

Instructions for completing Allergan's NATRELLE™ Silicone-Filled Breast Implant Device Tracking Form

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-Filled 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:

I. Complete upon Implantation

a. Device and Surgery Information

For implantation surgery, affix the Device Tracking Label attached to the inner product box labeling to page 1 of the forms and place the breast implant chart label to page 2 and page 3 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 if device Destroyed or Discarded

III. Complete if NATRELLE™ Silicone-Filled Breast Implant(s) were removed

After completion of the Device Tracking Form and ensuring that the serial number information is on each form, healthcare personnel remove page 1 and return to Allergan in the envelope provided and keep page 2 for your records. Provide page 3 to the patient, for completion of enrollment in the Allergan Device Tracking program.

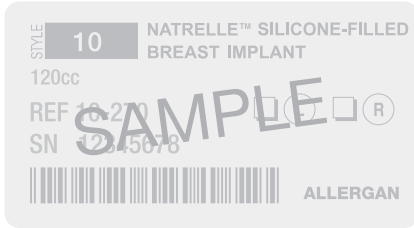
Upon receipt of the first page of the form by Allergan, patient specific information is entered in the Device Tracking database. Patient's who do NOT wish to participate in the Device Tracking Program or choose NOT to release their information to any third parties, such as the FDA, check the appropriate box and Allergan will remove their personal information from the database upon receipt of their form.

I. Complete Upon Implant

Device and Surgery Information

DATE OF IMPLANTATION mm _____ /dd _____ /yy _____

Affix Left Device Tracking Label OR Fill In The Device Data

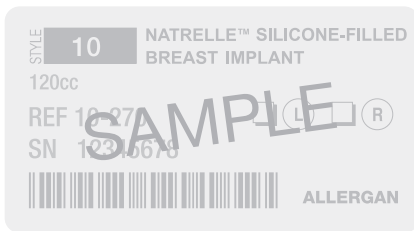


(Left) REF _____

(Left) SN _____

Reconstruction Augmentation
 Revision

Affix Right Device Tracking Label OR Fill In The Device Data



(Right) REF _____

(Right) SN _____

Reconstruction Augmentation
 Revision

IMPLANTING/EXPLANTING PHYSICIAN INFORMATION

LAST NAME		FIRST NAME	
ADDRESS		CITY, STATE/PROVINCE	
E-MAIL		TELEPHONE	
		FAX	
ZIP/POSTAL CODE			

ATTENDING/FOLLOWING PHYSICIAN INFORMATION (if different from above)

LAST NAME		FIRST NAME	
ADDRESS		CITY, STATE/PROVINCE	
E-MAIL		TELEPHONE	
		FAX	
ZIP/POSTAL CODE			

PATIENT INFORMATION

LAST NAME		FIRST NAME	
ADDRESS		CITY, STATE/PROVINCE	
DATE OF BIRTH		SOCIAL SECURITY NUMBER	
		TELEPHONE	
ZIP/POSTAL CODE			

II. Complete if Device Discarded or Destroyed

N/A

Device(s) on this form were discarded/destroyed prior to completion of this procedure

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

III. Complete if NATRELLE™ Silicone-Filled Breast Implants Were Removed

N/A

Explanted Device Information

Date of explant mm _____ /dd _____ /yy _____

(Left) Serial # _____ <input type="checkbox"/> Unknown	(Right) Serial # _____ <input type="checkbox"/> Unknown
(Left) Ref # _____ <input type="checkbox"/> Unknown	(Right) Ref # _____ <input type="checkbox"/> Unknown
Reason for removal _____	Reason for removal _____
Original implant date: mm _____ /dd _____ /yy _____ <input type="checkbox"/> Unknown	Original implant date: mm _____ /dd _____ /yy _____ <input type="checkbox"/> Unknown
Original implanting physician _____ <input type="checkbox"/> Unknown	Original implanting physician _____ <input type="checkbox"/> Unknown

**COMPLETE AND RETURN THIS PAGE TO ALLERGAN IN THE ATTACHED ENVELOPE
OR FAX TO 800.432.8803**

I. Complete Upon Implant
DEVICE AND SURGERY INFORMATION

DATE OF IMPLANTATION mm _____ /dd _____ /yy _____

Affix LEFT breast implant chart 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

(L) (R)

(Left) REF _____

(Left) SN _____

 Reconstruction Augmentation
 Revision

Affix RIGHT breast implant chart 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

(L) (R)

(Right) REF _____

(Right) SN _____

 Reconstruction Augmentation
 Revision

IMPLANTING/EXPLANTING PHYSICIAN INFORMATION

LAST NAME		FIRST NAME	
ADDRESS		CITY, STATE/PROVINCE	ZIP/POSTAL CODE
E-MAIL	TELEPHONE	FAX	

ATTENDING/FOLLOWING PHYSICIAN INFORMATION (if different from above)

LAST NAME		FIRST NAME	
ADDRESS		CITY, STATE/PROVINCE	ZIP/POSTAL CODE
E-MAIL	TELEPHONE	FAX	

PATIENT INFORMATION

LAST NAME		FIRST NAME	
ADDRESS		CITY, STATE/PROVINCE	ZIP/POSTAL CODE
DATE OF BIRTH	SOCIAL SECURITY NUMBER	TELEPHONE	

II. Complete if Device Discarded or Destroyed
 N/A

 Device(s) on this form were discarded/destroyed prior to completion of this procedure

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

III. Complete if NATRELLE™ Silicone-Filled Breast Implants Were Removed
 N/A

Explanted Device Information

Date of explant mm _____ /dd _____ /yy _____

(Left) Serial # _____ <input type="checkbox"/> Unknown	(Right) Serial # _____ <input type="checkbox"/> Unknown
(Left) Ref # _____ <input type="checkbox"/> Unknown	(Right) Ref # _____ <input type="checkbox"/> Unknown
Reason for removal _____	Reason for removal _____
Original implant date: mm _____ /dd _____ /yy _____ <input type="checkbox"/> Unknown	Original implant date: mm _____ /dd _____ /yy _____ <input type="checkbox"/> Unknown
Original implanting physician _____ <input type="checkbox"/> Unknown	Original implanting physician _____ <input type="checkbox"/> Unknown

KEEP THIS PAGE FOR YOUR RECORDS

I. Complete Upon Implant
DEVICE AND SURGERY INFORMATION

DATE OF IMPLANTATION mm _____ /dd _____ /yy _____

Affix LEFT breast implant chart 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

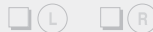
Affix RIGHT breast implant chart label here. If label is not available, record REF and Serial Number below.

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
E-MAIL	TELEPHONE	FAX	

ATTENDING/FOLLOWING PHYSICIAN INFORMATION (if different from above)

LAST NAME		FIRST NAME	
ADDRESS		CITY, STATE/PROVINCE	ZIP/POSTAL CODE
E-MAIL	TELEPHONE	FAX	

PATIENT INFORMATION

LAST NAME		FIRST NAME	
ADDRESS		CITY, STATE/PROVINCE	ZIP/POSTAL CODE
DATE OF BIRTH	SOCIAL SECURITY NUMBER	TELEPHONE	

II. Required information to be completed by the patient

Dear Patient:

 Please complete this section and return this page to Allergan in the envelope provided in your **NATRELLE™ Silicone-Filled Breast Implant Patient Planner**. If your surgeon did NOT provide you with the Patient Planner you can fax this form to Allergan at 800.432.8803 or return by mail to the address at the top of the form.

 My surgeon provided me with Allergan's **NATRELLE™ Silicone-Filled Breast Implant Patient Planner** 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.

 No, I do not want to participate in the Device Tracking Program

As part of the Device Tracking program Allergan may occasionally be asked to release 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.

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

GIVE THIS ENTIRE PAGE TO THE PATIENT TO SEND TO ALLERGAN IN THE ENVELOPE SUPPLIED IN THEIR PATIENT PLANNER OR FAX TO 800.432.8803