems. However, the majority (57.5%) are done in response to patient request, mostly regarding change in shape, size, style or ptosis [Fig. 23, Table 3]. The most common reported complication leading to reoperation was Capsular Contracture, representing 14% of all reported reoperations [Table 3]. Of note, the following are not listed in the table as each represents less than 0.3% of the reasons for reoperation: Hematoma, Seroma and Skin Necrosis.

Figure 23 – *Reasons for Reoperation*

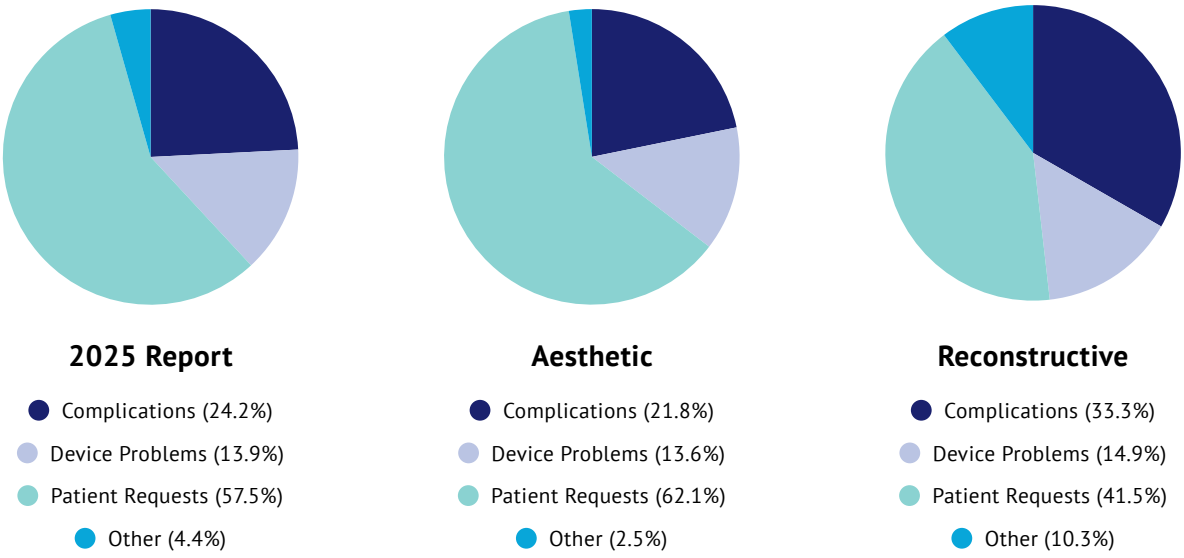


Table 3 – *Reasons for Reoperation*

Complications	Reop Category	2025 Report	Aesthetic	Recon
Change Size/Shape/Style	Patient Request	47.44%	50.37%	38.36%
Capsular Contracture	Complications	14.17%	13.75%	15.32%
Suspected/Actual Deflation/ Rupture	Device Issues	11.03%	11.34%	9.41%
Ptosis	Patient Request	10.02%	11.71%	3.15%
Device Migration/Implant Mal-position	Complications	8.41%	7.28%	13.64%
Wrinkling/Rippling	Device Issues	2.87%	2.26%	5.47%
Staged Reconstruction	Other	1.14%	0.27%	4.65%
Infection	Complications	0.49%	0.19%	1.35%
Wound Problems	Complications	0.45%	0.21%	1.28%
Need for Biopsy/Tumor	Other	0.18%	0.13%	0.37%
Recurrent Cancer	Other	0.08%	0.01%	0.33%
BIA-ALCL	Other	0.03%	0.02%	0.03%
BIA-SCC	Other	0.00%	0.00%	0.00%
Lymphoma	Other	0.00%	0.00%	0.00%
Other Cancer	Other	0.03%	0.02%	0.07%
Other	Other	2.93%	2.05%	4.86%

**reflects % of reported reasons for reoperation*

Tables 4-6 show the trends in Device Texture, Shape and Fill reported over the past five years. The use of textured implants has remained at 0.6% or below (Table 4) over the last five years, and contour implants have remained at 0.7% or below (Table 5). The use of Silicone-filled implants is showing a slightly upward trend over the last five years (Table 6).

Table 4 – *Trends in Device Texture*

Device Texture	2020	2021	2022	2023	2024	2025
Polyurethane	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Smooth	99.4%	99.4%	99.5%	99.4%	99.5%	99.4%
Textured	0.5%	0.5%	0.5%	0.6%	0.5%	0.6%

Table 5 – *Trends in Device Shape*

Device Shape	2020	2021	2022	2023	2024	2025
Contour	0.6%	0.6%	0.7%	0.5%	0.2%	0.4%
Round	99.4%	99.4%	99.4%	99.5%	99.8%	99.6%

Table 6 – *Trends in Device Fill*

Device Fill	2020	2021	2022	2023	2024	2025
Saline	11.9%	11.1%	9.4%	8.8%	7.5%	7.1%
Silicone	85.4%	86.6%	87.9%	90.0%	91.5%	91.9%
Saline/Silicone Gel	2.6%	2.3%	2.6%	1.1%	1.0%	1.0%

Future Perspectives

Increase Registry Use

In the upcoming year, the NBIR Steering Committee will focus on developing initiatives to help increase the number of NBIR Participants and the number of cases collected in the registry, including a focus on academic center engagement. This will include making modifications to the data entry platform that will improve the user experience, the development of additional resources for NBIR Participants, and the development of an aggressive awareness campaign.

The PSF will also continue to work with the breast implant manufacturers to promote the use of device tracking/registration using the NBIR to help increase NBIR participation and data collection.

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NBIR
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