

INAMED® Silicone -Filled Breast Implants Frequently Asked Questions

This document contains information and answers to some of the most frequently asked questions related to the approval of INAMED® Silicone-Filled Breast Implants and how that approval may impact your practice. Questions ranging from how clinical study conduct is affected by the approval to how to complete the Allergan Physician Certification Program to ensure access to INAMED® Silicone-Filled Breast Implants are covered. We hope you find this document a useful resource in the coming days as you encounter questions relating to some of the FDA conditions of approval of INAMED® Silicone-Filled Breast Implants. We are committed to ensuring a seamless integration of silicone-gel filled breast implants in your practice and are here to help you navigate some of these changing requirements. If after reviewing this FAQ you still have questions or need assistance please do not hesitate to call your Allergan Breast Aesthetics Business Development Manager who can walk you through any special concerns or questions you have as well as introduce you to the programs and materials we have developed to ensure you can seamlessly integrate INAMED® Silicone-Filled Breast Implants into your practice.

ALLERGAN PHYSICIAN CERTIFICATION PROCESS

Q. I have been implanting silicone gel-filled breast implants in your Core and Adjunct Studies for years. Why do I have to go through certification?

A. Physician Certification for access to INAMED® Silicone-Filled Breast Implants is a condition of FDA's approval of Allergan's PMA application.

Q. I attended a plastic surgery society meeting where they discussed silicone training. Will that satisfy the certification requirement?

A. FDA has stipulated that certification is each manufacturer's responsibility and that each manufacturer must confirm certification has been completed prior to shipping silicone gel-filled breast implants to any physician.

Q. Once I finish the Certification Live Event can I order INAMED® Silicone-Filled Breast Implants?

A. Live event attendance is the first part of successful completion of the Allergan Physician Certification Program. Within 30 days of this live event, simply go to **www.allerganacademy.com** to complete the process.

Q. How do I finish the certification process?

A. Following this live event go to **www.allerganacademy.com** and select the physician certification link. If you have not previously registered, you will need to complete the registration process. To do so, select "Sign Up". You will be directed through a series of screens to create your certification profile which includes your name, address and surgery facilities. If you have previously registered, select "Log In". Enter the Live Event Code in the selection screen and enter Submit.

Q. What do I do with the code I received at the certification live event?

A. When you log in to the Allergan Physician Certification Program at **www.allerganacademy.com** you will enter this code to bypass the on-line certification modules and proceed directly to the completion screen.

Q. Once I complete these steps on **www.allerganacademy.com** will I be able to order INAMED® Silicone-Filled Breast Implants?

A. Within 48 hours of completion of the final certification process, you will receive an email notifying you of your status as a certified physician. Once you have this email confirmation you will be able to order INAMED® Silicone-Filled Breast Implants.

Q. Can you write these instructions down for me?

A. Yes. On the Allergan Physician Certification Program homepage you'll see a link to an Adobe Acrobat document with complete instructions for registration and completion of the certification process. You can access the Allergan Physician Certification Program homepage through **www.allerganacademy.com**.

Q. Can I update my personal information or add new surgery centers to my certification profile?

A. Yes. You can contact our Allergan Physician Certification Administrator at 800.624.4261 or by e-mail at **physiciancertification@allergan.com** to update your profile at any time.

Q. Do I need to present confirmation of certification to administrators at the hospitals where I perform breast implant surgery?

A. Each hospital may have a policy on this topic. Your confirming email following successful certification can serve as confirmation of your status. In addition, you will receive a wallet sized card from Allergan that can be used to confirm your status as an Allergan Certified Physician.

Q. Who at Allergan can I talk to if I have questions about certification once I return to my office?

A. Allergan has established a Certification Administrator to ensure you have the support you need to complete certification and incorporate INAMED® Silicone-Filled Breast Implants in your practice. You can reach the Certification Administrator at 800.624.4261 or by email at **physiciancertification@allergan.com**.

CORE STUDY CONDUCT

Q. I am a CORE Study investigator. How will PMA approval impact this study?

A. Please continue to conduct CORE Study activity as outlined in the current protocol contained in your Investigator Brochure (all patients need to continue to be followed through the 10 year follow-up visit). You will be contacted by your Research Associate to discuss the Core Post-Approval Study, a condition of FDA's approval of our PMA application.

ADJUNCT STUDY CONDUCT

Q. Does approval mean the Adjunct Study is over?

A. New enrollment in the Adjunct Study terminated on the day of FDA's approval of Allergan's PMA for silicone gel-filled breast implants. However, post-approval conditions require that each enrolled patient be followed through her 5 year follow-up visit.

Q. Will I still be required to submit case reports forms on my Adjunct Study patients?

A. Yes. Please continue to schedule patients for their 1, 3 and 5 year follow-ups and submit all required case reports forms including follow-up visits, complications, discontinuations and secondary surgery data.

Q. My IRB is about to expire. If the Adjunct Study is over, can I let my IRB lapse?

A. While new patient enrollment has ceased, the Adjunct Study will continue as part of FDA's approval of Allergan's PMA for silicone-filled breast implants. IRB renewal will be necessary at any facility where study patients were implanted.

Q. When can I end my Adjunct Study obligations?

A. At this time, each of your patients will be followed through 5 years. When your last patient has traversed her 5 year window, we will begin preparation for your Adjunct Study closeout.

Q. Can I get all this information in writing?

A. Immediately following FDA's approval of the Allergan Silicone-filled Breast Implant PMA, a communication outlining this information was faxed and then mailed to all current Adjunct Study investigators.

Q. Will the Adjunct Study continue to be monitored?

A. Yes, the FDA requires that Allergan conduct monitoring visits until the study has closed.

Q. If I consented a patient in the Adjunct Study but implanted her after Allergan's PMA approval will she be considered a study patient?

A. No, you should inform her that enrollment into the Adjunct Study ended as soon as Allergan's PMA approval was announced. She should not be considered a study patient. To ensure the patient has all the latest information supplied by Allergan on surgery with silicone gel-filled breast implants you should provide the patient with the approved patient labeling (see Labeling section).

NOTE: A Device Tracking form should be submitted for each silicone gel-filled breast implant surgery that was performed after PMA approval (see Device Tracking below).

Q. If a patient is enrolled in the Adjunct Study but is explanted after approval will I still need to follow her through year 5?

A. If both implants are explanted, you will simply complete an explant CRF and she will no longer be considered a study patient. If only one implant is explanted and she still has an implant that she received in the Adjunct Study, she should continue to be followed through her 5 year visit.

DEVICE TRACKING

Q. What is Device Tracking?

A. Device Tracking is a program intended to facilitate notification to the patient of product recall in the event a device presents a serious risk to health that requires prompt attention.

Q. Are all breast implants subject to Device Tracking?

A. Only silicone gel-filled breast implants are subject to Device Tracking.

Q. How will Device Tracking be implemented?

A. Allergan has developed a Device Tracking form that is included in every silicone gel-filled breast implant package that leaves our facility after PMA approval.

Q. What about the silicone gel-filled breast implant inventory I have in my office? Is this product subject to tracking?

A. All silicone gel-filled breast implants are subject to Device Tracking following PMA approval. As you use your silicone gel-filled breast implant office inventory please complete your portion of the Device Tracking form and return to Allergan in the envelope attached to the form.

Q. How do I obtain Device Tracking forms?

A. Allergan will supply a Device Tracking form in each silicone gel-filled breast implant package that ships from our facility following approval. In addition, we have sent a supply of Device Tracking forms to our Adjunct investigators to address silicone gel-filled breast implants in their possession at approval. Additional Device Tracking forms are available upon request from either Allergan Customer Care or your local Allergan Breast Aesthetics Business Development Manager.

Q. Is this the same program you had for Saline breast implants a few years back?

A. Saline-filled breast implants were subject to Device Tracking until 1997. The program for our silicone gel-filled breast implants is very similar.

Q. Do I have to send patient specific information as part of the Device Tracking Program?

A. Device Tracking regulations require the health care facility provide information on the device and the patient following surgery with silicone gel-filled breast implants.

Q. What if my patients don't want to participate in Allergan's Device Tracking Program?

A. Each silicone gel-filled breast implant patient has the opportunity to request their personal information be removed from Allergan's device tracking database. Be sure your patients get their copy of the Device Tracking form following surgery and that they return this form to Allergan in the envelope supplied in their Patient Planner.

Q. What will Allergan do with the information in the Device Tracking database?

A. Allergan's Device Tracking database is designed to meet the reporting requirements outlined in 21 CFR part 821. Allergan will NOT use the information for any purpose other than to comply with the FDA condition of approval of the INAMED® Silicone-Filled Breast Implant PMA.

Q. Is there someone at Allergan I can call with questions about Device Tracking?

A. Allergan has staffed a Device Tracking Department to ensure you have the support you need to implement device tracking with your silicone gel-filled breast implant surgeries. You can reach our Device Tracking Support Specialists at 800.972.9378.

LABELING

Q. What has changed in the Directions for Use (DFU) for INAMED® Silicone-Filled Breast Implants?

A. Allergan's Directions for Use for our silicone gel-filled breast implants now contains 4 year data from our Core Clinical Study. In addition, the DFU contains information on special considerations and risks to be discussed with the patient.

Q. How can I get a copy of the new DFU?

A. In addition to the review included as part of the Allergan Physician Certification Program, hard copies of the DFU are available upon request from Allergan through our Labeling Hotline 888.474.5665, through your local Allergan Breast Aesthetics Business Development Manager, or you can view a copy of the DFU online at **www.inamedlabeling.com**.

Q. Is there a new patient brochure for silicone gel-filled breast implants?

A. Yes, Allergan has developed several documents to assist you in discussing silicone gel-filled breast implants with your patients. The risks, benefits and clinical summaries are included in the 'patient labeling' which is available online at **www.inamedlabeling.com** or through FDA's website at <http://www.fda.gov/cdrh/breastimplants/>. You can also request a hard copy from our Labeling Hotline 888.474.5665. Allergan has developed a patient label for augmentation patients and one for reconstruction patients.

Q. Is this 'patient labeling' the document I should use to assist with preoperative consultations?

A. Allergan has developed a unique *Augmentation (or Reconstruction) Surgery with INAMED® Silicone-Filled Breast Implants Patient Planner* to assist you and your patient coordinator in the preoperative discussion. The patient labeling is just one component of this patient planner which is designed to act as a diary for the patient, a place where she can store all information related to her surgery. Contact your local Allergan Breast Aesthetics Business Development Manager for more information on the range of patient communication tools offered by Allergan, including the Patient Planner.

A SUMMARY OF THE BREAST IMPLANT FOLLOW-UP STUDY (BIFS)

Allergan welcomes the opportunity to further validate the safety of its silicone gel-filled breast implants and looks forward to working with physicians and patients to implement the BIFS study, an innovative post market surveillance study designed to assess long term safety of silicone breast implants in a large population of women.

WHAT IS BIFS?

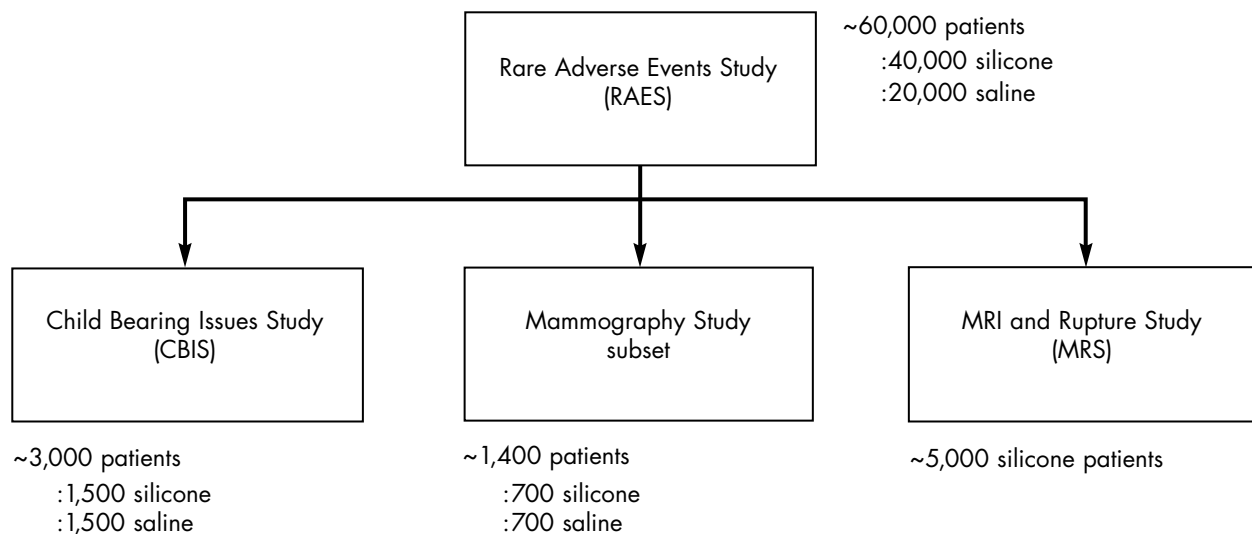
BIFS is a post-market surveillance study including both silicone and saline breast implant patients who will be enrolled over a 24 month window. Their experience will be evaluated at intervals over 10 years through a combination of web based surveys and in-office visits. BIFS includes arms to assess adverse events, child bearing issues, impact of mammography on implant integrity and compliance with MRI recommendations and implant rupture rates.

The Rare Adverse Events Study The RAES study will evaluate the rate of rare adverse events, such as connective tissue disorders (e.g., fibromyalgia and scleroderma), breast cancer and neurological diseases, which have been anecdotally linked to silicone gel-filled breast implants.

The Child Bearing Issues Study The CBIS study will compare and evaluate potential reproductive complications and lactation issues that may be associated with saline and silicone breast implants over a 10 year period.

The Mammography Study The mammography study will compare the impact of mammography on saline and silicone gel-filled breast implants. In the event a patient suspects her implant has ruptured during a mammogram, she would receive a referral to receive an MRI to confirm whether a rupture has occurred and to determine its cause.

The MRI and Rupture Study The MRS study will evaluate patient compliance with healthcare instructions regarding MRIs, as well as determine the rate of rupture based on the results of the MRIs.



Q. When will the BIFS study start?

A. Enrollment will start no later than 90 days following the approval of Allergan's silicone-filled breast implant PMA. More information on enrollment specifics will follow.

Q. What do I need to do to prepare my practice for this new study?

A. While we encourage all our physicians to participate as investigators in the BIFS study, we are not yet prepared to inservice sites or enroll patients. More information will follow as the study design is finalized.

Q. What will my responsibilities be as an investigator?

A. As a BIFS investigator we'll ask you to enroll as many patients as possible: a minimum of 50% of all breast implant surgery patients. In addition, we'll request you see all enrolled silicone patients for their follow-up visits at year 1, 4 and 10. Saline patients will require NO in-office follow-up.

Q. Why should I participate as a BIFS investigator?

A. We recognize the impact participation in the BIFS study may represent and have developed the study protocol to minimize any disruption to your practice. In addition, we have developed compensation that recognizes your contribution as a key investigator.

- The bulk of study follow-up is conducted on-line through our proprietary web site.
- For every 20 subjects enrolled, you will receive a complimentary pair of breast implants.
- In-office visits at 1, 4 and 10 years are limited to silicone patients only.
- Allergan will provide a \$100 gift certificate to these patients towards an in-office procedure with Allergan Facial Aesthetics Products.

Q. Who do I contact to become a BIFS investigator?

A. We are collecting potential investigator information at **www.allerganacademy.com**. Please submit your information and we'll contact you as soon as we are ready to initiate the study.