

# Acknowledgement of Informed Decision

I understand that the patient labeling provided by Allergan is intended to provide information regarding the benefits and risks of silicone gel breast implants. I understand that some of this information is about breast implants in general and some is specific to Allergan's breast implants. I understand that choosing to have reconstruction breast surgery with implants involves both benefits and risks. I also understand that scientists and doctors have not been able to identify or quantify all of the risks of breast reconstruction with implants and that, over time, additional information may become available.

I have had adequate time to review and understand the information presented in the patient labeling, *Important Information for Women about Breast Reconstruction with NATRELLE® Silicone-Filled Breast Implants and NATRELLE INSPIRA® Breast Implants*. My concerns and questions have been addressed by my doctor. I have considered alternatives to reconstruction surgery, including use of external prostheses or surgery with saline-filled breast implants.

I am choosing to proceed with silicone gel-filled breast implant surgery.

By circling my response for each statement below and signing below, I acknowledge that:

**Yes / No** I have had adequate time to read and fully understand the information in this brochure,

**Yes / No** I have had an opportunity to discuss this information with my surgeon and to ask any questions I may have,

**Yes / No** I have carefully considered options other than reconstruction surgery with breast implants and have decided to proceed with silicone gel breast implant surgery,

**Yes / No** I have been advised to wait an adequate amount of time after reviewing and considering this information before scheduling my silicone gel breast implant surgery,

**Yes / No** I am aware that this patient labeling is available online, and I am aware that I may also ask my surgeon for a copy of this signed acknowledgment

Patient Name (Printed): \_\_\_\_\_

Patient Signature: \_\_\_\_\_

Date: \_\_\_\_\_



By my signature below, I acknowledge that:

- My patient has been given an opportunity to ask any and all questions related to this brochure, or any other issues of concern;
- All questions outlined above have been answered "Yes" by my patient;
- My patient has had an adequate amount of time before making her final decision, unless an earlier surgery was deemed medically necessary,
- This Acknowledgement of Informed Decision will be retained in my patient's permanent record, and
- I have provided the device tracking form to my patient.

Surgeon Name (Printed): \_\_\_\_\_

Surgeon Signature: \_\_\_\_\_

Date: \_\_\_\_\_