Instructions for completing Allergan's Device Tracking Form for *NATRELLE*® Silicone and Saline Breast Implants

IMPORTANT: Read and remove these instructions prior to completing the Device Tracking Form. For Device Tracking purposes the physician/health care facility **MUST** notify Allergan upon implantation, explantation or when a ***NATRELLE***® Silicone or Saline Breast Implant is discarded or destroyed. Failure to comply could result in violation of Federal law.

Healthcare facility, please complete the following sections of the form. Device tracking information can also be provided electronically via the **AbbVie Device Management Portal**, the National Breast Implant Registry, or the Aesthetic One app. **To use the AbbVie Device Management Portal, go to devicemanagement.abbvie.com to register and start data entry.** For the National Breast Implant Registry, go to thepsf.org/NBIR to register and start data entry. To use the Aesthetic One app, go to https://www.surgery.org/downloads/microsite/aestheticone/index.php to register and start data entry.

I. Complete upon Implantation

a. Device and Surgery Information

For implantation surgery, affix the breast implant label attached to the inner product box labeling to page 1 of the forms and place the device tracking label to page 2 of the forms, L for the left breast implant and R for the right breast implant. If labels are not available, please record the catalog number (REF) and serial number (SN) in the space provided for each page of the form.

b. Implanting/Explanting Physician Information

c. Attending /Following Physician Information

d. Patient Information

II. Complete only for new devices opened and discarded/destroyed

Complete this section if ***NATRELLE***® Breast Implant(s) were opened and not used for any reason during surgery and discarded or destroyed. If not applicable, mark N/A. If applicable, provide serial number(s), date of occurrence and reason/comments in the space provided. Allergan requires the device to be returned if defective, otherwise if available, you may choose to return it to: 1800 Waters Ridge Drive Suit 100, Lewisville, TX 75057, Attn: Allergan Device Analysis Laboratory with contact information, serial number(s) and reason for return.

III. Complete ONLY if *NATRELLE*® Breast Implant(s) were removed

After completing the Device Tracking Form and ensuring that the serial number information is on each form, remove page 1 and send by mail or provide electronically through the AbbVie Device Management Portal, NBIR, or Aesthetic One app (detailed above). Provide page 2 to the patient, for completion of enrollment in the Allergan Device Tracking program.

Upon receipt of the first page of the form by Allergan, patient specific information is entered in the Device Tracking database. Patients who do NOT wish to participate in the Device Tracking Program or choose NOT to release their information to any third parties unless legally required, check the appropriate box and unless legally required to retain their personal information, Allergan will remove their personal information from the database upon receipt of their form.

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DEVICE TRACKING
NATRELLE® **Silicone and Saline Breast Implants**
Mailing Address: AbbVie Device Tracking 1 N. Waukegan Rd. Bldg. J23-2
North Chicago, IL 60064
1.800.972.9378

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
EMAIL		
DATE OF BIRTH	SOCIAL SECURITY NUMBER ❑ NOT AVAILABLE	TELEPHONE

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

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

PLEASE USE A BALLPOINT PEN AND PRESS FIRMLY TO COMPLETE. SEND BY MAIL OR PROVIDE ELECTRONICALLY THROUGH THE ABBVIE DEVICE MANAGEMENT PORTAL, NBIR, OR AESTHETIC ONE APP. SEE INSTRUCTIONS PAGE FOR DETAILS

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North Chicago, IL 60064
1.800.972.9378

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
EMAIL		
DATE OF BIRTH	SOCIAL SECURITY NUMBER	TELEPHONE

Required Information to be Completed by the Patient

Dear Patient:

By completing and submitting the Device Tracking Form, you acknowledge that:

- Your surgeon provided you with Allergan's patient labeling documents; you have had adequate time to review and understand the risks and benefits of breast surgery; you reviewed the patient decision checklist with your surgeon, signed it and received a copy to retain for your records; and your surgeon provided you with a device identification card
  ❑ Yes ❑ No
- You have not opted out of providing personal information (including name, address, phone number, date of birth, email and SSN) to Allergan's Device Tracking Program. You understand that your personal information will be provided to Allergan and any of its vendors or third parties providing device tracking services on its behalf, and any relevant regulatory authorities for device tracking purposes, in accordance with applicable laws and regulations; and
- You are aware that you should report any changes in your contact information to Allergan by emailing AbbVie_Device_Tracking@AbbVie.com

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.

❑ 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. 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 SEND BY MAIL OR PROVIDE ELECTRONICALLY THROUGH THE ABBVIE DEVICE MANAGEMENT PORTAL, NBIR, OR AESTHETIC ONE APP

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