Instructions for Completing Allergan's *NATRELLE*® Silicone and Saline Breast Implant Device Registration Form

Please read the instructions below and complete ONE of the attached forms in either English or French.

IMPORTANT: Health Canada has mandated the inclusion of an implant registration form with each of our silicone-filled breast implants. Allergan is also including an implant registration form with each of our saline-filled breast implants. The purpose of this Device Registration Form is to enable Allergan to notify you and your patients of new information concerning the safety, effectiveness or performance of the implant, and any required corrective action. The physician/health care facility is required to offer patients the option of being included in a voluntary patient registry upon implantation of *NATRELLE*® Silicone or Saline Implants prior to inclusion of the patient's personal information on the form.

Once completed, an Allergan *NATRELLE*® Silicone and Saline Breast Implant Device Registration Form should be mailed to the manufacturer to report implantation of *NATRELLE*® Silicone or Saline Breast Implants. **Device tracking information can also be provided via the AbbVie Device Management Portal. Go to devicemanagement.abbvie.com to register and start data entry.**

The healthcare facility is to complete the form, with the exception of the patient information section. For each implantation surgery, complete the implant device and surgery information section. If implants are being explanted as part of the current surgery, please also complete the explanted device information section. If not applicable, mark N/A. For implantation surgery, affix the Device Labels to the Device Registration Form, labeling L for the left breast implant and R for the right breast implant. Labels must be applied to pages 1 and 2 of the form. Product labels can be found attached to the inner product box. If labels are not available, please record the catalog number (REF) and serial number (SN) in the space provided.

Patients who choose the option of being included in the voluntary patient registry, must complete the patient information section, sign and date the form on Page 1. By doing this, the patient is consenting to release their information to the manufacturer.

After completion of the Device Registration Form and ensuring that the serial number information is on each form, Healthcare personnel should remove the top copy and either fax to Allergan at 1.800.432.8803 or mail to AbbVie Device Tracking, 1 N. Waukegan Rd, Bldg. J23-2, North Chicago, IL 60064. The bottom copies (Pages 2 and 3) are to be given to the patient for their records.

Note: If any *NATRELLE*® Silicone or Saline Breast Implants are discarded or destroyed during surgery please contact Allergan Medical Aesthetics Device Tracking Department at 1.800.972.9378 to report this final disposition.

Allergan™

Allergan
2525 Dupont Drive
Irvine, CA 92612

Allergan™

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

Complete If *NATRELLE*® Silicone- and Saline-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 Left removal _____	Reason for Right removal _____
Original implant date: mm _____ /dd _____ /yy _____ ❑ Unknown	Original implant date: mm _____ /dd _____ /yy _____ ❑ Unknown
Original implanting physician _____ ❑ Unknown	Original implanting physician _____ ❑ Unknown

Complete Upon Implant

IMPLANT DEVICE AND SURGERY INFORMATION

Affix Left Device Label or fill in the device data

_____
LEFT SIDE REF

_____
LEFT SIDE SERIAL NUMBER

❑ Reconstruction ❑ Augmentation
❑ Revision

Affix Right Device Label or fill in the device data

_____
RIGHT SIDE REF

_____
RIGHT SIDE SERIAL NUMBER

❑ Reconstruction ❑ Augmentation
❑ Revision

DATE OF SURGERY mm _____ /dd _____ /yy _____

PHYSICIAN INFORMATION

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

HEALTH CARE FACILITY INFORMATION

NAME OF THE HEALTH CARE FACILITY AT WHICH THE IMPLANT PROCEDURE TOOK PLACE		
ADDRESS	CITY/PROVINCE	POSTAL CODE
HEALTH CARE FACILITY PATIENT IDENTIFICATION NUMBER	TELEPHONE	FAX

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

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

TO BE COMPLETED BY THE PATIENT

I RELEASE THE FOLLOWING INFORMATION TO THE MANUFACTURER: _____
PATIENT SIGNATURE/DATE

PATIENT INFORMATION

LAST NAME	FIRST NAME	
ADDRESS	CITY/PROVINCE	POSTAL CODE
DATE OF BIRTH	EMAIL	TELEPHONE

PLEASE SUBMIT VIA THE ABBVIE DEVICE MANAGEMENT PORTAL OR SEND VIA EMAIL

Allergan™

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

Complete If *NATRELLE*® Silicone- and Saline-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 Left removal _____	Reason for Right removal _____
Original implant date: mm _____ /dd _____ /yy _____ ☐ Unknown	Original implant date: mm _____ /dd _____ /yy _____ ☐ Unknown
Original implanting physician _____ ☐ Unknown	Original implanting physician _____ ☐ Unknown

Complete Upon Implant

IMPLANT DEVICE AND SURGERY INFORMATION

Affix Left Device Label or fill in the device data

LEFT SIDE REF _____

LEFT SIDE SERIAL NUMBER _____

☐ Reconstruction ☐ Augmentation
☐ Revision

Affix Left Device Label or fill in the device data

RIGHT SIDE REF _____

RIGHT SIDE SERIAL NUMBER _____

☐ Reconstruction ☐ Augmentation
☐ Revision

DATE OF SURGERY mm _____ /dd _____ /yy _____

PHYSICIAN INFORMATION

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

HEALTH CARE FACILITY INFORMATION

NAME OF THE HEALTH CARE FACILITY AT WHICH THE IMPLANT PROCEDURE TOOK PLACE		
ADDRESS	CITY/PROVINCE	POSTAL CODE
HEALTH CARE FACILITY PATIENT IDENTIFICATION NUMBER	TELEPHONE	FAX

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

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

TO BE COMPLETED BY THE PATIENT

I RELEASE THE FOLLOWING INFORMATION TO THE MANUFACTURER: _____
PATIENT SIGNATURE/DATE

PATIENT INFORMATION

LAST NAME	FIRST NAME	
ADDRESS	CITY/PROVINCE	POSTAL CODE
DATE OF BIRTH	EMAIL	TELEPHONE

GIVE THIS PAGE TO THE PATIENT

Notice to the patient: the purpose of device registration is to enable the manufacturer to notify you of new information concerning the safety, effectiveness or performance of the implant, and any required corrective action; and for that reason you should notify the manufacturer of any change of address.

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Allergan™

CANADIAN DEVICE REGISTRATION
***NATRELLE*® Silicone and Saline Breast Implants**
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North Chicago, IL 60064
ph.: 1.800.972.9378

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 and that you have had adequate time to review and understand the risk and benefits of breast surgery; and
- 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

In accordance with applicable regulations, 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 Health Canada and/or as required by law. 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 applicable regulation.

☐ No, I do not want my patient specific information to be released to any third parties, subject to the noted disclosures.

"If you marked "no," please contact AbbVie by email *(AbbVie_Device_Tracking@AbbVie.com)* or by telephone *(1.800.972.9378)*.

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Notice to the patient: the purpose of device registration is to enable the manufacturer to notify you of new information concerning the safety, effectiveness or performance of the implant, and any required corrective action; and for that reason you should notify the manufacturer of any change of address.