

**F. CLINICAL STUDIES POST-APPROVAL PLAN**

Inamed's proposal for post-approval clinical data collection involves continued follow-up of patients enrolled in the Core and Adjunct Clinical Studies. No post-approval data collection is proposed for patients enrolled in the 1990 Study because this study has already been closed. The final report was submitted to FDA for the saline-filled breast implant arm of the study (McGhan Medical PMA for McGhan Saline-Filled Breast Implants, PMA #P990074, November 15, 1999) in June, 2000. The final report for the silicone-filled breast implant arm of the study is included as part of this current PMA submission for McGhan Silicone-Filled Breast Implants.

Post-approval data collection for the Core Study patients will involve annual follow-up through 10 years post-implant to obtain long-term information regarding the safety and effectiveness of McGhan Silicone-Filled Breast Implants. Post-approval data collection for the Adjunct Study patients will involve follow-up through 1 year post-implant to monitor the large number of enrolled study patients for short-term medical complications. Details of the

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post-approval data collection for the Core Study and Adjunct Study patients are described below.

**1. Core Clinical Study Plan (G980106)**

The results presented in this PMA include complete data for the first two years after implant surgery. The third year of follow-up is currently in progress. Post-approval data will be obtained through the 10<sup>th</sup> year after implant surgery from continuation of the Core Clinical Study through the 3<sup>rd</sup>, 4<sup>th</sup>, and 5<sup>th</sup> year intervals, followed by a Post-Approval Survey Study for the 6<sup>th</sup> through 10<sup>th</sup> year intervals. These two phases of post-approval data collection will be administered separately under distinct protocols. This 2-phase approach to post-approval data collection is consistent with the post-approval method used to obtain long-term follow-up information for McGhan Saline-Filled Breast Implants. The specifics for each of the two post-approval phases are described below.

**a. Phase I: Core Clinical Study – Follow-Up Through 5 Years**

The first phase of post-approval data collection will involve patients being seen by their physicians as part of the Core Clinical Study. Full data collection will be conducted for patients' 3<sup>rd</sup>, 4<sup>th</sup>, and 5<sup>th</sup> years of follow-up in the Core Study, including assessment of medical complications, reoperations, post-implant medical history, patient satisfaction and quality of life for all patients, as well as serial MRI for the subset of patients participating in that component of the study. After all patients have traversed their 5<sup>th</sup> year interval in the Core Study, data cleaning will be completed, site monitoring close-out visits will be conducted, and the study will be closed at each participating site and IRB.

**b. Phase II: Post-Approval Survey Study – Follow-Up From 6-10 Years**

The second phase of post-approval data collection will involve patients completing a mail survey reporting the status of their breast implants for selected critical safety outcomes and satisfaction. Patients will be mailed a survey to complete on their original implant surgery anniversary each year from the 6<sup>th</sup> through 10<sup>th</sup> years post-implant. Patients will be asked to sign the Post-Approval Survey Study Informed Consent in advance of their first survey mailing, and a contract IRB will review and approve the study for all patients.

The post-approval survey study will be designed to follow enrolled Core Study patients from their 6<sup>th</sup> through 10<sup>th</sup> years post-implant as outlined below.

**Core Post-Approval Survey Study Overview**

- The primary objective of the survey study will be to obtain long-term follow-up information concerning major safety outcomes and

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benefits associated with these devices, from patients implanted with McGhan Silicone-Filled Breast Implants.

- There are no medical risks associated with participation in this study, which will be a passive self-reported patient survey. The primary benefit of participation in this study will be to provide women with information concerning the long-term risks and benefits associated with McGhan Silicone-Filled Breast Implants.

#### **Patient Participation/Enrollment**

- All patients enrolled in the Core Study who have not been discontinued through the 5<sup>th</sup> year post-implant will be asked to participate in the survey study.
- Patients who are lost-to-follow-up at 5 years post-implant will be contacted in an effort to include these patients in the post-market group.

#### **Informed Consent**

- Patients will be consented to participate in the survey study from 6-10 years post-implant.

#### **Core Post-Approval Survey Study Design**

- A patient survey will be mailed to each participant annually from 6-10 years post-implant on the anniversary of her primary breast implant surgery. The survey will consist of questions for the patient to self-report on the status of her breast implants in the following areas:
  - Breast pain
  - Capsular contracture
  - Implant rupture
  - Reoperation (including implant replacement/removal)
  - Patient satisfaction
- A variety of measures will be utilized in the study to maximize patient compliance, including:
  - Multiple mailings for each annual patient survey
  - Phone calls to non-responsive patients
  - Search for missing patients
  - Future mailings to non-responsive patients
  - Patient incentive payments

#### **Core Post-Approval Survey Analyses**

- Data will be analyzed separately for the augmentation, reconstruction, and revision cohorts.
- Data obtained from the 1-5 year physician follow-up Core Study will be combined with data from the 6-10 year Post-Approval Survey Study to obtain long-term risk rates for each of the complications assessed in the survey study.

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