ARISE 2025 Annual Report

ARISE

American Registry for Breast Implant Surveillance and Evaluation

The Aesthetic Foundation

The Aesthetic Society

The data included in this report was captured from Arise-Aesthetic One Data Base 2021-2025.

ARISE Oversight Committee 2025-2026

Caroline Glicksman, MD, MSJ	*Chair, ARISE Committee, Past-President, The Aesthetic Foundation*
William P. Adams, Jr., MD	*Past-President, The Aesthetic Society and The Aesthetic Foundation*
Frank Im, MBA	*COO, The Aesthetic Society*
Terri Cornelison, MD, PhD	Director Office Innovative Development, FDA
Danica Marinac-Dabic, MD, PhD	Office of Clinical Evidence and Analysis, FDA
Art Sedrakyan, MD, PhD	Director Institute for Health Technologies and Interventions, MDEpinet
Anu Antony, MD, MPH, MBA	Epidemiology, PROMs
Joshua Der	*Mentor – Johnson & Johnson*
Margie Rose, MPH	*Motiva- Establishment Labs*
Melissa Pathmajeyan, PhD	*Allergan*
Sara Saul, PhD	*Sientra- Tiger*

The 2024 Annual Report has been compiled by the American Registry for Breast Implant Surveillance and Evaluation (ARISE).

For any questions or feedback regarding this report, please reach out to:

ARISE – Aesthetic One Attention:

- Frank Im, COO, The Aesthetic Society @frank@theaestheticsociety.org

- Caroline Glicksman, MD,MSJ, Chair, The ARISE Committee, The Aesthetic Foundation @ drglicksman.office@gmail.com

Launched in 2021

The fastest-growing implant registration platform in the US.

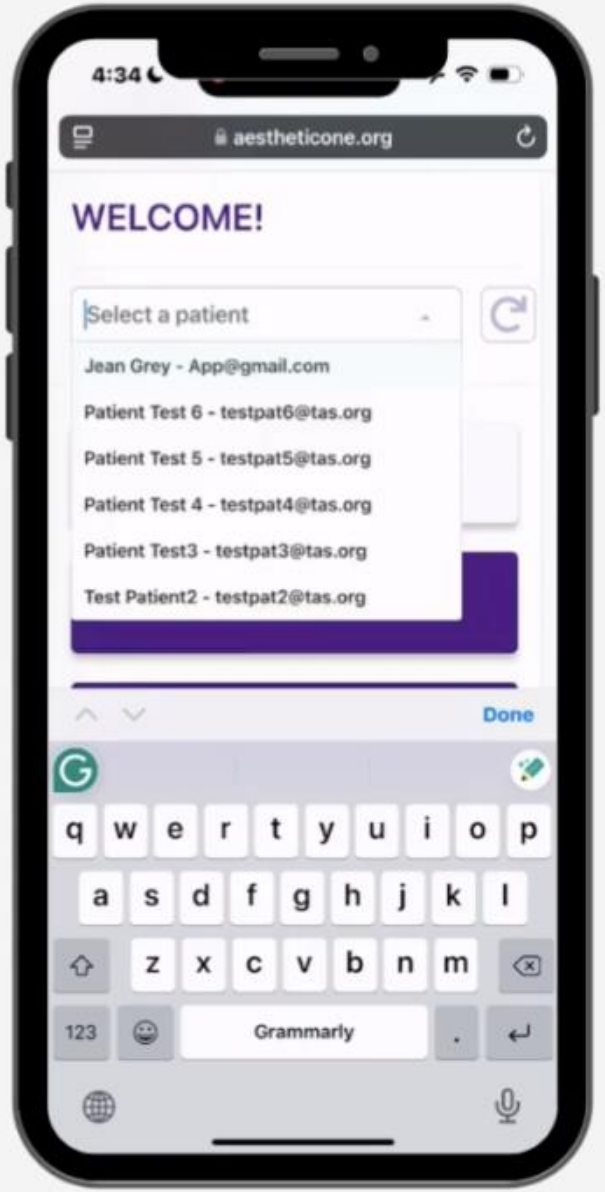
Allergan Aesthetics
an AbbVie company

Motiva®

MENTOR®

sientra
a Tiger Aesthetics™ brand

Implant Registration Made Easy.



First Registry to connect directly with the patient-PROM

First Registry to run a prospective clinical trial: **STAR Study**

Over 120,000* devices registered since 2021

* September 2025

ARISE
POWERED BY aesthetic one

Table of Contents:

Letter from the Chair ARISE Task Force and President the Aesthetic Foundation

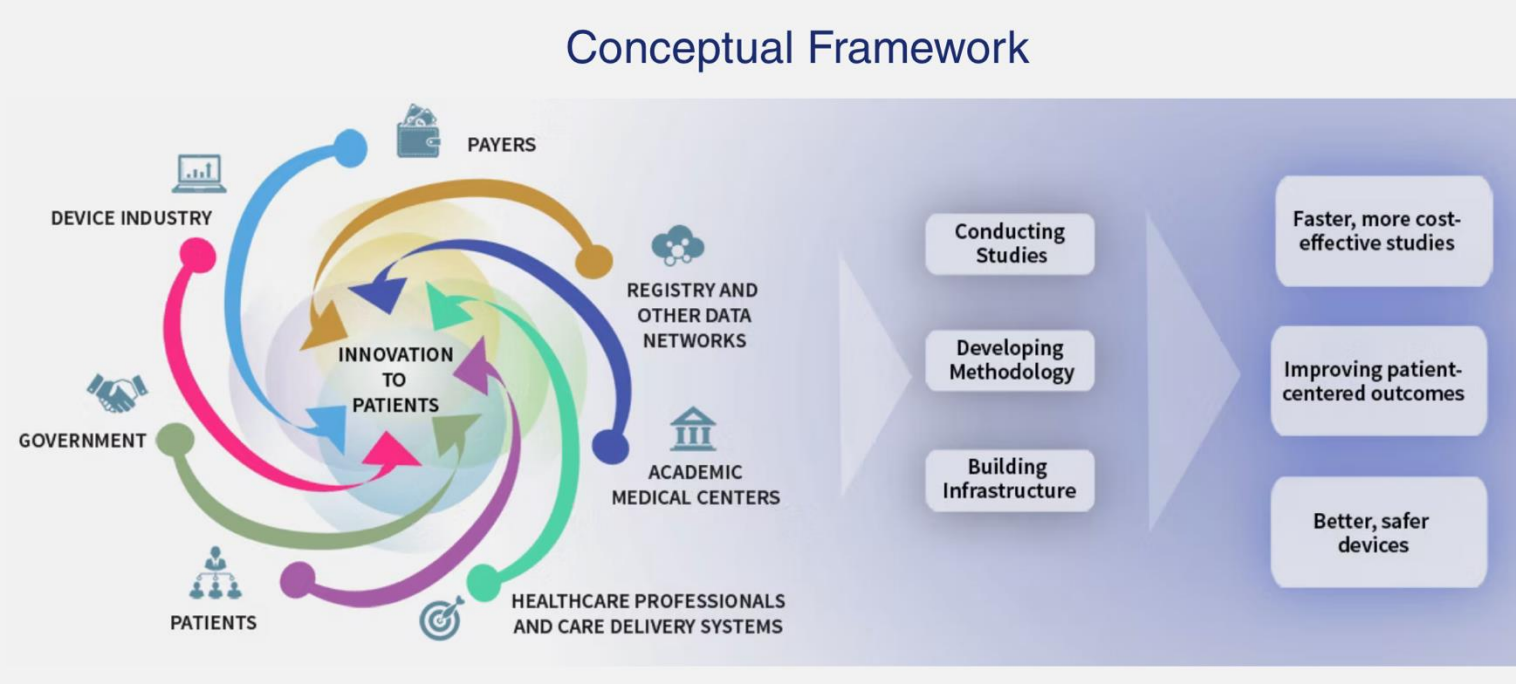
The ARISE Registry launched in 2021 on the Aesthetic One platform. The focus was to collect more granular data than any prior medical device registry. In 2024 Aesthetic One migrated to its new platform improving functionality, speed, and capabilities. Now, real- data from device placement to explantation is broken down into its most detailed elements to be shared with manufacturers, patients, and the FDA.

ARISE is the first US registry to initiate a prospective clinical trial on breast implant safety, the STAR study. Launched in 2024, the STAR study will enroll 1,000 patients and will collect breast data pre-operatively and for two years post-operatively.

We are excited to publish our first annual report and look forward to working alongside our committed surgeons and motivated patients, generating useful data to be shared with other registries wide.

Caroline Glicksman, MD., MSJ
Chair, ARISE Committee, The Aesthetic Foundation

Patricia McGuire, MD President, The Aesthetic Foundation

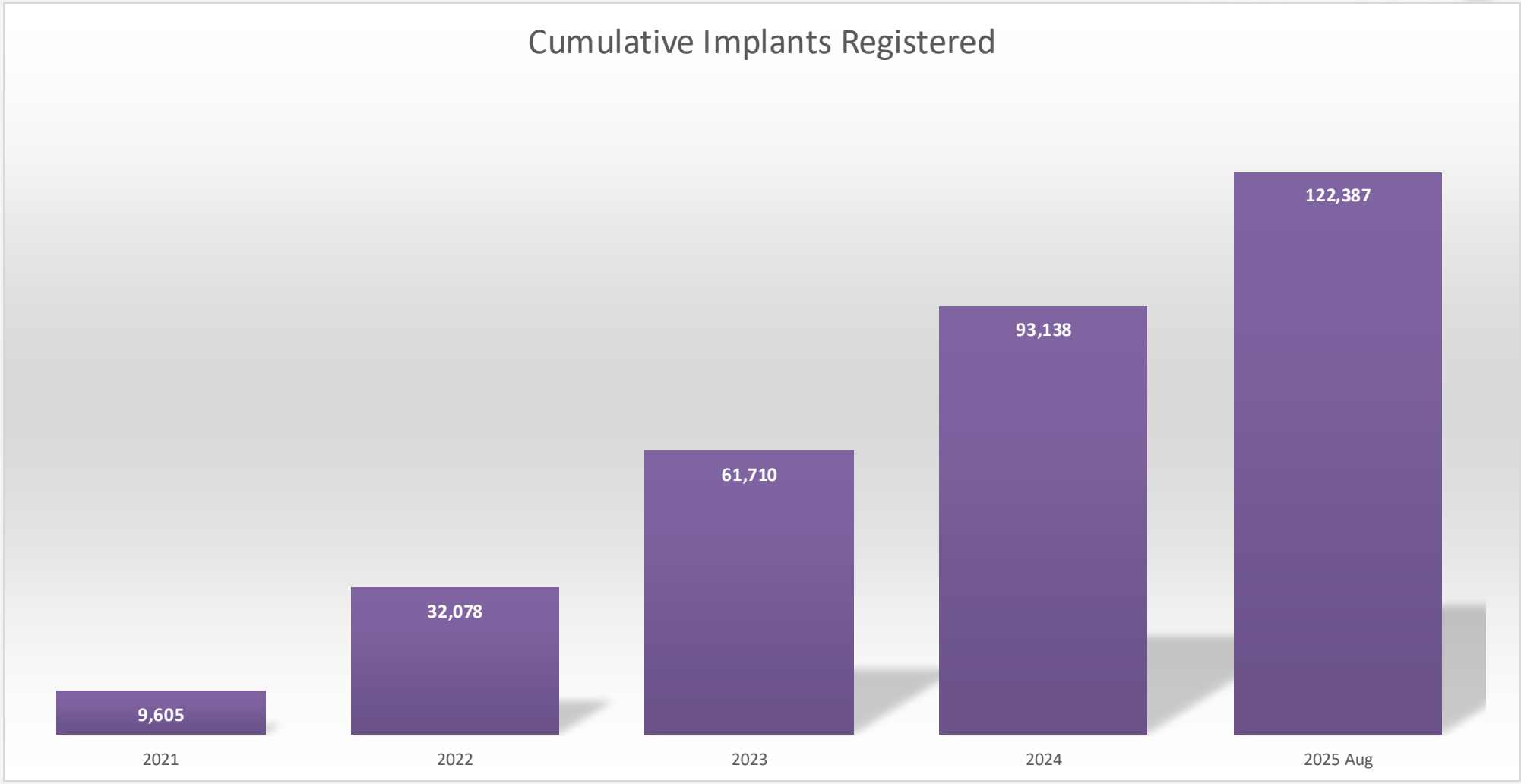


In December 2024 ARISE and Aesthetic One partnered with MDEpinet, a national patient-centered medical device evaluation and surveillance system.

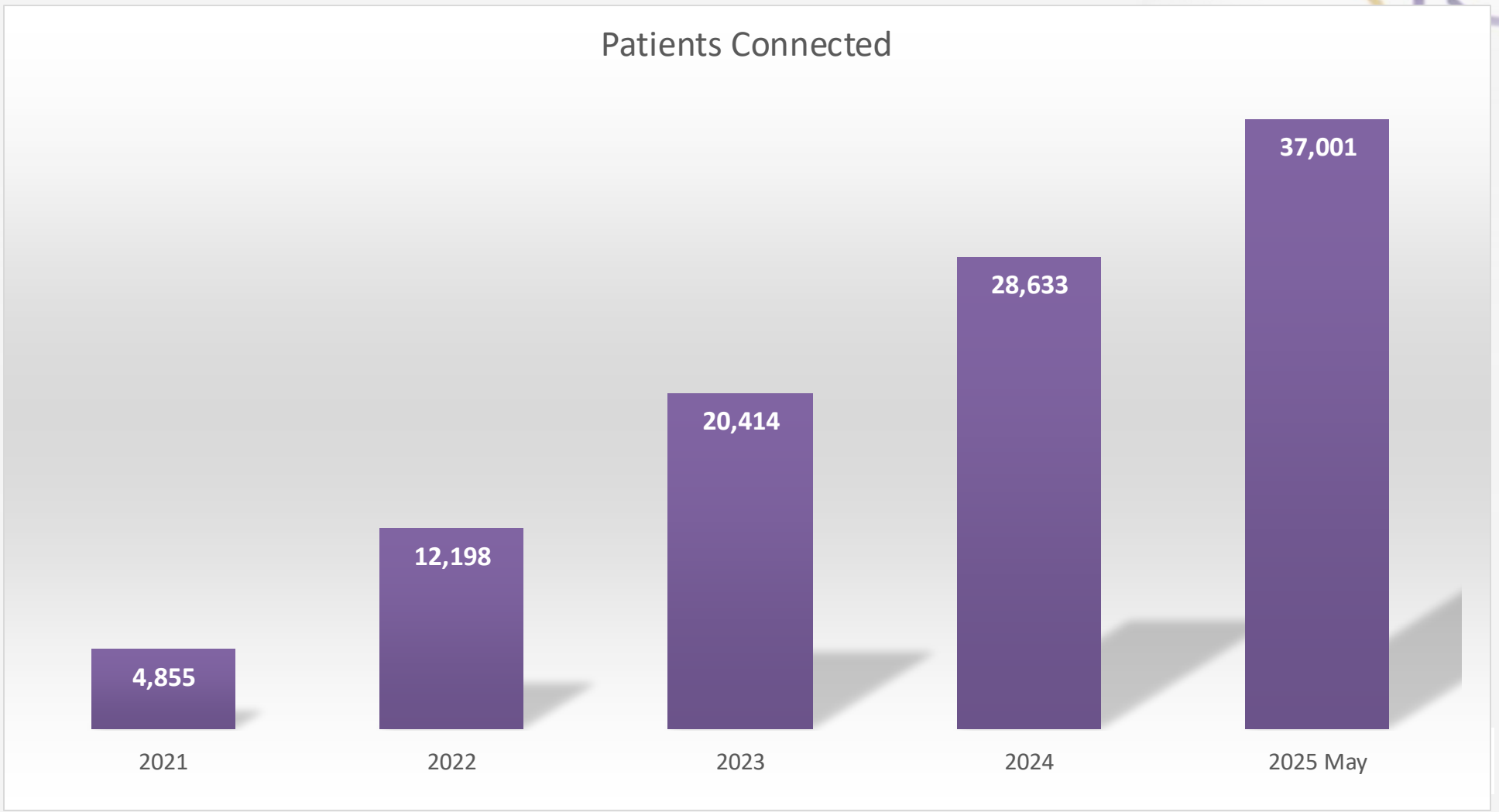
MDEpinet is affiliated with the US Food and Drug Administration and utilizes the DNA-Hive technology platform initially developed by the FDA for advancing medical device registries.

ARISE supports data collection throughout the breast implant lifecycle and advances clinical research through this innovative research network.

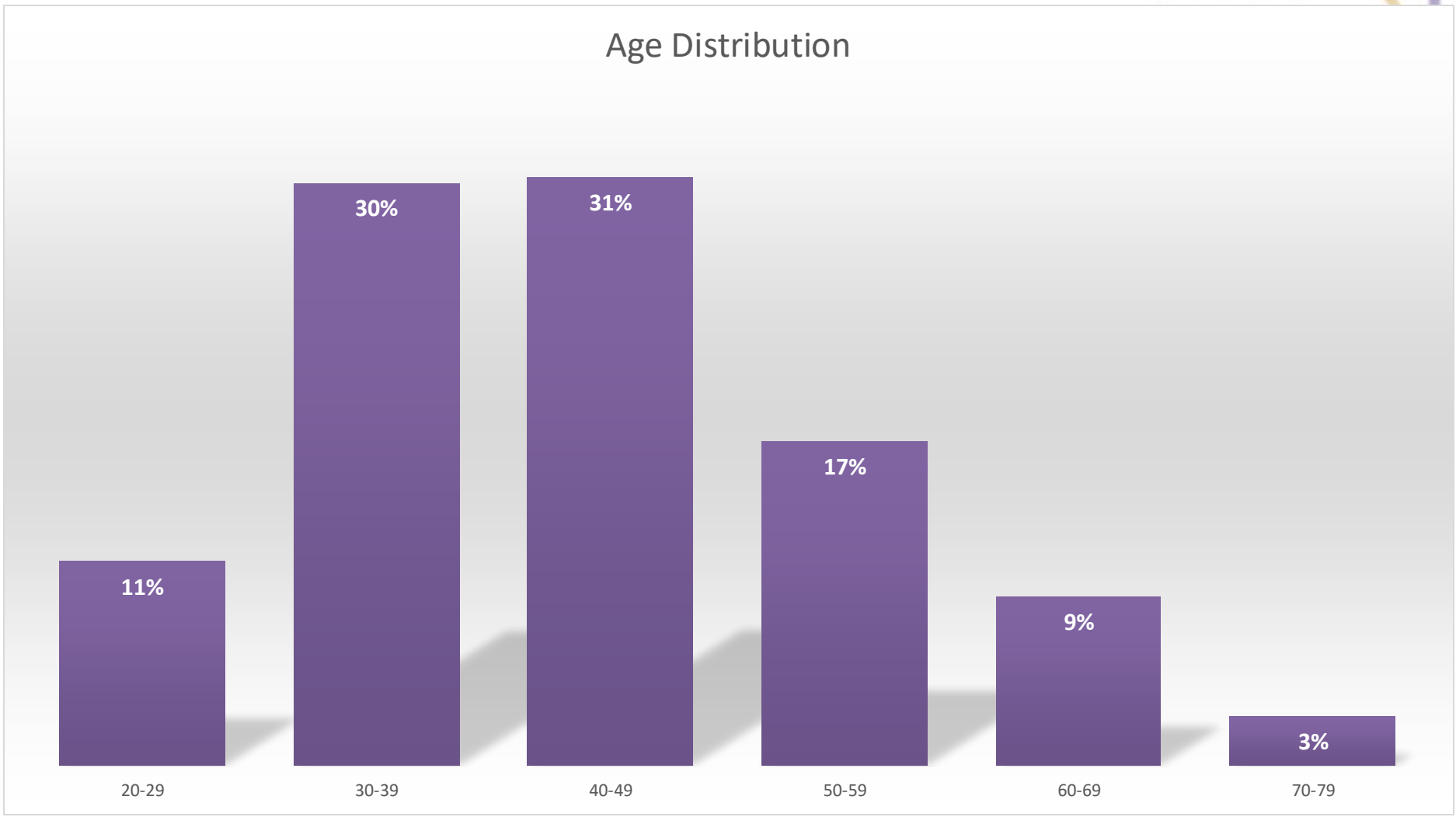
Device Registration 2021-2025



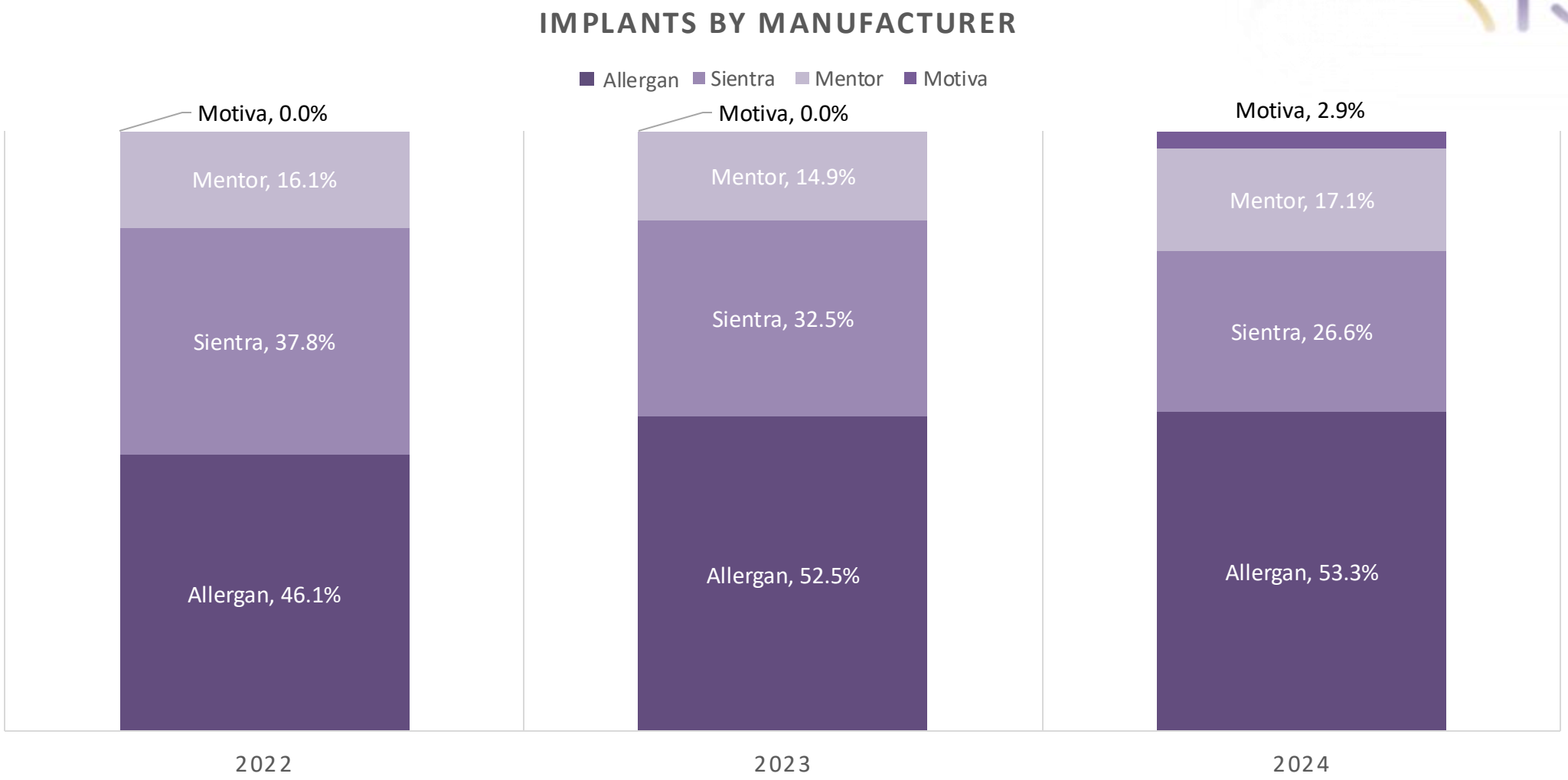
Patient Connectivity- PROM



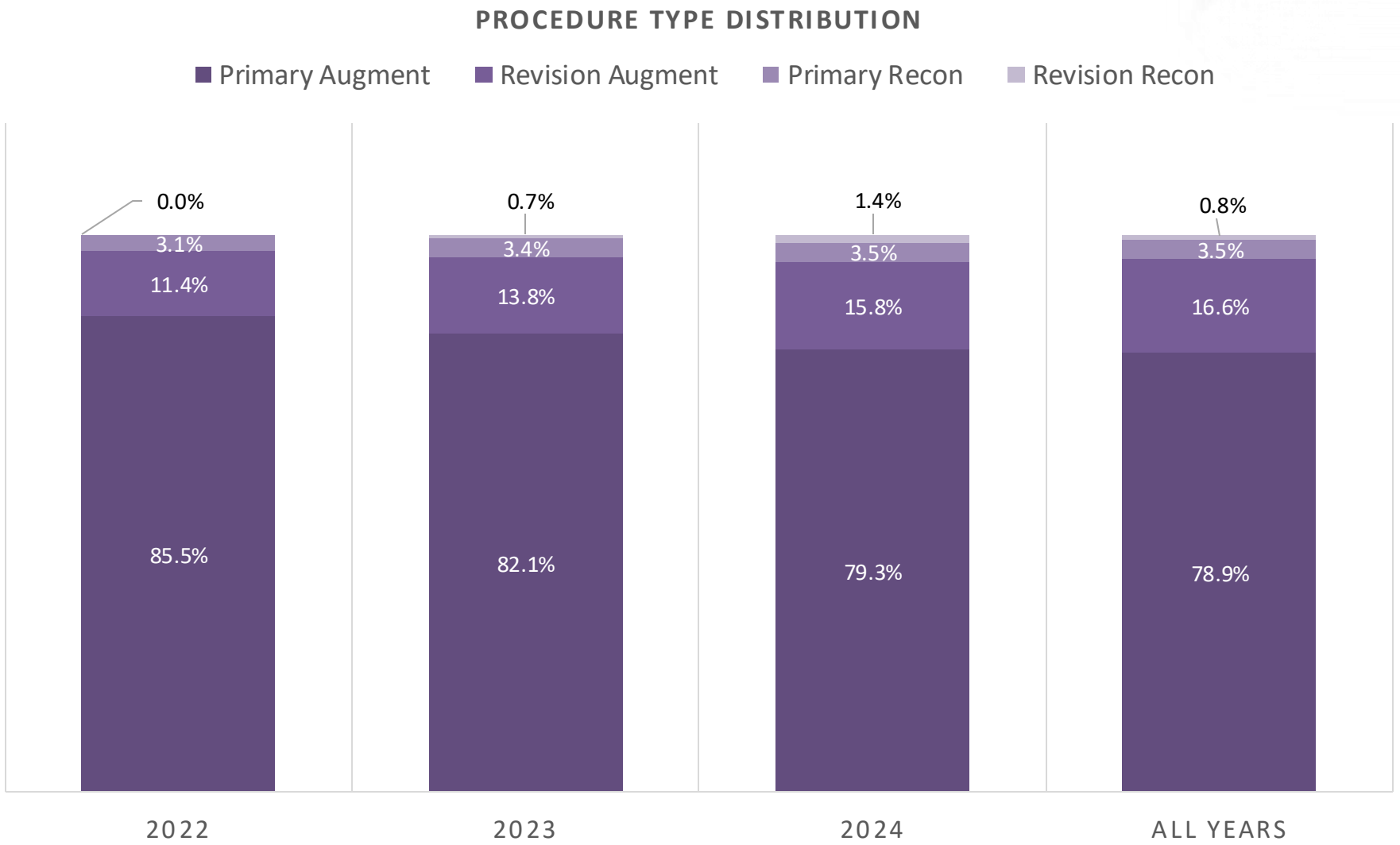
Registry Data: Patient Age Distribution



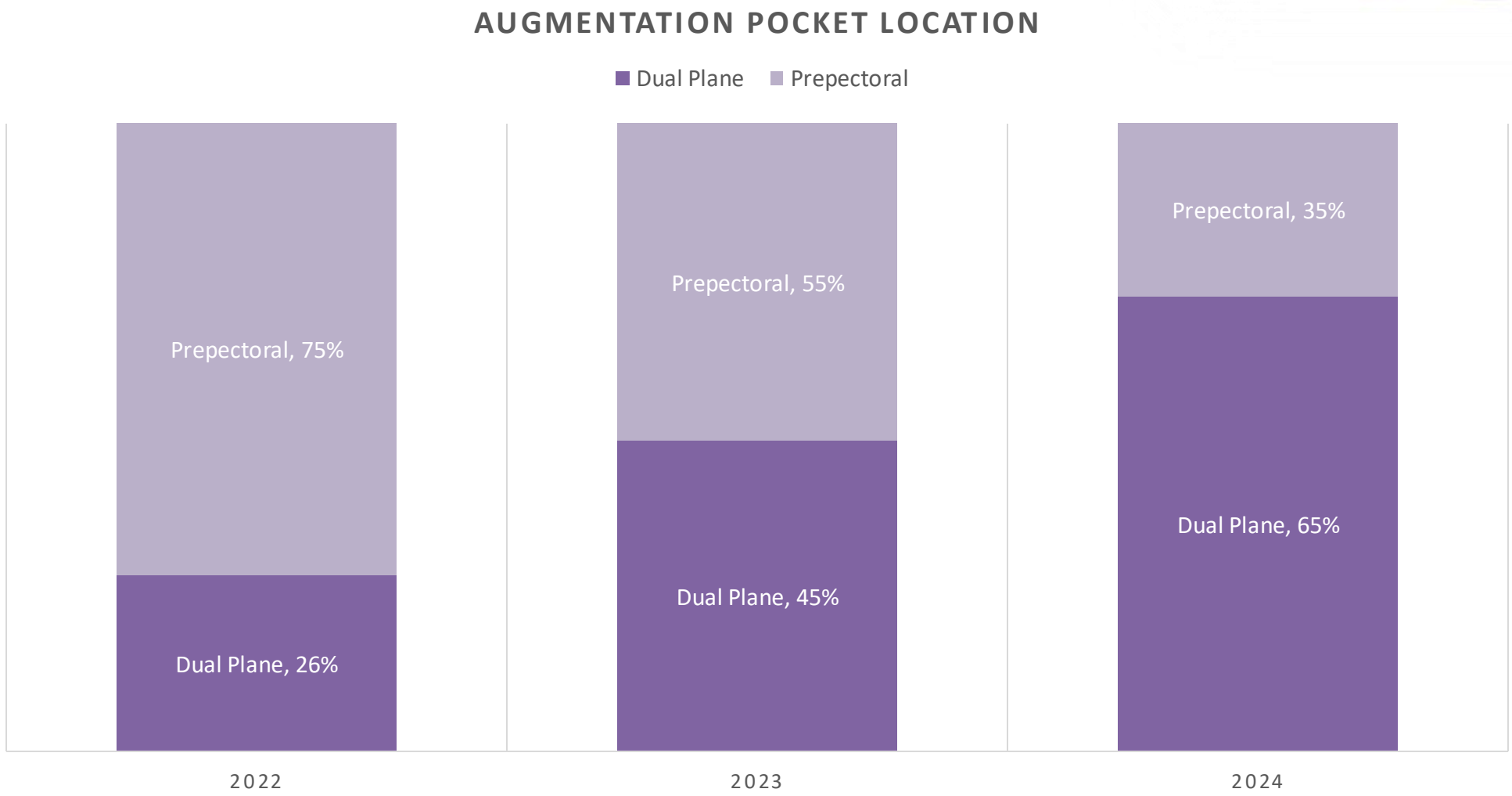
Registry Data: Implant by Manufacturer



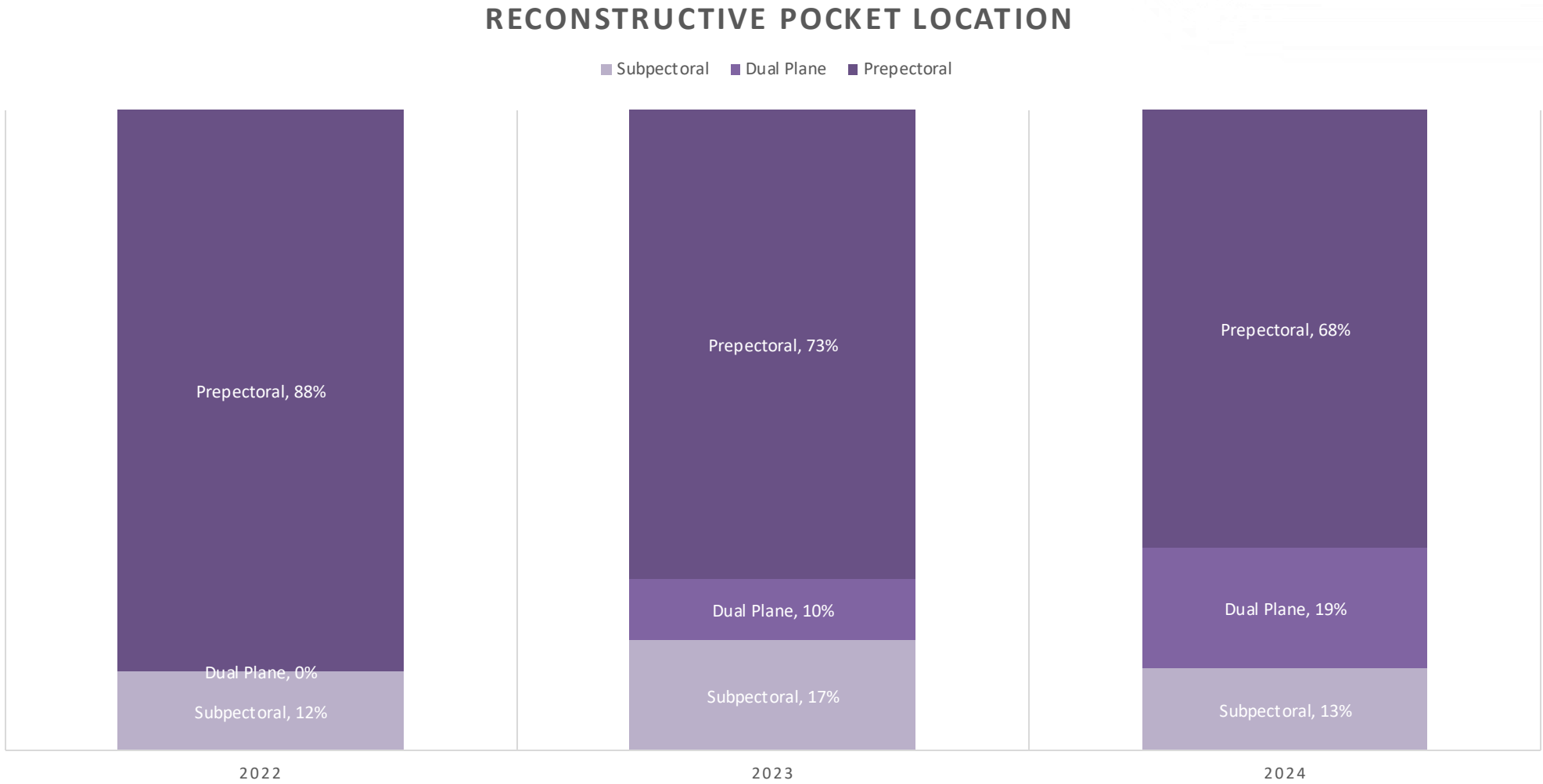
Registry Data: Procedure Type



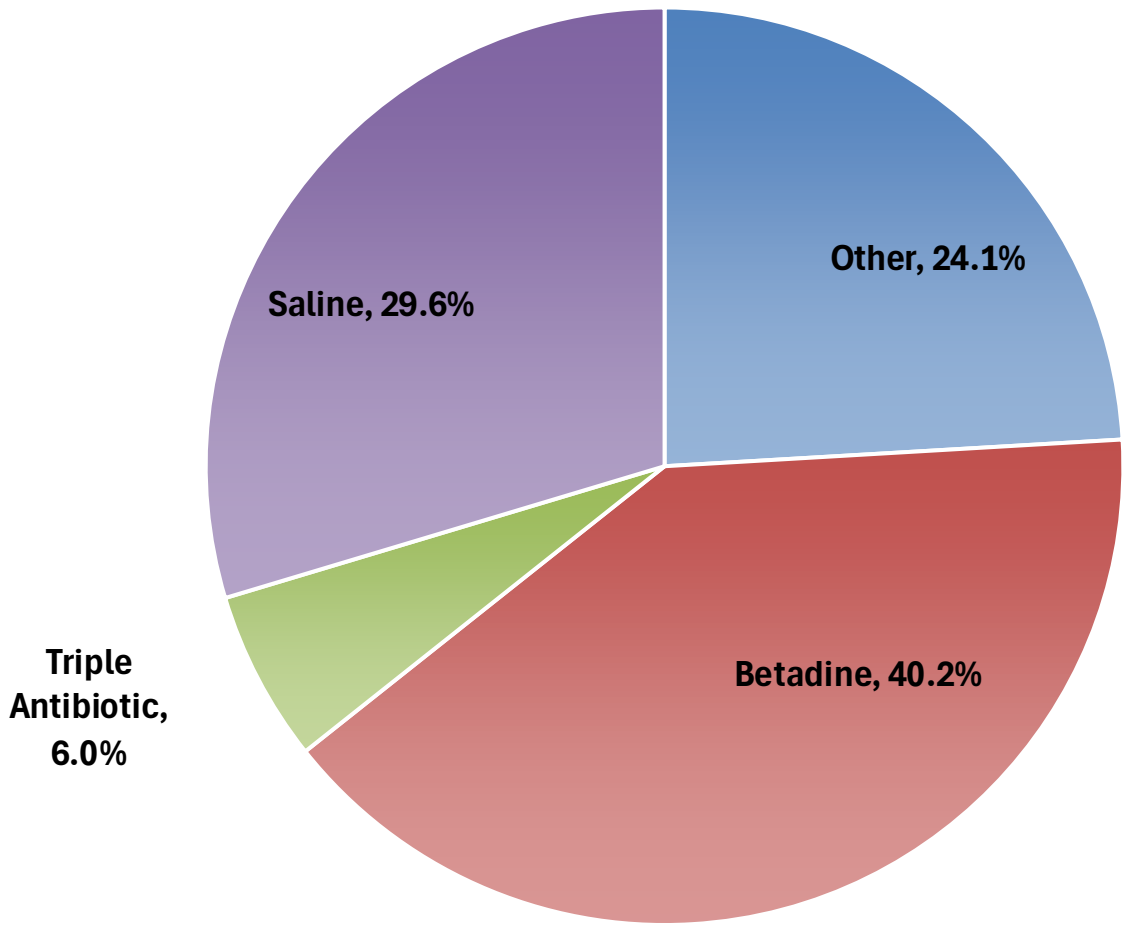
Registry Data: Pocket Location Augmentation and Revision Augmentation



Registry Data: Pocket Location Reconstruction and Revision Reconstruction



Registry Data: Use of Pocket Irrigation



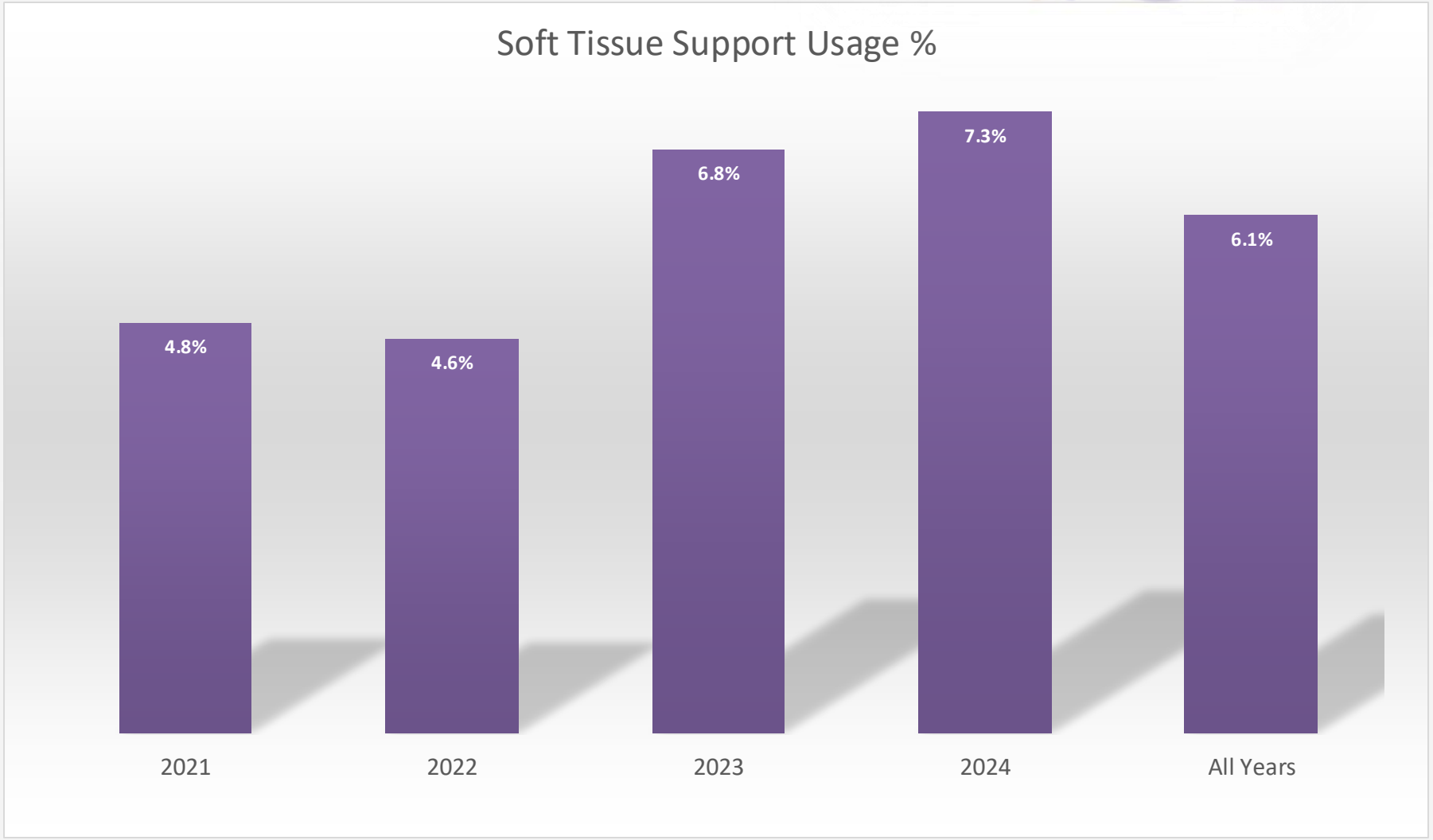
- Other
- Betadine
- Triple Antibiotic
- Saline

Betadine_100%	2.6%
Betadine_25%	1.1%
Betadine_50%	14.8%
Betadine_Less_than_25%	5.0%
Betadine-Triple Antibiotic combination	16.8%

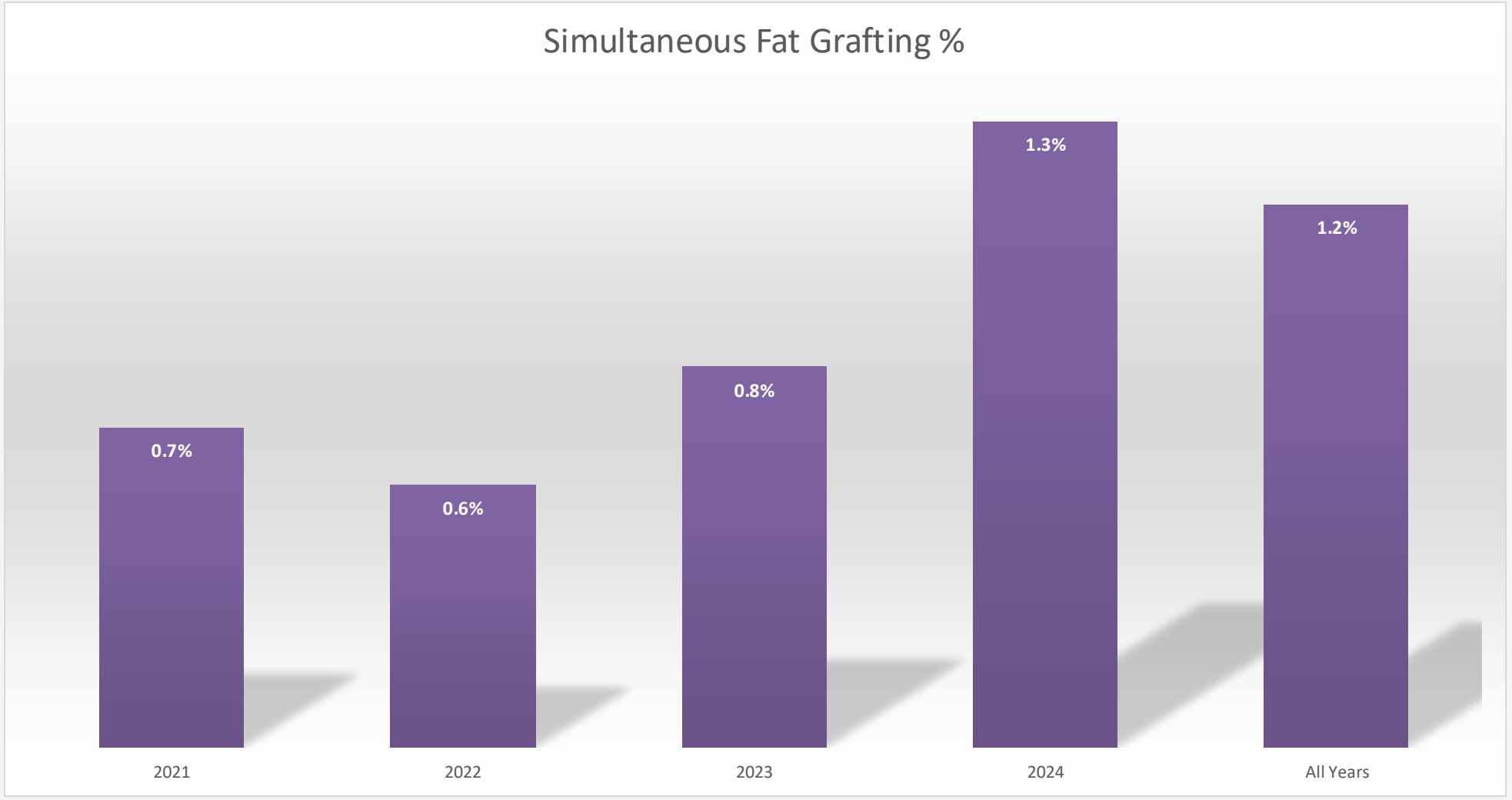
Other:
Stock dilute Hypochlorous Acid
Stock dilute Chlorhexidine

Registry Data: Use of Soft Tissue Support- ADM and Scaffolds

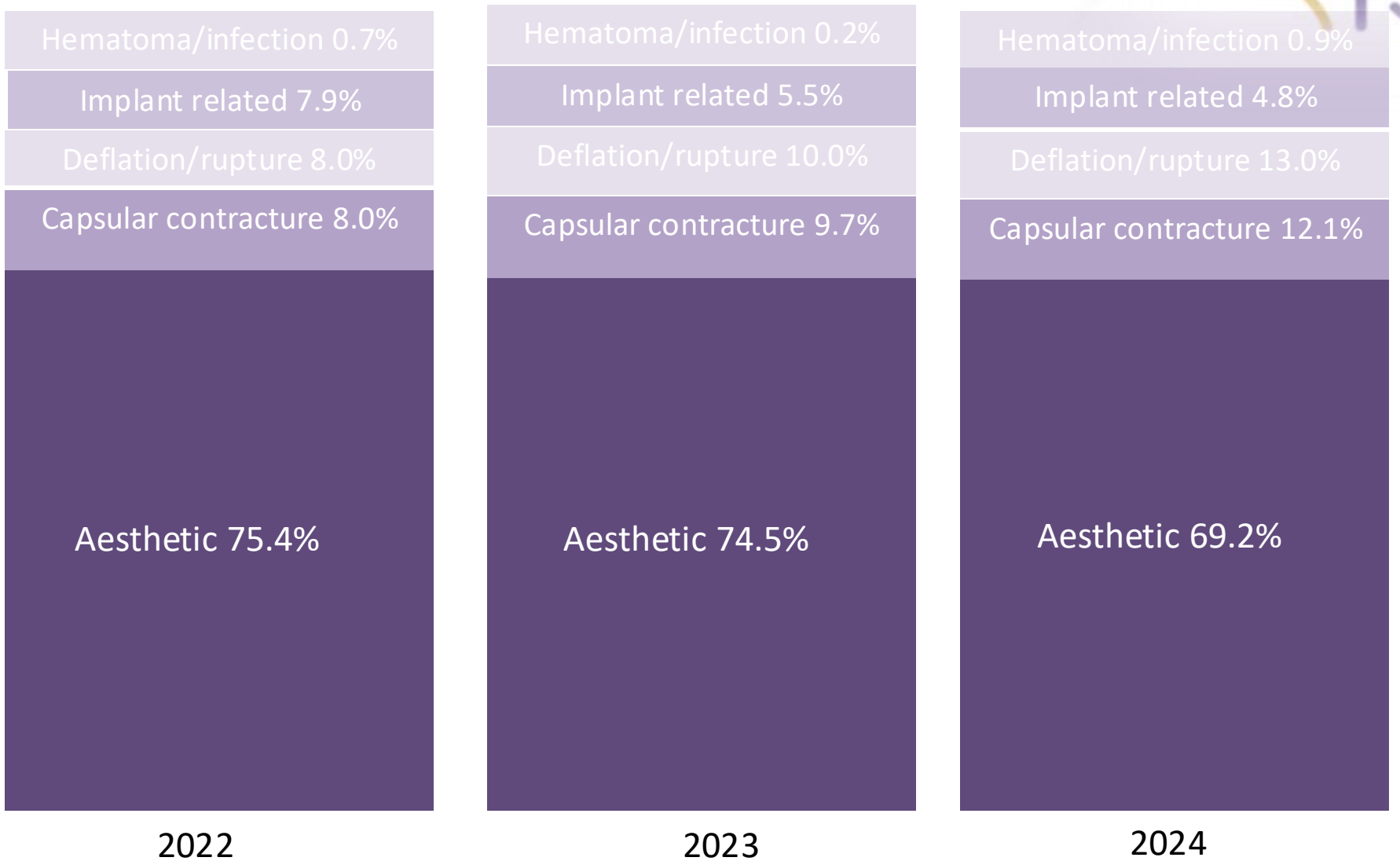
Allergan-AlloDerm™
Allergan-Stattice™
Medline-Allomax®
MTF-FlexHD®
BD-GalaFlex™
Telabio-OviTex®
Novus Scientific-Tigr Matrix®
Ethicon-Vicryl Mesh®



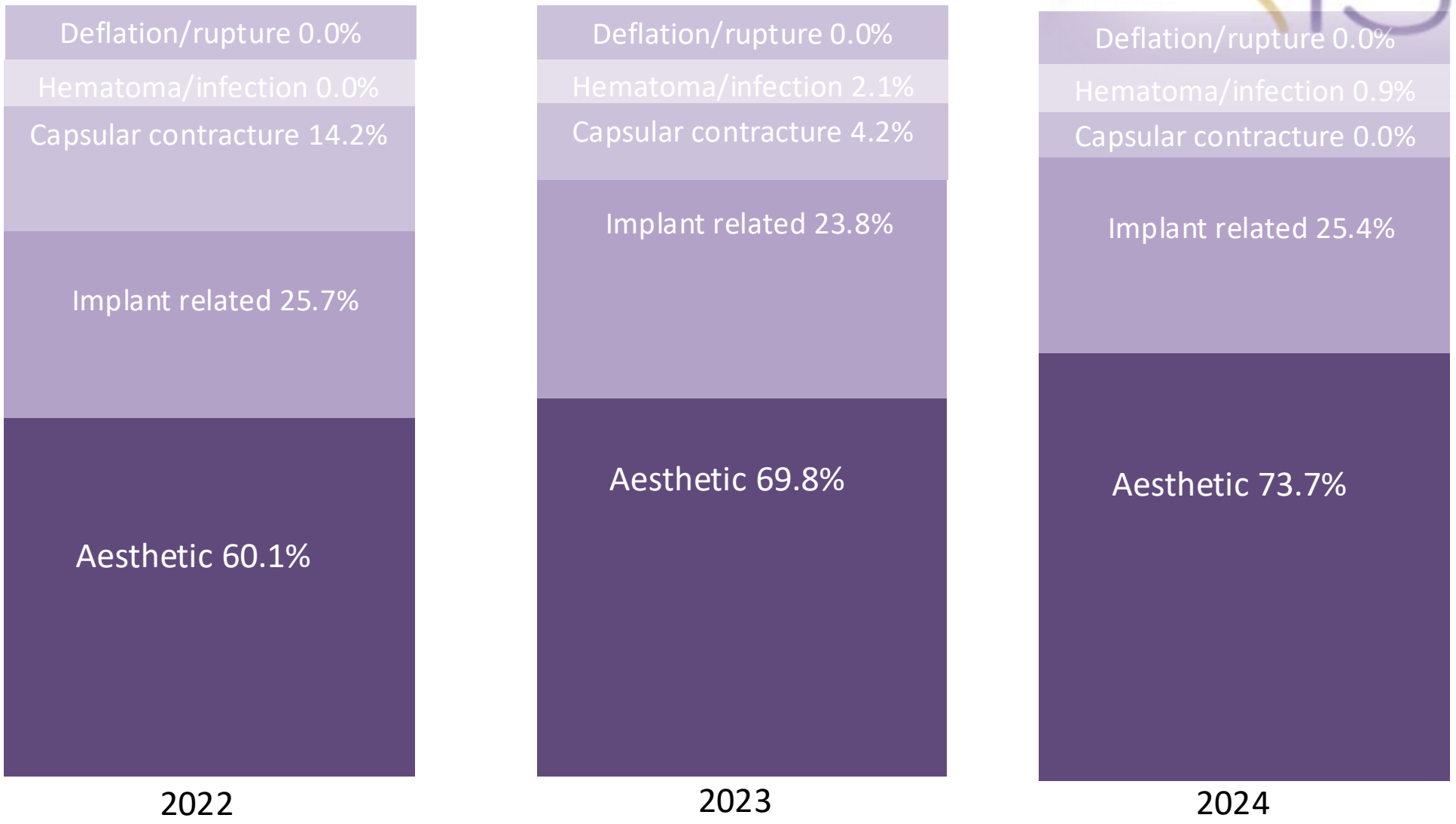
Registry Data: Use of Autologous Fat Transfer at Time of Implantation



Registry Data: Reason for Revision- Revision Augmentation



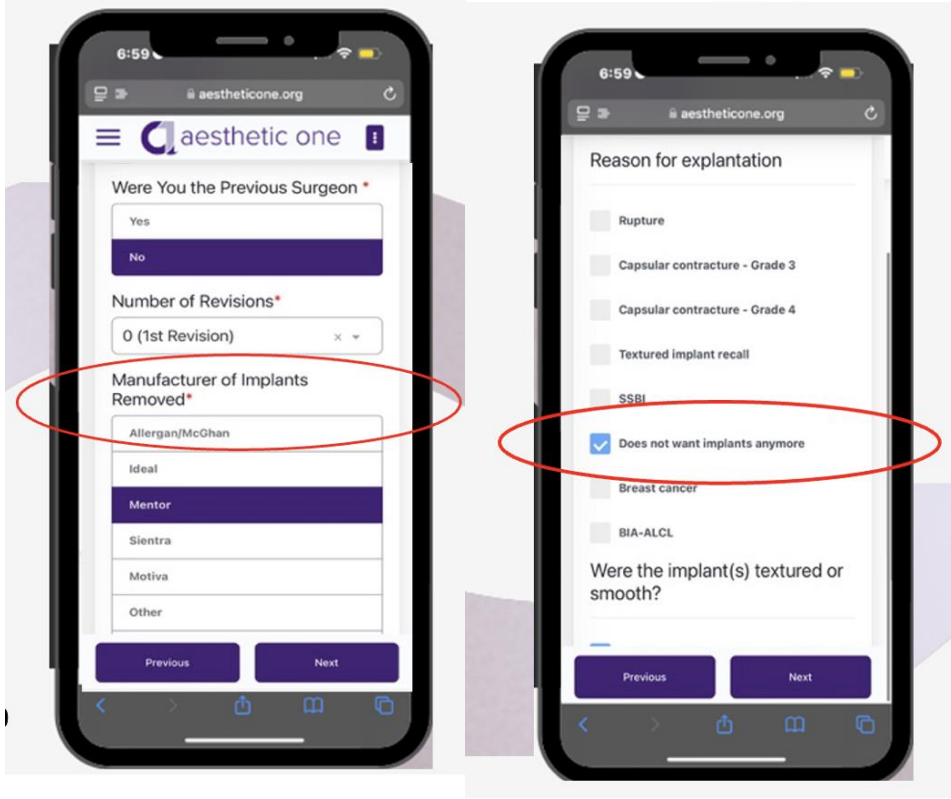
Registry Data: Reason for Revision- Revision Reconstruction



Registry Data: Explantation Without Replacement

Additional data fields added in 2025

- ❑ Name of manufacturer
- ❑ Serial number if available
- ❑ Number of years implanted
- ❑ Reason for removal: Rupture
  - Capsular contracture
  - Textured implant recall
    - BIA-ALCL
    - Breast cancer
    - BII
    - Does not want implants anymore
- ❑ Additional Aesthetic Procedure performed:
  - Mastopexy
  - Fat grafting



STAR Study

Purpose:

Systemic Symptoms Associated with Breast Implants (SSBI) also labeled Breast Implant Illness (BII) is a vague constellation of self-diagnosed systemic symptoms reported by some women with breast implants.

The STAR study is the first prospective clinical study to include validated methodology that pulls data directly from ARISE through the patient interface.

Design:

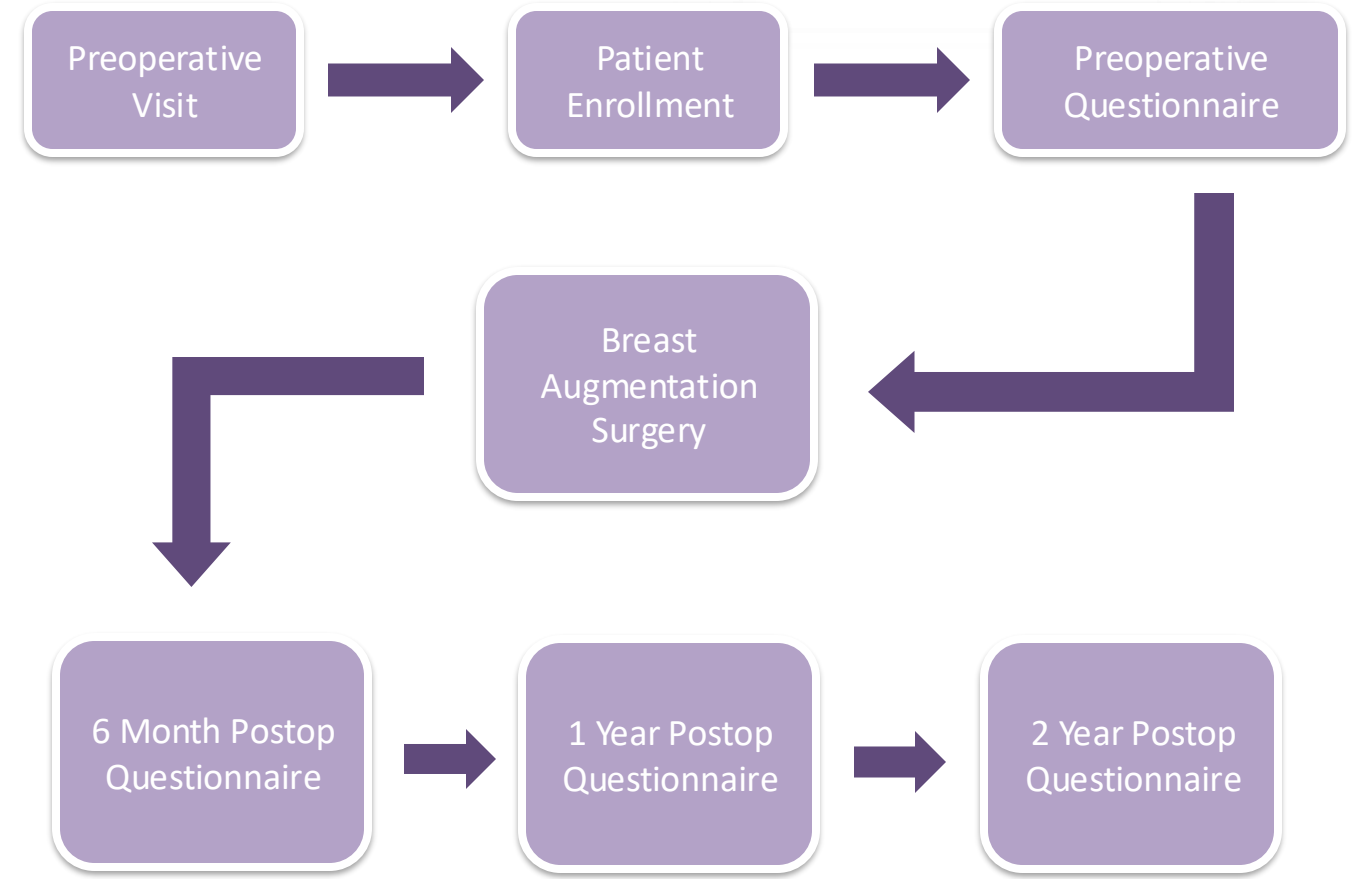
Patients complete all parts of the study electronically and independently allowing investigators to enroll study subjects from multiple sites with minimal administrative oversight.

1000 primary breast augmentation and augmentation mastopexy subjects will be enrolled in the STAR study and followed for 2-years post surgery.

STAR Study- Purpose and Design

Data collection through ARISE includes:

- Demographic details
- Previous health and surgical history
- PROMIS-29 evaluation
- Whiteley Index 6 evaluation
- Michigan body mapping
- Mapping of breast/chest discomfort
- Online questionnaire for questions



Registry Collaboration and Expansion

Targets 2025-2026:

- ❑ The Aesthetic Foundation oversees the ARISE Committee and is tasked with encouraging US surgeons to register breast implants, collect procedural data, and directly communicate with patients, manufacturers, and the FDA.
- ❑ Prepare for 2025-2026 Internal Audit and research publications.
- ❑ Enhance collaboration with other national and international breast implant registries.


ARISE


The
Aesthetic
Foundation


The
Aesthetic
Society