ALLERGAN BREAST IMPLANT DEVICE TRACKING FOR HEALTHCARE PROVIDERS

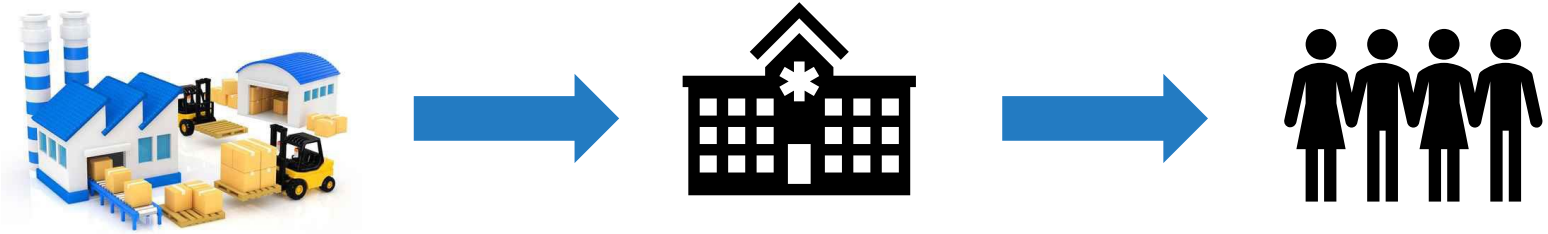
May 2020

TRAINING OBJECTIVES

- Understand the Healthcare Provider's role in meeting Medical Device Tracking Requirements for Allergan breast implants
- Assist Healthcare Providers in fulfilling device tracking requirements

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 Allergan's *Natrelle*® breast implants

ALLERGAN IMPLANT DEVICE TRACKING TIMELINE

Nov 2006

- FDA approves *Natrelle*® round implants & issues device tracking order.

Feb 2013

- FDA approves *Natrelle*® 410 implants & issues device tracking order.

June 2019

- FDA expands device tracking order to Saline-filled implants.

Note: All BIOCELL textured implants were withdrawn from the market on July 24, 2019 however they still require tracking for explant surgeries.

MANUFACTURER DEVICE TRACKING REQUIREMENTS

As the manufacturer, Allergan is required to collect certain device tracking information for our breast implants.

MANUFACTURERS (*Allergan*)	Before Device is Implanted	After Device is Implanted, Explanted, or Opened & Discarded
What to track:	Distributor / Final Distributor (Healthcare Provider): • Name • Address • Telephone # • Device location	Physician/Patient: • Name • Address • Telephone # • SSN (patient) Device: • SN or Lot # • Ship date • Implant date • Explant date (if applicable) • Disposal date (if applicable)

HEALTHCARE PROVIDER DEVICE TRACKING REQUIREMENTS

Final Distributor (Healthcare Providers)	Before Device is Implanted	After Device is Implanted, Explanted, or Opened & Discarded
Information provided to Allergan:	Healthcare Provider: • Name • Address • Telephone # • Device location Requirement met by completing and returning a Device Disposition Report sent by Allergan 60 days after implant purchase	Implanting Physician/Patient: • Name • Address • Telephone # • SSN (patient) Device: • SN or Lot # • 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 on the NBIR website

- **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 three options for Healthcare Providers to send Allergan Breast Implant Tracking Information:

1. **Device Tracking (DT) Forms** - After Implant / Explant procedure, complete and return the DT form to Allergan. They are included in the packaging of every implant and available online (https://www.allergan.com/medical-aesthetics)

2. **National Breast Implant Registry (NBIR)** - Register the implant on the NBIR website available online at https://www.thepsf.org/research/registries/nbir

3. **Device Disposition Report (DDR)** – Complete for any breast implants not implanted within 60 days (e.g. remaining in inventory). These will be sent by Allergan

DEVICE TRACKING FORM – PAGE 1

Packaged with all breast implants or available online at: https://www.allergan.com/products/natrelle-inspira

- You should complete this form and fax or mail it to Allergan after removing the breast implant from it's package.

Section 1: Complete if an Allergan Breast Implant is implanted.

DEVICE TRACKING

Allergan
THE SCIENCE OF REJUVENATION

NATRELLE® Silicone and Saline Breast Implants
Mailing Address: PO Box 51470 Ontario, CA 91761-0070
1.800.972.9378 f: 1.800.432.8803

I. Complete Upon Implant

DEVICE AND SURGERY INFORMATION

DATE OF IMPLANTATION mm /dd /yy

Affix LEFT breast implant label here. If label is not available, record REF and Serial Number below.

(Left) REF

(Left) SN

❑ Reconstruction ❑ Augmentation
❑ Revision

Affix RIGHT breast implant label here. If label is not available, record REF and Serial Number below.

(Right) REF

(Right) SN

❑ Reconstruction ❑ Augmentation
❑ Revision

IMPLANTING/EXPLANTING PHYSICIAN INFORMATION

LAST NAME FIRST NAME
ADDRESS CITY, STATE/PROVINCE ZIP/POSTAL CODE
EMAIL TELEPHONE FAX

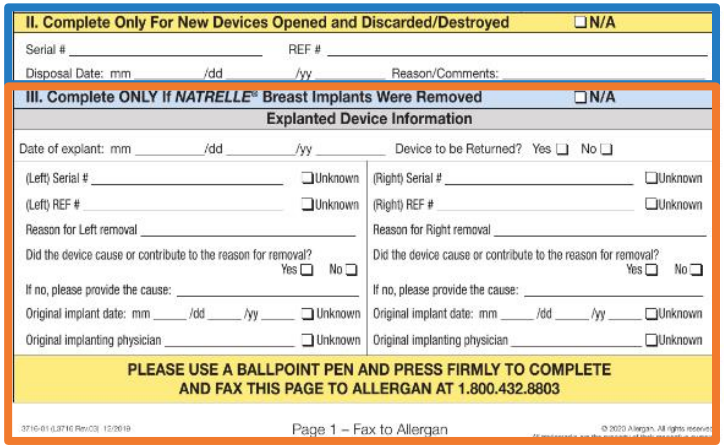
ATTENDING/FOLLOWING PHYSICIAN INFORMATION *(if different from above)*

LAST NAME FIRST NAME
ADDRESS CITY, STATE/PROVINCE ZIP/POSTAL CODE
EMAIL TELEPHONE FAX

PATIENT INFORMATION

LAST NAME FIRST NAME
ADDRESS CITY, STATE/PROVINCE ZIP/POSTAL CODE
DATE OF BIRTH SOCIAL SECURITY NUMBER ❑ NOT AVAILABLE TELEPHONE

Section 2: Complete if an Allergan Breast Implant is opened and immediately discarded or destroyed.



II. Complete Only For New Devices Opened and Discarded/Destroyed ❑ N/A

Serial # REF #

Disposal Date: mm /dd /yy Reason/Comments:

III. Complete ONLY If *NATRELLE*® Breast Implants Were Removed ❑ N/A

Explanted Device Information

Date of explant: mm /dd /yy Device to be Returned? Yes ❑ No ❑

(Left) Serial # ❑ Unknown	(Right) Serial # ❑ Unknown
(Left) REF # ❑ Unknown	(Right) REF # ❑ Unknown
Reason for Left removal	Reason for Right removal
Did the device cause or contribute to the reason for removal? Yes ❑ No ❑	Did the device cause or contribute to the reason for removal? Yes ❑ No ❑
If no, please provide the cause:	If no, please provide the cause:
Original implant date: mm /dd /yy ❑ Unknown	Original implant date: mm /dd /yy ❑ Unknown
Original implanting physician ❑ Unknown	Original implanting physician ❑ Unknown

PLEASE USE A BALLPOINT PEN AND PRESS FIRMLY TO COMPLETE AND FAX THIS PAGE TO ALLERGAN AT 1.800.432.8803

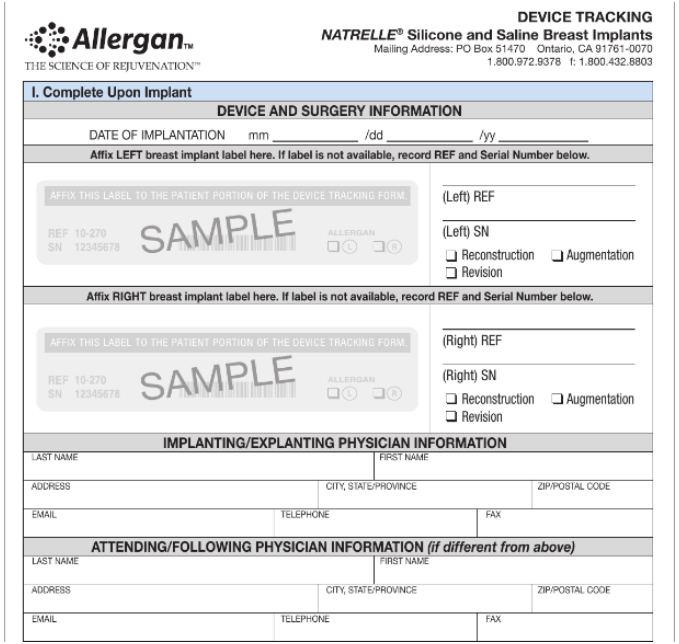
3716-01 (L3716 Rev03) 12/2019 Page 1 – Fax to Allergan © 2020 Allergan. All rights reserved.

Section 3: Complete if an Allergan Breast Implant is explanted.

DEVICE TRACKING FORM – PAGE 2

Patient Consent Form

- Healthcare Providers should complete this form with the patient after the procedure.



Allergan™
THE SCIENCE OF REJUVENATION™

DEVICE TRACKING
NATRELLE® Silicone and Saline Breast Implants
Mailing Address: PO Box 51470 Ontario, CA 91761-0070
1.800.972.9378 f: 1.800.432.8803

I. Complete Upon Implant

DEVICE AND SURGERY INFORMATION

DATE OF IMPLANTATION mm _____ /dd _____ /yy _____

Affix LEFT breast implant label here. If label is not available, record REF and Serial Number below.

AFFIX THIS LABEL TO THE PATIENT PORTION OF THE DEVICE TRACKING FORM.
REF 10-270
SN 12345678
SAMPLE
ALLERGAN

(Left) REF _____
(Left) SN _____
❑ Reconstruction ❑ Augmentation
❑ Revision

Affix RIGHT breast implant label here. If label is not available, record REF and Serial Number below.

AFFIX THIS LABEL TO THE PATIENT PORTION OF THE DEVICE TRACKING FORM.
REF 10-270
SN 12345678
SAMPLE
ALLERGAN

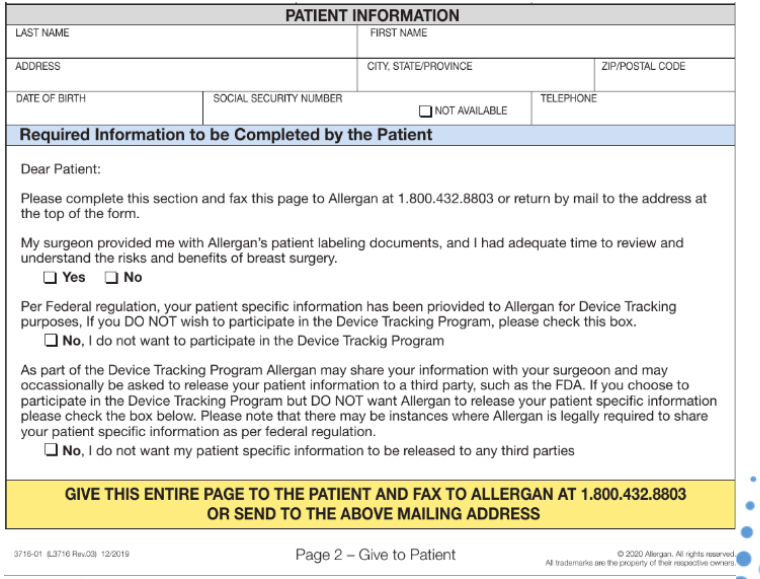
(Right) REF _____
(Right) SN _____
❑ Reconstruction ❑ Augmentation
❑ Revision

IMPLANTING/EXPLANTING PHYSICIAN INFORMATION

LAST NAME	FIRST NAME	
ADDRESS	CITY, STATE/PROVINCE	ZIP/POSTAL CODE
EMAIL	TELEPHONE	FAX

ATTENDING/FOLLOWING PHYSICIAN INFORMATION *(if different from above)*

LAST NAME	FIRST NAME	
ADDRESS	CITY, STATE/PROVINCE	ZIP/POSTAL CODE
EMAIL	TELEPHONE	FAX



PATIENT INFORMATION

LAST NAME	FIRST NAME	
ADDRESS	CITY, STATE/PROVINCE	ZIP/POSTAL CODE
DATE OF BIRTH	SOCIAL SECURITY NUMBER ❑ NOT AVAILABLE	TELEPHONE

Required Information to be Completed by the Patient

Dear Patient:

Please complete this section and fax this page to Allergan at 1.800.432.8803 or return by mail to the address at the top of the form.

My surgeon provided me with Allergan's patient labeling documents, and I had adequate time to review and understand the risks and benefits of breast surgery.

❑ **Yes** ❑ **No**

Per Federal regulation, your patient specific information has been priovided to Allergan for Device Tracking purposes, If you DO NOT wish to participate in the Device Tracking Program, please check this box.

❑ **No**, I do not want to participate in the Device Trackig Program

As part of the Device Tracking Program Allergan may share your information with your surgeoon and may occassionally be asked to release your patient information to a third party, such as the FDA. If you choose to participate in the Device Tracking Program but DO NOT want Allergan to release your patient specific information please check the box below. Please note that there may be instances where Allergan is legally required to share your patient specific information as per federal regulation.

❑ **No**, I do not want my patient specific information to be released to any third parties

GIVE THIS ENTIRE PAGE TO THE PATIENT AND FAX TO ALLERGAN AT 1.800.432.8803 OR SEND TO THE ABOVE MAILING ADDRESS

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Page 2 – Give to Patient

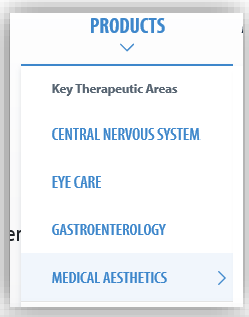
PATIENT CONFIDENTIALITY

- Patient Privacy is very important, and Allergan's Device Tracking Program makes it a top priority
- Patients may refuse to release their identifying information (name, address, phone #, 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 for **health/safety purposes**

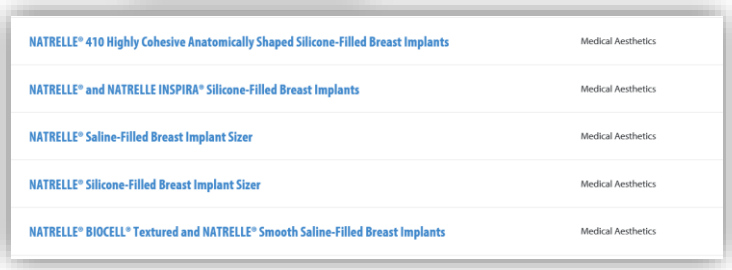
WHERE CAN I FIND A DEVICE TRACKING FORM?

1. Visit www.Allergan.com

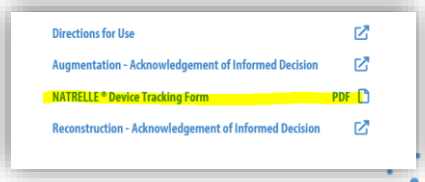
2. Select ***Products*** → ***Medical Aesthetics***



3. Select the applicable product link



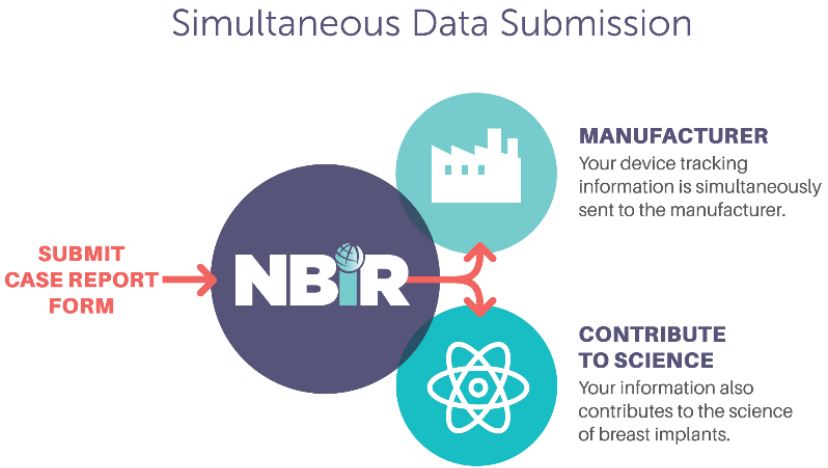
4. Download the Device Tracking form



ALTERNATE OPTION

National Breast Implant Registry (NBIR)

- Healthcare Providers can submit device tracking information on the NBIR website instead of completing Allergan's Device Tracking form
- Allergan has real-time access to its device tracking information on the NBIR website



NBIR PROCESS

1. Physicians can register to participate at the NBIR website

2. Download the NBIR Barcode Scanner from the Apple App Store or Google Play Store

3. In order for the app to recognize a case is ready for scanning, physicians must add the case to the NBIR dashboard, complete the required fields, and send the case to the app
   - *Required Fields: Patient Name, DOB, Procedure Date, Indication (Left/Right), & Operation (Left/Right)*

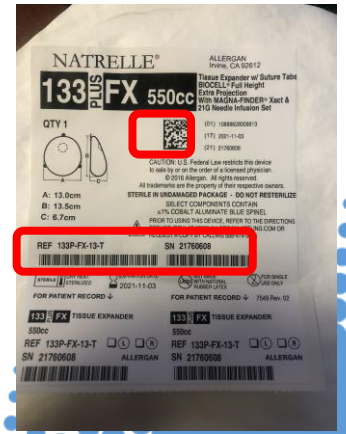
4. Log into the app, select the appropriate case, and scan the Unique Device Identifier (UDI) or QR code on the implant box or primary package label*

* 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**

NBIR Barcode Scanner 12+
FIGMD Inc.
4.5, 2 Ratings
Free

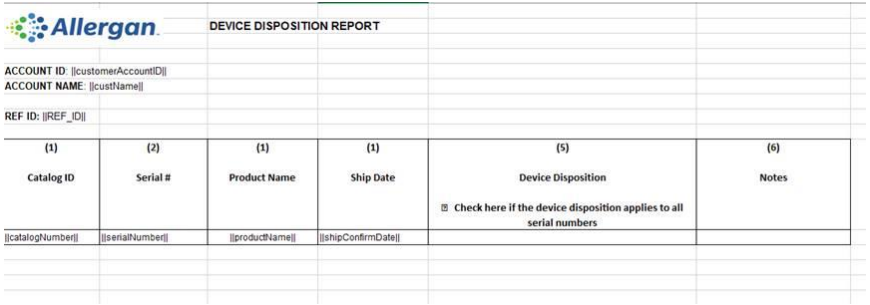
Click on the following links for more detailed information:

- How to Sign Up
- How to Edit Navigate the NBIR Dashboard
- How to Use the NBIR Barcode Scanner



DEVICE DISPOSITION REPORTS

- Device Disposition Reports are used by Allergan 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
- 60 days from the date of the initial sales transaction, Allergan 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, fax or to the mailing address on record
- Allergan will make 3 additional attempts to retrieve updated information at 75 days, 90 days, and 105 days
- Implants that have been returned to Allergan or are included on a Device Tracking form will not appear on the Device Disposition Report.



Allergan DEVICE DISPOSITION REPORT

ACCOUNT ID: ||customerAccountID||
ACCOUNT NAME: ||custName||

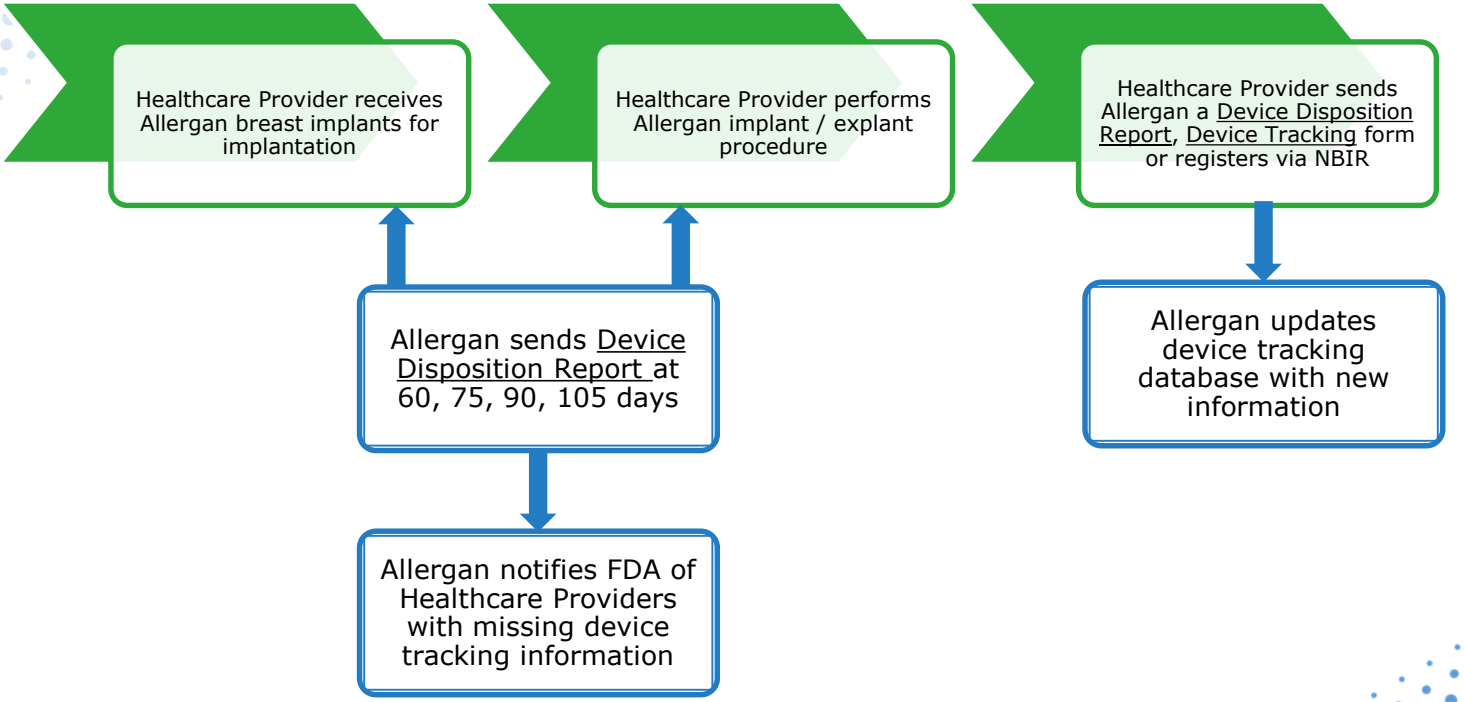
REF ID: ||REF_ID||

(1) Catalog ID	(2) Serial #	(1) Product Name	(1) Ship Date	(5) Device Disposition ☑ Check here if the device disposition applies to all serial numbers	(6) Notes
||catalogNumber||	||serialNumber||	||productName||	||shipConfirmDate||		

FDA NOTIFICATION

- All implant manufacturers, including Allergan are required to notify the FDA when a Healthcare Provider does not provide updated device tracking information
- Allergan 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 all attempts to retrieve device tracking information have failed, Allergan will provide a written notification to the FDA district office responsible for the area in which the Healthcare Provider resides
- The written notification will include the Healthcare Provider's name, address, and the list of breast implants (by Serial Number) which are unaccounted for
- This FDA notification will be delivered every six months as necessary

DEVICE TRACKING PROCESS



KEY TAKEAWAYS

- Healthcare Providers who implant / explant Allergan's breast implants are required to comply with device tracking regulations per 21 CFR Part 821 by:
  - Accurately completing & returning a Device Tracking form or submitting a Case Report Form via NBIR after:
    - Implanting / Explanting a breast implant
    - Opening and immediately discarding a new breast implant
- Allergan will perform multiple follow-up attempts to retrieve updated device tracking information from Healthcare Providers via a Device Disposition Report
- Allergan is required to notify the FDA of any Healthcare Providers not providing updated device tracking information
- Allergan will make several attempts to retrieve device tracking information and is available to assist Healthcare Providers in complying with these regulations

QUESTIONS?

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

References

- PART 821—MEDICAL DEVICE TRACKING REQUIREMENTS
- Medical Device Tracking Guidance for Industry and FDA
- L3716: Allergan Device Tracking Form, US
- National Breast Implant Registry