

ATTACHMENT 12
Adjunct Clinical Study – Postapproval Plan

**Inamed Corporation
Adjunct Clinical Study
Close-Out Plan**

INAMED will continue to follow Adjunct Clinical Study patients through their 5-year follow-up visit. Within 7-10 business days of PMA P020056 approval, INAMED will fax all Adjunct Study Investigators the attached letter notifying them to cease enrollment of patients into Inamed's Adjunct Clinical Study. In addition, INAMED will send the attached letter via regular mail to all Investigators and their Institutional Review Boards.

INAMED will continue regular monitoring of the Adjunct Clinical Study and will continue all other Adjunct Clinical Study follow-up activities per the existing protocol and good clinical practices. Monitoring visits will continue until all study patients have been seen or have been attempted to be seen through their 5-year visit. Current efforts to encourage patient compliance with follow-up will continue.

Once an Investigator has met all investigator obligations for the study, Inamed will initiate closing out the site. INAMED will work with each Investigator at the time of site closing to collect all outstanding case report forms, resolve all data queries, and notify the governing IRB that the study has been completed and should be considered closed at that site. All required reporting will be completed and filed with the Agency and IRBs as appropriate.

{MONTH DAY, YEAR}

DR. NAME
ADDRESS
CITY, ST. ZIP}

RE: Inamed's "McGhan Medical Silicone-Filled Breast Implant Adjunct Clinical Study"

Dear Dr. <<LAST NAME>>:

All of us at Inamed wish to thank you for the time and effort that you and your staff have devoted to the Adjunct Clinical Study.

On <<Approval Date>> the Food and Drug Administration (FDA) approved Inamed's PMA for silicone-filled breast implants. As a result, after your last scheduled Adjunct patient has been implanted, no new patients may be enrolled into the Adjunct Clinical Study. You must cease using the Adjunct Clinical Study Informed Consent and must successfully complete Inamed's certification program before implanting any new patients. Contact <<TBD>> to find out how to become certified, and then follow the Patient Communication/Making an Informed Decision process outlined as part of the INAMED Silicone Filled Breast Implant Certification Program to render informed consent to your future patients. Note however, that all patients you enrolled into the Adjunct Study must continue to be followed for 5 years from their implantation date per the existing protocol.

Please continue to conduct all other study related activities for enrolled patients, ensuring patient compliance at 1, 3 and 5 years post implantation. Inamed will continue to notify you of upcoming patient follow-up visit windows and IRB expirations. We will also continue to follow-up with you regarding device reconciliation, data corrections, and resolution of any outstanding study issues. IRB approval must be maintained for the duration of the study.

As an Investigator in this clinical study, and per Federal Regulation 21 CFR 812.110: "An investigator shall conduct an investigation in accordance with the signed agreement with the sponsor, the investigational plan, this part and other applicable FDA regulations, and any conditions of approval imposed by an IRB or FDA". We appreciate all that you have done in the recruitment of this very important study and we encourage you to do your best to follow your patients and keep your compliance up through the end of the study.

We look forward to working closely with you for the duration of the study. We will begin preparation for your site close-out from the study once your last patient's final 5-year visit window is being crossed.

If you have any questions, please contact your Research Associate, <<Name of RA>>, at (800) 862-4426 ext. <<RA Extension>>.

Sincerely,

Beth Walls
Adjunct Clinical Study Project Lead

cc: <<Institutional Review Boards >>