Allergan Aesthetics
an AbbVie company

Allergan Aesthetics Breast Implant Device Tracking for Healthcare Providers

December 2024

Not actual patients.

Training Objectives

1

Understand the healthcare provider's role in meeting medical device tracking requirements for Allergan Aesthetics breast implants

2

Educate healthcare providers about the importance of fulfilling device tracking requirements

Not actual patients.

Background

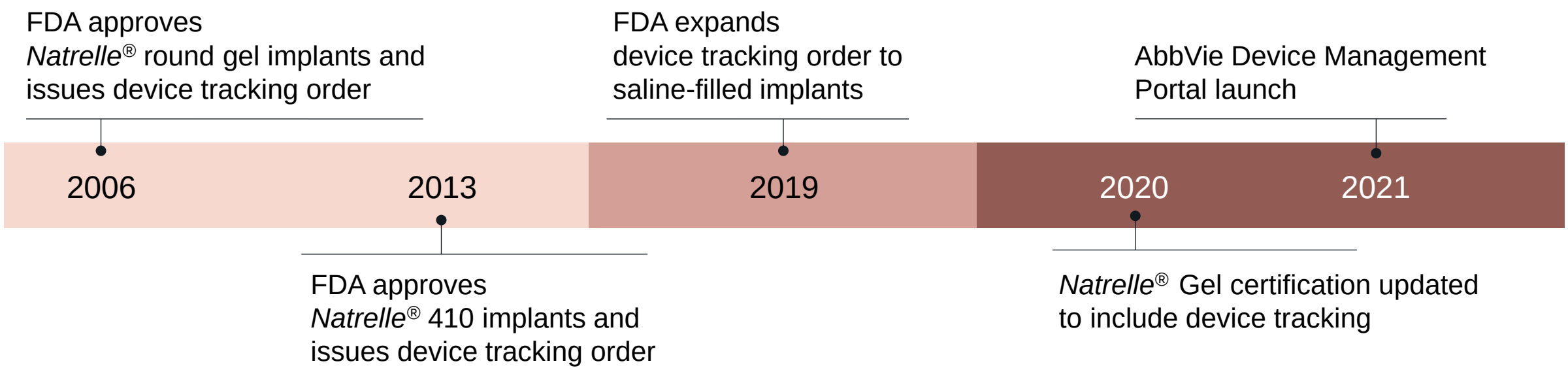
The FDA issued medical device tracking requirements to ensure certain devices can be traced through the distribution chain from the manufacturing facility to the patient for the useful life of the device

- These requirements are intended to facilitate notifications and recalls if a device poses a serious health risk
- Medical device tracking is a requirement for all breast implants in the US including Allergan Aesthetics *Natrelle*® Breast Implants

FDA Notification Requirement

- **All implant manufacturers**, including Allergan Aesthetics, are required to notify the FDA when a healthcare provider does not provide updated device tracking information
- **Allergan Aesthetics is committed** to working with our healthcare providers to ensure every effort is made to retrieve updated device tracking information prior to any FDA notification being sent
- **If efforts are unsuccessful, then the noncompliant customer will be reported to the FDA**

Allergan Aesthetics Implant Device Tracking Timeline



NOTE: All BIOCELL textured implants were withdrawn from the market on July 24, 2019; however, they still require tracking for explant surgeries.

FDA Medical Device Tracking Requirements

AbbVie and societies have collaborated to assist device tracking.

After Device Is Implanted, Explanted, or Opened & Discarded	
Implanting Physician/Patient:	**Device:**
• Name • Address • Telephone # • SSN (patient)	• Serial number or Lot # • Ship date • Implant date • Explant date (if applicable) • Disposal date (if applicable) Requirement met by completing and returning a Device Tracking form or by registering the implant electronically

- As the final distributor, healthcare providers are required to share device tracking information with the manufacturer
- The manufacturer is required to notify the FDA when a healthcare provider does not provide device tracking information

Submitting Device Tracking Information

There are 4 options for healthcare providers to send Allergan Aesthetics Breast Implant Tracking Information*:

AbbVie Device Management Portal
Register the implant through the AbbVie Device Management Portal online at https://www.devicemanagement.abbvie.com/s/?language=en_US

American Registry for Breast Implant Surveillance (ARISE), powered by Aesthetic One
Register the implant online at https://www.aestheticone.org/app/login

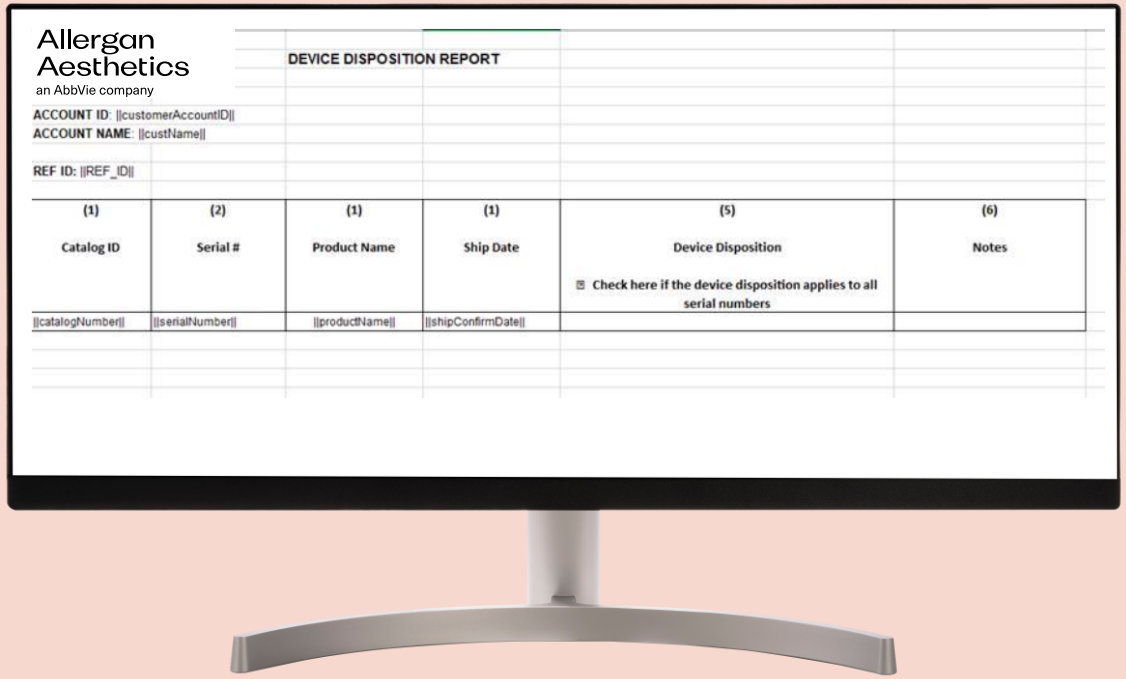
National Breast Implant Registry (NBIR)
Register the implant on the NBIR website at https://psrn.plasticsurgery.org/Dashboard/login.aspx

Mail
AbbVie Device Tracking
1 N. Waukegan Rd.
BLDG J23-2
North Chicago, IL 60064
USA

*Each of these 4 options are HIPAA compliant.

Device Disposition Reports

- **Device Disposition Reports are used by** Allergan Aesthetics to get updated information on the status of implants before the device has been implanted or for which a Device Tracking form has not been received
- **90 days from the date of the initial sales** transaction, Allergan Aesthetics will send a list of sold devices (by serial number) via the Device Disposition Report to the healthcare provider
- **The Device Disposition Report** will be sent via email
- **Allergan Aesthetics** sends monthly reports to provide timely updates on outstanding devices
- **Implants that have been returned to Allergan Aesthetics or are included on a Device Tracking form** will not appear on the Device Disposition Report
- **Leverage 1 of the 4 methods for device tracking** for any implant implanted or any that have not been used on this form

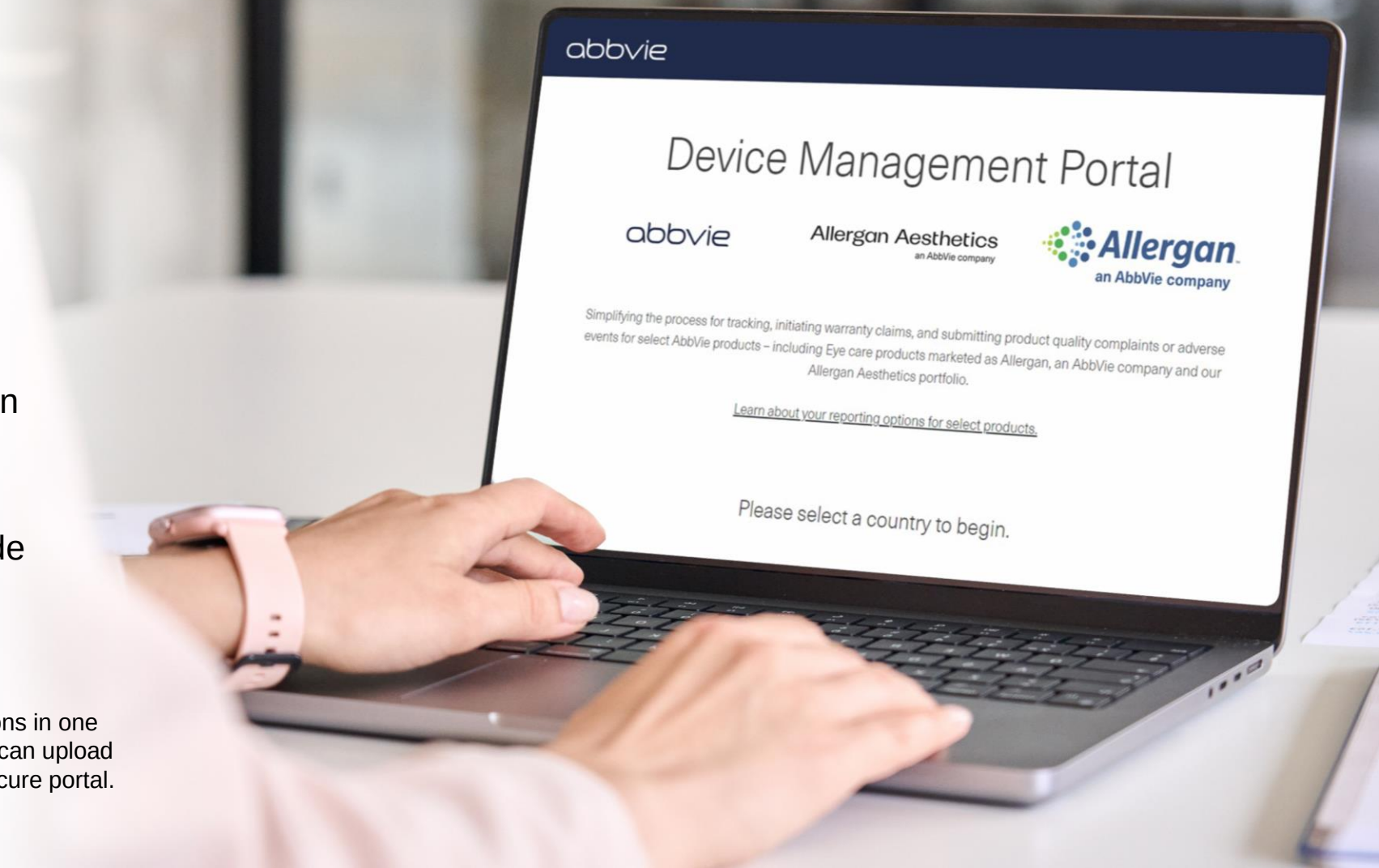


AbbVie Device Management Portal

Single-point log-in is both simple and secure

abbvie

1. Register your practice on your computer or tablet
   - See your information populate automatically with every submission devicemanagement.abbvie.com
2. Scan in the unique device serial numbers using the scannable barcode



NOTE: This portal was created to facilitate more submissions in one place with your user experience in mind. If you prefer, you can upload completed scanned forms and submit them through our secure portal.

American Registry for Breast Implant Surveillance (ARISE), Powered by Aesthetic One

Effortlessly Prepare for Surgery

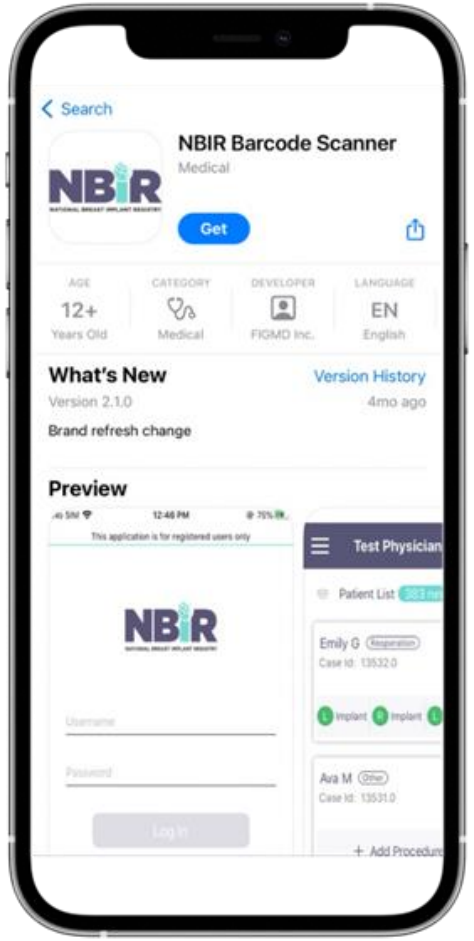
ARISE
POWERED BY aesthetic one

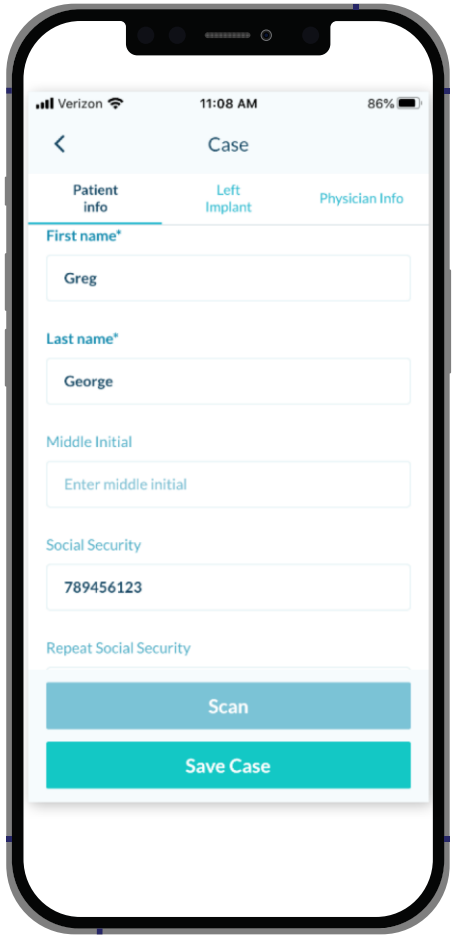
1. Register your physician information using the web-based portal at **aestheticone.org/app/login**. You can access the portal from any browser on your phone, tablet, or computer
2. Once surgery is scheduled, tap "Add Patient" to create a profile with all essential details—everything you need, perfectly organized and ready
3. On surgery day, select the profile, tap "Start Surgery," and scan the QR code found on device box to auto-populate your *Natrelle*® device information.

NOTE: Once complete, the registration is sent to the manufacturer and an operative summary will be available to both you and your patient.

National Breast Implant Registry (NBIR)

Physicians can register to participate at the NBIR website





Click on the following links for more detailed information:

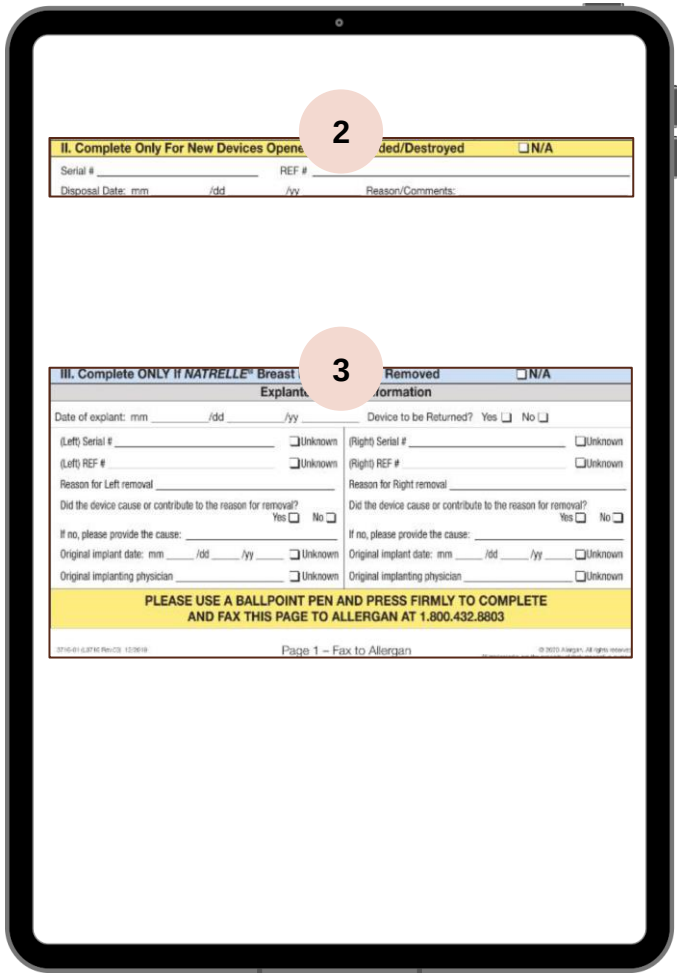
- How to Use the NBIR Device Tracking App
- How to Sign Up
- How to Navigate the NBIR Dashboard
- How to Use the NBIR Barcode Scanner*
- FAQ site on NBIR

*The NBIR process currently requires the implanting physician to scan the UDI / QR code, **which is only available on the implant box or primary package label.**

Device Tracking Form - Page 1*

1. **Section 1:** Complete if an Allergan Aesthetics breast implant is implanted.
2. **Section 2:** Complete if an Allergan Aesthetics breast implant is opened and immediately discarded or destroyed.
3. **Section 3:** Complete if an Allergan Aesthetics breast implant is explanted.

Device Tracking Form may be mailed and/or uploaded.



*Please see page 1 for device tracking and page 2 for patient privacy information.

Patient Confidentiality

- **Patient privacy is very important**, and the Allergan Aesthetics Device Tracking Program makes it a top priority
- **Patients may refuse to release their identifying information** (name, address, phone number, SSN) for device tracking purposes
- **Any information submitted to third parties** (including the FDA) will be protected from public disclosure
- **Regardless of whether a patient agrees to participate in the device tracking program**, healthcare providers are authorized to share patient names and other identifiers with Allergan Aesthetics for **health/safety purposes**

Not an actual patient or provider.

Allergan Aesthetics Key Takeaways

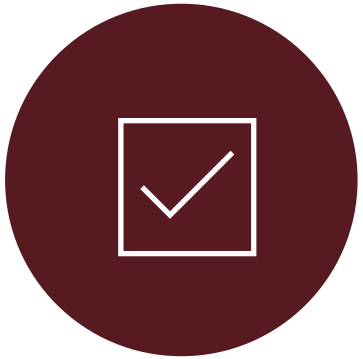
Operating with Allergan Aesthetics breast implants requires complying with device tracking regulations

Accurately registering each device if:

- Implanting / explanting a breast implant
- Opening and immediately discarding a new breast implant

Multiple follow-up attempts will be made to retrieve updated device tracking information from healthcare providers via a Device Disposition Report

Allergan Aesthetics will notify the FDA of any healthcare providers not providing updated device tracking information



Continued attempts will be made to retrieve device tracking information and Allergan Aesthetics is available to educate healthcare providers in complying with these regulations

For FDA medical device tracking requirements, click here.

To see options for submitting device tracking information, click here.

To learn more about Device Disposition Reports, click here.

Questions?

Contact your local Allergan Aesthetics Sales Representative or the Allergan Aesthetics Device Tracking Information line at 800-972-9378 if you have questions regarding the Allergan Aesthetics Device Tracking Program

Explore these key resources—at your fingertips:

PART 821 MEDICAL DEVICE TRACKING REQUIREMENTS

Medical Device Tracking Guidance for Industry and FDA

Device Tracking Form for *NATRELLE*® Silicone and Saline Breast Implants

AbbVie Device Management Portal

ARISE by Aesthetic One

National Breast Implant Registry

abbvie_device_tracking@abbvie.com or 800-972-9378

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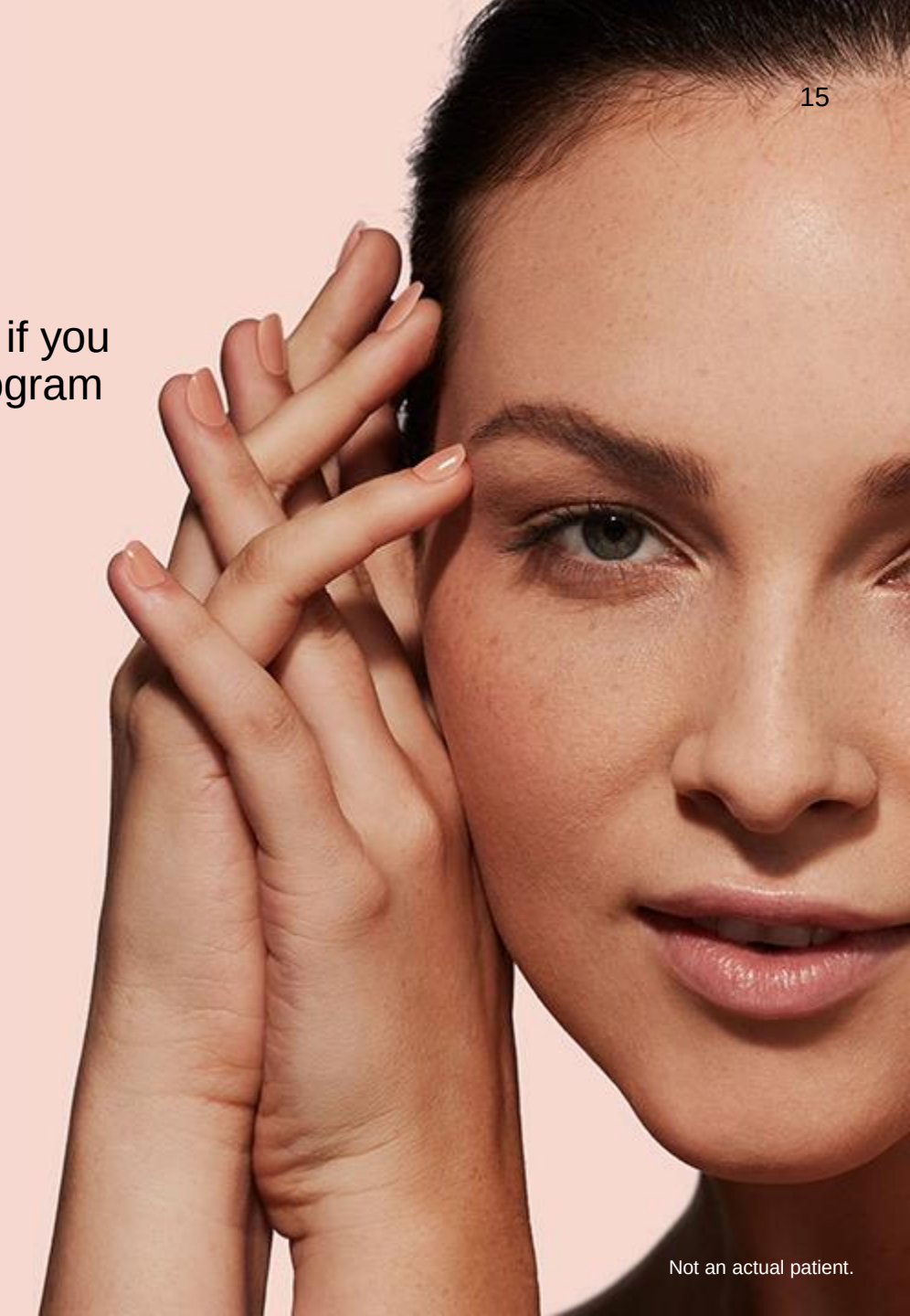

Not an actual patient.