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Note: All BIOCELL textured implants were withdrawn from the market on July 24, 2019 however they still require tracking for explant surgeries.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

<table>
<thead>
<tr>
<th>MANUFACTURERS (Allergan)</th>
<th>Before Device is Implanted</th>
<th>After Device is Implanted, Explanted, or Opened &amp; Discarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>What to track:</td>
<td>Distributor / Final Distributor (Healthcare Provider):</td>
<td>Physician/Patient:</td>
</tr>
<tr>
<td></td>
<td>• Name</td>
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<td>• Address</td>
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<td>• Telephone #</td>
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<td></td>
<td>• Device location</td>
<td>• SSN (patient)</td>
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<td>Device:</td>
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<td>• SN or Lot #</td>
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<td></td>
<td>• Ship date</td>
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<td>• Implant date</td>
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<td></td>
<td>• Explant date (if applicable)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Disposal date (if applicable)</td>
</tr>
</tbody>
</table>
HEALTHCARE PROVIDER DEVICE TRACKING REQUIREMENTS

<table>
<thead>
<tr>
<th>Final Distributor (Healthcare Providers)</th>
<th>Before Device is Implanted</th>
<th>After Device is Implanted, Explanted, or Opened &amp; Discarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information provided to Allergan:</td>
<td>Healthcare Provider:</td>
<td>Implanting Physician/Patient:</td>
</tr>
<tr>
<td></td>
<td>• Name</td>
<td>• Name</td>
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<td>• Telephone #</td>
<td>• Telephone #</td>
</tr>
<tr>
<td></td>
<td>• Device location</td>
<td>• SSN (patient)</td>
</tr>
<tr>
<td></td>
<td>Requirement met by completing and returning a Device Disposition Report sent by Allergan 60 days after implant purchase</td>
<td>Device:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• SN or Lot #</td>
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<td>• Implant date</td>
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<td>• Explant date (if applicable)</td>
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<tr>
<td></td>
<td></td>
<td>• Disposal date (if applicable)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Requirement met by completing and returning a Device Tracking form or by registering the implant on the NBIR website</td>
</tr>
</tbody>
</table>

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

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

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

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

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

### Patient Information

<table>
<thead>
<tr>
<th><strong>Last Name</strong></th>
<th><strong>First Name</strong></th>
</tr>
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<tbody>
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</table>

<table>
<thead>
<tr>
<th><strong>Address</strong></th>
<th><strong>City, State/Province, Zip Code</strong></th>
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</table>

<table>
<thead>
<tr>
<th><strong>Date of Birth</strong></th>
<th><strong>Social Security Number</strong></th>
<th><strong>Not Available</strong></th>
<th><strong>Telephone</strong></th>
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</table>

**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 provided to Allergan for Device Tracking purposes. If you DO NOT wish to participate in the Device Tracking Program, please check this box.

- [ ] Yes  [ ] No, I do not want to participate in the Device Tracking Program

As part of the Device Tracking Program Allergan may share your information with your surgeon and may occasionally 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.

- [ ] Yes  [ ] 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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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*
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.

**Simultaneous Data Submission**

- **MANUFACTURER**
  Your device tracking information is simultaneously sent to the manufacturer.
- **CONTRIBUTE TO SCIENCE**
  Your information also contributes to the science of breast implants.
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*

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 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.
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

Healthcare Provider receives Allergan breast implants for implantation

Healthcare Provider performs Allergan implant / explant procedure

Healthcare Provider sends Allergan a Device Disposition Report, Device Tracking form or registers via NBIR

Allergan sends Device Disposition Report at 60, 75, 90, 105 days

Allergan notifies FDA of Healthcare Providers with missing device tracking information

Allergan updates device tracking database with new information
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
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