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**ADJUNCT CLINICAL STUDY
RECONSTRUCTION COHORT**

December 12, 2002

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RECONSTRUCTION COHORT
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ABSTRACT

The McGhan Medical Corporation Silicone-Filled Breast Implant Adjunct Clinical Study is a prospective, 5-year, multi-center clinical study conducted to examine the safety of McGhan Silicone-Filled Breast Implants for reconstruction and revision patients. This report presents the results from the reconstruction cohort through 3 years post-implant.

Data from 15,465 patients who received 26,935 silicone-filled breast implants for the purpose of unilateral or bilateral reconstruction of the breast are presented in this report. The extract date of the database used for this report is August 30, 2002. The reconstruction patients were enrolled between November 25, 1997 and August 22, 2002.

The safety data collected in this study are complications (e.g., device rupture, capsular contracture) and reoperations involving the breast/chest area (e.g., implant replacement/removal). Safety data is collected at scheduled follow-up intervals (1 year, 3 years, and 5 years post-implant) as well as during unscheduled visits. At all scheduled follow-up visits, both the patient's and physician's level of satisfaction with the breast implantation is assessed.

As of this report, 533 (3.4%) of the 15,465 implanted patients have been discontinued from the study due to removal of all study devices (n=259), patient choice (n=119), other reasons (n=101; e.g., patient moved out of the country), or death (n=54). The majority of the patient deaths were due to cancer; other causes of death were accidents (e.g., motor vehicle), drug overdose, and non-implant related medical conditions (e.g., brain tumor). Taking into account patients who died or had all study devices removed without replacement with other study devices, follow-up compliance was 53.8% at the 1-year follow-up visit and 27.0% at the 3-year follow-up visit.

To estimate the risk of complications following implantation, Kaplan-Meier survival analysis was conducted on the time to first occurrence of each event. Table 1 of this abstract summarizes the 3-year by-patient risk rate associated with various complications, including the following types of outcomes:

- General Breast Surgery Complications (e.g., breast pain)
- Breast Implant Surgery – Cosmetic Complications (e.g., wrinkling/rippling, implant palpability/visibility)
- Breast Implant Surgery – Non-Cosmetic Complications (e.g., capsular contracture, implant rupture)

The complications with the highest 3-year risk rate by patient were capsular contracture (17.6%), asymmetry (16.3%), and implant palpability (10.3%). All other complications occurred at a by-patient risk rate of less than 10.0%.

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A total of 2,034 patients underwent 2,341 reoperations through 3 years post-implant, with a 3-year by-patient risk of reoperation of 44.1%. By the end of the 3-year post-implant visit, 1,014 patients had 1,101 primary study devices removed, with a 3-year by-patient risk of implant replacement/removal of 28.2%.

More than 90% of both patients and physicians indicated being satisfied with the outcome of the breast implant surgery at both the 1-year and 3-year follow-up visit intervals. On a 1 (definitely dissatisfied) to 5 (definitely satisfied) scale, the average satisfaction level for physicians and patients ranged between 4.3 and 4.4 during each follow-up interval.

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Table 1. Adjunct Clinical Study - Reconstruction Cohort Summary of 3-Year Risk Rate for Specific Complications		
Complication	3-Year Risk By Patient	3-Year Risk By Implant
Capsular Contracture	17.6%	12.7%
Asymmetry	16.3%	N/A
Implant Palpability	10.3%	8.4%
Wrinkling	9.4%	7.3%
Implant Malposition	8.5%	6.1%
Breast Pain	7.9%	5.5%
Implant Visibility	6.3%	4.9%
Loss of Nipple Sensation	5.8%	4.9%
Hypertrophic Scarring	3.4%	3.1%
Capsule Calcification	3.2%	2.3%
Skin Paresthesia	2.6%	2.3%
Swelling	2.3%	1.7%
Other Complications	2.0%	1.5%
Implant Rupture	1.6%	1.1%
Nipple Hypersensitivity	1.4%	1.2%
Implant Extrusion	1.3%	0.9%
Redness	1.2%	0.8%
Nipple Paresthesia	1.1%	1.0%
Infection	1.0%	0.7%
Pneumothorax	1.0%	0.7%
Irritation	1.0%	0.6%
Delayed Wound Healing	0.8%	0.6%
Bruising	0.7%	0.6%
Seroma	0.7%	0.4%
Skin Rash	0.6%	0.5%
Skin Hypersensitivity	0.6%	0.4%
Hematoma	0.4%	0.2%
Lymphadenopathy	0.4%	0.2%
Tissue or Skin Necrosis	0.3%	0.2%

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INTRODUCTION

The McGhan Medical Corporation Silicone-Filled Breast Implant Adjunct Clinical Study is a prospective, 5-year, multi-center clinical study designed to examine the safety of McGhan Silicone-Filled Breast Implants for reconstruction and revision patients. This report presents the results from the reconstruction cohort. As this study is still ongoing, including enrollment of new patients, this report represents interim 1-year and 3-year post-implant data, with limited safety data available beyond 3 years included in Appendix A.

METHODS

A. SUBJECTS

1. Patient Enrollment

A total of 15,465 reconstruction patients were enrolled in this study, where enrollment is defined as undergoing implant surgery. The first reconstruction patient was enrolled on November 25, 1997 and the last reconstruction patient implanted as of this report was enrolled on August 22, 2002. Following enrollment of the first patient, the Adjunct protocol was revised, and FDA approved the amended protocol on March 30, 1998. The first reconstruction patient under the revised protocol was enrolled on May 6, 1998. New patient enrollment is ongoing in this study.

Patients were enrolled in this study if they met the following eligibility criteria:

- Female of any age
- Primary breast reconstruction indicated for the following:

For affected breast:

- Post mastectomy surgical removal of the breast for cancer or other diseases
- Post trauma or post surgery where there was total or partial removal of the breast resulting in significant deformity (for any reason)
- Severe ptosis requiring reconstruction (i.e., mastopexy)
- Any congenital or acquired discrepancy in breast size such as to represent a significant physical deformity. This does not include normal variants of asymmetry. Examples include, but are not limited to, those listed below:
 - Pectus excavatum—congenital concave chest wall deformity with abnormalities of the sternum and anterior ribs
 - Pectus carinatum—congenital convex chest wall deformity with abnormalities of the sternum and anterior ribs
 - Thoracic hypoplasia (Poland's syndrome)—congenital chest wall deformity with underdevelopment of the ribs and breast on one side

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- Scoliosis—congenital or acquired curvature of the spine, which may result in a substantial compensatory deformity of the sternum and anterior ribs
- Isolated rib deformities—congenital or acquired absence or distortion of isolated ribs, which may produce an anterior chest wall deformity
- Tuberous breasts—usually congenital developmental deformity of one or both breasts characterized by an abnormal appearing breast with an enlarged pedunculated and protuberant nipple combined with a constricted breast base circumference
- Congenital absence—a typically unexplained absence of one or both breasts

For unaffected breast:

- Contralateral mammoplasty in unaffected breast as a result of the affected breast requiring surgery (for one of the aforementioned circumstances), when medically indicated to provide symmetry
- Adequate tissue available to cover implants
- Saline-filled implants are not an appropriate choice
- Willingness to follow all study requirements, such as agreeing to all required follow-up visits, and acceptance of the risks involved as indicated by signing of the study Patient Informed Consent document

Patients were not enrolled in the study if they had any of the following characteristics:

- Advanced fibrocystic disease considered to be premalignant without accompanying subcutaneous mastectomy
- Existing carcinoma of the breast, without mastectomy
- Abscess or infection in the body at the time of enrollment
- Pregnant or nursing
- Have any disease, including uncontrolled diabetes, which is clinically known to impact wound healing ability
- Show tissue characteristics that are clinically incompatible with mammoplasty, such as tissue damage resulting from radiation, inadequate tissue, compromised vascularity or ulceration
- Have, or under treatment for, any condition which, in the opinion of the surgeon, may constitute an unwarranted surgical risk
- Show psychological characteristics which, in the opinion of the surgeon, may be incompatible with the surgical procedure and the prosthesis, such as inappropriate attitude or motivation
- Wish to have augmentation mammoplasty, but do not have at least one of the diagnoses identified in Patient Inclusion Criteria
- Are not willing to undergo further surgery for revision, if medically required
- Diagnosis of lupus or scleroderma

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- Replacement of saline-filled implants solely for a less than desirable cosmetic outcome, such as wrinkling

2. Investigators

A total of 1,272 Principal Investigators (PIs) at 2,355 sites (defined as a unique PI-IRB combination) are participating in the Adjunct Clinical Study for reconstruction or revision enrollment/follow-up. A site listing (i.e., Investigational Sites by Principal Investigator and Institutional Review Board [IRB]) is provided as an attachment to this module of the PMA submission.

B. PROCEDURE FOR DATA COLLECTION

1. Safety Data Collection

Per the study protocol, patients are required to come in for follow-up visits at 1, 3, and 5 years post-implant. Additionally, post-implant observations/complications are recorded for patients who come in for visits between scheduled visit intervals.

Assessment of safety is based on the occurrence of the following:

a. Unanticipated Adverse Device Effects

An unanticipated adverse device effect is defined on the Unanticipated Adverse Event Form as:

any serious adverse effect on health or safety or any life-threatening problem or death caused by or associated with the McGhan Breast Implant or use of the McGhan Breast Implant, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence.

Unanticipated adverse events are captured on an Unanticipated Adverse Event Form. All UAE Forms are reviewed by the Medical Monitor to ascertain if the reported event represents a true UAE or a known medical complication that was incorrectly reported on the UAE Form.

b. Medical Complications

All medical complications are recorded on the Follow-Up Form.

c. Reoperations

All reoperations are captured on a Secondary Procedures Form.

d. Implant Replacement/Removal

All implant replacements/removals are captured on a Secondary Procedures Form.

2. Effectiveness Data Collection

At each scheduled follow-up visit, both the physician and patient are asked to indicate their satisfaction with the implant surgery on a scale from "definitely dissatisfied" to "definitely satisfied". This data is collected on the Follow-Up Form.

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C. GENERAL ANALYSIS APPROACH

1. Analysis of Data Through Three Years

The extract of the database housing the data that was used for the current report was taken on August 30, 2002.

Because this study is continuing to enroll new patients, not all patients have reached a scheduled follow-up visit time point. As of the date of final database extract, 68% of the reconstruction patients have traversed their 1-year follow-up visit window and 17% have traversed their 3-year follow-up visit window. No reconstruction patients have yet traversed their 5-year follow-up visit window. As a representation of safety beyond 3 years, all post 3-year occurrences of the medical complications listed in Methods Section D.3.b are summarized in Appendix A of this report.

The results of this study are reported by specific post-implant visit intervals (i.e., 1 year, 3 years) as well as cumulatively through 3 years. Depending on the data point reported and the type of follow-up information collected, the visit intervals are defined in one of two corresponding ways.

The first approach to data analysis is based on specific follow-up time points defined in terms of number of days post-implant. Complication and reoperation information is collected by specific reported event follow-up visit dates. Thus, these outcome variables are analyzed and reported based on the specific follow-up time points in the study and are defined in exact number of days post-implant:

- 1 Year: 365 days
- 3 Years: 1095 days

The method of analysis of the complication and reoperation data is survival analysis, using the Kaplan-Meier product limit method, of the time to first occurrence of the particular event under consideration, with time assessed in days post-implant. The "Number Affected" is the number of patients/implants with at least one occurrence of the event on or before the follow-up time point being reported. The "Number Remaining" is the number of patients/implants without the reported event and who were not lost to follow-up prior to the reported follow-up time point. For each reported follow-up time point, the failure rate is provided along with the associated 95% confidence interval.

The second approach to data analysis is based on visit windows. These windows are defined in terms of intervals around each follow-up time frame. Patient compliance and satisfaction are analyzed and reported based on follow-up visit intervals defined as:

- 1 Year: 6 months, 1 day through 18 months, 0 days post-implant
- 3 Years: 30 months, 1 day through 42 months, 0 days post-implant

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Discontinuation data reported "through 3 years" is inclusive of all results obtained through 42 months post-implant.

2. Analysis of Primary Enrolled Study Implants

This report documents the results obtained for primary enrolled study implants (i.e., original devices implanted). If a primary study implant was removed and replaced with another study device ("secondary" implant), data continues to be gathered on the secondary study implant, adhering to the patient's same ongoing study schedule as for the primary study implant. However, data collected on these secondary implants was not included in the primary analysis. Outcomes following replacement surgery are presented in a separate report for the revision cohort enrolled in the Adjunct Clinical Study. Appendix B contains a summary of the medical complications listed in Methods Section D.3.b that occurred following explant and replacement in the reconstruction cohort.

If a patient enrolled into the study on one side only (i.e., unilaterally) and later received a study device on the contralateral side, then all by-patient analyses were performed based on the surgery date for the patient's first implant. All by-implant analyses were based on the separate implant surgery dates for each device.

Analyses were conducted using the number of patients and/or the number of implants as the unit of analysis, as appropriate. For example, all demographic data are reported by patient only, whereas data on the type of device styles are reported by implant only. Complication rates are reported both by patient and by implant (except for asymmetry, which is reported by patient only).

3. Open-Ended Response Coding

To effectively capture the relevant clinical information recorded in the open-ended "Other" complication field on the Follow-Up Form, specific categories were developed to report these responses. All open-ended responses reviewed were assigned to a category and given a corresponding numeric code that was entered into the clinical database.

A comprehensive approach was used for this coding process. When the grammatical structure of the response was confusing or incomplete, the entire clinical study form and/or patient case history was reviewed and assessed in order to adequately determine which category and code to apply. In some cases the study investigator's office was contacted to clarify the response. Specific coding rules were documented and applied to the overall coding process.

D. METHODS FOR DATA ANALYSIS

1. Patient Enrollment and Surgical Treatment

a. Demographic Variables

For each patient, the following demographic characteristics are reported:

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- Age
- Marital Status
- Occupation
- Education

For marital status and occupation, the sum total of responses may be greater than the total number of enrolled patients due to the fact that all responses are reported, including multiple responses to the item for the same patient. For patients where more than one educational level was provided, the highest indicated level is reported.

b. Product Styles

A frequency distribution of device styles utilized in this study is reported by implant.

c. Surgical Complications

The number of patients who had an intraoperative complication is reported.

2. Patient Compliance and Discontinuation

Patient compliance at each follow-up visit interval is presented using the visit intervals described previously. "Theoretically Due" refers to patients who were at least 2 months past their due date for a follow-up visit (i.e., patients who should be examined according to their follow-up visit schedule).

Patients became ineligible to be followed up if they:

- died
- had all study devices removed without replacement
- had all study devices removed and replaced with non-McGhan devices
- had all study devices removed and replaced with McGhan non-study devices

The number of "Expected" patients is derived from the difference between those who were theoretically due and those who died or were discontinued due to explantation of all study devices. "Actual Evaluated" during each visit interval is defined as the number of patients who were seen for a follow-up visit at least once during the interval. "% Follow-Up" is calculated as the number of patients who were evaluated divided by the total number of expected patients for that study interval.

If the patient completes a follow-up visit and also has a discontinuation date within the same visit interval, then the patient is considered compliant for that interval and is considered discontinued in the compliance calculation for the next visit interval. In contrast, if the patient dies prior to completion of a follow-up visit, then the patient is considered discontinued in the compliance calculation for that visit interval in which her death occurred.

The following measures were taken to minimize the number of patients who were lost to follow-up:

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- An active compliance follow-up program was implemented to further remind sites of which patients were due to be seen for required follow-up visits through the use of quarterly mailings to each investigator that provided their site's current percentage of patients seen for the required 1-year and 3-year follow-up visit, plus a report of patients due for a visit in the subsequent quarter
- Patients who relocated were transferred to a new Investigator in their area for follow-up; new Investigators were recruited and enrolled in the study in order to follow patients who moved to areas without an existing Investigator
- A professional search company was used to locate patients when the site was unable to reach patients at previously known addresses due to relocation

The number of patients discontinued through the end of the 3-year visit interval is reported according to one of four primary reasons for discontinuation (see Appendix C for copies of the discontinuation forms):

- Patient no longer has any McGhan silicone-filled study implants
- Patient death
- Patient choice
- Other

Appendix D contains copies of patient Discontinuation Forms for all patients discontinued after the 3-year visit interval.

3. Safety Assessment

a. Unanticipated Adverse Device Effects

Unanticipated Adverse Events (UAEs) were collected on the Unanticipated Adverse Event Form. The number of UAEs is reported.

b. Medical Complications

Complications were identified from the check-box questions on the Follow-Up Form. Open-ended responses capturing other complications that were not provided as check boxes on the form were coded as described previously. Complications collected were the following:

- asymmetry
- breast pain
- bruising
- capsular contracture
- capsule calcification
- delayed wound healing
- hematoma
- hypertrophic scarring

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- implant extrusion
- implant malposition
- implant palpability
- implant rupture
- implant visibility
- infection
- irritation
- loss of nipple sensation
- lymphadenopathy
- nipple hypersensitivity
- nipple paresthesia
- pneumothorax
- redness
- seroma
- skin hypersensitivity
- skin paresthesia
- skin rash
- swelling
- tissue or skin necrosis
- wrinkling
- other complications (e.g., breast ptosis)

For the implant extrusion, implant rupture, and pneumothorax complications, all reported occurrences are included in the analysis regardless of the severity rating provided by the physician (i.e., very mild, mild, moderate, severe, or very severe). As determined in consultation with Inamed's Medical Advisor, Dr. Scott Spear, for all other complications, only reported occurrences that were in the moderate, severe, or very severe range are included in the analysis (for capsular contracture, Baker Grades III and IV were included in the analysis). Very mild and mild indications of these events (for capsular contracture, Baker Grades I and II) are not considered clinical problems; rather, these occurrences are within the range of what is considered normal for women with implant surgery. This method for reporting complications is identical to the approach used in the McGhan Medical PMA for saline-filled breast implants (PMA #P990074, approved May 10, 2000).

Cumulative risk (Kaplan-Meier) was used to describe these complications. The method of risk analysis used for this report is not subject to the problem of competing risks (FDA/McGhan Teleconference March 17, 2000) because once a patient experiences her first complication (e.g., breast pain at 15 days post-implant) she is not removed from the pool of patients who may experience (and be reported as having) another complication (e.g., capsular contracture at 45 days post-implant).

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c. Reoperations

A "reoperation" is defined as a visit during which at least one secondary procedure was performed involving one or more primary study devices. Analyses describing reoperations are:

- Cumulative risk (Kaplan-Meier)
- Number of reoperations per patient
- Intraoperative complications during reoperation

If the only procedure performed during a reoperation was a nipple reconstruction/nipple tattoo, then the reoperation is not included in the analysis because these reoperations are considered planned. Nipple tattoo procedures were identified by the check-box on the Secondary Procedures Form. Additionally, an effort was made to exclude reoperations that involved a nipple reconstruction procedure only (as identified by the terms "Nipple Reconstruction" or "Nipple Recon" in the open-ended 'Specify Other' procedure field on the Secondary Procedures Form).

d. Implant Replacement/Removal

Kaplan-Meier analysis is conducted on the time to first occurrence of implant replacement/removal both by patient and by implant.

4. Effectiveness Assessment

Frequency distributions of the degree of physician and patient satisfaction regarding the breast implantation are presented for each study visit interval. If more than one assessment is reported by the physician or patient during a visit interval, the worst-case (more dissatisfied) assessment indicated is reported. The total number of patients included in the satisfaction analysis for any visit interval may be different from the total number of patients seen during that interval (as indicated in the compliance table) due to the inclusion of patients who were seen for a follow-up visit but who have not yet traversed their target window, or due to the exclusion of patients for whom no assessment of their implants was made during the follow-up visit.

RESULTS

A. PATIENT ENROLLMENT AND SURGICAL TREATMENT

1. Demographic Characteristics

Tables 1 – 3

Patients' pre-implant demographic characteristics are presented in Tables 1-3.

Table 1 reports patient age and marital status. The median patient age was 44 years. A total of 61.8% of the patients were married, 16.6% were divorced, and 12.6% were single.

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As reported in Table 2, 40.9% of the patients were employed in professional jobs and 16.5% were housewives.

Education data are presented in Table 3. The majority (72.5%) of patients had at least some college education.

2. Product Styles

Table 4

Table 4 presents a distribution of the device styles used for the reconstruction patients in this study. A total of 26,935 primary study devices were implanted in the 15,465 patients. Textured device styles were more commonly used (65.9%) than were smooth styles (31.8%), and round styles were more commonly used (66.0%) than were shaped styles (31.7%). A small number of product styles are reported as unknown; these data issues are actively being followed up on with the sites.

3. Surgical Complications

Table 5

A total of 95 (0.6%) reconstruction patients had an intraoperative complication during their primary implant surgery (Table 5).

B. PATIENT COMPLIANCE AND DISCONTINUATION

Tables 6 – 7

Of the 15,465 reconstruction patients, 10,453 (67.6%) have traversed their 1-year follow-up visit window and 2,567 (16.6%) have traversed their 3-year follow-up visit window. Accounting for those patients who were discontinued due to death or explant of all study devices, compliance was 53.8% at the 1-year follow-up visit and 27.0% at the 3-year follow-up visit (Table 6).

Based on data obtained through 3 years, 533 of the 15,465 patients (3.4%) were discontinued from the study (Table 7). Of these, 259 patients were discontinued due to removal of all study devices, 119 patients chose to discontinue, 54 patients died, and 101 patients discontinued for other reasons. The majority of patient deaths were due to cancer; other causes of death were accidents (e.g., motor vehicle), drug overdose, and non-implant related medical conditions (e.g., brain tumor). "Other" reasons for discontinuation included the patient being terminally ill, moving out of the country, or not wanting to transfer to another doctor when her physician discontinued from the study.

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C. SAFETY ASSESSMENT

1. Unanticipated Adverse Events

There were no Unanticipated Adverse Events (UAEs) associated with the silicone-filled breast implants in this study. Twenty-six (26) Unanticipated Adverse Event Forms have been received for the reconstruction patients. Each of the 26 reported events was reviewed by the Medical Monitor who determined that none of the observations met the definition of a UAE; rather, all reports were known medical complications (e.g., capsular contracture, infection, seroma).

2. Medical Complications

Tables 8 – 36

Tables 8-36 present the Kaplan-Meier risk analysis results for each of the medical complications assessed in this study.

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The following table summarizes the 3-year risk rates and associated 95% confidence intervals for each complication, both by patient and by implant. Complications are sorted from the highest to the lowest 3-year risk rates by patient. The risks reported in this table are not additive because a patient may experience more than one complication and would be included in the risk for each complication.

Complication	3-Year Risk By Patient % (95% CI)	3-Year Risk By Implant % (95% CI)
Capsular Contracture	17.6% (15.7%, 19.4%)	12.7% (11.5%, 14.0%)
Asymmetry	16.3% (14.4%, 18.2%)	N/A
Implant Palpability	10.3% (8.7%, 11.8%)	8.4% (7.3%, 9.5%)
Wrinkling	9.4% (7.9%, 10.8%)	7.3% (6.3%, 8.3%)
Implant Malposition	8.5% (7.1%, 9.9%)	6.1% (5.2%, 7.1%)
Breast Pain	7.9% (6.5%, 9.3%)	5.5% (4.6%, 6.4%)
Implant Visibility	6.3% (5.1%, 7.6%)	4.9% (4.0%, 5.7%)
Loss of Nipple Sensation	5.8% (4.6%, 7.0%)	4.9% (4.1%, 5.7%)
Hypertrophic Scarring	3.4% (2.6%, 4.3%)	3.1% (2.5%, 3.8%)
Capsule Calcification	3.2% (2.3%, 4.2%)	2.3% (1.7%, 2.9%)
Skin Paresthesia	2.6% (1.9%, 3.3%)	2.3% (1.7%, 2.8%)
Swelling	2.3% (1.8%, 2.9%)	1.7% (1.4%, 2.1%)
Other Complications	2.0% (1.2%, 2.7%)	1.5% (1.0%, 2.0%)
Implant Rupture	1.6% (0.9%, 2.4%)	1.1% (0.6%, 1.6%)
Nipple Hypersensitivity	1.4% (0.8%, 2.1%)	1.2% (0.8%, 1.6%)
Implant Extrusion	1.3% (0.6%, 2.0%)	0.9% (0.5%, 1.3%)
Redness	1.2% (0.8%, 1.7%)	0.8% (0.5%, 1.1%)
Nipple Paresthesia	1.1% (0.7%, 1.6%)	1.0% (0.6%, 1.4%)
Infection	1.0% (0.6%, 1.4%)	0.7% (0.4%, 0.9%)
Pneumothorax	1.0% (0.4%, 1.7%)	0.7% (0.4%, 1.1%)
Irritation	1.0% (0.5%, 1.5%)	0.6% (0.3%, 0.9%)
Delayed Wound Healing	0.8% (0.4%, 1.2%)	0.6% (0.4%, 0.9%)
Bruising	0.7% (0.4%, 1.1%)	0.6% (0.4%, 0.8%)
Seroma	0.7% (0.4%, 1.0%)	0.4% (0.2%, 0.6%)
Skin Rash	0.6% (0.2%, 0.9%)	0.5% (0.3%, 0.8%)
Skin Hypersensitivity	0.6% (0.3%, 0.9%)	0.4% (0.3%, 0.7%)
Hematoma	0.4% (0.2%, 0.6%)	0.2% (0.1%, 0.4%)
Lymphadenopathy	0.4% (0.1%, 0.8%)	0.2% (0.0%, 0.5%)
Tissue or Skin Necrosis	0.3% (0.1%, 0.5%)	0.2% (0.1%, 0.3%)

The highest 3-year by-patient risk rates were observed for capsular contracture (17.6%), asymmetry (16.3%), and implant palpability (10.3%). All other complications occurred at a by-patient risk of less than 10.0%. The category "Other Complications" consists of complications that were not collected via the check boxes provided on the Follow-Up Form, such as ptosis, inadequate nipple projection, breast lump, and implant size dissatisfaction.

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3. Reoperations

Tables 37 – 39

Tables 37-39 present results pertaining to reoperations performed through 3 years. The 3-year risk of reoperation was 44.1% by patient and 37.2% by implant (Table 37). A total of 2,341 reoperations were performed on 2,034 patients (13.2% of 15,465 enrolled patients) through 3 years post-implant. Most of the patients who had a reoperation (88.5%) had one reoperation (Table 38). Intraoperative complications were reported during 68 of the 2,341 reoperations (2.9%), (Table 39).

4. Implant Replacement/Removal

Table 40

Table 40 describes the occurrence of implant replacement/removal. The 3-year risk of implant replacement/removal (i.e., device explant with or without replacement) was 28.2% by patient and 21.9% by implant.

D. EFFECTIVENESS ASSESSMENT

Tables 41 – 42

Tables 41 and 42 report physician and patient satisfaction with the implant surgery based on primary study devices. More than 90% of both physicians and patients indicated being satisfied with the results of breast implant surgery at both the 1-year and 3-year visit intervals. On a 1 (definitely dissatisfied) to 5 (definitely satisfied) scale, the average satisfaction level for physicians and patients ranged between 4.3 and 4.4 during each follow-up interval.

DISCUSSION

Overall, the results of this study revealed that McGhan Silicone-Filled Breast Implants are safe devices for use in breast reconstruction. This conclusion is based on data from a total of 15,465 reconstruction patients who received these devices and were followed for up to 3 years post-implant. Follow-up data is available for 5,537 patients at 1 year post-implant and 670 patients at 3 years post-implant, providing findings related to safety outcomes for a large number of patients.

In terms of the safety of McGhan Silicone-Filled Breast Implants, results revealed clinically acceptable rates for medical complications and reoperations at 3 years post-implant. The highest 3-year by-patient risk rates for medical complications were capsular contracture (17.6%), asymmetry (16.3%), and implant palpability (10.3%). The lowest 3-year by-patient risk rates, all of which were under 1%, were for delayed wound healing, bruising, seroma, skin rash, skin hypersensitivity, hematoma, lymphadenopathy, and tissue or skin necrosis. The 3-year risk of reoperation was 44.1% by patient, and the 3-year risk of implant replacement/removal was 28.2% by patient.

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In terms of effectiveness, patients were highly satisfied with their breast implants. More than 90% of both physicians and patients reported being satisfied with the outcome of the breast implant surgery at each of the follow-up visit intervals.

In sum, the results of this study revealed that the risk of complications associated with breast implant surgery for reconstruction, including reoperations, is relatively low and patient satisfaction is very high. These results are consistent with previous findings that, despite the risks associated with breast implant surgery, women perceive significant positive benefit to the procedure (Handel et al., 1993; Young et al., 1994; McGhan Medical RTV Saline-Filled Mammary Implant PMA #P990074, Original PMA Volume 6).

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REFERENCES

- Handel N, Wellisch D, Silverstein MJ, Jensen JA, Waisman E. Knowledge, concern, and satisfaction among augmentation mammoplasty patients. *Annals of Plastic Surgery* 1993; 30: 1-20.
- Young VL, Nemecek JR, Nemecek DA. The efficacy of breast augmentation: Breast size increase, patient satisfaction, and psychological effects. *Plastic and Reconstructive Surgery* 1994; 94: 958-969.

ADJUNCT RECONSTRUCTION TABLES

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Table 1: Patient Age and Marital Status

Characteristic	Patients (N = 15465)	
	n	%
Less Than 18	36	0.2%
18-19	108	0.7%
20-29	1271	8.2%
30-39	3411	22.1%
40-50	4640	30.0%
50-60	3562	23.0%
60-70	1454	9.4%
70 & over	508	3.3%
Not Provided	475	3.1%
	<hr/> 15465	<hr/> 100.0%
Median = 44 years		
Range = 14 to 98 years		
Single	1946	12.6%
Married	9562	61.8%
Widowed	538	3.5%
Separated	357	2.3%
Divorced	2561	16.6%
Not Provided	539	3.5%
	<hr/> 15503	<hr/> 100.2%

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Table 2: Patient Occupation

Occupation	Patients (N = 15465)	
	n	%
Clerical	1814	11.7%
Professional	6325	40.9%
Trade	924	6.0%
Housewife	2556	16.5%
Not Employed	909	5.9%
Other	2423	15.7%
Not Provided	782	5.1%
	<hr/> 15733	<hr/> 101.7%

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Table 3: Patient Education

Education	Patients (N = 15465)	
	n	%
Less Than High School	350	2.3%
High School Graduate	3160	20.4%
Some College	4897	31.7%
College Graduate	4257	27.5%
Post College	2053	13.3%
Not Provided	748	4.8%
	<hr/> 15465	<hr/> 100.0%

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Table 4: Product Styles

Product Style	Implants (N = 26935)	
	n	%
Smooth		
Style 10 (round)	24	0.1%
Style 20 (round)	21	0.1%
Style 40 (round)	5448	20.2%
Style 45 (round)	3072	11.4%
	8565	31.8%
Textured		
Style 110 (round)	6448	23.9%
Style 120 (round)	2761	10.3%
Style 153 (shaped)	8535	31.7%
	17744	65.9%
Unknown	626	2.3%

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Table 5: Intraoperative Complications

Intraoperative Complications	Patients (N = 15465)	
	n	%
Yes	95	0.6%
No	14638	94.7%
Missing	732	4.7%
	15465	100.0%

Table 6: Patient Compliance Through 3 Years

	1 Year	3 Years
Theoretically Due	10453	2567
Deaths*	28	16
Explant-Related Discontinuations*	134	69
Without Replacement	53	25
Replacement with Non-Study Device	23	8
Unknown Replacement Status	58	36
Expected	10291	2482
Actual Number Evaluated	5537	670
(Additional Number Evaluated**)	149	85
Lost-to-Follow-Up	4754	1812
% Follow-Up	53.8%	27.0%

* Deaths and Explant-Related Discontinuations are reported cumulatively.

** These patients have been seen in their 1-year or 3-year follow-up window but have not yet traversed their target window (12-14 months or 36-38 months post-implantation); therefore, they are not counted in the "Theoretically Due" row of this table or included in the calculation of "% Follow-Up".

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Table 7: Patient Discontinuation Through 3 Years

Discontinuation	Patients (N = 15465)	
	n	%
Not Discontinued	14932	96.6%
Discontinued		
Death	54	0.3%
Explanted of All Study Devices	259	1.7%
Patient Choice	119	0.8%
Other	101	0.7%
	<u>15465</u>	<u>100.0%</u>

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Table 7 (cont.): Patient Discontinuation Through 3 Years

Patient Death Discontinuation Specified (N = 54)

Pt Seq#	Patient Death Discontinuation
001	CANCER-NOT RELATED TO IMPLANT
002	BREAST CA WITH METS.
003	METASTATIC CARCINOMA RESPIRATORY COMPLICATIONS
004	PULMONARY METASISIS PT DAUGHTER DID NOT INFORM OUR OFFICE UNTIL 4/8/99
005	OVERDOSE
006	BREAST CA.
007	METASTATIC BREAST CARCINOMA
008	BREAST CANCER SPREAD TO LIVER
009	COMPLICATIONS FROM VIRAL INFECTION DURING CHEMOTHERAPY TREATMENT
010	COMPLICATIONS OF EHLERS-DANLOS SYNDROME(NATURAL CAUSES)NOT RELATED TO IMPLANT.
011	BREAST CANCER METASTASIS
012	PATIENT HAD RECURRENCE OF BREAST CANCER WITH SUBSEQUENT METASTASIS.EXPIRATION DUE TO METS.
013	SUSPECTED DRUG OVERDOSE
014	BREAST CA
015	CA METASTASIS TO LUNGS &LIVER.
016	METASTATIC BREAST CA
017	BREAST CANCER METASHASIS
018	BILATERAL PULMONARY EMBOLI DUE TO PROBABLE DEEP LEG VEIN THROMBOSIS.
019	METASTATIC BREAST CANCER.
020	METASTOTIC CARCINOMA
021	METASTATIC CARCINOMA
022	BREAST CANCER HAD SPREAD TO THE BRIN AND SPINAL CANAL -LEPTOMENINGEAL CARCINOMA-
023	METASTATIC BREAST CANCER
024	BREAST CANCER
025	BRAIN TUMOR
026	PANCREATIC CANCER
027	METASTATIC BREAST DISEASE
028	HUSBAND INDICATED SHE PASSED AWAY - SITE DID NOT OBTAIN CAUSE

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Table 7 (cont.): Patient Discontinuation Through 3 Years

Patient Death Discontinuation Specified (N = 54)

Pt Seq#	Patient Death Discontinuation
029	BREAST CANCER
030	METASTATIC BREAST CANCER
031	CA BREAST CAUSED CARDIOSULMONARY ARREST
032	NO INFORMATION AVAILABLE
033	METASTATIC BREAST CA
034	UNKNOWN FROM FAMILY, PATIENT PASSED AWAY IN HER SLEEP
035	BRAIN MALIGNANT EDEMA AFTER METASTASIS EXCISION
036	METASTATIC DISEASE, CANCER
037	METASTASIS TO BACK&LUNGS PER PHONE CALL TO HOME-02/00
038	END STAGE BREAST CANCER; LUNG METASTES'
039	CANCER
040	UNABLE TO LOCATE ANYONE IN FAMILY. CONFIRMED PT DEATH WITH DISABILITY SERVICES(SHE APPLIED FOR DISABILITY BEFORE HER DEATH
041	LIVER CANCER?
042	RECURRENT BREAST CA NON-RESPONSIVE TO TREATMENT
043	ADVANCED CA-METAST TO BONE, BRAIN
044	METASTATIC BREAST CANCER
045	MOTOR VEHICLE COLLISION
046	-LUNG CANCR-
047	METASTATIC BREAST CANCER
048	MOTOR VECHILE ACCIDENT THIS PAST WEEKEND
049	RECURRENT CANCER WITH METS
050	CANCER METASTASIZED
051	METASTATIC BREAST CANCER
052	HORSEBACK RIDING ACCIDENT
053	DISEASE RELATED
054	METASTATIC BREAST CANCER->BRAIN

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Table 8: Risk of First Occurrence of Asymmetry

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
1 Year	195	4527	3.4% (2.9%, 3.8%)	n	n	% (95% CI)
3 Years	427	496	16.3% (14.4%, 18.2%)		N/A	N/A

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Table 9: Risk of First Occurrence of Breast Pain

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
1 Year	108	4546	1.8% (1.5%, 2.2%)	136	7728	1.3% (1.1%, 1.6%)
3 Years	207	507	7.9% (6.5%, 9.3%)	253	852	5.5% (4.6%, 6.4%)

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Table 10: Risk of First Occurrence of Bruising

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n			n	n		
1 Year	29	4557	0.5%	(0.3%, 0.6%)	39	7738	0.4%	(0.3%, 0.5%)
3 Years	34	523	0.7%	(0.4%, 1.1%)	46	868	0.6%	(0.4%, 0.8%)

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Table 11: Risk of First Occurrence of Capsular Contracture

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n			n	n		
1 Year	230	4526	4.0%	(3.5%, 4.5%)	281	7708	2.9%	(2.6%, 3.2%)
3 Years	494	492	17.6%	(15.7%,19.4%)	600	835	12.7%	(11.5%,14.0%)

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Table 12: Risk of First Occurrence of Capsule Calcification

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
1 Year	35	4565	0.6% (0.4%, 0.8%)		41	7748	0.4% (0.3%, 0.6%)	
3 Years	75	519	3.2% (2.3%, 4.2%)		92	863	2.3% (1.7%, 2.9%)	

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Table 13: Risk of First Occurrence of Delayed Wound Healing

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
1 Year	25	4565	0.4% (0.3%, 0.6%)	32	7749	0.3% (0.2%, 0.4%)
3 Years	31	521	0.8% (0.4%, 1.2%)	40	865	0.6% (0.4%, 0.9%)

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Table 14: Risk of First Occurrence of Hematoma

Time	By Patient				By Implant			
	Number Affected		Cumulative Risk		Number Affected		Cumulative Risk	
	n	% (95% CI)	Number Remaining	% (95% CI)	n	% (95% CI)	Number Remaining	% (95% CI)
1 Year	14	0.2% (0.1%, 0.3%)	4563	0.2% (0.1%, 0.3%)	14	0.1% (0.1%, 0.2%)	7746	0.1% (0.1%, 0.2%)
3 Years	18	0.4% (0.2%, 0.6%)	525	0.4% (0.2%, 0.6%)	18	0.2% (0.1%, 0.4%)	869	0.2% (0.1%, 0.4%)

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Table 15: Risk of First Occurrence of Hypertrophic Scarring

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
1 Year	20	4568	0.4%	(0.2%, 0.5%)	35	7746	0.4%	(0.3%, 0.5%)
3 Years	84	520	3.4%	(2.6%, 4.3%)	131	861	3.1%	(2.5%, 3.8%)

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Table 16: Risk of First Occurrence of Implant Extrusion

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n			n	n		
1 Year	19	4564	0.3%	(0.2%, 0.5%)	26	7746	0.3%	(0.2%, 0.4%)
3 Years	30	521	1.3%	(0.6%, 2.0%)	39	864	0.9%	(0.5%, 1.3%)

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Table 17: Risk of First Occurrence of Implant Malposition

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
1 Year	122	4548	2.1%	(1.7%, 2.5%)	149	7728	1.5%	(1.3%, 1.8%)
3 Years	238	516	8.5%	(7.1%, 9.9%)	285	859	6.1%	(5.2%, 7.1%)

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Table 18: Risk of First Occurrence of Implant Palpability.

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
1 Year	76	4562	1.4%	(1.1%, 1.7%)	104	7741	1.1%	(0.9%, 1.3%)
3 Years	239	511	10.3%	(8.7%, 11.8%)	323	852	8.4%	(7.3%, 9.5%)

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Table 19: Risk of First Occurrence of Implant Rupture

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
1 Year	19	4569	0.3%	(0.2%, 0.5%)	26	7749	0.3%	(0.2%, 0.4%)
3 Years	36	521	1.6%	(0.9%, 2.4%)	45	864	1.1%	(0.6%, 1.6%)

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Table 20: Risk of First Occurrence of Implant Visibility

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n			n	n		
1 Year	54	4566	1.0%	(0.7%, 1.2%)	65	7750	0.7%	(0.5%, 0.9%)
3 Years	150	520	6.3%	(5.1%, 7.6%)	187	863	4.9%	(4.0%, 5.7%)

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Table 21: Risk of First Occurrence of Infection

Time	By Patient				By Implant			
	Number Affected		Cumulative Risk		Number Affected		Cumulative Risk	
	n	% (95% CI)	Number Remaining	% (95% CI)	n	% (95% CI)	Number Remaining	% (95% CI)
1 Year	24	0.4% (0.2%, 0.6%)	4565	0.4% (0.2%, 0.6%)	25	0.2% (0.1%, 0.3%)	7749	0.2% (0.1%, 0.3%)
3 Years	34	1.0% (0.6%, 1.4%)	522	1.0% (0.6%, 1.4%)	37	0.7% (0.4%, 0.9%)	867	0.7% (0.4%, 0.9%)

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Table 22: Risk of First Occurrence of Irritation

Time	By Patient				By Implant			
	Number Affected		Cumulative Risk		Number Affected		Cumulative Risk	
	n	% (95% CI)	Number Remaining	% (95% CI)	n	% (95% CI)	Number Remaining	% (95% CI)
1 Year	9	0.1% (0.1%, 0.2%)	4567	0.1% (0.1%, 0.2%)	10	0.1% (0.0%, 0.2%)	7751	0.1% (0.0%, 0.2%)
3 Years	23	1.0% (0.5%, 1.5%)	524	1.0% (0.5%, 1.5%)	25	0.6% (0.3%, 0.9%)	868	0.6% (0.3%, 0.9%)

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Table 23: Risk of First Occurrence of Loss of Nipple Sensation

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
1 Year	34	4564	0.6% (0.4%, 0.8%)		50	7744	0.5% (0.4%, 0.7%)	
3 Years	134	515	5.8% (4.6%, 7.0%)		193	856	4.9% (4.1%, 5.7%)	

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Table 24: Risk of First Occurrence of Lymphadenopathy

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
1 Year	0	4572	0.0%	--	0	7754	0.0%	--
3 Years	7	524	0.4% (0.1%, 0.8%)		7	868	0.2% (0.0%, 0.5%)	

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Table 25: Risk of First Occurrence of Nipple Hypersensitivity

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
1 Year	6	4572	0.1% (0.0%, 0.2%)	10	7754	0.1% (0.0%, 0.2%)
3 Years	30	522	1.4% (0.8%, 2.1%)	44	866	1.2% (0.8%, 1.6%)

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Table 26: Risk of First Occurrence of Nipple Paresthesia

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
1 Year	9	4570	0.2% (0.1%, 0.3%)	11	7753	0.1% (0.0%, 0.2%)
3 Years	30	523	1.1% (0.7%, 1.6%)	41	867	1.0% (0.6%, 1.4%)

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Table 27: Risk of First Occurrence of Pneumothorax

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
1 Year	9	4569	0.2% (0.1%, 0.3%)	14	7749	0.1% (0.1%, 0.2%)
3 Years	21	521	1.0% (0.4%, 1.7%)	28	864	0.7% (0.4%, 1.1%)

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Table 28: Risk of First Occurrence of Redness

Time	By Patient				By Implant			
	Number Affected		Cumulative Risk		Number Affected		Cumulative Risk	
	n	% (95% CI)	Number Remaining	% (95% CI)	n	% (95% CI)	Number Remaining	% (95% CI)
1 Year	42	0.7% (0.5%, 0.9%)	4560	0.7% (0.5%, 0.9%)	46	0.4% (0.3%, 0.6%)	7744	0.4% (0.3%, 0.6%)
3 Years	53	1.2% (0.8%, 1.7%)	522	1.2% (0.8%, 1.7%)	58	0.8% (0.5%, 1.1%)	867	0.8% (0.5%, 1.1%)

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Table 29: Risk of First Occurrence of Seroma

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
1 Year	23	4564	0.4% (0.2%, 0.5%)	24	7747	0.2% (0.1%, 0.3%)
3 Years	28	523	0.7% (0.4%, 1.0%)	29	868	0.4% (0.2%, 0.6%)

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Table 30: Risk of First Occurrence of Skin Hypersensitivity

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
1 Year	6	4571	0.1%	(0.0%, 0.2%)	7	7753	0.1%	(0.0%, 0.1%)
3 Years	18	525	0.6%	(0.3%, 0.9%)	25	869	0.4%	(0.3%, 0.7%)

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Table 31: Risk of First Occurrence of Skin Paresthesia

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
1 Year	21	4566	0.4% (0.2%, 0.6%)		29	7745	0.3% (0.2%, 0.5%)	
3 Years	69	519	2.6% (1.9%, 3.3%)		97	862	2.3% (1.7%, 2.8%)	

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Table 32: Risk of First Occurrence of Skin Rash

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
1 Year	9	4569	0.1% (0.1%, 0.2%)	11	7750	0.1% (0.0%, 0.2%)
3 Years	15	522	0.6% (0.2%, 0.9%)	21	864	0.5% (0.3%, 0.8%)

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Table 33: Risk of First Occurrence of Swelling

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
1 Year	92	4538	1.5% (1.2%, 1.8%)	122	7714	1.1% (0.9%, 1.4%)
3 Years	109	518	2.3% (1.8%, 2.9%)	142	862	1.7% (1.4%, 2.1%)

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Table 34: Risk of First Occurrence of Tissue or Skin Necrosis

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
1 Year	14	4567	0.2% (0.1%, 0.3%)	15	7751	0.1% (0.1%, 0.2%)
3 Years	16	522	0.3% (0.1%, 0.5%)	18	867	0.2% (0.1%, 0.3%)

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Table 35: Risk of First Occurrence of Wrinkling

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
1 Year	92	4554	1.6%	(1.3%, 2.0%)	119	7733	1.3%	(1.0%, 1.5%)
3 Years	251	503	9.4%	(7.9%, 10.8%)	328	841	7.3%	(6.3%, 8.3%)

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Table 36: Risk of First Occurrence of Other Complications

Time	By Patient				By Implant			
	Number Affected		Cumulative Risk		Number Affected		Cumulative Risk	
	n	% (95% CI)	Number Remaining	% (95% CI)	n	% (95% CI)	Number Remaining	% (95% CI)
1 Year	15	0.2% (0.1%, 0.4%)	4570	0.2% (0.1%, 0.4%)	19	0.2% (0.1%, 0.3%)	7752	0.2% (0.1%, 0.3%)
3 Years	45	2.0% (1.2%, 2.7%)	522	2.0% (1.2%, 2.7%)	57	1.5% (1.0%, 2.0%)	866	1.5% (1.0%, 2.0%)

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Table 37: Risk of First Occurrence of Reoperation

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n			n	n		
1 Year	1643	4205	23.4%	(22.4%, 24.4%)	2011	7208	17.9%	(17.2%, 18.6%)
3 Years	2034	457	44.1%	(42.0%, 46.2%)	2577	794	37.2%	(35.5%, 38.8%)

Table 38: Number of Reoperations Per Patient

	Patients (N = 15465)	
	n	%
No Reoperations	13431	86.8%
At Least One Reoperation	2034	13.2%
Total	15465	100.0%
Breakdown (# of Reoperations)		
1	1800	88.5%
2	185	9.1%
3	37	1.8%
4	6	0.3%
5	2	0.1%
6	2	0.1%
7	2	0.1%
Total	2034	100.0%
Total Number of Reoperations	2341*	100.0%

* Total number of reoperations is calculated as:
 (1800*1 reoperation) + (185*2 reoperations) +
 (37*3 reoperations) + (6*4 reoperations) +
 (2*5 reoperations) + (2*6 reoperations) +
 (2*7 reoperations) = 2341 reoperations

Table 39: Intraoperative Complications During Reoperation

Intraoperative Complications	Reoperations (N = 2341)	
	n	%
Yes	68	2.9%
No	2246	95.9%
Missing	27	1.2%
	<hr/> 2341	<hr/> 100.0%

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Table 40: Risk of First Occurrence of Implant Replacement/Removal

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n			n	n		
1 Year	747	4600	11.2%	(10.4%,11.9%)	724	7844	6.7%	(6.2%, 7.1%)
3 Years	1014	514	28.2%	(26.1%,30.3%)	1101	878	21.9%	(20.3%,23.5%)

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Table 41: Physician Assessment of Implants

Time	Patients	Satisfaction Level* (Allowable Range 1 - 5)					Mean	SD
		Definitely Dissat- isfied	Somewhat Dissat- isfied	Somewhat Satisfied	Definitely Satisfied	Descriptive Statistics		
1 Year	5385	2.3%	4.4%	7.8%	24.9%	60.6%	4.4	1.0
3 Years	718	2.9%	4.2%	9.3%	26.3%	57.2%	4.3	1.0

* Satisfaction level could range from 1 (definitely dissatisfied) to 5 (definitely satisfied).

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Table 42: Patient Assessment of Implants

Time	Patients	Satisfaction Level* (Allowable Range 1 - 5)						Mean	SD
		Definitely Dissatisfied	Somewhat Dissatisfied	Satisfied	Somewhat Satisfied	Definitely Satisfied	Descriptive Statistics		
1 Year	5501	2.7%	4.5%	7.4%	25.4%	59.9%	4.4	1.0	
3 Years	732	3.0%	4.2%	9.3%	23.6%	59.8%	4.3	1.0	

* Satisfaction level could range from 1 (definitely dissatisfied) to 5 (definitely satisfied).

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ADJUNCT RECONSTRUCTION APPENDICES

APPENDIX A

List of Complications Occurring Beyond 3 Years (1095 Days) Post-Implant

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Appendix A: List of Complications Occurring Beyond 3 Years (1095 Days)
 Post-Implant

Complication	# of Post 3-Year Occurrences	
	Patients (n = 93)	Implants (n = 124)
Asymmetry	23	26
Breast Pain	13	18
Bruising	0	0
Capsular Contracture	34	42
Capsule Calcification	7	10
Delayed Wound Healing	0	0
Hematoma	0	0
Hypertrophic Scarring	2	3
Implant Extrusion	0	0
Implant Malposition	20	22
Implant Palpability	14	20
Implant Rupture	0	0
Implant Visibility	7	9
Infection	1	1
Irritation	1	1
Loss of Nipple Sensation	6	9
Lymphadenopathy	0	0
Nipple Hypersensitivity	3	4
Nipple Paresthesia	1	2
Pneumothorax	0	0
Redness	1	1
Seroma	0	0
Skin Hypersensitivity	0	0
Skin Paresthesia	2	3
Skin Rash	1	1
Swelling	0	0
Tissue or Skin Necrosis	0	0
Wrinkling	14	23
Other Complications	2	2

APPENDIX B

Summary of Complications Following Primary Implant Removal With Replacement

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Appendix B: Summary of Complications Following
 Primary Implant Removal With Replacement

Complication	# of Occurrences	
	Patients (n = 63)	Implants (n = 74)
Asymmetry	26	27
Breast Pain	6	7
Bruising	2	2
Capsular Contracture	18	20
Capsule Calcification	2	2
Delayed Wound Healing	5	5
Hematoma	0	0
Hypertrophic Scarring	3	4
Implant Extrusion	1	1
Implant Malposition	12	13
Implant Palpability	8	10
Implant Rupture	0	0
Implant Visibility	9	10
Infection	4	4
Irritation	0	0
Loss of Nipple Sensation	7	8
Lymphadenopathy	1	1
Nipple Hypersensitivity	0	0
Nipple Paresthesia	1	1
Pneumothorax	0	0
Redness	4	4
Seroma	2	2
Skin Hypersensitivity	0	0
Skin Paresthesia	2	2
Skin Rash	0	0
Swelling	4	5
Tissue or Skin Necrosis	1	1
Wrinkling	12	14
Other Complications	1	1