

The National Breast Implant Registry

Annual Report 2023



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

Any inquiries or comments regarding this publication should be directed to:

National Breast Implant Registry
Attn: Katie Sommers, MPH,
Director of Research and Scientific Affairs
444 East Algonquin Road
Arlington Heights IL 60005
ksommers@plasticsurgery.org

The data contained in this report was captured during the NBIR Phase II Pilot and the first five years of registry operations (November 2017 – September 30, 2023).

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

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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, 2021-September 30, 2023):

*Andrea Pusic, MD (Chair) | **The PSF***

Colleen McCarthy, MD, MS (co-Chair)

*Debra Johnson, MD | **ASPS/PSF***

*Melissa Pathmajeyan | **Allergan Aesthetics***

*Denise Dajles | **Sientra***

*Joshua Der | **Mentor***

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

*Sung Yoon, MD | **FDA***

*Myles Cockburn, PhD | **Epidemiologist***

*Ashley Libby Diaz | **Patient***

*Holly Adams | **Patient***

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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 five years of registry operations (October 3, 2018 – September 30, 2023). During this timeframe, the NBIR captured data on nearly 87,000 breast implant procedures reported by physicians across the United States.

This report includes a detailed summary of data pertaining to patient demographic, 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.

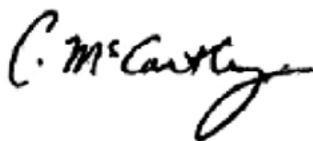
We are happy to share the substantial growth we saw in registry participation and case collection. We appreciate the commitment to patient safety from our NBIR participants, and we look forward to their continued participation in this very important initiative.

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 continuing to evolve the NBIR to further benefit patients and physicians.

Sincerely,



Andrea L. Pusic, MD
Co-Chair
NBIR Steering Committee



Colleen McCarthy, MD, FRCS(C)
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 demographic, 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. As of July 1, 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 for physicians to enter their 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 five full years of data collection which has included an overwhelming push of registration from surgeons across a wide variety practice types and locations.

Figure 1: NBIR Registrants by Year

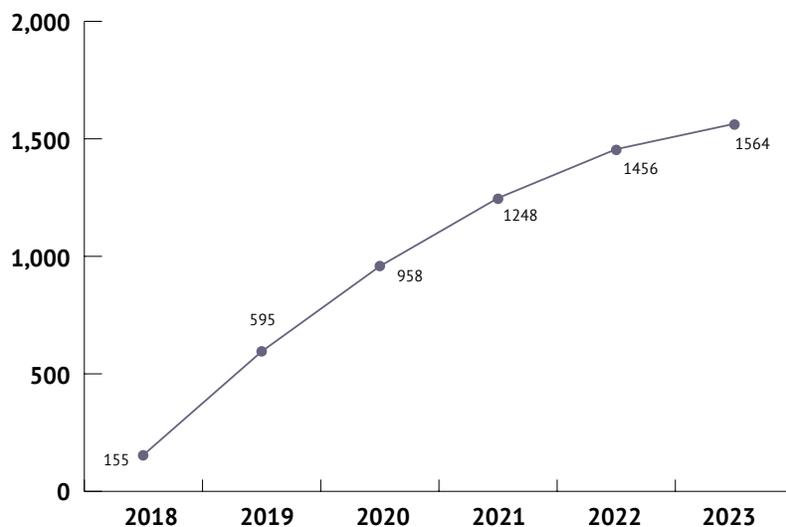


Figure 2: NBIR Cases Entered

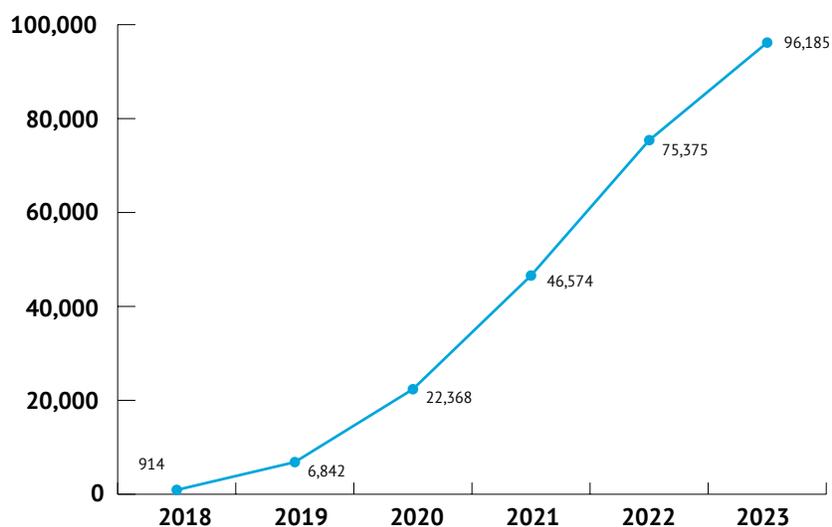
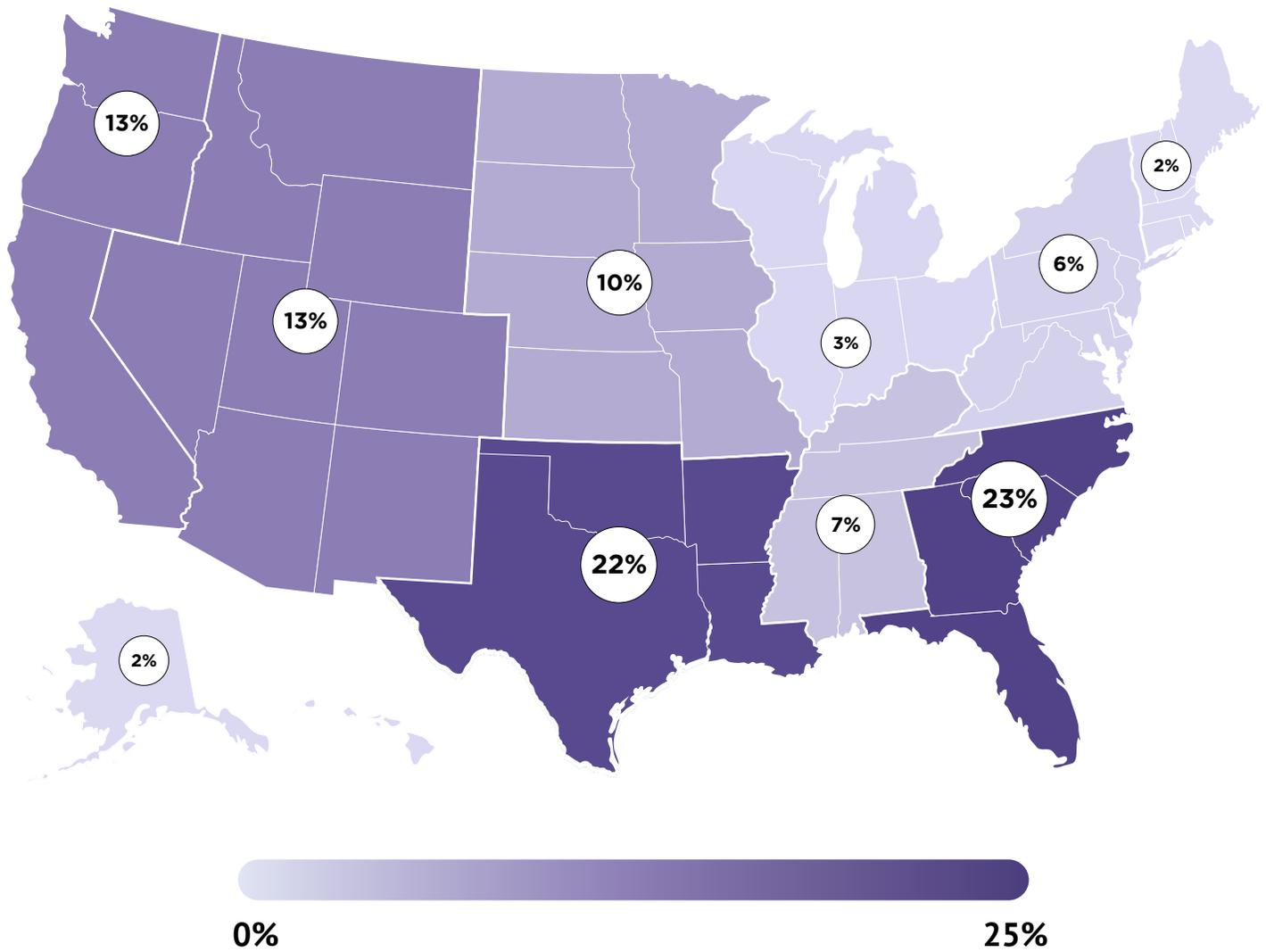


Table 1. Geographic Breakdown by Region



Registry Findings

Clinical Demographics

The average patient age is 42.5 years old with a range of 15 to 100 years old. (Table 2). The median patient age was 41 years old. Aesthetic patients tended to be younger (median: 38 years old), than reconstructive patients (median: 54 years old). Figure 3 shows the age distribution of NBIR patients, indicating that reconstructive patients tended to be older than the aesthetic patients.

Of the participants with race and ethnicity reported, 92% were White/Caucasian race, and 87% reported an ethnicity of non-Hispanic [Fig. 4,5]. African American and Asian patients made up 3.9% and 3.2% respectively. Majority of cases entered involved female patients (99%), and a combined 1% involved male or transgender patients [Fig. 6]. Race was only reported in 33% of patients, while ethnicity was only reported in 28% of patients. Gender was reported in 44% of patients.

Table 2 – Age of NBIR participants variables

Age (years)	2023 Report		Aesthetic	Reconstructive
	Range	15 - 100	15 - 100	15 - 92
Average	42.5	39.8	53.9	
Median	41.0	38.0	54.0	

Figure 3 – Age Range

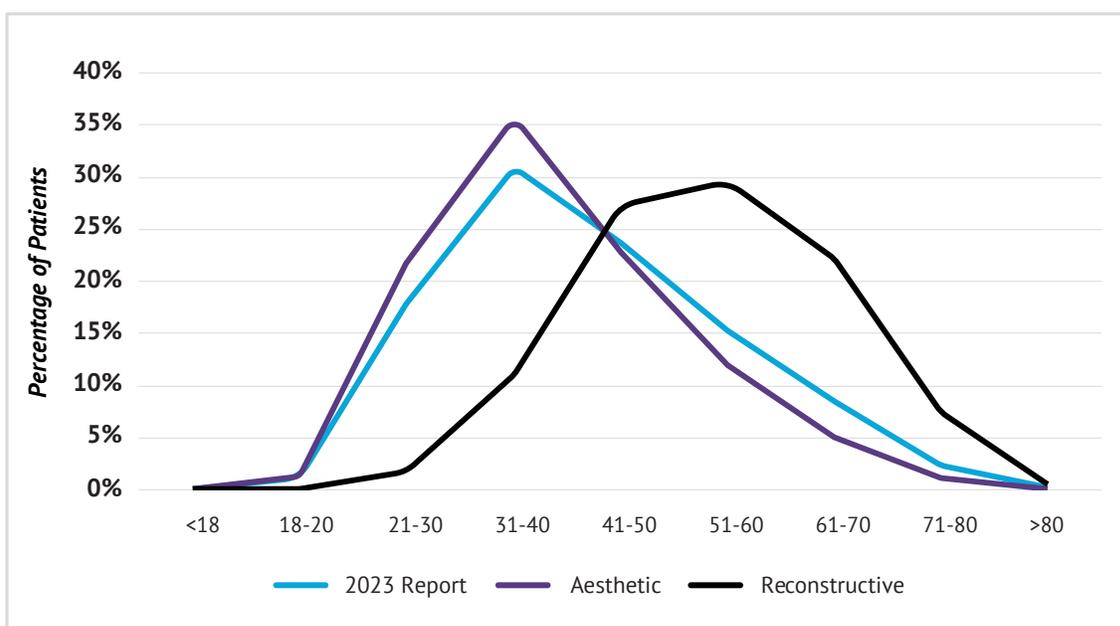
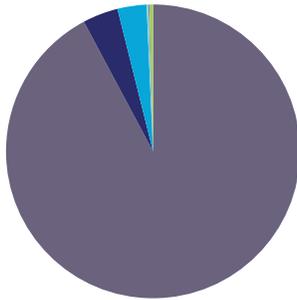
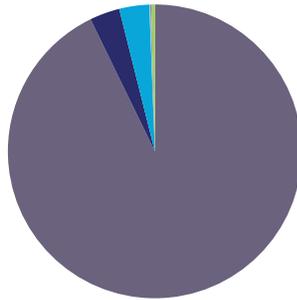


Figure 4 – Race



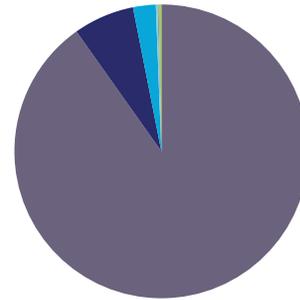
2023 Report

- White/Caucasian (92.3%)
- Black or African American (3.9%) ● Asian (3.2%)
- Native Hawaiian or Other Pacific Islander (0.2%)
- American Indian or Alaska Native (0.1%)
- Multiracial (0.4%)



Aesthetic

- White/Caucasian (92.7%)
- Black or African American (3.3%) ● Asian (3.3%)
- Native Hawaiian or Other Pacific Islander (0.1%)
- American Indian or Alaska Native (0.1%)
- Multiracial (0.4%)

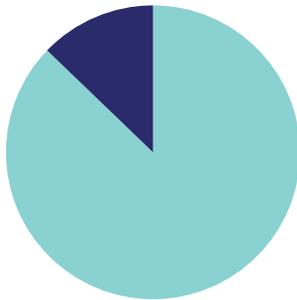


Reconstructive

- White/Caucasian (90.1%)
- Black or African American (6.7%) ● Asian (2.5%)
- Native Hawaiian or Other Pacific Islander (0.2%)
- American Indian or Alaska Native (0.1%)
- Multiracial (0.3%)

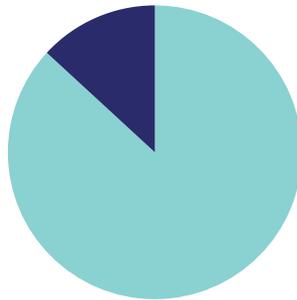
* Multiple values can be selected; not a mandatory field

Figure 5 – Ethnicity



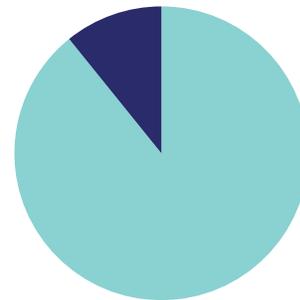
2023 Report

- Non-Hispanic (87.2%)
- Hispanic (12.8%)



Aesthetic

- Non-Hispanic (86.8%)
- Hispanic (13.2%)

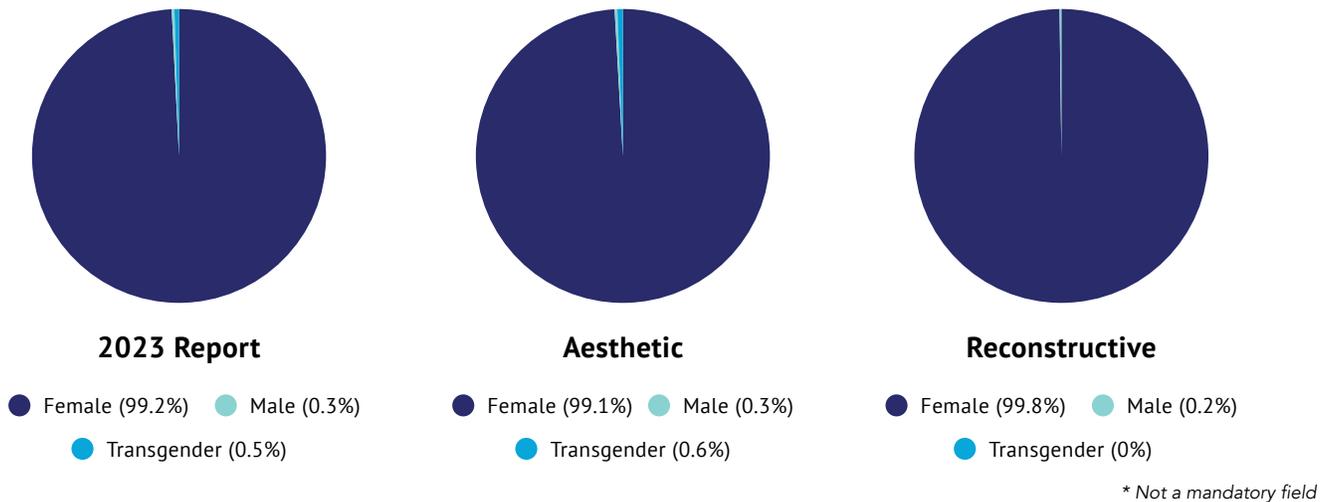


Reconstructive

- Non-Hispanic (89.2%)
- Hispanic (10.8%)

* Not a mandatory field

Figure 6 – Gender



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. Eighteen percent of cases reported a prior diagnosis of breast cancer [Fig. 7], which is consistent with previous Annual Reports. Patients often had a history of more than one medical condition. Twenty-one percent of cases reported at least one medical condition in the past [Fig. 8]. Only 7 percent of NBIR cases are reported current smokers (Fig. 10).

Figure 7 – History of Breast Cancer

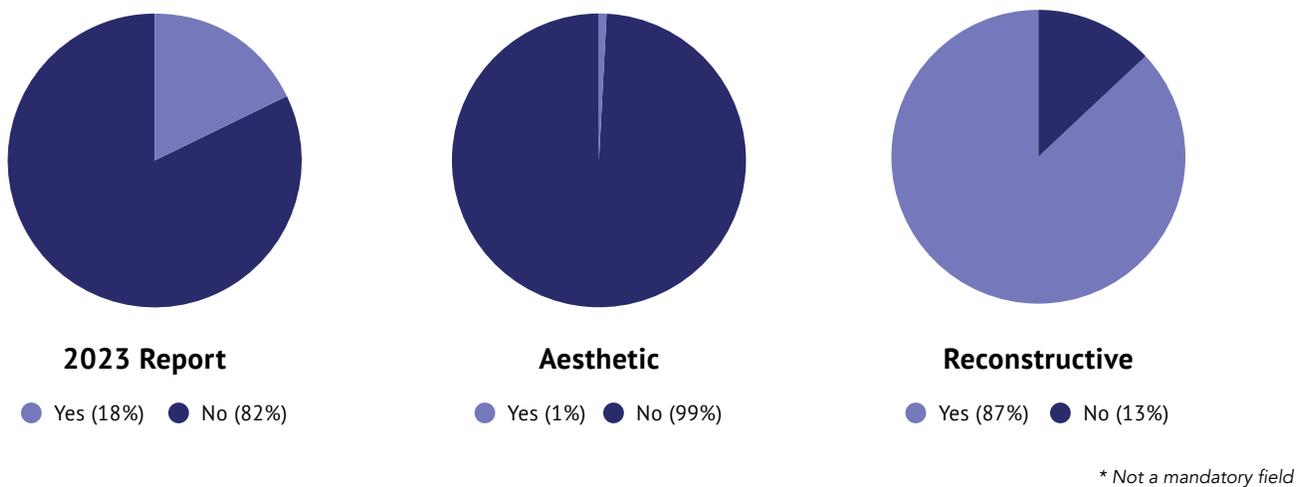


Figure 8 – Presence of Prior Medical Condition

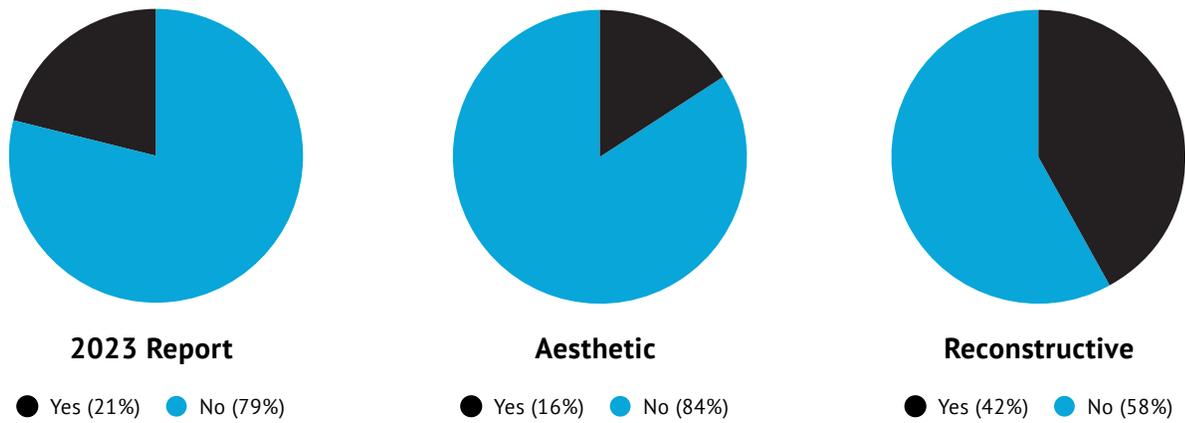
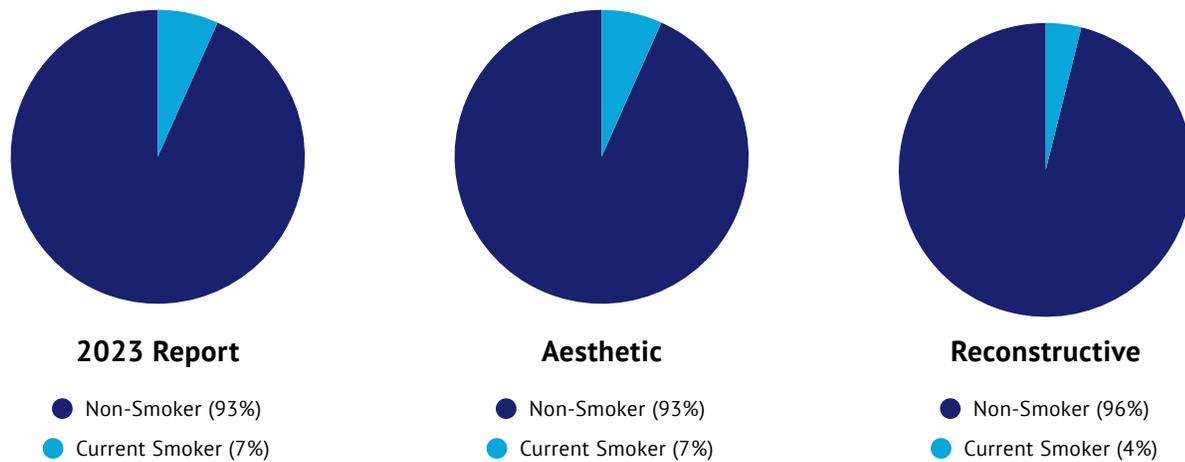


Figure 9 – Medical Issues Identified

Medical Issues Reported	NBIR	%
Diabetes	614	2%
Renal Disease	100	0%
Cardiac Disease	332	1%
Lung Cancer	30	0%
Hypertension	2228	7%
RA	140	0%
Other	4924	15%

* User can select more than one field.

Figure 10 – Smoking Status



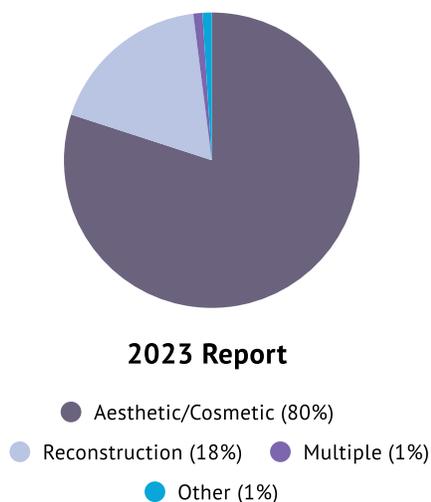
Procedure Information

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 collect 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 80% of all reported indications [Fig. 11]. Approximately 27% of the total procedures are reoperation cases and 73% involved an initial operation. [Fig. 12]. Of note, reconstructive procedures have a higher percentage of revision or reoperations than do aesthetic procedures. Figure 12 breaks down the type of procedure. Figure 13 highlights that 90% of all procedures involve the placement of a breast implant, while one percent of all procedures

in the registry are for explanting devices. The most common reoperation is the implant exchange/replacement occurring in 22% of all procedures.

Figure 11 – Procedure Indication



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: surgical mesh (2%), fat grafting (4%), drains (12%) or acellular dermal matrix (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 80% of incision types used, and submuscular/pectoral implant location made up 84% 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

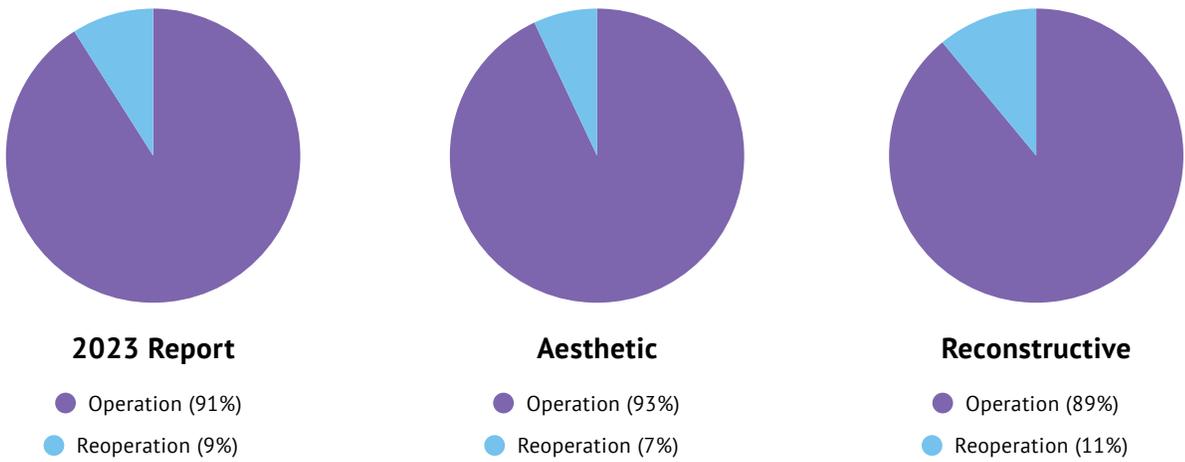
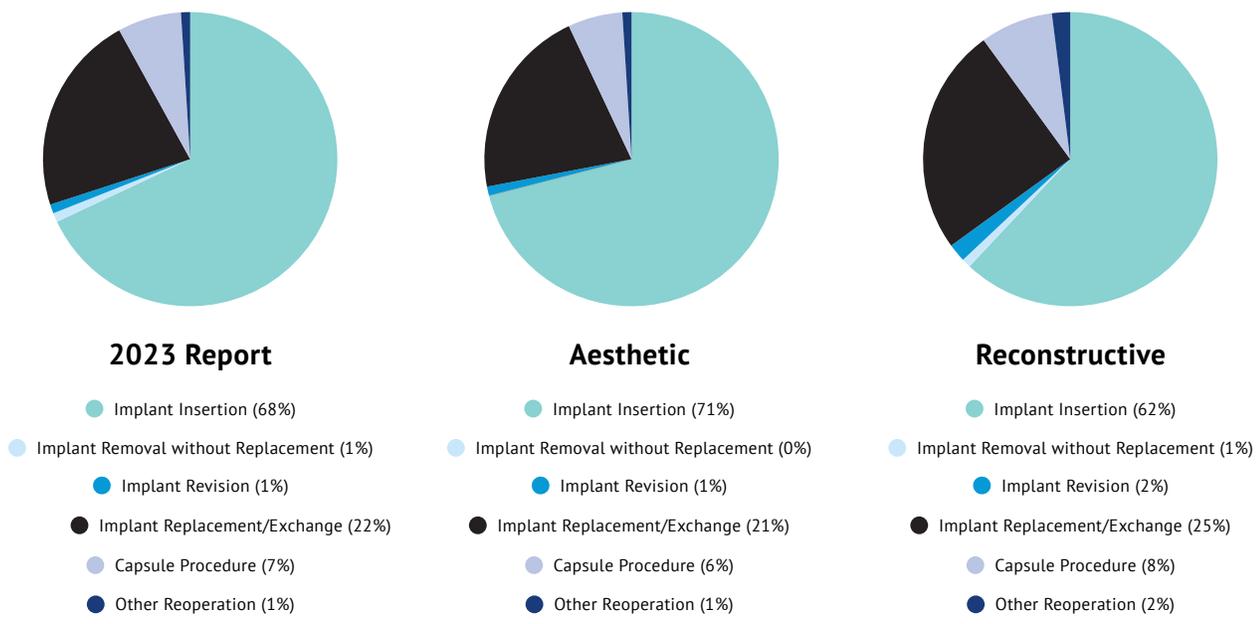


Figure 13 – Operation Types*



* More than one option can be selected

Figure 14 – Drain Usage

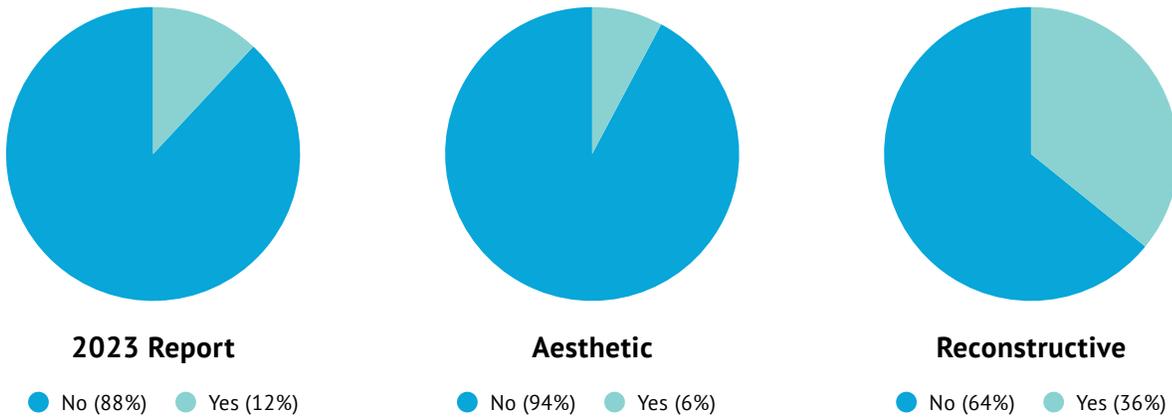


Figure 15 – Acellular Dermal Matrix (ADM)

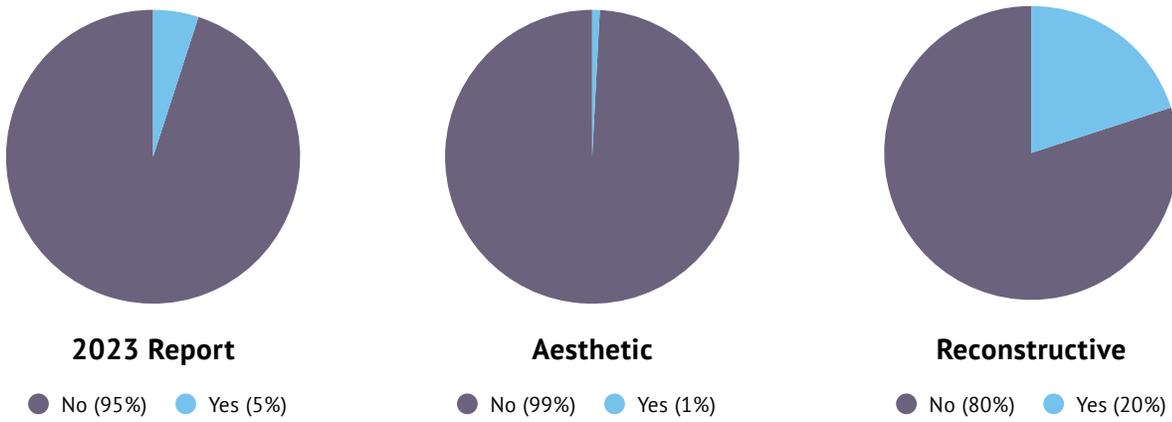


Figure 16 – Surgical Mesh

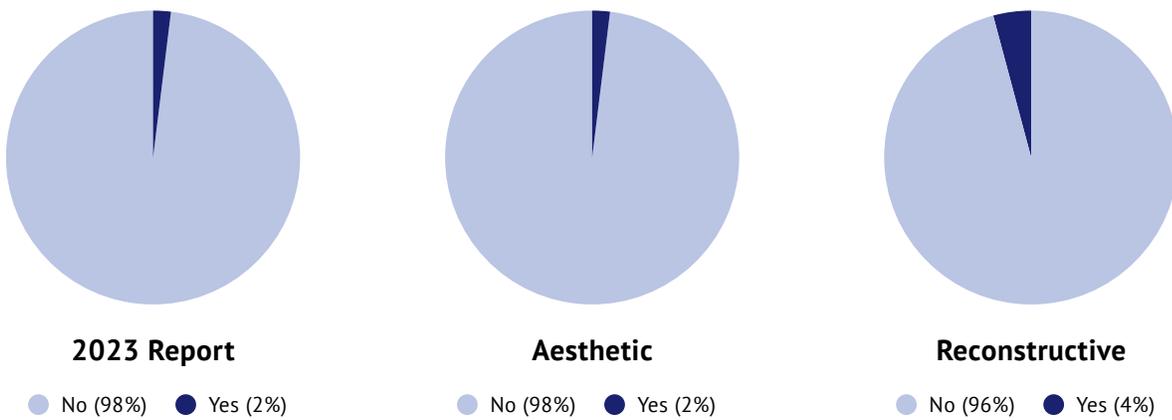
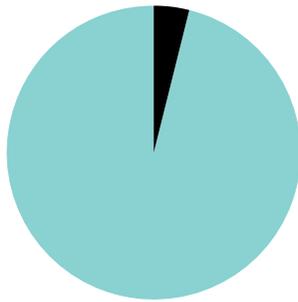
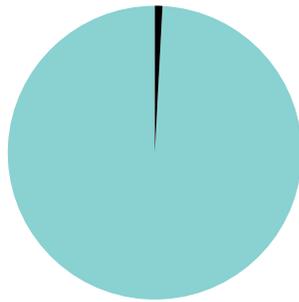


Figure 17 – Fat Grafting



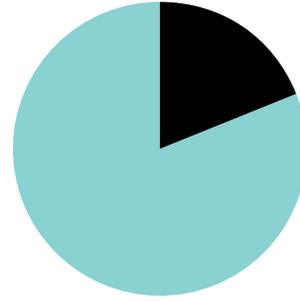
2023 Report

● No (96%) ● Yes (4%)



Aesthetic

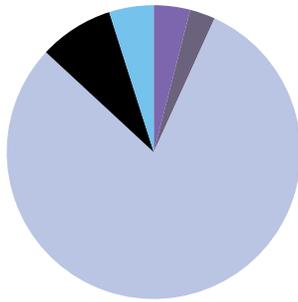
● No (99%) ● Yes (1%)



Reconstructive

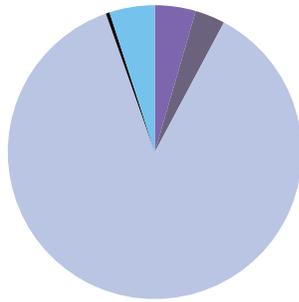
● No (81%) ● Yes (19%)

Figure 18 – Incision Type



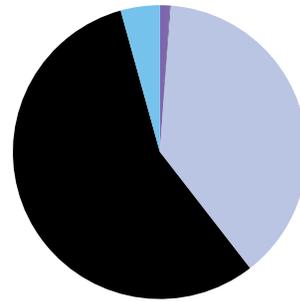
2023 Report

● Axillary (2.8%) ● Inframammary (80.1%)
 ● Mastectomy Incision/Scar (8.2%)
 ● Other (4.9%)
 ● Areolar (4.0%)



Aesthetic

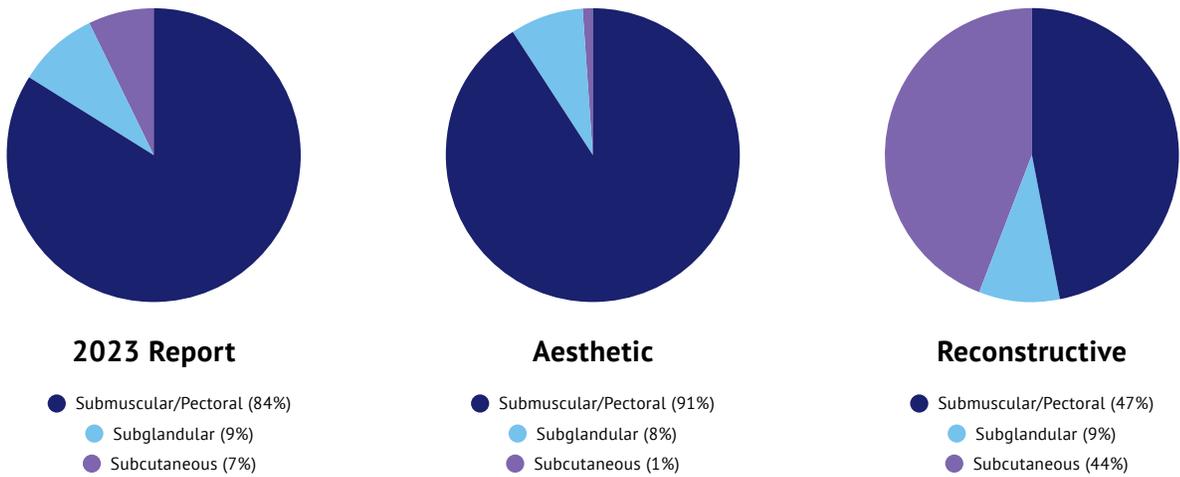
● Axillary (3.3%) ● Inframammary (86.9%)
 ● Mastectomy Incision/Scar (0.4%)
 ● Other (5.0%)
 ● Areolar (4.5%)



Reconstructive

● Axillary (0.1%) ● Inframammary (38.3%)
 ● Mastectomy Incision/Scar (56.2%)
 ● Other (4.3%)
 ● Areolar (1.1%)

Figure 19 – Implant Placement Location



Device Information

A variety of implant types have been reported in the registry, with certain devices predominating. Surgeons reported use of smooth implants in 99% and round implants almost 100% respectively [Fig. 20, 21]. Silicone is the typical implant fill (88%) followed by 10% filled with saline. [Fig. 22].

Figure 20 – Device Texture

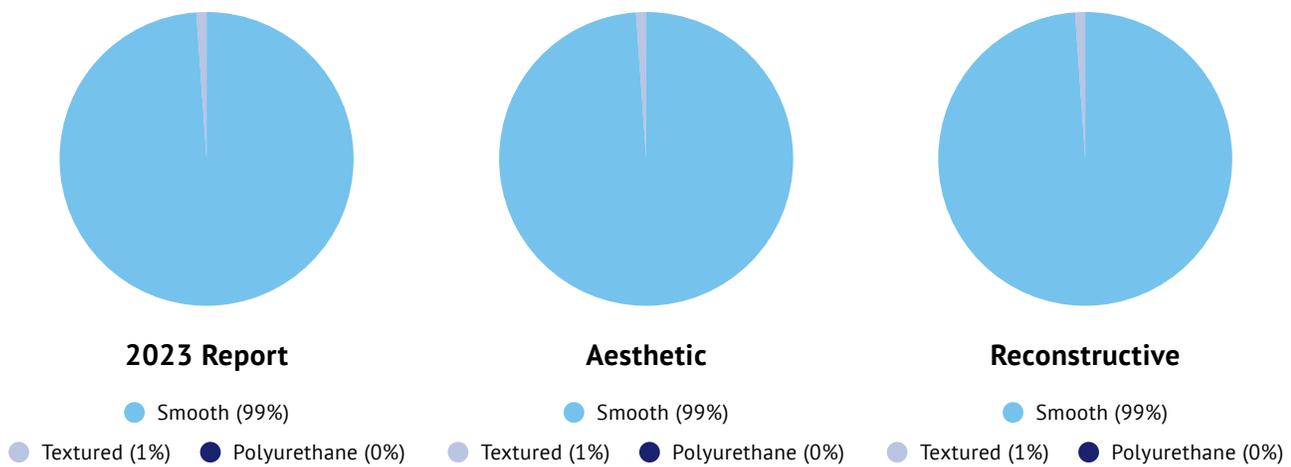
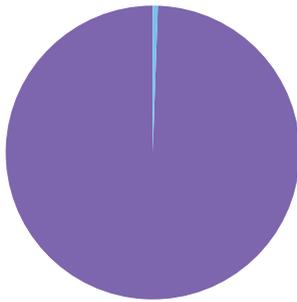
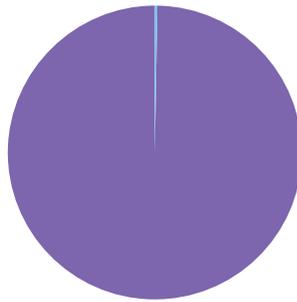


Figure 21 – Device Shape



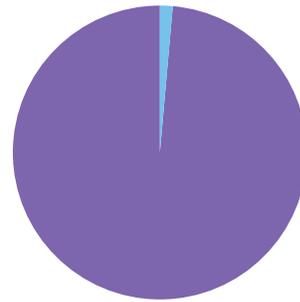
2023 Report

- Round (99.3%)
- Contour (0.7%)



Aesthetic

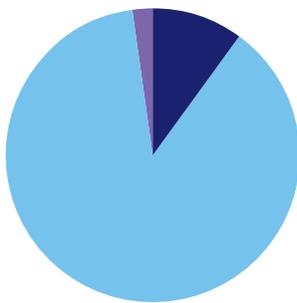
- Round (99.5%)
- Contour (0.5%)



Reconstructive

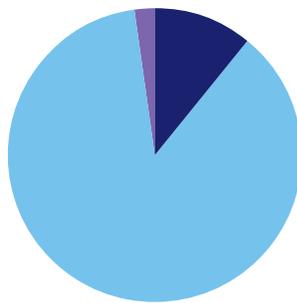
- Round (98.6%)
- Contour (1.4%)

Figure 22 – Device Fill



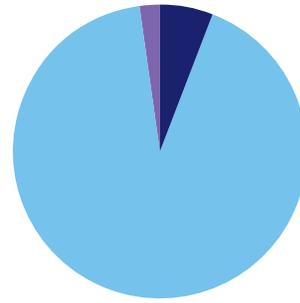
2023 Report

- Saline (10%)
- Silicone (88%)
- Saline/Silicone Gel (2%)
- Hydrogel (0%)



Aesthetic

- Saline (11%)
- Silicone (87%)
- Saline/Silicone Gel (2%)
- Hydrogel (0%)



Reconstructive

- Saline (6%)
- Silicone (92%)
- Saline/Silicone Gel (2%)
- Hydrogel (0%)

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, but the majority (58%) are done in response to patient request mostly regarding change in shape, size, or style [Fig. 23, 24]. The most common reported complication leading to reoperation was Capsular Contracture, representing 14% of all reported operations (Figure 24). Of note, the following are not listed in the table as each represents less than one percent of the reasons for reoperations: Hematoma, Seroma, Skin Necrosis, Wound Problems, Need for Biopsy/Tumor, Recurrent Cancer, BIA-ALCL, BIA-SCC, Lymphoma, Other Cancer.

Figure 23 – Reasons for Reoperation

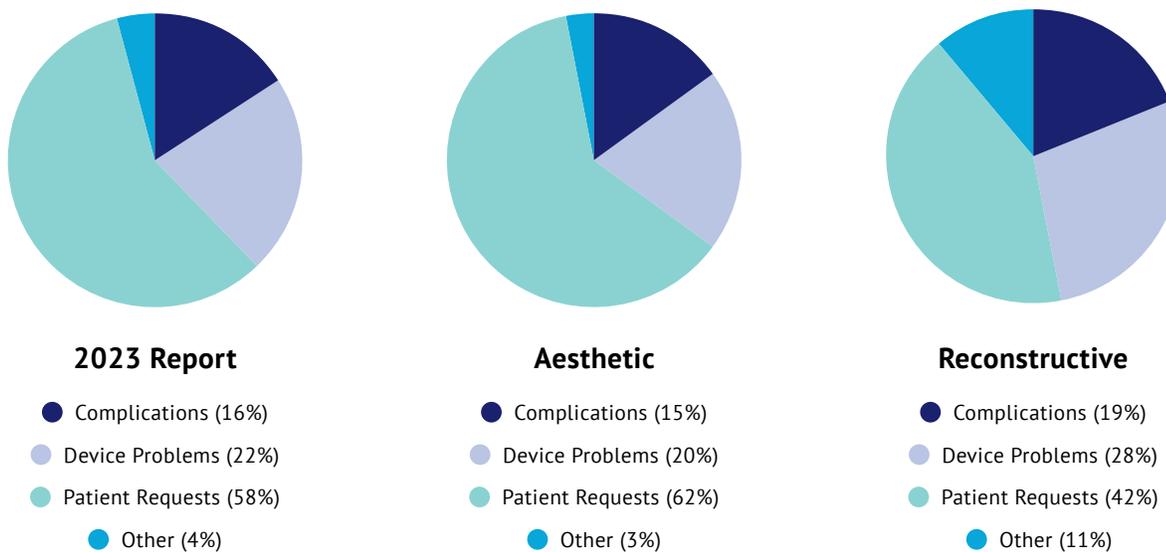
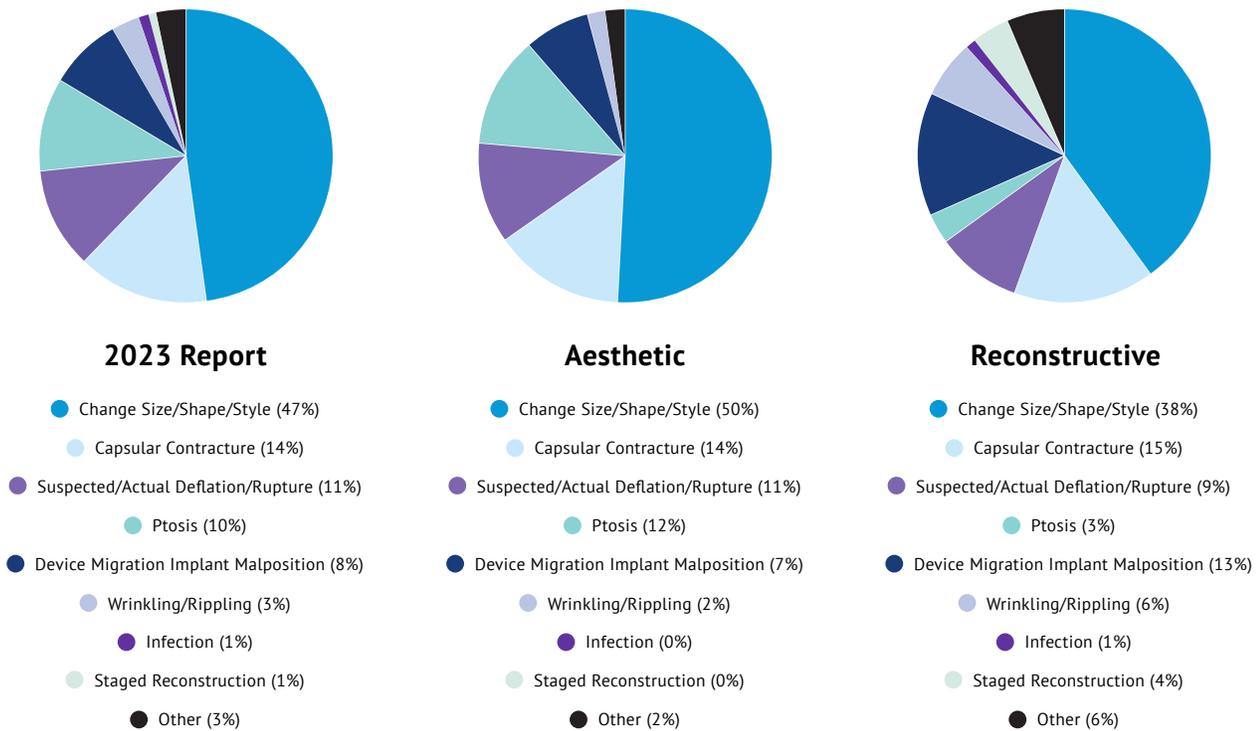


Figure 24 – Reasons for Reoperation

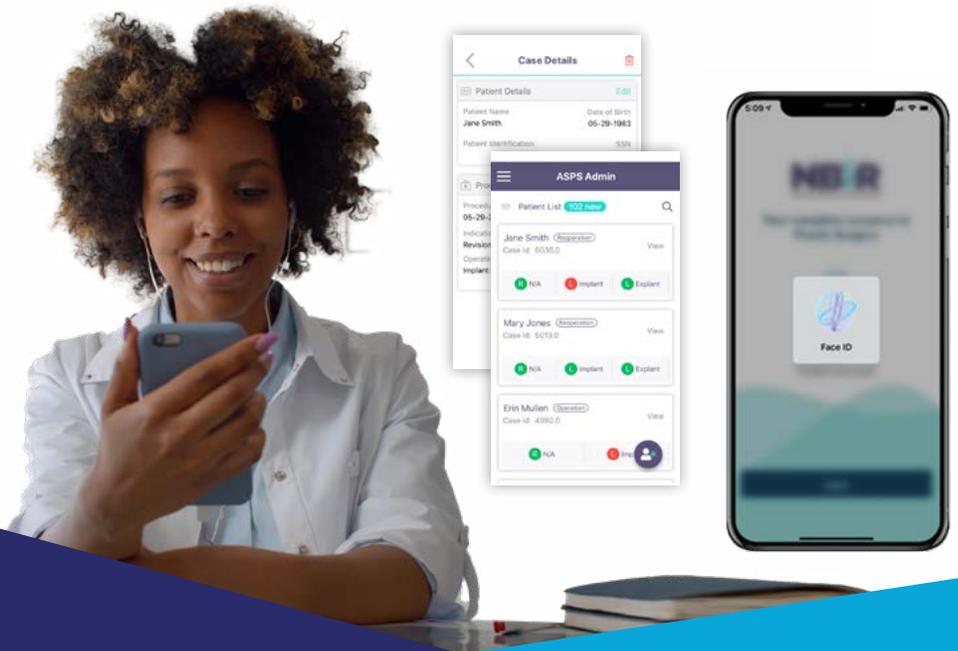


**reflects % of reported reasons for reoperation*

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. 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.



Acknowledgements:

The work on this annual report would not be possible without the tremendous contributions from ASPS/PSF Staff and Physician leadership. On behalf of the NBIR Steering Committee, we wish to thank Maria Jones, Katie Sommers, Gina McClure, Maegan Newell, Surinder Kaur, and Angela Bochucinski for their efforts to support the National Breast Implant Registry, as well as the development of this report.

NBIR

NATIONAL BREAST IMPLANT REGISTRY