Instructions for completing Allergan's Device Tracking Form for *NATRELLE*® Silicone-Filled Breast Implants and *NATRELLE*® 410 Highly Cohesive Anatomically Shaped Silicone-Filled 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***® Gel-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 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***® Gel-Filled 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 if *NATRELLE*® Gel-Filled 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 fax to Allergan. 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, such as the FDA, check the appropriate box and Allergan will remove their personal information from the database upon receipt of their form.

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DEVICE TRACKING
NATRELLE® Silicone-Filled Breast Implants
NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants

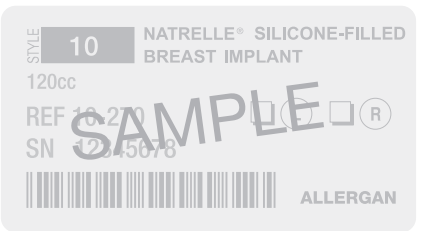
Mailing Address: PO Box 51470 Ontario, CA 91761-0070
1.800.972.9378 *f:* 1.800.432.8803

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.

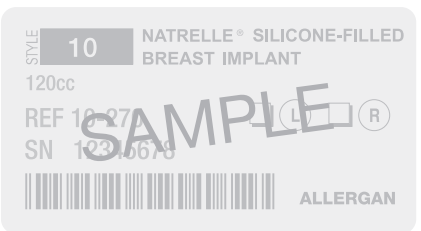


_____
(Left) REF

_____
(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
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 ❑ 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 If *NATRELLE*® Gel-Filled Breast Implants Were Removed ❑ N/A

Explanted Device Information

Date of explant mm _____ /dd _____ /yy _____

(Left) Serial # _____ ❑ Unknown	(Right) Serial # _____ ❑ Unknown
(Left) Ref # _____ ❑ Unknown	(Right) Ref # _____ ❑ Unknown
Reason for removal _____	Reason for removal _____
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

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DEVICE TRACKING
NATRELLE® Silicone-Filled Breast Implants
NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants

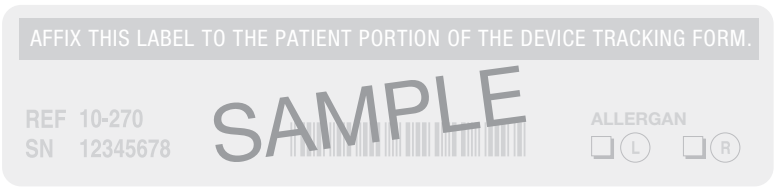
Mailing Address: PO Box 51470 Ontario, CA 91761-0070
1.800.972.9378 *f:* 1.800.432.8803

Complete Upon Implant

DEVICE AND SURGERY INFORMATION

DATE OF IMPLANTATION mm_____ /dd _____ /yy _____

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

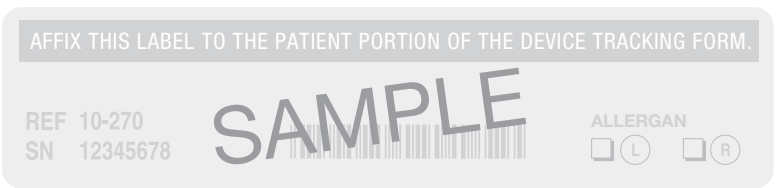


(Left) REF _____

(Left) SN _____

❑ Reconstruction ❑ Augmentation
❑ Revision

Affix RIGHT device tracking 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
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 ❑ 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, *Important Information for Women about Breast Augmentation/Reconstruction with NATRELLE® Silicone-Filled Breast Implants* or *Breast Augmentation/Reconstruction with NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants* 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 FAX TO ALLERGAN AT 1.800.432.8803 OR SEND TO THE ABOVE MAILING ADDRESS