

PANEL MEMBER PACKAGE
for
OCTOBER 14-15TH PANEL MEETING

P020056

INAMED CORPORATION'S
MCGHAN SILICONE-FILLED BREAST
IMPLANTS

September 12, 2003

Dear Panel Member:

In preparation of the upcoming Advisory Panel meeting on October 14th-15th to discuss P020056, Inamed Corporation's McGhan Silicone-Filled Breast Implants, FDA is providing you with this 3-ring binder of information.

This binder includes:

- **Tab 1 – Inamed's CD with hardcopy of CD table of contents**
There is one CD with a table of contents for that CD.
- **Tab 2 – FDA's "Summary Panel Memorandum" and "Inamed Clinical Summary Memorandum"**
FDA's "Summary Panel Memorandum" combines all individual reviews except for the prospective clinical review. FDA's "Inamed Clinical Summary Memorandum" was left as a separate memo based on its length.
- **Tab 3 – Draft Panel questions**
FDA will present these questions to the Panel for discussion. However, they are subject to change prior to the meeting.
- **Tab 4 - Comprehensive table of data/information**
This table outlines all PMA topics/elements provided by Inamed. The bolded items are included on the enclosed CD. Please let us know if you would like any additional information sent to you, either via hardcopy or CD.

If you have any questions or would like any additional information sent to you, either via hardcopy or CD, please contact me at 301-594-3090, ext. 139 or by email at rxn@cdrh.fda.gov.

Sincerely,

Samie Allen
Breast Implant Team Leader
Plastic and Reconstructive Surgery Devices Branch
Division of General, Restorative, and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

TAB 3 – DRAFT PANEL QUESTIONS

1. Prospective MRI screening for asymptomatic rupture was conducted in a subset of Core Study participants (approximately 34%). Complete MRI screening data are available for the 1-year post-operative timepoint for each indication and partial 3-year data are available for the augmentation indication at the time of database closure. Continued MRI screening of this Core Study subset is planned for at years 3, 5, 7, and 9 after implantation.

Of the 15 implant ruptures that Inamed reports as confirmed at the time of database closure, the majority--9 implants (60%)--were initially detected by MRI screening and were asymptomatic:

- Core Augmentation, 0 of 3 ruptures
- Core Reconstruction, 6 of 8 ruptures
- Core Revision, 3 of 5 ruptures.

Additionally, published literature on silicone gel implant rupture, although not specific to Inamed's implants, indicates that rupture rate increases with implant age and that depending on implant type, manufacturer, and age, between 26% (median implant age 12 years) and 55% (median implant age 16.4 years) of implants assessed by MRI had MRI evidence of rupture.

Please discuss the adequacy of the information to determine the safety of this product with respect to asymptomatic rupture.

(Question 6 below is a labeling questions related to asymptomatic rupture.)

2. Potential long-term and general health effect issues for these implants include the risk of cancer(s), connective tissue disorders (typical and atypical), gel migration, interference of implant on ability of mammography to detect tumors in implanted breasts, interference with breast feeding, reproductive/teratogenic effects, and the later effects on offspring from women with implants. To address these issues, Inamed utilized historical published literature, which is not specific to Inamed's implants, as well as animal studies on their product. Please discuss the adequacy of the literature and preclinical testing to determine the safety of this product with respect to long-term and general health effects.
3. Considering the safety data reported for the augmentation group:
 - local complications reported in Core Study, Adjunct Study, and AR90 Study
 - asymptomatic/silent rupture information based on approximately 30% of the patients in the Core Study with only the first of 5 prospective serial screenings with complete data
 - published historical literature and animal data to address long term and general health effects.

Given these data, and that the augmentation patient generally has breast implant surgery at a younger age which includes childbearing years compared to the other indications, is there reasonable assurance that the device is safe¹ for augmentation patients?

¹ 21 CFR 860.7(d)(1) states that there is a reasonable assurance that a device is safe when it can be determined that the probable benefits to health from use of the device for its intended uses, when accompanied by adequate instructions for use and warnings against unsafe use, outweigh any probable risks.

4. Considering the safety data reported for the reconstruction and revision groups:
 - local complications reported in Core Study, Adjunct Study, and AR90 Study
 - asymptomatic/silent rupture information based on approximately 30% of the patients in the Core Study with only the first of 5 prospective serial screenings with complete data
 - published historical literature and animal data to address long term and general health effects.

Given these data, and that reconstruction and revision patients generally undergo breast implantation at an older age than augmentation patients, is there reasonable assurance that the device is safe¹ for reconstruction and revision patients?

5. To evaluate device effectiveness, Inamed collected data on patient satisfaction and health status/quality of life (e.g. SF-36, MOS-20, Body Esteem Scale, etc.). Based on these data, has Inamed adequately demonstrated reasonable assurance of effectiveness² of the implants for each of the augmentation, reconstruction, and revision indications?
6. Given the information in question 1, please address the following with respect to labeling for the device:
 - a. Provide your recommendations for the frequency and method of screening for asymptomatic rupture, given that prospective screening for asymptomatic rupture is not currently routinely performed.
 - b. Provide your recommendations for the necessity of explantation of asymptomatic implant ruptures.
7. Inamed provided a brief description of their postapproval study plan. The Core Study protocol, as well as informed consent, currently requires yearly follow-up with a physician. Inamed is now proposing a change to the study requirements as follows. More specifically, Inamed is proposing a 2-phase postapproval study. Phase I involves continued physician evaluation as per the IDE protocol through a patient's 5-year follow-up timepoint. Phase II involves mail-in surveys completed by the patient from their 6 to 10-year follow-up timepoints. In the proposed Phase II protocol, for example, MRI screening for asymptomatic rupture would not be captured. Given this proposal:
 - a. Please comment on the method of data collection (mailed survey) from the 6 to 10-year timepoints.
 - b. Please describe any other specific endpoints which should be captured as part of the postapproval study.

² 21 CFR 860.7(e)(1) states that there is a reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warning against unsafe use, will provide clinically significant results.

	[REDACTED]
[REDACTED]	[REDACTED]

