CONFIDENTIAL
Informed Consent Form

NATRELLE® Breast Implant Follow-up Study (BIFS), 410-Arm

STUDY NUMBER: BIFS-001 Amendment 5

Subject Identification Number: _____

1. Introduction

You have been invited to participate in a research study sponsored by Allergan of subjects with FDA approved NATRELLE® Breast Implants. This consent form describes the study and your role in it. Your physician has reviewed the study and has agreed to participate as an Investigator (study doctor). The Investigator will answer any questions you have about this study or this consent form. Please read this form carefully and ask any questions you have regarding the information it contains.

2. Purpose of Study

The purpose of the study is to compare Allergan silicone gel-filled breast implants with saline implants or national norms in regard to:

1) Long-term safety
   - Connective Tissue Diseases (CTD)
   - Rheumatologic and neurologic signs and symptoms
   - Cancer (lung and breast)
   - Suicide or attempted suicide
   - Local complications and the need for reoperations
2) Reproduction, pregnancy outcomes, and lactation
   - Pregnancy outcomes
   - Problems related to lactation in subjects who attempt to breastfeed
   - Targeted AEs occurring in offspring
3) Effects on mammography
   - Detection of breast cancer
   - Rate of rupture
4) Effects on satisfaction with breasts and psychosocial well-being

5) Silicone subject compliance with MRI recommendations
   - Rupture rate associated with MRI

Approximately 530 subjects with NATRELLE® Style 410 Breast Implants will be enrolled in the 410 arm of the BIFS program under Amendment 5.

3. Duration of Subject Participation

Each subject will be followed for 10 years after device implantation.

4. In order to participate:

Subjects must meet all of the following inclusion criteria at the time of surgery:

1) Female, age 18 years or older (age 22 or older for breast augmentation patients)
2) Exhibit fluency and literacy in English or Spanish
3) Give written informed consent

5. You may not participate if:

1) You are transgender
2) The Investigator decides that you are not a suitable candidate for a long-term observational study

In addition to the above, the Investigator will discuss with you other reasons why you may not be eligible to participate in the study.

6. Study Procedures

As part of this post approval study, you will be contacted annually by the Sponsor during the 10-year term of the post approval study so that ongoing information regarding your health and the status of your implants can be collected. The information you will be asked to provide will be similar to information collected on the Baseline Questionnaire that you have completed prior to your breast implant surgery. You will complete the annual follow-up questionnaires in their entirety. In addition, you will be asked to complete a Quality of Life Questionnaire at years 1, 4, and 10.

As part of this post approval study, you will be asked to see your Surgeon at years 1, 4, 10, and at any time (unscheduled) if you have a complication related to your breast implants.

At any time throughout the 10-year study period, you can report any complications or other items being tracked in this study by contacting the BIFS Participant Support Call Center (866-619-2437) or by logging into the secure BIFS website on the Internet (www.bifs.us). The Surgeon will also report any complications related to your breast implant surgery noted on any physical exams.

7. Subject Responsibilities

As a subject, you are responsible for following the study directions and those of your Investigator. This includes returning promptly to your Investigator's office for all necessary study follow-up visits, report any changes regarding your health and the status of your implants, and report any changes in how you feel to the Investigator. If you experience any illness or discomfort during the study, you should notify your Investigator. Your Investigator will then evaluate you to determine if you should continue the study. If you become pregnant during this study, you must immediately notify your investigator.

8. Prohibited Treatments

Surgery to remove one or both of the original NATRELLE® Style 410 Breast Implants and replace it/them with different types of implants will result in you being withdrawn from the study.

9. Reasonably Foreseeable Risks or Discomfort to the Subject

The post approval study does not involve experimental drugs, devices, or procedures and there is no risk to participate. Although no physical risk is apparent, there may be a risk as a result of breach in privacy and confidentiality.

10. Medical Benefits

You may not receive any direct medical benefit from participating in this study; however, the Study will provide valuable information regarding the long term effects of breast implants. As a participant in the Study you will have access to various

website resources and medical information relative to your breast implants.

11. Alternative Treatments

The purpose of this study is only to evaluate the safety of the study treatment in healthy volunteers. Therefore, there are no alternative treatments and your option is to not participate in the study.

12. Confidentiality

A report of the results of this study may be published or sent to the appropriate health authorities in any country in which NATRELLE® 410 Breast Implants may be marketed, but your name will not be disclosed in these documents. The sponsor's monitors, the auditor(s), the Institutional Review Board (IRB)/Independent Ethics Committee (IEC), the regulatory authority(ies) including the United States Food and Drug Administration (FDA) will be granted access to your medical records, as permitted by the applicable laws and regulations, for verification of clinical study procedures and/or clinical study data. Appropriate care will be taken to maintain confidentiality of your medical records and personal health information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

13. Costs

There will be no charge to you for your participation in this study. However, there may be a cost for the study follow-up physical exams at years 1, 4, and 10. All costs incurred for other medical care are contracted between you and your Surgeon.

14. Compensation

For each annual questionnaire you complete, you will receive $20. If you have silicone-filled implants, you will receive $100 as compensation for your time in attending the physical exams at each of years 1, 4, and 10. The study site is receiving payment for the conduct of the clinical study.

15. Whom to Contact

You are encouraged to ask the Investigator any questions about this study or this consent form, and you should receive satisfactory answers to your questions. If you experience any research-related injuries during the study, you should contact Dr._____ at _____.

If you have any questions concerning your rights as a research subject, you should contact the Institutional Review Board (IRB) listed below:

IRB Company, Inc.
Phone: (877) 680-4138
Email: irb@irbco.com
Website: www.irbco.com

If you have any questions concerning this study, you may contact the Sponsor listed below:

Allergan, Inc.
Clinical Research Dept.
2525 Dupont Drive
Irvine, CA 92612

Phone: (866) 619-BIFS (2437)
Fax: (805) 456-4321

16. Participation

Your participation in this study is entirely voluntary. You may refuse to participate or may withdraw from this study at any time without penalty or loss of any rights or benefits to which you are otherwise entitled.

You may withdraw or take away your permission to use and share your personal health information at any time. You can do this by sending a letter to the Investigator. If you withdraw or take away your permission, you will no longer be able to participate in the study and no new personal health information about you will be gathered. The information that was gathered prior to your withdrawal may still be used and given to others for the purposes described in this consent.

The Investigator or Allergan may also stop your participation in the study at any time. Allergan may stop this study at any time for reasons it determines are appropriate. If you decide to withdraw from the study you should contact your study doctor immediately.

17. New Information

The Investigator will inform you (or if applicable your legally authorized representative) of any new information about the study that might develop during the course of this research and might influence your willingness to participate in the study.

You will be given a signed and dated copy of this consent form for your records prior to participation in the study.

CALIFORNIA ONLY: You will also be given a signed and dated copy of the "Bill of Rights for Investigational Subjects" regarding research subjects.

By signing below, I acknowledge that:

1) I have read all sections of this Informed Consent Form
2) I have had my questions answered
3) I voluntarily consent to participate in this research study

Printed Name of Subject _____

Signature _____ Date _____
(To be signed and dated by subject)

Signature _____ Date _____
(To be signed and dated by the legally authorized representative, if applicable)

Signature _____ Date _____
(To be signed and dated by the person who conducted the informed consent discussion)