

Inamed Corporation
Modular Submission M010040
McGhan Silicone-Filled Breast Implants

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**CORE CLINICAL STUDY
RECONSTRUCTION COHORT**

December 16, 2002

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RECONSTRUCTION COHORT
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ABSTRACT

The McGhan Medical Corporation Silicone-Filled Breast Implant Core Clinical Study is a prospective, 10-year, multi-center clinical study conducted to examine the safety and effectiveness of McGhan Silicone-Filled Breast Implants for augmentation, reconstruction, and revision patients. This report presents the results from the reconstruction cohort through 2 years post-implant.

Data from 221 patients who received 361 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 February 9, 1999 and June 27, 2000. The majority of patients are Caucasian with a median age at study entry of 50 years.

The primary 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). Additionally, all post-implant reports of reproduction/lactation problems, connective tissue/autoimmune disease, and breast disease/carcinoma are documented. Safety data is collected at scheduled follow-up intervals (0-4 weeks, 6 months, and annually at 1-10 years post-implant) as well as during unscheduled visits.

Two types of effectiveness data are collected. First, at all scheduled follow-up visits, both the patient's and the physician's level of satisfaction with the breast implantation are assessed. Second, prior to implantation and at 1, 2, 4, 6, 8, and 10 years post-implant patients complete a questionnaire to assess their quality of life covering a variety of parameters, including general health, self-esteem, and body image.

As of this report, 21 (9.5%) of the 221 patients initially enrolled (implanted) have been discontinued from the study. Twelve (12) of the 21 patients were discontinued due to permanent removal of all study devices, 6 patients died, 1 patient chose to discontinue, and 2 patients discontinued for other reasons. Five (5) of the 6 patient deaths were the result of cancer and one patient died in a car accident. Taking into account patients who died or had all study devices removed without replacement with other study devices, follow-up compliance was 93.5% at the 1-year follow-up visit and 94.6% at the 2-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. To assess change in quality of life among the three available measured time points (baseline/pre-implant, 1 year post-implant, and 2 years post-implant), a repeated-measures analysis of variance was conducted on the mean score for each quality of life scale.

Table 1 of this abstract summarizes the 2-year by-patient risk rate associated with various complications, including the following types of outcomes:

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

The complications with the highest 2-year risk rate by patient were capsular contracture (13.5%), asymmetry (11.9%), and implant malposition (5.8%). All other complications occurred at a by-patient risk rate of less than 5.0%. Overall, more than two thirds (70.1%) of complications were resolved within the period of this report. Of those complications that were resolved, the majority (68.3%) were resolved either without treatment or with non-surgical treatment.

A total of 11 devices were suspected of rupture through 2 years post-implant. Three (3) of the 11 devices have been explanted and the remaining 8 devices are still implanted. Of the 11 suspected device ruptures, 1 device was found to be intact (i.e., false report of rupture), 2 devices were confirmed ruptured, and 8 devices remain unconfirmed ruptures. Based on confirmed and unconfirmed ruptures, the 2-year by-patient risk of implant rupture was 4.8%.

A total of 80 patients underwent 104 reoperations through 2 years post-implant, with a 2-year by-patient risk of reoperation of 36.9%. Of the 104 reoperations, the most common procedures performed were implant removal with replacement (30.8%), scar revision (14.4%), and capsulotomy (12.5%).

By the end of the 2-year post-implant visit, 37 patients had 45 study devices removed, with a 2-year by-patient risk of implant replacement/removal for any reason of 17.2%. Of the 45 devices that were explanted, 12 (26.7%) were removed due to capsular contracture and 11 (24.4%) were removed due to asymmetry. Most devices (86.7%) were replaced.

Fifty-one (51) patients (23.1%) reported reproduction problems prior to implantation. The most prevalent problems were spontaneous abortion/miscarriage and infertility. Two (2) patients (0.9%) had 2 reports of post-implant reproduction problems through 2 years, of which 1 was planned abortion to treat a medical problem and 1 was no menses. One of the 2 patients who had a post-implant reproduction problem also had a pre-implant reproduction problem.

Twenty-six (26) patients (11.8%) reported lactation problems prior to implantation, most commonly inadequate milk production and mastitis that required treatment. No patients reported lactation problems through 2 years post-implant.

Two hundred and seventeen (217) patients (98.2%) reported breast disease prior to implantation, of which 207 were malignant disease and 10 were benign breast disease. Thirteen (13) patients (5.9%) had reports of post-implant breast disease through 2 years, of which 4 were confirmed malignant disease and 9 were benign breast disease. All 4

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patients with post-implant malignant disease had confirmed malignant disease pre-implant.

None of the patients reported connective tissue/autoimmune disease (CTD) prior to implantation. One (1) patient reported a CTD through 2 years post implant. This 42-year old patient had a confirmed diagnosis of systemic sclerosis/scleroderma with an onset date of 4 months after implant surgery.

More than 90% of both physicians and patients indicated being satisfied with the outcome of the breast implant surgery at each of the four follow-up visit intervals. Indeed, on a 1 (definitely dissatisfied) to 5 (definitely satisfied) scale, the average satisfaction level for physicians and patients ranged between 4.5 and 4.8 during each follow-up interval.

Quality of life results are summarized in Table 2 of this abstract. As measured by the "SF-36 Status Survey", the population of women participating in this clinical study indicated a higher quality of life than the general U.S. female population for 5 of the 8 scales for which comparative values are available. On each of these scales, the women in this study scored between 1 and 9 points higher on average at baseline (out of 100 total points) than the comparison group.

A number of quality of life domains were assessed: general health and physical/mental well being (e.g., the SF-36 and MOS-20 surveys), self-related concepts (e.g., physical self concept and self esteem), and breast-related concepts (e.g., satisfaction with breast size and shape). Table 2 of this abstract summarizes the results pertaining to changes in quality of life pre-implant/baseline vs. 1 year post-implant. Similar changes in quality of life were observed comparing pre-implant to 2-year post-implant results.

For most of the general health concepts and specific self-related concepts, there was no change between average scores at baseline and 1 year post-implant. In contrast, all of the specific measures of breast-related concepts showed significantly higher scores at 1 year vs. baseline, and the magnitude of the difference was generally large. Patients' feelings of satisfaction with their breasts on a variety of assessments showed substantial increases at 1 year vs. baseline.

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Table 1. Core Clinical Study - Reconstruction Cohort Summary of 2-Year Risk Rate for Specific Complications		
Complication	2-Year Risk By Patient	2-Year Risk By Implant
Capsular Contracture	13.5%	9.2%
Asymmetry	11.9%	N/A
Implant Malposition	5.8%	4.7%
Other Nipple Related Observation	4.4%	3.9%
Tissue or Skin Necrosis	3.8%	2.7%
Swelling	3.7%	2.8%
Breast Pain	3.3%	2.6%
Wrinkling/Rippling	2.9%	2.4%
Hypertrophic Scarring	2.4%	1.8%
Infection	2.3%	1.7%
Other Complications	2.3%	1.4%
Delayed Wound Healing	2.3%	1.4%
Seroma	1.8%	1.1%
Bruising	1.4%	1.1%
Skin Rash	1.4%	1.1%
Other Abnormal Scarring	1.0%	0.6%
Ptosis	1.0%	0.6%
Redness	1.0%	0.6%
Pneumothorax	0.5%	0.3%
Implant Extrusion	0.5%	0.3%
Hematoma	0.4%	0.3%
Implant Palpability	0.4%	0.3%
Implant Visibility	0.4%	0.3%
Capsule Calcification	0.0%	0.0%
Fluid Accumulation	0.0%	0.0%
Irritation	0.0%	0.0%
Loss of Nipple Sensation	0.0%	0.0%
Loss of Skin Sensation	0.0%	0.0%
Lymphadenopathy	0.0%	0.0%
Lymphedema	0.0%	0.0%
Nipple Hypersensitivity	0.0%	0.0%
Nipple Paresthesia	0.0%	0.0%
Skin Hypersensitivity	0.0%	0.0%
Skin Paresthesia	0.0%	0.0%

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Table 2. Core Clinical Study – Reconstruction Cohort Summary of Quality of Life Outcome Measures					
	Scale Range	General Population	Baseline	1 Year	Significant
General Health Concepts					
SF36: Role Limitations due to Emotional Problems	0 – 100	79.5	80.8	86.1	—
SF36: Role Limitations due to Physical Health Problems	0 – 100	77.8	70.6	82.6	*↑
SF36: General Health	0 – 100	70.6	78.7	78.2	—
SF36: Bodily Pain	0 – 100	73.6	77.7	82.8	—
SF36: Social Functioning	0 – 100	81.5	87.7	91.3	—
SF36: Physical Functioning	0 – 100	81.5	87.1	90.2	—
SF36: Vitality	0 – 100	58.4	65.0	66.4	—
SF36: Mental Health	0 – 100	73.3	79.8	80.7	—
SF36: Reported Health Transition	0 – 100	—	43.8	22.6	↓*
MOS20: Health Perceptions	0 – 100	—	78.3	80.6	—
MOS20: Physical Functioning	0 – 100	—	76.8	82.1	*↑
MOS20: Role Functioning	0 – 100	—	82.3	87.9	—
MOS20: Social Functioning	0 – 100	—	90.7	93.9	—
MOS20: Mental Health	0 – 100	—	79.0	80.0	—
Specific Self- and Breast-Related Concepts					
Self Concept – Physical Self	18 – 90	—	69.8	70.0	—
Self Esteem	10 – 40	—	35.0	35.3	—
Self vs. Breast Semantic Differential	(-6) – (+6)	—	0.0	-0.1	—
Body Esteem – Total Score	32 – 160	—	112.2	110.9	—
Body Esteem – Sexual Attractiveness	13 – 65	—	48.4	48.0	—
Body Esteem – Weight Concern	10 – 50	—	30.9	30.3	—
Body Esteem – Physical Condition	9 – 45	—	32.8	32.7	—
Personal Life Satisfaction	1 – 6	—	4.5	4.5	—
Satisfaction with Breasts	1 – 5	—	2.8	4.1	*↑
How Well Breasts Matched	1 – 6	—	2.8	4.6	*↑
Satisfaction with Breast Shape	1 – 5	—	2.5	3.9	*↑
Satisfaction with Breast Size	1 – 5	—	2.6	4.0	*↑
Satisfaction with Breast Feel or Touch	1 – 5	—	2.5	3.7	*↑
Rowland Expectation: Improve Self Image	1 – 5	—	3.1	3.1	—
Rowland Expectation: Improve Social Relations	1 – 5	—	1.3	1.7	*↑
Rowland Expectation: Improve Daily Living	1 – 5	—	3.3	2.9	↓*
Rowland Expectation: Improve Well-Being	1 – 5	—	3.3	3.4	—

* Significance is indicated if the overall repeated-measures analysis was significant and the post-hoc comparisons revealed a significant difference between the quality of life scores at baseline and 1 year post-implant.

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INTRODUCTION

The McGhan Medical Corporation Silicone-Filled Breast Implant Core Clinical Study is a prospective, 10-year, multi-center clinical study designed to examine the safety and effectiveness of McGhan Silicone-Filled Breast Implants for augmentation, reconstruction, and revision patients. This report presents the results from the reconstruction cohort. As this study is still ongoing, this report represents complete 2-year follow-up data, with limited available 3-year safety data included in Appendix D.

METHODS

A. SUBJECTS

1. Patient Enrollment

A total of 221 reconstruction patients were enrolled in this study, where enrollment is defined as undergoing implant surgery. The first reconstruction patient was enrolled on February 9, 1999, and the last reconstruction patient was enrolled on June 27, 2000.

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

- Female, age 18 years or older
- Primary breast reconstruction (i.e., no previous breast implant surgery other than implantation of tissue expanders or contralateral augmentation for asymmetry) indicated for the following:

For affected breast:

- Mastectomy for cancer
- Prophylactic mastectomy
- Breast trauma (resulting in mastectomy)

For unaffected breast:

- Contralateral asymmetry (may be performed on the date of the mastectomy or the date when permanent implants are placed in the reconstruction breast)
- Adequate tissue available to cover implants
- Patient is willing to follow all study requirements, including agreeing to attend all required follow-up visits, and accepts the risks involved as indicated by signing and dating the study Patient Informed Consent prior to surgery

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

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- 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 (e.g., Hb A_{1c} > 8%), that 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 that may constitute an unwarranted surgical risk (e.g., unstable cardiac or pulmonary problems)
- Show psychological characteristics that may be incompatible with the surgical procedure and the prosthesis, such as inappropriate attitude or motivation (e.g., body dysmorphic disorder)
- Are not willing to undergo further surgery for revision, if medically required

2. Investigators

A total of 25 Principal Investigators (PIs) at 34 sites (defined as a unique PI-IRB combination) enrolled reconstruction patients in the Core Clinical Study. Additionally, there are currently 2 other non-implanting Principal Investigators at 3 sites who later joined the study for the purpose of following patients who were enrolled by a different physician (e.g., patients who relocated to another state). A number of the 25 implanting investigators had difficulty enrolling the target minimum of 10 reconstruction patients indicated in the protocol. Factors that contributed to this were the lengthy commitment period required from the patients, the concurrent availability of participation in the Adjunct Study, the delay in investigators obtaining IRB approval, and the difficulty in enrolling large numbers of reconstruction patients at individual sites. However, 7 of the 25 Principal Investigators did enroll 10 or more reconstruction patients each. A site listing and enrollment distribution is provided in Appendices A-C:

- Appendix A: Investigational Sites by Principal Investigator and Institutional Review Board (IRB)
- Appendix B: Distribution of Patient Enrollment by Implanting Physician
- Appendix C: Distribution of Product Styles by Implanting Physician

B. PROCEDURE FOR DATA COLLECTION

1. Safety Data Collection

Per the study protocol, patients are required to come in for follow-up visits at 0-4 weeks, 6 months, and annually through 10 years post-implant. Additionally, post-implant observations/complications are recorded for patients who come in for unscheduled visits between scheduled visit intervals. Assessment of safety is based on the occurrence of the following:

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a. Unanticipated Adverse Device Effects

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

any serious adverse effect on health or safety or any life-threatening problem or death caused by or associated with the McGhan Mammary Implant or use of the McGhan Mammary Implant, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence, or any other unanticipated serious problem associated with the device that relates to the rights, safety, or welfare of subjects.

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 Scheduled Follow-Up Visits Form and/or the Complications/Treatment Log Form.

c. Implant Rupture

All implant ruptures are recorded on the Complications/Treatment Log Form, the Explant Form, and/or the MRI Results or Central Reviewer Forms.

d. Reoperations

All reoperations, including the specific types of secondary procedures performed, are captured on a Secondary Surgery Form.

e. Implant Replacement/Removals

Every time an explant is performed, the procedure and details regarding the implant removal are recorded on an Explant Form.

2. Medical History Data Collection

a. Reproduction and Lactation Problems

Reproduction and lactation information was obtained both pre- and post-implant. Pre-implant reproduction and lactation problems are collected on the Medical and Breast Screening History Form. Post-implant reproduction and lactation problems are recorded on the Scheduled Follow-Up Visits Form.

b. Breast Disease

Breast disease information was obtained both pre- and post-implant. Pre-implant breast disease and the results of any pre-implant mammogram within the preceding year are documented on the Medical and Breast Screening History Form. Post-implant breast disease and the results of any post-implant mammogram are recorded on the Scheduled Follow-Up Visits Form and/or the Complications/Treatment Log

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Form. Additionally, diagnoses of breast cancer are recorded on the Breast Cancer Form, which collects detailed information regarding the cancer (e.g., tumor size).

c. Connective Tissue/Autoimmune Disease

Pre- and post-implant reports of connective tissue/autoimmune disease are captured on the CTD Confirmation Form. For all patient self-reports of CTD, the investigator attempts to obtain confirmation of the diagnosis from a rheumatologist or attending physician. If the diagnosing physician determines that the patient does not have the CTD she self-reported, then this is recorded as a false report on the CTD Confirmation Form.

Additionally, patients complete an Activities & Lifestyle Questionnaire pre-implant and at 1, 2, 4, 6, 8, and 10 years post-implant. Investigators review each patient's completed questionnaire and refer the patient to a rheumatologist, if necessary, for further evaluation for a possible CTD. If a patient was referred to a rheumatologist and the referral confirmed that the patient had a possible CTD, then a CTD Confirmation Form was completed.

3. Effectiveness Data Collection

Assessment of the effectiveness of McGhan Silicone-Filled Breast Implants is based on the following measures:

a. Changes in Anatomical Configuration

An analysis to determine change in anatomical configuration was not performed among the reconstruction patients. The major purpose of reconstructive surgery is to restore rather than enhance the appearance of a woman's breast. Thus, a measure of the change in pre- and post-implant breast size is not relevant or meaningful for the reconstruction population as a measure of effectiveness.

b. Satisfaction with Outcome

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", and to specify any reasons for dissatisfaction. This data is collected on the Scheduled Follow-Up Visits Form.

c. Quality of Life

A variety of quality of life measurements are obtained to target the domains of general health, depression, self-concept and self-esteem, body image, and expectation/satisfaction with breast implant(s). Quality of life information is collected prior to implantation and at 1, 2, 4, 6, 8 and 10 years post-implant. This data is collected on the Quality of Life Form - Pre/Post.

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C. GENERAL ANALYSIS APPROACH

1. Overview

Patients from all investigational sites were pooled together for analysis. Inamed believes that the 25 Principal Investigators (representing 34 enrolling sites) participating in the reconstruction portion of the Core Clinical Study ensure a good representation of clinical practice and a representative sample of the patient population under study (see Appendices A-C).

2. Analysis of Data Through Two Years

The extract of the database housing the data that was used for the current report was taken on August 30, 2002. For major variables being reported, any known outstanding issues, inconsistencies, or errors were resolved after the final extract using the best available information.

As of the date of the final database extract, all patients have traversed the 2-year follow-up visit interval, and complete 2-year data is available. Thus, the primary analyses presented and discussed in this report are based on the complete 2-year data. Some patients have been seen for their 3-year follow-up visit. However, only 19.9% of reconstruction patients have traversed the 3-year follow-up visit interval (those who were at least 2 months past their due date for a 3-year follow-up visit). The 3-year visit interval will not be completed for all patients until August 27, 2003. As a representation of safety beyond 2 years, all post 2-year occurrences of the medical complications listed in Methods Section D.3.b are summarized in Appendix D of this report.

The results of this study are reported by specific post-implant visit intervals (i.e., 0-4 weeks, 6 months, 1 year, 2 years) as well as cumulatively through 2 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 with the specific date of onset/occurrence recorded. 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:

- 0-4 Weeks: 30 days
- 6 Months: 183 days
- 1 Year: 365 days
- 2 Years: 730 days

The primary 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

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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 secondary method of analysis of the complication and reoperation data is prevalence and incidence. At each follow-up time point, prevalence is calculated based on all patients/implants who experienced the event, and incidence is calculated based only on the number of new patients/implants who experienced the event since the last follow-up time point. The "Number Evaluated" at each follow-up time point is the number of patients/implants who had a visit during or after the reported follow-up time point. For example, if a patient was seen in the 2-year interval, she is included in the denominator for the 2-year interval, as well as for all previous intervals (e.g., 0-4 weeks, 6 months, and 1 year), even if she did not have a follow-up visit during the previous intervals, because all complications since the last evaluation would be captured at the 2-year visit.

The second approach to data analysis is based on visit windows. These windows are defined in terms of all inclusive, non-overlapping intervals around each follow-up time frame. Reproduction and lactation problems, breast disease, connective tissue/autoimmune disease, and patient satisfaction information were collected at required patient follow-up visits. Additionally, patient compliance is defined based on these same required follow-up visits. These variables are analyzed and reported based on follow-up visit intervals defined as:

- 0-4 Weeks: 0 days through 3 months, 0 days post-implant
- 6 Months: 3 months, 1 day through 9 months, 0 days post-implant
- 1 Year: 9 months, 1 day through 18 months, 0 days post-implant
- 2 Years: 18 months, 1 day through 30 months, 0 days post-implant

Data reported "through 2 years" is inclusive of all results obtained through 30 months post-implant.

3. 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, with the exception of patient quality of life and patient satisfaction. Secondary implants were included in the analysis of these latter measures since patients' assessment may be influenced by the occurrence of implant replacement procedures. Outcomes following replacement surgery are presented in a separate report for the revision cohort enrolled in the Core Clinical Study. Appendix

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H 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 and size 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).

4. Open-Ended Response Coding

To effectively capture the relevant clinical information recorded in open-ended textual responses on the Case Report Forms (CRFs), 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 obtained pre-implant are reported:

- Age
- Race
- Marital Status
- Occupation
- Education
- Height
- Weight

For race 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

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multiple responses to the item for the same patient. For patients with more than one educational level provided, the highest indicated level is reported.

The median and range were calculated for patient's age, height, and weight. Patients with missing or invalid data for a variable were not included in the calculation of the median and range for that specific characteristic.

b. Product Styles and Sizes

A frequency distribution of device styles utilized in this study is reported by implant. Additionally, separate frequency distributions by device size are presented for each product style.

c. Primary Surgical Treatment Characteristics

Patients were classified into one of ten possible indications for reconstruction surgery based on the Primary Surgery Form:

- Bilateral Implants
 - Bilateral Mastectomy for Cancer
 - Bilateral Prophylactic Mastectomy
 - Unilateral Mastectomy for Cancer & Prophylactic Mastectomy
 - Unilateral Mastectomy for Cancer & Breast Trauma
 - Unilateral Mastectomy for Cancer & Contralateral Augmentation for Asymmetry
- Unilateral Implants
 - Unilateral Mastectomy for Cancer
 - Unilateral Mastectomy for Cancer & Contralateral Flap
 - Unilateral Prophylactic Mastectomy
 - Unilateral Prophylactic Mastectomy & Contralateral Flap
 - Unilateral Contralateral Augmentation for Asymmetry & Tram Flap on Post-Mastectomy Side

If a patient had reconstruction surgery performed in one breast with an augmentation for symmetry performed in the contralateral breast, then the patient is classified as a reconstruction patient and both devices are classified as reconstruction devices. The patient and both her implanted devices were classified as reconstruction because the outcomes in either breast may be affected by systemic treatments such as chemotherapy or radiation treatment that a breast cancer patient may undergo.

The specific type of reconstructive procedure performed is reported as immediate or delayed timing following mastectomy, and as involving placement of a tissue expander prior to implant placement or direct placement of the implant following mastectomy.

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Anesthesia used for the patient's primary implant surgery was reported as general if general anesthesia was marked on the Primary Surgery Form. Notably, patients reported as sedated through general anesthesia also may have been administered a local anesthetic. If general anesthesia was not checked on the form, then the patient was reported as having been administered a local anesthetic, which may include intravenous sedation.

The type of facility where primary implant surgery occurred, the surgical placement of the device in the breast, and whether drains were placed during primary surgery is reported as documented, based on check boxes on the Primary Surgery Form.

The incision site for implant placement is reported as documented on the Primary Surgery Form. Open-ended responses indicating incision site were coded as described previously. If a check-box incision site was indicated (e.g., axillary) and a mastopexy incision also was noted in the open-ended response, the check-box incision site was used as the incision site for implant placement. If more than one incision site was indicated (excluding mastopexy), the incision site is reported as "Other".

The number of implants with concurrent procedures performed during primary implant surgery is reported. Open-ended responses reporting concurrent procedures were coded as described previously. All concurrent procedures performed on implanted sides are reported. The sum of all implants across concurrent procedures may be more than the number of implants with concurrent procedures because some implanted sides had more than one type of concurrent procedure performed.

Separate frequency distributions are presented for the number of implants/patients for which intraoperative medication was delivered via pocket irrigation or parenteral medication. Open-ended responses reporting intraoperative medications were coded as described previously. Solutions such as saline or local anesthetic are not reported. The sum total across medications may be greater than the total number of implants/patients with intraoperative medication due to cases where more than one medication was administered to a patient via the same route of administration.

d. Surgical Complications

The number of patients for whom an intraoperative complication was noted is reported. For patients with an intraoperative complication, the specific nature and type of complication is described. To uniquely identify patients in the table, a sequential number starting with 001 was arbitrarily assigned to all patients with an intraoperative complication.

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).

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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 scheduled 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 or is explanted of all study devices 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 or explant occurred.

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

- 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 periodic reminder faxes and phone calls to the Study Coordinators
- Monthly letters were sent to each Investigator providing their site's current percentage of patients seen for the required 2-year follow-up visit
- Monthly letters were sent to each Investigator with a list of patients overdue for their required follow-up visit and asking the Investigator to personally call these patients to schedule their follow-up visit
- Sample letters were provided to sites to send to patients asking the patient to call to schedule her follow-up appointment and to stress the importance of follow-up visits for the study.
- A Patient and Investigational Site Incentive Program is included as part of the study protocol
- A Patient Follow-Up Study Coordinator Bonus Program for the 2-year follow-up interval was implemented
- A professional search company was used to locate patients when the site was unable to reach patients at previously known addresses due to relocation
- 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

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- Patients who were unable to see an enrolled Investigator during the follow-up interval were able to see another doctor for their required visit (preferably an Investigator participating in a McGhan breast implant study), who would then forward visit notes to the patient's Investigator for completion of the appropriate case report forms

The study sites indicated that non-compliant patients missed their scheduled follow-up visits for a variety of reasons, including: being out of the country, unable to be located, and failure to respond despite repeated contacts made by the site requesting the patient return for a follow-up visit.

The number of patients discontinued through the end of the 2-year visit interval is reported according to one of four primary reasons for discontinuation (see Appendix E for copies of the patient Discontinuation Forms):

- Patient no longer has any McGhan Silicone-Filled Breast Implants
- Patient death
- Patient choice
- Other

Appendix F contains copies of patient Discontinuation Forms for all patients discontinued after the 2-year visit interval.

3. Safety Assessment

a. Unanticipated Adverse Device Effects

Unanticipated Adverse Events (UAE) 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 Complications / Treatment Log 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
- capsule calcification
- capsular contracture
- delayed wound healing
- fluid accumulation
- hematoma
- hypertrophic scarring
- implant extrusion

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- implant malposition
- implant palpability
- implant visibility
- infection
- irritation
- loss of nipple sensation
- loss of skin sensation
- lymphadenopathy
- lymphedema
- nipple hypersensitivity
- nipple paresthesia
- other abnormal scarring
- other nipple related observation
- pneumothorax
- ptosis
- redness
- seroma
- skin hypersensitivity
- skin paresthesia
- skin rash
- swelling
- tissue or skin necrosis
- wrinkling/rippling
- other complications

Analyses performed to describe these complications were:

- Cumulative risk (Kaplan-Meier)
- Prevalence
- Incidence
- Method of resolution
- Duration (time to resolution)

For the implant extrusion 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 submission for saline-filled breast implants (PMA #P990074, approved May 10, 2000). For completeness, a distribution

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of all severity levels for each complication also is provided, including very mild and mild occurrences (for capsular contracture, Baker Grades I and II).

For comparison purposes, the 2-year risk rates observed in this study are discussed relative to the 2-year risk rates observed in the 1995 Saline Reconstruction Clinical Study.

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).

The analysis of method of resolution for each complication was conducted on a by-patient basis. The following resolution hierarchy was used:

- Undergoing treatment
- Treatment not possible
- Refused treatment
- Resolved with treatment
 - Reoperation with explantation
 - Reoperation without explantation
 - Non-surgical treatment
- Resolved without treatment

Although a patient may have undergone multiple treatments for a particular complication, the treatment that actually resulted in resolution of the complication is reported. Additionally, patients may concurrently undergo one type of treatment to resolve one complication and a different type of treatment to resolve a second complication. For example, a patient experiencing both capsular contracture and a skin rash may be explanted due to capsular contracture. The reoperation with explantation resolves the capsular contracture; however, the skin rash is resolved several months later with topical cream, a non-surgical treatment. Patients are categorized as "Resolved with Treatment" via reoperation if the physician marked "Resolved with Treatment" on the Complications/Treatment Log Form and a Secondary Surgery Form was completed for a reoperation occurring 0-30 days prior to the resolution date of the complication for the purpose of treating that type of complication. Further, these patients are divided into one of the two reoperation categories: reoperation with explantation (an Explant Form was completed) and reoperation without explantation. If a patient experienced the same complication on both breasts, then the breast with the worst-case method of resolution (higher in the hierarchy) was used in the analysis.

Duration (time to resolution) of the complication was also analyzed on a by-patient basis. If a patient experienced the same complication on both breasts, then the breast with the longest duration of time to resolution was used for analysis. Time to

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resolution was derived from the difference between the date of resolution and the date of onset for the complication. If the complication was resolved the same day as the day of onset, then time to resolution is reported as 1 day. If the complication was not resolved, then the elapsed treatment time was calculated as the difference between the date of onset and the last date the patient was seen by her physician (i.e., completion of Scheduled Follow-Up Visits Form and/or the Complications/Treatment Log Form).

c. Implant Rupture

Implant rupture was identified from three sources:

- the check-box “suspected rupture” question on the Complications / Treatment Log Form
- evidence of rupture observed by the physician upon reoperation or device explant (Explant Form)
- devices identified as ruptured or indeterminate for rupture via MRI (MRI Results and Central Reviewer Forms), for those patients participating in the serial MRI portion of this study (a separate report detailing the results of patients’ 1st serial MRI is included in this PMA submission)

All devices are categorized according to whether rupture was suspected. If implant rupture was identified, the specific method used to identify the rupture is reported: explant, MRI, reoperation, mammography, ultrasound, or physician exam. If rupture was identified by physician exam, the specific physical symptoms of rupture are presented.

For each suspected rupture, the Investigator determined the appropriate follow-up treatment with the patient (e.g., explantation, additional diagnostic testing, no treatment). Based on the results of this follow-up, all suspected ruptures were classified into one of the following three categories:

- Confirmed rupture via explant
- False report: device intact
 - Explant indicated no rupture
 - Mammography indicated no rupture
 - Ultrasound indicated no rupture
 - MRI indicated no rupture
- Unconfirmed rupture

Ruptures determined to be false reports based upon additional Investigator follow-up are not included in the analyses for implant rupture.

The onset date provided for symptomatic ruptures identified by the physician is used in the analysis. For ruptures identified via reoperation/explant or diagnostic testing (i.e., asymptomatic or silent ruptures), the exact date of occurrence of the rupture is unknown. Thus, the onset time for silent rupture was estimated as halfway back from the date of the patient’s reoperation/explant or diagnostic test to the last date the

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implant was known to be intact (i.e., date of implantation). For example, if a patient had her 1st serial MRI performed after her 2-year follow-up visit (e.g., at 800 days post-implant) where evidence of rupture was noted, then the estimated date of onset of silent rupture would be recorded as 400 days post-implant.

Analyses performed to describe implant rupture were:

- Cumulative risk (Kaplan-Meier)
- Prevalence
- Incidence
- Method of resolution

d. Reoperations

A “reoperation” is defined as a visit during which at least one secondary procedure was performed involving one or more primary study devices. Each patient may have more than one reoperation, and more than one secondary procedure may be performed during each reoperation. Analyses describing reoperations are:

- Cumulative risk (Kaplan-Meier)
- Number of reoperations per patient
- Intraoperative complications during reoperation
- Primary reason for reoperation
- Primary procedure performed
- Number of procedures performed per reoperation
- Types of procedures performed during reoperation

The number of intraoperative complications occurring during reoperation is reported. For reoperations where an intraoperative complication was indicated, a description of the complication is provided in the table. In order to uniquely identify patients in the table, a sequential number starting with 001 was arbitrarily assigned to all patients with an intraoperative complication.

Open-ended responses reporting other reasons for reoperation (i.e., reasons not included in the check boxes on the Secondary Surgery Form and Explant Form) and other procedures performed (i.e., procedures not included in the check boxes on the Secondary Surgery Form) were coded as described previously.

If more than one reason for reoperation was identified, then the primary reason was reported based on the following hierarchy:

- Device Malfunction – Rupture
- Injury – Iatrogenic or Traumatic
- Breast Cancer
- Capsular Contracture
- Infection

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- Healing Related
 - Extrusion
 - Necrosis
 - Hematoma/Seroma
 - Delayed Wound Healing
 - Nipple Complications
- Pain
- Unsatisfactory Cosmetic Result
 - Breast Tissue Contour Deformity
 - Malposition
 - Wrinkling/Rippling
 - Implant Palpability/Visibility
 - Asymmetry
 - Ptosis
 - Scarring
- Patient Request
 - Style/Size Change
 - Media Anxiety
- Need for Biopsy
- Other

This hierarchy was derived using FDA's Guidance Document "*Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Final Guidance for Industry*". The following reasons, which were not included in FDA's guidance document, were added to the hierarchy used in order to be comprehensive of all reasons for reoperation reported: Injury – Iatrogenic or Traumatic, Breast Cancer, Delayed Wound Healing, Nipple Complications, Implant Palpability/Visibility, Ptosis, Breast Tissue Contour Deformity, Need for Biopsy, and Media Anxiety.

At each reoperation, a patient/implant may have more than one procedure performed. If more than one procedure was performed, then the primary procedure for each reoperation was reported based on the following hierarchy:

- Implant Removal
 - With Replacement
 - Without Replacement
- Capsule Procedure
 - Capsulotomy
 - Capsulorrhaphy
 - Capsulectomy
- Flap Procedure
- Pocket Revision
- Reposition Implant
- Surgical Exploration of Breast Area or Implant

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- Mastopexy
- Breast Reduction
- Wound Repair
- Aspiration of Hematoma/Seroma
- Liposuction
- Removal of Excess Tissue/Lesion/Cyst
- Revision of Nipple Reconstruction/Tattoo
- Scar Revision
- Biopsy
- Other

If both a capsule procedure and a reposition implant procedure were performed together during a single reoperation, the capsule procedure is reported only if capsular contracture was specifically stated as a reason for the reoperation; otherwise, only reposition implant is reported, because a capsule procedure was necessary in order to reposition the implant. If both implant removal without replacement and a capsule or flap procedure were performed together during a single reoperation, then only implant removal is reported, because the capsule or flap procedure was necessary to remove the implant. If the only procedure performed was a nipple reconstruction/nipple tattoo, then the procedure/reoperation is not included in the analysis because these nipple-related procedures are considered planned.

e. Implant Replacement/Removal

Kaplan-Meier analysis is conducted on the time to first occurrence of implant replacement/removal both by patient and by implant. Additionally, separate risk analyses are performed on the time to first occurrence of implant removal with replacement and implant removal without replacement.

A frequency distribution of the primary reasons for implant replacement/removal is provided. If more than one reason was indicated for an explanted side, the primary reason for explant was identified based on the primary reason for reoperation hierarchy described in Methods Section D.3.d.

For implants that were replaced, the types of replacement devices inserted after removal of the primary enrolled study device are reported. Each replacement device was classified as follows:

- a McGhan study device
- other McGhan device (non-study)
- non-McGhan device
- unknown replacement device type

The size of the replacement device relative to the primary enrolled study device is presented for those implants replaced with another McGhan study device (where the size of the replacement device was known). Replacement devices were categorized

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according to whether they were larger, smaller, or the same size as the original study device.

Finally, the physician's evaluation of each explanted device is presented for ruptured and non-ruptured (intact) devices. The physician's evaluations of the following four device characteristics are presented: capsule torn (not intact), extracapsular gel, gel on implant surface, and difficulty removing the device.

f. Risk of Any Complication

The risk of any complication is presented in three separate analyses, which group the 34 medical complications, implant rupture, and reasons for reoperation/replacement/removal into three distinct categories based on the type of complication: general breast surgery, breast implant surgery – cosmetic, or breast implant surgery – non-cosmetic.

i. General Breast Surgery Complications

General breast surgery complications were defined as complications, which are related to breast surgery or resulting from surgery in general. The specific events included in the general breast surgery complication category were:

- Breast Pain
- Bruising
- Delayed Wound Healing
- Fluid Accumulation
- Hematoma
- Hypertrophic Scarring
- Infection
- Irritation
- Lymphadenopathy
- Lymphedema
- Loss of Nipple Sensation
- Loss of Skin Sensation
- Nipple Hypersensitivity
- Nipple Paresthesia
- Other Abnormal Scarring
- Other Complication
- Other Nipple Related Observation
- Pneumothorax
- Ptosis
- Redness
- Seroma
- Skin Hypersensitivity
- Skin Paresthesia
- Skin Rash
- Swelling
- Tissue or Skin Necrosis

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- Reoperation/Replacement/Removal for:
 - Breast Cancer
 - Breast Tissue Contour Deformity
 - Delayed Wound Healing
 - Hematoma/Seroma
 - Infection
 - Injury – Iatrogenic or Traumatic
 - Necrosis
 - Need for Biopsy
 - Nipple Complications
 - Other
 - Pain
 - Ptosis
 - Unsatisfactory Scar

ii. Breast Implant Surgery – Cosmetic Complications

Breast implant surgery – cosmetic complications were defined as complications resulting from the breast implant surgery, which are related to the cosmetic appearance of the breast and are not considered medical complications. The specific events included in the breast implant surgery – cosmetic complication category were:

- Asymmetry
- Implant Malposition
- Implant Palpability
- Implant Visibility
- Wrinkling/Rippling
- Reoperation/Replacement/Removal for:
 - Malposition
 - Wrinkling
 - Implant Palpability/Visibility
 - Asymmetry
 - Patient Request (Style/Size Change)

iii. Breast Implant Surgery – Non-Cosmetic Complications

Breast implant surgery – non-cosmetic complications were defined as complications resulting from the breast implant surgery, which are not considered strictly cosmetic in nature. The specific events included in the breast implant surgery – non-cosmetic complication category were:

- Capsule Calcification
- Capsular Contracture
- Implant Extrusion

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- Implant Rupture
- Reoperation/Replacement/Removal for:
 - Capsular Contracture
 - Device Malfunction – Rupture
 - Extrusion
 - Patient Request (Media Anxiety)

4. Medical History

Unlike specific medical complications such as implant extrusion, capsular contracture, and wrinkling/rippling, there is no valid scientific evidence to suggest that breast implants are causally associated with systemic conditions such as breast cancer or connective tissue/autoimmune diseases (Bondurant, 2000). As such, the frequency of occurrence is used to report reproduction and lactation problems, breast cancer and benign breast disease, and connective tissue/autoimmune disease, rather than the cumulative risk used to report medical complications.

a. Reproduction and Lactation Problems

The number of patients who reported reproduction or lactation problems is presented separately for pre-implant and post-implant reports. The total number of reproduction or lactation problems could exceed the number of patients who experienced problems due to the fact that patients could have more than one reproduction or lactation problem. Open-ended responses indicating reproduction or lactation problems were coded as described previously. The number of patients who had both pre- and post-implant reproduction or lactation problems also is provided.

b. Breast Cancer and Benign Breast Disease

The number of patients with a pre-implant and/or post-implant occurrence of breast cancer or benign breast disease is reported. To identify patients with pre-implant breast disease, the Medical and Breast Screening History Form and the Breast Cancer Form were used. To identify patients with post-implant breast disease, the Breast Cancer Form, Complications/Treatment Log Form, and Scheduled Follow-Up Visits Form were examined. Patients with a reported breast disease were classified based on the following hierarchy:

- Confirmed Malignant Disease
- Unconfirmed Malignant Disease
- Benign Disease (including Fibrocystic Disease)
- Unknown Breast Disease

Results of pre-implant and post-implant mammograms (i.e., abnormal vs. normal mammogram results) are reported for all patients. For any abnormal mammogram result, the patient's breast disease status is provided using the same hierarchy described above.

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c. Connective Tissue/Autoimmune Disease

The number of patients who reported a connective tissue/autoimmune disease (CTD) is presented separately for pre-implant reports and post-implant reports. All patient self-reports of a CTD were recorded on the CTD Confirmation Form. For each self-report, the Investigator attempted to obtain confirmation of the patient's self-reported CTD from a diagnosing physician. Based on the results of this follow-up, all patient self-reported CTDs were classified into one of the following 3 categories:

- Confirmed CTD (a diagnosing physician confirmed the CTD self-reported by the patient)
- Unconfirmed CTD (confirmation from a diagnosing physician was not able to be obtained; e.g., the patient did not visit a rheumatologist for further evaluation)
- False Report (a diagnosing physician indicated that the patient does not have the CTD the patient self-reported)

5. Effectiveness Assessment

a. Changes in Anatomical Configuration

Analyses to determine change in anatomical configuration were not performed for reconstruction patients.

b. Satisfaction with Outcome

Frequency distributions of the degree of patient and physician satisfaction regarding the breast implantation are presented for each study visit interval. If more than one assessment is reported by the patient or physician during a visit interval, the worst-case (more dissatisfied) assessment indicated is reported. The total number of patients included in the analysis for any visit interval may be less than the total number of patients seen during that interval (as indicated in the compliance table) due to patients who were seen for a follow-up visit but for whom no assessment of their implants was made during the visit.

A frequency distribution of the specific dissatisfactions expressed by physicians and patients is provided. Some dissatisfaction reasons were specified even though the physician/patient did not indicate being dissatisfied in the forced choice rating scale. Open-ended responses reporting dissatisfaction by patients and physicians were coded as described previously into one of four categories:

- Aesthetic: dissatisfaction related to the aesthetic outcome of the surgery
- Implant Design: any comment regarding the design of the implant (e.g., thicker)
- Medical/Procedural: dissatisfaction related to the medical or procedural outcome of the surgery
- Other

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Additionally, a frequency distribution of the degree of patient satisfaction regarding the breast implantation is presented for each study interval, including patients with both primary and secondary study devices (i.e., those who underwent device removal and replacement with another McGhan study device during the course of the study).

c. Quality of Life

A repeated-measures design, with a pre-surgical baseline measurement and periodic reassessments post-implant, was used to assess the effect of breast implants on different domains of quality of life. Given that no quality of life instruments exist specifically for use with breast implant recipients, patients were asked to answer multiple validated and non-validated scales. The scales are described below.

Quality of life analyses were conducted including patients with both primary and secondary study devices (i.e., those who underwent device removal and replacement during the course of the study).

i. General Health

Portions of two widely used surveys were employed to measure general health: The Medical Outcomes Study (MOS) 20-Item Health Survey (Ware et al., 1993) and the SF-36 Status Survey (Stewart, 1988). Both surveys measure generic quality of life outcomes (i.e., mental health and bodily pain) and were developed from the surveys used in the Medical Outcomes Study, an observational study of variations in physician practice style and patient outcomes in different systems of care (Stewart, 1988; Ware et al., 1993).

Data from the following MOS-20 scales are collected and analyzed in the current study:

- health perceptions
- physical functioning
- role functioning
- social functioning
- mental health

Data from the following SF-36 scales are collected and analyzed in the current study:

- role limitations due to emotional problems
- role limitations due to physical health problems
- general health
- bodily pain
- social functioning
- physical functioning
- vitality

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- mental health
- reported health transition

As data is available for the SF-36 scales from the general U.S. female population, a comparison to the results obtained from this study population was conducted.

ii. Depression Screen

Three depression screening questions were used to assess the presence of chronic depression in the study population (Burnam et al., 1988).

iii. Self-Concept and Self-Esteem

A portion of the Tennessee Self-Concept Scale (TSCS), a widely used and validated instrument (Fitts, 1989), was incorporated into the quality of life assessment for this study. Specifically, the TSCS Physical Self Scale was utilized and contains 18 items that are scored on a 5-point scale ranging from "completely true" to "completely false". This scale reflects the respondent's view of her body and state of health, as well as her attitude about appearance, skills, and sexuality.

Since self-concept was relatively broad, the Rosenberg Scale, which focuses specifically on self-esteem, was included in the quality of life questionnaire in an attempt to increase sensitivity to detecting the quality of life outcomes that result from breast implantation. The Rosenberg Scale is a 10-item scale that measures the respondent's feelings concerning self-worth and self-acceptance.

Respondents were asked to what extent they agreed or disagreed with each of ten statements concerning self-esteem. The four possible responses range from "strongly disagree" to "strongly agree". The Rosenberg Scale has been widely used and is frequently the standard by which developers of other self-esteem measures seek convergence (Rosenberg, 1965).

iv. Body Image

The Body Esteem Scale is used to measure one's degree of satisfaction or dissatisfaction with the various parts or processes of the body (Franzoi et al., 1984). The Body Esteem Scale contains 32 items that are scored on a 5-point scale ranging from 1 (have strong negative feelings) to 5 (have strong positive feelings). The subscales within this measure (for females) are sexual attractiveness, weight concern, and physical condition.

In addition, based on the Semantic Differential Test (Osgood, 1952), measures of body image specific to "my breasts" and to "myself" were included in this quality of life instrument. The Semantic Differential Test consists of pairs of bipolar terms divided by a continuum. The respondent is asked to check the point on each continuum that best reflects his/her feelings. Originated in 1952, the Semantic Differential Test attempts to measure the way a respondent feels by

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relating feelings to certain words representative of the positive or negative (Osgood, 1952). In this study, the Semantic Differential Test was used to determine whether breast reconstruction surgery promotes congruence between body-part and overall self-image.

v. Motivations

Included in the baseline quality of life questionnaire was a listing of possible motivations for implant surgery. Patients were asked to rate their motivations for undergoing breast reconstruction according to importance.

vi. Expectation and Satisfaction

Several measures were included to assess patients' pre-implant expectation and post-implant satisfaction with their breast implants. First patients were asked at baseline how satisfied they expected to be with their breast implants. At follow-up, a parallel question was asked to measure patients' actual satisfaction with their implants. Possible responses to these questions range from "very dissatisfied" to "very satisfied".

Second, a 16-item scale developed to measure expectation and perceived results of breast implant surgery among reconstruction patients was used (Rowland, 1984). Thirteen (13) of the items were relevant for all types of breast implant patients and assess general quality of life outcomes (e.g., made me feel more attractive, made me feel more self-confident), whereas 3 of the items are relevant only for reconstruction patients and assess outcomes specific to breast reconstruction surgery (e.g., helped me feel less conscious of having had breast cancer, helped me hide the mastectomy better). The reconstruction patients answered all 16 items, which comprise the following 4 scales:

- Improve Self Image
- Improve Social Relations
- Improve Daily Living
- Improve Well-Being

Finally, several other satisfaction questions were included in the quality of life instrument that pertain to the patient's satisfaction with her personal life and breasts. The questions that ask specifically about satisfaction with different aspects of the breast (e.g., shape, size, and feel of breasts) were included in order to provide insight on how successful the surgery was, based on the patient's perspective and independent of her expectations.

vii. Worry

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Two questions were included to elicit information concerning the amount of worry a patient has concerning her implants. These questions were asked of the patient only at post-implant.

viii. Pain and Problems with Work/Activities

One question was included to measure the amount of bodily pain a patient attributes to her implants. This question was asked only post-implant with response choices ranging from "not at all" to "extremely".

One question was included to record, in the past 4 weeks, to what extent the patient had problems in performing her work or activities due to her implants.

ix. Scoring and Analysis

Each quality of life scale was scored independently with only the items that were included in that scale.

Change in quality of life scores pre- vs. post-implant was examined to provide information regarding the effect of breast reconstruction with McGhan Silicone-Filled Breast Implants on patients' quality of life. Repeated-measures analyses were employed to measure change.

Two different types of repeated-measures analyses were conducted:

- For scales involving interval-level data where means were computed, a repeated-measures ANOVA was conducted. If the overall repeated-measures analysis was significant, post-hoc comparisons using Tukey's multiple comparison technique were conducted to determine which specific means differed. The Type III partial sum of squares p-value was reported.
- For items with a dichotomous response (e.g., YES/NO), a Cochran-Mantel-Haenszel General Association Statistic was computed with Scheffé's correction for multiple comparisons.

A patient was included in a particular repeated-measures analysis if a score was provided at all relevant time points. If a patient was missing an observation at any of the time points used in the analysis, then she was omitted from the analysis because repeated-measures analysis with missing data is not recommended (Walker, 1997). Also, if more than 50% of items in a scale are missing, then the scale score is not calculated and left missing.

As indicated in FDA's Guidance Document "*Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Final Guidance for Industry*", it is important to adjust the Type I error rate when multiple hypothesis tests are conducted. For the quality of life analyses, the Type I error rate was adjusted using a Bonferroni

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correction (Godfrey, 1992). Specifically, for measures that contained multiple subscales (e.g., SF-36) the overall probability of committing a Type I error for the instrument was set at 0.05, with the alpha divided equally for each subscale tested. That is, the individual alpha level for each subscale was equal to 0.05 divided by the total number of subscales (i.e., the number of tests performed). If the measure also had an overall scale score that was analyzed, then the alpha was set at 0.05 for the overall test but the alpha was adjusted for the multiple subscales tested.

When significant results were obtained, effect sizes were calculated to identify clinically meaningful changes in quality of life scores. The effect size was calculated by dividing the difference between the pre-implant mean and the 1-year post-implant mean by the pre-implant standard deviation (Kazis et al., 1989). Small effect sizes (i.e., < 0.20) indicate little, if any, clinically meaningful change in health-related quality of life. Cohen (1988) describes a moderate effect size as 0.50 and a large effect size as 0.80.

Finally, an independent samples t-test was conducted to compare baseline quality of life scores with similar scale scores obtained from the general U.S. female population for the SF-36 scales.

6. Risk Factor Analysis

As suggested in FDA's Guidance Document "*Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Final Guidance for Industry*" an analysis was conducted to examine whether specific patient, device, and surgical characteristics are risk factors associated with clinical outcomes. The following five critical clinical outcomes were examined:

- reoperation
- implant replacement/removal
- implant rupture
- capsular contracture
- infection

The following 7 patient, device, and surgical characteristics, suggested in FDA's Guidance Document, were selected as potential risk factors:

- patient age (≤ 40 vs. > 40) (Table 1)
- pocket irrigation-antibiotic (yes vs. no) (Table 16)
- pocket irrigation-betadine (yes vs. no) (Table 16)
- implant placement (submuscular vs. other) (Table 13)
- incision site (periareolar vs. inframammary vs. axillary vs. other) (Table 12)
- device texture (smooth vs. textured) (Table 4)
- device shape (round vs. shaped) (Table 4)

A Cox proportional hazards regression analysis was performed by implant for each of the five outcome variables to identify any significant risk factors. Both univariate and

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Multivariable techniques were used. First, univariate models were fit for each potential risk factor. The potential risk factors that resulted in a significance of $p < .25$ from the univariate models were then entered into a multivariate model (Hosmer et al., 2000). The multivariate model was derived using the backward elimination model building technique with $p < .01$ for stay criteria. The significance level of 0.05 was adjusted to 0.01 for each of the 5 multivariate models using a Bonferroni correction (Godfrey, 1992), with the alpha divided equally for each of the 5 outcomes.

For each clinical outcome, the characteristics that were found to be statistically significant risk factors in the multivariate model are reported. For each outcome, two tables are used to present the risk factor analysis results. The first table presents the frequency of the outcome for each level of the risk factors that were significant (e.g., 18.9% of round devices underwent implant replacement/removal vs. 9.0% of shaped devices). The second table presents the unadjusted risk ratio for each risk factor as well as the adjusted risk ratio and associated 95% confidence interval. The unadjusted risk ratio is calculated as the ratio of the percentage of devices with the outcome for the two levels of the characteristic. The adjusted risk ratio is from the multivariate model and adjusts for the other significant factors in the model.

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RESULTS

A. PATIENT ENROLLMENT AND SURGICAL TREATMENT

1. Demographic Characteristics

Tables 1 – 3

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

As reported in Table 1, the median patient age was 50 years, with a range from 26 to 82 years. Most patients were Caucasian (87.8%); one patient indicated more than one race, yielding a total percentage greater than 100%. Nearly three quarters (74.7%) of patients were married.

Table 2 reports occupation and education data for the reconstruction patients. Half of the patients (50.7%) were employed in professional jobs. The vast majority of patients (77.4%) had at least some college education.

As reported in Table 3, patients' median height was 5'5", with a range of 4'9" to 6'2", and their median weight was 138 pounds, with a range of 91 to 240 pounds.

The demographic profile obtained for the reconstruction patients enrolled in this Core Clinical Study is comparable to the demographic characteristics of the reconstruction patients enrolled in Inamed's 1995 Saline Reconstruction Clinical Study (R95). In the R95 Saline Study, patients' median age was 47 years, 94.1% were Caucasian, 76.4% were married, 42.2% were employed in professional jobs, 67.1% had at least some college education, patients' median height was 5'4", and patients' median weight was 140 lbs.

2. Product Styles and Sizes

Tables 4 – 9

Table 4 presents a distribution of the device styles used for the reconstruction patients in this study. Three hundred and sixty-one (361) primary study devices were implanted in the 221 reconstruction patients. Textured devices were more commonly used (86.7%) than were smooth devices (13.3%), and shaped devices were used more often (64.8%) than were round devices (35.2%).

Tables 5-9 present a distribution of the device sizes implanted for each product style.

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3. Surgical Treatment Characteristics

Tables 10 – 17

Table 10A presents a distribution of the indications for breast reconstruction surgery. Nearly two thirds (63.3%) of patients had bilateral implants placed, with the remaining patients (36.7%) having an implant placed only on one side. The vast majority of the patient reconstruction surgeries (87.3%) involved a tissue expander, and two thirds of patients (71.5%) underwent immediate reconstruction following mastectomy (Table 10B).

Tables 11-17 describe the characteristics of patients' primary implant surgery.

Most patients were administered a general anesthetic (99.1%), with the remaining patients anesthetized solely using a local anesthetic (0.9%), (Table 11).

More than two thirds of patient reconstruction surgeries (69.2%) were performed in a hospital and the remaining surgeries (30.8%) were performed at a free standing surgical facility (Table 11).

The most common incision site for implant placement was the mastectomy scar (76.5%), (Table 12).

The majority of devices were placed submuscularly (88.6%), (Table 13).

Nearly two thirds of devices (62.3%) were inserted with the use of drains (Table 14).

Concurrent breast procedures were performed for 253 (70.1%) of the 361 device surgeries (Table 15). A total of 432 concurrent procedures were performed during the 253 device surgeries, most commonly partial capsulectomy procedures (39.5%), nipple areolar complex procedures (36.8%), and mastectomies (22.5%). The sum across concurrent procedures is greater than 100% because some device surgeries involved more than one concurrent procedure.

The majority of the 361 device surgeries (86.4%) involved administration of some type of medication through pocket irrigation (Table 16). The medications used most frequently during device surgeries were antibiotics (70.5%) and betadine (62.2%). The sum across intraoperative medications administered through pocket irrigation is greater than 100% because some implant surgeries involved administration of more than one type of medication via this route.

The vast majority of the 221 patients (95.0%) were administered parenteral medication, most commonly antibiotics (99.5%), (Table 17). The sum across medications was greater than 100% because some patients were administered more than one type of medication by this route.

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4. Surgical Complications

Table 18

An intraoperative complication occurred during 1 of the 361 primary implant surgeries (Table 18). Specifically, the doctor reported the intraoperative complication as: "reopened to verify hemostasis [sic] – no hematoma".

B. PATIENT COMPLIANCE AND DISCONTINUATION

All of the 221 enrolled patients (100.0%) were evaluated during at least one post-operative follow-up visit through 2 years.

Accounting for those patients who were discontinued due to death or explant of all study devices, compliance was 93.5% at the 1-year follow-up visit and 94.6% at the 2-year follow-up visit (Table 19).

Based on data obtained through 2 years, 21 of the 221 reconstruction patients (9.5%) were discontinued from the study (Table 20). Of these 21 discontinuations, 6 were due to death, 12 were due to removal of all study devices, 1 was due to patient choice to discontinue from the study, and 2 were due to other reasons (i.e., conflict between patient and physician). Five (5) of the 6 patient deaths were the result of cancer and one patient died in a car accident.

C. SAFETY ASSESSMENT

1. Unanticipated Adverse Events

No Unanticipated Adverse Event Forms have been received for reconstruction patients. There have been no Unanticipated Adverse Events (UAEs) associated with McGhan Silicone-Filled Breast Implants for any reconstruction patients.

2. Medical Complications

Tables 21 – 157

Tables 21-156 present the following results for each of the medical complications assessed in this study:

- Kaplan-Meier risk analysis
- Prevalence and incidence analysis
- Duration of complication
- Method of resolution

For example, analyses are presented for asymmetry in Tables 21-24. Table 21 shows the risk of first occurrence of asymmetry using Kaplan-Meier analysis. Table 22 reports the incidence and prevalence of asymmetry during each study interval. Table 23 presents the time to resolution of asymmetry. Table 24 shows the distribution of resolution status for asymmetry.

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The following table summarizes the 2-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 2-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	(Table #)	2-Year Risk By Patient % (95% CI)	2-Year Risk By Implant % (95% CI)
Capsular Contracture	(37)	13.5% (8.8%, 18.1%)	9.2% (6.1%, 12.3%)
Asymmetry	(21)	11.9% (7.5%, 16.3%)	N/A
Implant Malposition	(61)	5.8% (2.6%, 8.9%)	4.7% (2.5%, 7.0%)
Other Nipple Related Observation	(109)	4.4% (1.6%, 7.3%)	3.9% (1.8%, 6.0%)
Tissue or Skin Necrosis	(145)	3.8% (1.2%, 6.5%)	2.7% (0.9%, 4.4%)
Swelling	(141)	3.7% (1.2%, 6.2%)	2.8% (1.1%, 4.5%)
Breast Pain	(25)	3.3% (0.9%, 5.7%)	2.6% (0.9%, 4.3%)
Wrinkling/Rippling	(149)	2.9% (0.6%, 5.2%)	2.4% (0.8%, 4.0%)
Hypertrophic Scarring	(53)	2.4% (0.3%, 4.5%)	1.8% (0.4%, 3.2%)
Infection	(73)	2.3% (0.3%, 4.3%)	1.7% (0.4%, 3.1%)
Other Complications	(153)	2.3% (0.3%, 4.4%)	1.4% (0.2%, 2.7%)
Delayed Wound Healing	(41)	2.3% (0.3%, 4.3%)	1.4% (0.2%, 2.7%)
Seroma	(125)	1.8% (0.1%, 3.6%)	1.1% (0.0%, 2.2%)
Bruising	(29)	1.4% (0.0%, 2.9%)	1.1% (0.0%, 2.2%)
Skin Rash	(137)	1.4% (0.0%, 2.9%)	1.1% (0.0%, 2.2%)
Other Abnormal Scarring	(105)	1.0% (0.0%, 2.4%)	0.6% (0.0%, 1.5%)
Ptoxis	(117)	1.0% (0.0%, 2.3%)	0.6% (0.0%, 1.4%)
Redness	(121)	1.0% (0.0%, 2.3%)	0.6% (0.0%, 1.4%)
Pneumothorax	(113)	0.5% (0.0%, 1.5%)	0.3% (0.0%, 0.9%)
Implant Extrusion	(57)	0.5% (0.0%, 1.4%)	0.3% (0.0%, 0.8%)
Hematoma	(49)	0.4% (0.0%, 1.3%)	0.3% (0.0%, 0.8%)
Implant Palpability	(65)	0.4% (0.0%, 1.3%)	0.3% (0.0%, 0.8%)
Implant Visibility	(69)	0.4% (0.0%, 1.3%)	0.3% (0.0%, 0.8%)
Capsule Calcification	(33)	0.0% —	0.0% —
Fluid Accumulation	(45)	0.0% —	0.0% —
Irritation	(77)	0.0% —	0.0% —
Loss of Nipple Sensation	(81)	0.0% —	0.0% —
Loss of Skin Sensation	(85)	0.0% —	0.0% —
Lymphadenopathy	(89)	0.0% —	0.0% —
Lymphedema	(93)	0.0% —	0.0% —
Nipple Hypersensitivity	(97)	0.0% —	0.0% —
Nipple Paresthesia	(101)	0.0% —	0.0% —
Skin Hypersensitivity	(129)	0.0% —	0.0% —
Skin Paresthesia	(133)	0.0% —	0.0% —

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Among the complications observed for reconstruction patients, the highest 2-year cumulative risk rates by patient were for capsular contracture (13.5%), asymmetry (11.9%), and implant malposition (5.8%). All other complications occurred at a by-patient risk rate of less than 5.0%.

The highest incidence rate across all complications was for capsular contracture at 6 months post-implant (4.1%) and for asymmetry at 0-4 weeks and 6 months post-implant (4.1%). The highest prevalence rate across all complications was for capsular contracture at 2 years post-implant (8.8%).

Median time to resolution among patients whose complications were resolved ranged from 1 day (implant extrusion) to 546 days (hypertrophic scarring). Among patients without resolution, median elapsed treatment time ranged from 383 days (implant malposition and asymmetry) to 770 days (tissue or skin necrosis). Inamed has contacted sites for patients who had unresolved complications with an elapsed time greater than one year in order to inquire about the status of follow-up on the complication.

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The following table summarizes the resolution status for each complication during the 2-year period of this report. Overall, more than two thirds (70.1%) of complications were resolved.

Complication	(Table #)	Resolution Status		
		Unresolved	Resolved	% Resolved
Asymmetry	(24)	9	16	64.0%
Breast Pain	(28)	1	6	85.7%
Bruising	(32)	0	3	100.0%
Capsule Calcification	(36)	0	0	N/A
Capsular Contracture	(40)	12	16	57.1%
Delayed Wound Healing	(44)	0	5	100.0%
Fluid Accumulation	(48)	0	0	N/A
Hematoma	(52)	0	1	100.0%
Hypertrophic Scarring	(56)	4	1	20.0%
Implant Extrusion	(60)	0	1	100.0%
Implant Malposition	(64)	3	9	75.0%
Implant Palpability	(68)	0	1	100.0%
Implant Visibility	(72)	0	1	100.0%
Infection	(76)	0	5	100.0%
Irritation	(80)	0	0	N/A
Loss of Nipple Sensation	(84)	0	0	N/A
Loss of Skin Sensation	(88)	0	0	N/A
Lymphadenopathy	(92)	0	0	N/A
Lymphedema	(96)	0	0	N/A
Nipple Hypersensitivity	(100)	0	0	N/A
Nipple Paresthesia	(104)	0	0	N/A
Other Abnormal Scarring	(108)	2	0	0.0%
Other Nipple Related Observation	(112)	5	4	44.4%
Pneumothorax	(116)	0	1	100.0%
Ptosis	(120)	1	1	50.0%
Redness	(124)	0	2	100.0%
Seroma	(128)	0	4	100.0%
Skin Hypersensitivity	(132)	0	0	N/A
Skin Paresthesia	(136)	0	0	N/A
Skin Rash	(140)	0	3	100.0%
Swelling	(144)	0	8	100.0%
Tissue or Skin Necrosis	(148)	1	7	87.5%
Wrinkling/Rippling	(152)	4	2	33.3%
Other Complications	(156)	1	4	80.0%
Total (N=144)		43	101	70.1%

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The following table summarizes the method of resolution for each complication that was resolved. Approximately one fourth (23.8%) of resolved complications were resolved without any type of treatment, and nearly half (44.6%) of resolved complications were resolved with non-surgical treatment.

Complication	(Table #)	Method of Resolution			
		Reoperation and Explantation	Reoperation without Explantation	Non-Surgical Treatment	Without Treatment
Asymmetry	(24)	9	0	5	2
Breast Pain	(28)	1	0	3	2
Bruising	(32)	0	0	0	3
Capsule Calcification	(36)	N/A	N/A	N/A	N/A
Capsular Contracture	(40)	6	1	6	3
Delayed Wound Healing	(44)	0	3	2	0
Fluid Accumulation	(48)	N/A	N/A	N/A	N/A
Hematoma	(52)	0	1	0	0
Hypertrophic Scarring	(56)	0	0	1	0
Implant Extrusion	(60)	1	0	0	0
Implant Malposition	(64)	3	4	2	0
Implant Palpability	(68)	0	0	1	0
Implant Visibility	(72)	0	0	1	0
Infection	(76)	0	0	3	2
Irritation	(80)	N/A	N/A	N/A	N/A
Loss of Nipple Sensation	(84)	N/A	N/A	N/A	N/A
Loss of Skin Sensation	(88)	N/A	N/A	N/A	N/A
Lymphadenopathy	(92)	N/A	N/A	N/A	N/A
Lymphedema	(96)	N/A	N/A	N/A	N/A
Nipple Hypersensitivity	(100)	N/A	N/A	N/A	N/A
Nipple Paresthesia	(104)	N/A	N/A	N/A	N/A
Other Abnormal Scarring	(108)	0	0	0	0
Other Nipple Related Observation	(112)	0	0	4	0
Pneumothorax	(116)	0	0	1	0
Ptosis	(120)	1	0	0	0
Redness	(124)	0	0	2	0
Seroma	(128)	0	1	0	3
Skin Hypersensitivity	(132)	N/A	N/A	N/A	N/A
Skin Paresthesia	(136)	N/A	N/A	N/A	N/A
Skin Rash	(140)	0	0	2	1
Swelling	(144)	0	0	2	6
Tissue or Skin Necrosis	(148)	0	0	6	1
Wrinkling/Rippling	(152)	1	0	1	0
Other Complications	(156)	0	0	3	1
Total (N=101)		22	10	45	24

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For historical comparison purposes, Appendix G summarizes the 2-year risk rates for reconstruction patients from this Core Clinical Study and for reconstruction patients from the 1995 Saline Reconstruction Clinical Study (R95).

Table 157 summarizes the worst case severity level reported for each complication by patient. On a 1 (very mild) to 5 (very severe) severity scale, the highest average severity levels are associated with implant extrusion ($M = 5.0$, $n = 1$), implant palpability ($M = 5.0$, $n = 1$), implant visibility ($M = 5.0$, $n = 1$), and pneumothorax ($M = 5.0$, $n = 1$). The lowest average severity levels are associated with lymphadenopathy ($M = 1.0$, $n = 1$) and bruising ($M = 1.9$, $n = 9$).

3. Implant Rupture

Tables 158 – 162

Tables 158-162 present the results pertaining to implant rupture. A total of 11 of the 361 primary implants (3.0%) showed evidence of rupture: 9 devices were suspected of rupture via MRI and 2 devices were suspected of rupture via ultrasound (Table 158). Of the 11 suspected implant ruptures, 2 were confirmed to be ruptured on explant, 1 was a false report of rupture whereby the device was found to be intact upon explant, and 8 devices have unconfirmed rupture status (Table 159).

Based on confirmed and unconfirmed ruptures, the 2-year risk of implant rupture was 4.8% by patient and 3.3% by implant (Table 160). The 2-year incidence of implant rupture was 4.7%, and the 2-year prevalence of implant rupture was 4.7% by patient (Table 161). Of the 9 implant ruptures by patient through 2 years post-implant, 7 are as yet unresolved (Table 162).

4. Reoperations

Tables 163 – 170

Tables 163-170 present results pertaining to reoperations performed through 2 years.

The 2-year risk of reoperation for any reason was 36.9% by patient and 30.1% by implant (Table 163).

A total of 104 reoperations were performed on 80 patients (36.2% of 221 enrolled reconstruction patients) through 2 years post-implant (Table 164). Most of the 80 patients (77.5%) had only one reoperation; 13 patients (16.3%) had two reoperations and 5 patients (6.3%) had three or more reoperations.

No intraoperative complications were reported for any of the 104 reoperations (Table 165).

Among the 104 reoperations, the primary reasons for reoperation were malposition (20.2%), scarring (17.3%), and capsular contracture (12.5%), (Table 166). The primary

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performed during reoperation was most commonly implant removal with replacement (30.8%), scar revision (14.4%), or capsulotomy (12.5%), (Table 167). In sum, the most frequently performed reoperations were implant replacement/removal due to unsatisfactory cosmetic result (19.2%), scar revision due to unsatisfactory cosmetic result (14.4%), and implant replacement/removal due to capsular contracture (8.7%), (Table 168).

During the 104 reoperations, a total of 202 individual surgical procedures were performed (Table 169). The majority of reoperations (78.8%) involved only one or two surgical procedures (e.g., bilateral implant replacement/removal is counted as 2 procedures). Of the 202 procedures performed, the most common procedures were implant removal with replacement (19.3%), scar revision (15.3%), and capsulotomy (13.9%), (Table 170).

5. Implant Replacement/Removal

Tables 171 – 177

Tables 171-177 describe the occurrence of implant replacement/removal. The 2-year risk of implant replacement/removal (i.e., device explant with or without replacement) was 17.2% by patient and 12.8% by implant (Table 171). The 2-year risk of implant removal with replacement was 15.0% by patient and 11.2% by implant (Table 172), and the 2-year risk of implant removal without replacement was 2.4% by patient and 1.8% by implant (Table 173).

Of the 45 primary explanted devices, the most common reasons for replacement/removal were capsular contracture (26.7%), asymmetry (24.4%), and malposition (17.8%), (Table 174).

Of the 45 explanted devices, all of which were intact upon explant, none had gel on the implant surface, extracapsular gel, or were difficult to remove (Table 175). Physicians indicated that 2 of the implants had a torn capsule.

A total of 39 of the 45 explanted devices were replaced (86.7%), (Table 176). Of the devices replaced, most (89.7%) were replaced with another McGhan study device. Of the 35 implants replaced with McGhan study devices, more than half (57.1%) were replaced with a smaller size and more than one third (34.3%) were replaced with a larger size (Table 177).

A summary of the medical complications listed in Methods Section D.3.b that occurred following removal and replacement of a primary study device are listed in Appendix H. Patients' assessment of their implants following replacement of all primary study devices also is presented in Appendix H.

6. Risk of Any Complication

Tables 178 – 180

Tables 178-180 present the risk of specific groupings of complications through 2 years post-implant. The 2-year by-patient risk of any general breast surgery complication is

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35.7% (Table 178). The 2-year by-patient risk of any breast implant surgery – cosmetic complication is 25.1% (Table 179). The 2-year by-patient risk of any breast implant surgery – non-cosmetic complication is 8.8% (Table 180). It is important to note that these risks are not additive because a patient may experience more than one type of complication and would be included in the risk for each type of complication.

D. PRE- VS. POST- IMPLANT MEDICAL HISTORY

1. Reproduction and Lactation Problems

Tables 181 – 184

Tables 181 and 182 report pre- and post-implant reproduction problems. Fifty-one (51) of the 221 reconstruction patients (23.1%) experienced pre-implant reproduction problems, most frequently spontaneous abortion/miscarriage (Table 181). Through 2 years post-implant, 2 patients (0.9%) had a total of 2 reproduction problems: 1 planned abortion to treat a medical problem and 1 other reproduction problem (no menses), (Table 182). One of the 2 patients who reported a post-implant reproduction problem also reported a pre-implant reproduction problem. This patient had a spontaneous abortion (miscarriage) prior to implant surgery and no menses post-implant.

Tables 183 and 184 report pre- and post-implant lactation problems. Twenty-six (26) of the 221 reconstruction patients (11.8%) experienced pre-implant lactation problems, most frequently inadequate milk production and mastitis requiring treatment (Table 183). Through 2 years post-implant, no patients reported lactation problems (Table 184).

2. Breast Cancer and Benign Breast Disease

Table 185 – 188

Tables 185 and 186 report pre- and post-implant occurrences of breast disease. Two hundred and seventeen (217) of the 221 reconstruction patients (98.2%) reported pre-implant breast disease, of which 207 were malignant disease and 10 were benign breast disease (Table 185). Through 2 years post-implant, 13 patients (5.9%) had an occurrence of breast disease: 4 with confirmed malignant disease and 9 with benign disease (Table 186). All four patients with post-implant malignant disease had confirmed malignant disease pre-implant.

Tables 187 and 188 report the results of pre- and post-implant mammograms. One hundred and thirty-seven (137) of the 221 reconstruction patients (62.0%) had a pre-implant abnormal mammogram result (Table 187). Of these 137 abnormal results, 131 indicated confirmed malignant disease and 6 indicated benign breast disease. Through 2 years post-implant, 105 patients had a mammogram, of which 10 showed an abnormal result (Table 188). Of the patients with abnormal mammogram results, 2 had no breast disease, 2 had confirmed malignant disease, and 6 had benign breast disease.

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3. Connective Tissue/Autoimmune Disease

Table 189 – 190

Tables 189 and 190 report pre- and post-implant occurrences of connective tissue/autoimmune disease (CTD). None of the reconstruction patients reported a CTD pre-implant (Table 189).

Through 2 years post-implant, one (1) patient reported a connective tissue/autoimmune disease (Table 190). Specifically, this 42-year-old patient had a confirmed report of systemic sclerosis/scleroderma with an onset date of 4 months after her primary implant surgery.

E. EFFECTIVENESS ASSESSMENT

1. Changes in Anatomical Configuration

Tables 191 – 194

Change in anatomical configuration was not assessed for reconstruction patients. Tables 191-194 were included and intentionally left blank to correspond with the table numbers in the Core Clinical Study - Augmentation Cohort Report.

2. Satisfaction with Outcome

Tables 195 – 201

Tables 195-197 report physician satisfaction with the implant surgery based on primary study devices. More than 95% of physicians indicated being satisfied with the results of breast implant surgery at each of the four follow-up visit intervals (Table 195). Indeed, on a 1 (definitely dissatisfied) to 5 (definitely satisfied) scale, the average satisfaction level for physicians was between 4.6 and 4.8 at each follow-up interval. Few physicians specified any type of dissatisfaction about the implant surgery at any of the follow-up intervals (Table 196). Of those physicians who did specify a dissatisfaction about the outcome of the patient's surgery, about one third (37.5%) were aesthetic dissatisfactions and two thirds (62.5%) were medical/procedural dissatisfactions at 0-4 weeks post-implant (Table 201). By 2 years post-implant, most physician dissatisfactions specified (90.0%) were medical/procedural in nature.

Tables 198-200 report patient satisfaction with the implant surgery based on primary study devices. Between 93-98% of patients indicated being satisfied with the results of breast implant surgery at each of the four follow-up visit intervals (Table 198). On a 1 (definitely dissatisfied) to 5 (definitely satisfied) scale, the average satisfaction level for patients was between 4.5 and 4.8 at each follow-up interval. Few patients specified any type of dissatisfaction about their implant surgery at any of the follow-up intervals (Table 199). Of those patients who did specify a dissatisfaction about the outcome of their breast implant surgery, approximately half were aesthetic dissatisfactions at each follow-up interval after 0-4 weeks (Table 200).

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Table 201 reports patient satisfaction with the implant surgery based on both primary and secondary study devices. Approximately 93-97% of patients indicated they were satisfied with the results of their breast implant surgery at each follow-up visit interval, with the average patient satisfaction level between 4.5 and 4.8 at each follow-up visit interval.

3. Quality of Life

The quality of life results reported are based on all reconstruction patients with McGhan Silicone-Filled Breast Implants, including both primary and secondary study devices.

a. Motivation for Surgery

Table 202

Table 202 reports on patients' motivation for surgery. More than two thirds (72.8%) of the reconstruction patients rated "to make me feel better about my physical appearance" as "quite a bit" or "extremely" important to them as a reason for having breast implant surgery. In contrast, most patients (85.6%) rated "to increase my chance of meeting a partner" as "not at all" important to them as a reason for their implant surgery.

b. Expectation and Satisfaction with Implants

Tables 203 – 209

Tables 203-204 present patients' pre-operative expectation vs. post-implant satisfaction with their breast implants. Patients were highly satisfied with their breast implants, with a satisfaction score of 4.3 and 4.2 on a 5-point scale at 1 and 2 years post-implant, respectively (Table 203). Statistically, patients' post-operative satisfaction was lower ($M = 4.2/4.3$) than their pre-operative expectation ($M = 4.6$), ($p < .001$). However, at least 85.0% of reconstruction patients indicated being "satisfied" or "very satisfied" with their breast implants post-operatively (86.7% at 1 year post-implant and 85.0% at 2 years post-implant), (Table 204).

Tables 205-209 present summary results from the scales that measured expectation and perceived results of implant surgery (i.e., Rowland). The results obtained from the Rowland expectation instrument are summarized in Table 205 and the details are provided in separate tables for the subscales of improve self image (Table 206), improve social relations (Table 207), improve daily living (Table 208), and improve well-being (Table 209). Improve social relations showed a statistically significant increase (Table 206) whereas improve daily living showed a significant decrease (Table 208) after implant surgery.

c. Comparison of Baseline SF-36 Scores to the General U.S. Female Population

Table 210

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At baseline, reconstruction patients scored significantly higher ($p < .001$) than did the general U.S. female population on 5 of the 8 SF-36 scales for which comparative values are available (general health, social functioning, physical functioning, vitality, and mental health), (Table 210). The largest difference (11.4%) was seen in the scale that measures vitality.

d. General Health

Tables 211 – 226

Tables 211-226 present summary results from the concepts that measured general health/well being (i.e., MOS-20 and SF-36 surveys). The results obtained from the SF-36 survey are summarized in Table 211 and the details are provided in separate tables for the subscales of role limitations due to emotional problems (Table 212), role limitations due to physical health problems (Table 213), general health (Table 214), bodily pain (Table 215), social functioning (Table 216), physical functioning (Table 217), vitality (Table 218), mental health (Table 219), and reported health transition (Table 220). The results obtained from the MOS-20 survey are summarized in Table 221 and the details are provided in separate tables for the subscales of health perceptions (Table 222), physical functioning (Table 223), role functioning (Table 224), social functioning (Table 225), and mental health (Table 226).

The results for most of the scales did not show statistically significant differences pre- vs. post-implant, with the exception of a significant increase for role limitations due to physical health problems (SF-36) post-implant, a significant decrease for reported health transition (SF-36) at 1-year post-implant but no difference between pre-implant and 2-year post-implant scores, and a significant increase for physical functioning (MOS-20) post-implant.

e. Depression Screen

Table 227

No significant change in depression status was seen pre- vs. post-implant (Table 227).

f. Self-Concept and Self-Esteem

Table 228 – 229

Results on the Tennessee Self-Concept Physical Self Scale revealed no significant difference pre- vs. post-implant in the way patients view their bodies and state of health, and their attitude about appearance, skills, and sexuality (Table 228).

Results on the Rosenberg Self-Esteem Scale also revealed no significant difference pre- vs. post-implant in patients' self-esteem (Table 229).

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g. Body Image

Table 230 – 235

Results on the Self vs. Breast Semantic Differential Scale revealed no significant difference in how patients rated themselves relative to their breasts pre- vs. post-implant (Table 230).

Table 231 presents summary results for the Body Esteem Scale and each subscale. None of the scales showed significant differences pre- vs. post-implant.

h. Satisfaction.

Tables 236 – 248

Table 236 presents summary results for the quality of life measurement of patient satisfaction. Only the personal life satisfaction scale did not show a significant change pre- vs. post-implant (Tables 237 and 238). All other satisfaction scales showed a significant positive increase pre- vs. post-implant ($p < .001$). Patient satisfaction with her breasts increased significantly from pre-implant ($M = 2.8$) to post-implant ($M = 4.0/4.1$), on a 1 (very dissatisfied) to 5 (very satisfied) scale (Tables 239 and 240). Patient ratings of how well her breasts matched increased significantly from pre-implant ($M = 2.8$) to post-implant ($M = 4.4/4.6$), on a 1 (very poor) to 6 (excellent) scale (Tables 241 and 242). Patient satisfaction with her breast shape increased significantly from pre-implant ($M = 2.5$) to post-implant ($M = 3.7/3.9$), on a 1 (very dissatisfied) to 5 (very satisfied) scale (Tables 243 and 244). Patient satisfaction with her breast size increased significantly from pre-implant ($M = 2.6$) to post-implant ($M = 3.9/4.0$), on a 1 (very dissatisfied) to 5 (very satisfied) scale (Tables 245 and 246). Finally, patient satisfaction with breast feel or touch increased significantly from pre-implant ($M = 2.5$) to post-implant ($M = 3.6/3.7$), on a 1 (very dissatisfied) to 5 (very satisfied) scale (Tables 247 and 248).

i. Worry

Tables 249 – 250

On average, patients expressed little worry about their breast implants and did not feel that any worry they experienced interfered with their daily activities (Tables 249 and 250).

j. Bodily Pain and Work/Activity Problems

Tables 251 – 252

On average, patients indicated experiencing very little bodily pain and problems with work/activities due to their breast implants (Tables 251 and 252).

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F. RISK FACTOR ANALYSIS

1. Reoperation

Tables 253 – 254

Of the 361 primary study implants, 105 have been involved in a reoperation (Table 163). Results from the Cox proportional hazards regression analysis revealed that none of the 7 characteristics examined was significantly related to reoperation.

2. Implant Replacement/Removal

Tables 255 – 256

Of the 361 primary study implants, 45 have been explanted (Table 171). Results from the Cox proportional hazards regression analysis revealed that 1 of the 7 characteristics examined was significantly related to implant replacement/removal (Wald $\chi^2 = 7.5$, $p = .006$).

a. Device Shape

A total of 18.9% of round devices underwent implant replacement/removal vs. 9.0% of shaped devices (Table 255). Round devices had a 2.3 times greater risk of implant replacement/removal than did shaped devices (Table 256).

3. Implant Rupture

Tables 257 – 258

Of the 361 primary study implants, 10 had implant rupture (Table 160). Results from the Cox proportional hazards regression analysis revealed that none of the 7 characteristics examined was significantly related to implant rupture.

4. Capsular Contracture

Tables 259 – 260

Of the 361 primary study implants, 31 had capsular contracture (Table 37). Results from the Cox proportional hazards regression analysis revealed that 2 of the 7 characteristics examined were significantly related to capsular contracture (Wald $\chi^2 = 18.4$, $p < .001$).

a. Pocket Irrigation - Betadine

A total of 3.6% of implants placed with betadine in the pocket implants had capsular contracture vs. 14.4% of implants placed without betadine in the pocket (Table 259). Use of betadine in the pocket was found to be a protective factor against capsular contracture (Table 260). Implants placed without betadine in the pocket had a 6.8 times greater risk of capsular contracture than did implants placed with the use of betadine in the pocket.

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b. Implant Placement

A total of 14.6% of implants with a non-submuscular placement had capsular contracture vs. 7.8% of implants with a submuscular placement (Table 259). Implants with a non-submuscular (other) placement had a 5.4 times greater risk of capsular contracture than did implants with a submuscular placement.

5. Infection

Tables 261 – 262

Of the 361 primary study implants, 6 have experienced an infection (Table 73). Results from the Cox proportional hazards regression analysis revealed that none of the 7 characteristics examined was significantly related to infection.

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DISCUSSION

Overall, the results of this study revealed that McGhan Silicone-Filled Breast Implants are both safe and effective devices for use in reconstruction following mastectomy. This conclusion is based on data from a total of 221 reconstruction patients who received these devices and were followed for 2 years post-implant. Patient follow-up compliance was quite high in this study, with an adjusted compliance rate of 93.5% at 1 year and 94.6% at 2 years post-implant. Thus, the results obtained in this study are based on a sufficient number of enrolled patients.

In terms of the safety of McGhan Silicone-Filled Breast Implants, results revealed clinically acceptable rates for medical complications and reoperations at 2 years post-implant. The highest 2-year by-patient risk rates for medical complications were capsular contracture (13.5%), asymmetry (11.9%), and implant malposition (5.8%). The lowest 2-year by-patient risk rates, all of which were 0%, were for capsule calcification, fluid accumulation, irritation, loss of nipple sensation, loss of skin sensation, lymphadenopathy, lymphedema, nipple hypersensitivity, nipple paresthesia, skin hypersensitivity, and skin paresthesia. In general, there were very few occurrences of most of the 34 potential medical complications assessed in this study through 2 years post-implant.

Most patients experienced a resolution to their complications within the 2-year period of data collection in this study. The remaining patients are either currently undergoing treatment, had previously refused treatment, or had a complication where treatment was not possible (e.g., hypertrophic scarring). Of the majority of complications that were resolved, nearly half were resolved with non-surgical treatment, and approximately one fourth were resolved without any type of treatment. Less than one third of complications required reoperation to resolve.

A total of 11 devices were suspected of rupture through 2 years post-implant. Three (3) of the 11 devices have been explanted and the remaining 8 devices remain implanted. Of the 11 suspected ruptures, 1 rupture was a false report (i.e., the device was found to be intact upon further follow-up), 2 devices were confirmed to be ruptured, and 8 devices are unconfirmed ruptures. Based on confirmed and unconfirmed ruptures, the 2-year by-patient risk of implant rupture was 4.8%.

The 2-year risk of reoperation was 36.9% by patient. Of all reoperations performed through 2 years post-implant, the most common were implant replacement/removal due to unsatisfactory cosmetic result (19.2%) and scar revision due to unsatisfactory cosmetic result (14.4%). The 2-year risk of implant replacement/removal was 17.2% by patient. The most common reasons for implant replacement/removal were capsular contracture (26.7%) and asymmetry (24.4%).

Overall, the 2-year complication risk rates observed for McGhan Silicone-Filled Breast Implants were either lower or equivalent to the 2-year complication risk rates observed for McGhan Saline-Filled Breast Implants in the 1995 Saline Reconstruction Study

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(R95). For those complications for which comparable 2-year risk rates are available, the risk for McGhan Silicone-Filled Breast Implants was significantly lower (as determined by non-overlapping 95% confidence intervals) for 10 of 27 safety outcomes assessed in both studies. Thirteen (13) complications showed nominally lower 2-year risk rates for McGhan Silicone-Filled Breast Implants (but with overlapping 95% confidence intervals), including implant replacement/removal and implant rupture/deflation. One (1) complication (lymphadenopathy) showed the same 2-year risk rate, and 3 complications showed nominally higher 2-year risk rates (but with overlapping 95% confidence intervals), including reoperation.

Through 2 years post-implant, 2 patients (0.9%) reported a total of 2 reproduction problems and no patients reported lactation problems. Through 2 years post-implant, 4 patients had confirmed malignant breast disease and 9 patients had reports of benign breast disease. One (1) 42-year-old patient (0.5%) reported a connective tissue disease through 2 years post-implant, specifically a confirmed diagnosis of systemic sclerosis/scleroderma with an onset date of 4 months after primary implant surgery.

A variety of quality of life measures were assessed in this study, including general health-related concepts, self-concept, self-esteem, and body esteem. For most of the general health concepts and specific self-related concepts, average scores at 1 and 2 years post-implant showed no significant changes vs. baseline. In terms of patients' expectation and perceived results of breast implant surgery, a significant positive change was observed pre- vs. post-implant in the social relations subscale and a significant decrease was observed in the daily living subscale.

In contrast to the general quality of life measures, patients' satisfaction with their breasts on a variety of assessments (i.e., how well breasts matched, breast shape, breast size, and breast feel) showed significantly increased scores at 1 and 2 years post-implant vs. baseline.

Patients were highly satisfied with their breast implants. More than 90% of both physicians and patients reported being satisfied with the outcome of the primary breast implant surgery at each of the follow-up visit intervals. Indeed, on a 1 (definitely dissatisfied) to 5 (definitely satisfied) scale, the average rating was between 4.5 and 4.8 at each follow-up interval. Patient ratings of satisfaction with their breasts from the quality of life questionnaire also revealed a highly significant increase, from a mean satisfaction score of 2.8 (out of 5) pre-implant to a mean score of 4.1 and 4.0 at 1 and 2 years post-implant.

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 that women who undergo reconstruction surgery are highly satisfied with the outcome. 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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CORE RECONSTRUCTION TABLES

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Table 1: Patient Age, Race, and Marital Status

Characteristic	Patients	
	n	%(N = 221)
Age		
18-19	0	0.0%
20-29	3	1.4%
30-39	27	12.2%
40-49	79	35.7%
50-59	76	34.4%
60-69	29	13.1%
70 & over	7	3.2%
	221	100.0%
Median = 50 years		
Range = 26 to 82 years		
Race		
Caucasian	194	87.8%
African-American	6	2.7%
Asian	5	2.3%
Hispanic	11	5.0%
Other	2	0.9%
Not Provided	4	1.8%
	222	100.5%
Marital Status		
Single	9	4.1%
Married	165	74.7%
Widowed	16	7.2%
Separated	3	1.4%
Divorced	28	12.7%
	221	100.0%

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Table 2: Patient Occupation and Education

Characteristic	Patients	
	n	%(N = 221)
Occupation		
Clerical	23	10.4%
Professional	112	50.7%
Trade	3	1.4%
Service	6	2.7%
Student	1	0.5%
Housewife	52	23.5%
Other	24	10.9%
	221	100.0%
Education		
Less Than High School	4	1.8%
High School Graduate	44	19.9%
Some College	52	23.5%
College Graduate	82	37.1%
Post College	37	16.7%
Not Provided	2	0.9%
	221	100.0%

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Table 3: Pre-Implant Height and Weight

Characteristic	Patients	
	n	%(N = 221)
Height		
4'11" & under	4	1.8%
5'0" - 5'2.9"	35	15.8%
5'3" - 5'5.9"	102	46.2%
5'6" - 5'8.9"	64	29.0%
5'9" - 5'11.9"	13	5.9%
6'0" & over	1	0.5%
Not Provided	2	0.9%
	221	100.0%
Median = 5'5"		
Range = 4'9" to 6'2"		
Weight		
99 lbs & under	2	0.9%
100 - 109	9	4.1%
110 - 119	23	10.4%
120 - 129	35	15.8%
130 - 139	47	21.3%
140 - 149	32	14.5%
150 - 159	19	8.6%
160 lbs & over	54	24.4%
	221	100.0%
Median = 138 lbs		
Range = 91 to 240 lbs		

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Table 4: Product Styles

Product Style	Implants	
	n	%(N = 361)
Smooth		
Style 40 (round)	43	11.9%
Style 45 (round)	5	1.4%
	48	13.3%
Textured		
Style 110 (round)	64	17.7%
Style 120 (round)	15	4.2%
Style 153 (shaped)	234	64.8%
	313	86.7%

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Table 5: Product Style 40

Size	Implants	
	n	%(N = 43)
80cc	0	0.0%
100cc	0	0.0%
120cc	0	0.0%
140cc	0	0.0%
160cc	0	0.0%
180cc	1	2.3%
200cc	3	7.0%
220cc	1	2.3%
240cc	3	7.0%
260cc	5	11.6%
280cc	1	2.3%
300cc	12	27.9%
320cc	2	4.7%
340cc	1	2.3%
360cc	4	9.3%
400cc	6	14.0%
460cc	4	9.3%
500cc	0	0.0%
	43	100.0%

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Table 6: Product Style 45

Size	Implants	
	n	%(N = 5)
120cc	0	0.0%
160cc	0	0.0%
200cc	0	0.0%
240cc	0	0.0%
280cc	2	40.0%
320cc	0	0.0%
360cc	0	0.0%
400cc	1	20.0%
460cc	2	40.0%
500cc	0	0.0%
550cc	0	0.0%
600cc	0	0.0%
650cc	0	0.0%
700cc	0	0.0%
800cc	0	0.0%
	5	100.0%

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Table 7: Product Style 110

Size	Implants	
	n	%(N = 64)
90cc	4	6.3%
120cc	2	3.1%
150cc	1	1.6%
180cc	3	4.7%
210cc	9	14.1%
240cc	10	15.6%
270cc	7	10.9%
300cc	6	9.4%
330cc	10	15.6%
360cc	6	9.4%
390cc	4	6.3%
420cc	0	0.0%
450cc	0	0.0%
480cc	0	0.0%
510cc	2	3.1%
	64	100.0%

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Table 8: Product Style 120

Size	Implants	
	n	%(N = 15)
180cc	0	0.0%
220cc	1	6.7%
260cc	2	13.3%
300cc	0	0.0%
340cc	0	0.0%
400cc	3	20.0%
440cc	0	0.0%
500cc	2	13.3%
550cc	1	6.7%
600cc	3	20.0%
650cc	3	20.0%
	15	100.0%

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Table 9: Product Style 153

Size	Implants	
	n	%(N = 234)
360cc	49	20.9%
450cc	49	20.9%
540cc	43	18.4%
630cc	57	24.4%
720cc	36	15.4%
	234	100.0%

Table 10A: Indication for Implant Placement

Indication	Patients (N = 221)	
	n	%
Bilateral Implants		
Bilateral Mastectomy for Cancer	28	12.7%
Bilateral Prophylactic Mastectomy	14	6.3%
Unilateral Mast for Cancer & Prophylactic Mast	59	26.7%
Unilateral Mast for Cancer & Breast Trauma	1	0.5%
Unilateral Mast for Cancer & Contra Aug for Asym	38	17.2%
	<u>140</u>	<u>63.3%</u>
Unilateral Implants		
Unilateral Mastectomy for Cancer	66	29.9%
Unilateral Mast for Cancer & Contralateral Flap	12	5.4%
Unilateral Prophylactic Mastectomy	1	0.5%
Unilateral Prophylactic Mast & Contra Flap	1	0.5%
Unilateral Contra Aug for Asym & Tram Flap on Post-Mastectomy Side	1	0.5%
	<u>81</u>	<u>36.7%</u>

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Table 10B: Procedure Performed

Procedure Performed	Patients (N = 221)	
	n	%
Immediate Reconstruction		
With Tissue Expander	140	63.3%
With Implant	18	8.1%
	158	71.5%
Delayed Reconstruction		
With Tissue Expander	53	24.0%
With Implant	9	4.1%
	62	28.1%
Contralateral Augmentation (Opposite Side Tram Flap Post-Mastectomy)	1	0.5%

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Table 11: Anesthesia and Surgical Facility

Characteristic	Patients	
	n	%(N = 221)
Anesthesia		
General	219	99.1%
Local	2	0.9%
	221	100.0%
Surgical Facility		
Hospital	153	69.2%
Free Standing Surgical Facility	68	30.8%
	221	100.0%

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Table 12: Incision Site

Incision Site	Implants	
	n	%(N = 361)
Periareolar	7	1.9%
Inframammary	72	19.9%
Mastectomy Scar	276	76.5%
Axillary	0	0.0%
Breast Scar	4	1.1%
Mastopexy Incision With Implant Placement	0	0.0%
Other	2	0.6%
	361	100.0%

Other Incision Site Specified (N = 2)

Imp Seq#	Other Incision Site Specified
001	LATERAL ASPECT
002	LATERAL ASPECT

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Table 13: Implant Location

Implant Location	Implants	
	n	%(N = 361)
Subcutaneous	1	0.3%
Subglandular	8	2.2%
Submuscular-Partial	211	58.4%
Submuscular-Complete	109	30.2%
Subtissue Flap	32	8.9%
	<u>361</u>	<u>100.0%</u>

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Table 14: Drains Placed

Drains Placed	Implants	
	n	%(N = 361)
Yes	225	62.3%
No	136	37.7%
	361	100.0%

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Table 15: Concurrent Breast Procedures

Concurrent Breast Procedures	Implants	
	n	%(N = 361)
No Concurrent Procedure	108	29.9%
Concurrent Procedure	253	70.1%
	361	100.0%

Type Of Concurrent Procedure	n	%(N = 253)
Capsulorrhaphy	16	6.3%
Capsulotomy	41	16.2%
Flap	37	14.6%
Full Capsulectomy	42	16.6%
Mastectomy	57	22.5%
Mastopexy	8	3.2%
Nipple Areolar Complex	93	36.8%
Partial Capsulectomy (Posterior)	25	9.9%
Partial Capsulectomy (Anterior)	75	29.6%
Reduction	1	0.4%
Removal of Excess Tissue/Lesion/Cyst	4	1.6%
Revision of Pocket or Fold	14	5.5%
Scar Revision	5	2.0%
Surgical Exploration of Breast Area or Implant	1	0.4%
Tissue Expander Removal	7	2.8%
Other	6	2.4%
	432*	170.8%

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Table 15 (cont.) : Concurrent Breast Procedures

Other Procedure Specified (N = 6)

Imp Seq#	Other Procedure Specified
001	REVISION OF SOFT TISSUE W/FLAP PROCEDURE, SCAR REVISION
002	TISSUE RE-ARRANGEMENT 2-PLASTY
003	REVISION RECONSTRUCTED BREAST WITH LIPOSUCTION
004	REMOVAL OF VENOUS ECCES PORT LEFT CHEST WALL
005	REMOVAL OF VENOUS ECCES PORT LEFT CHEST WALL
006	REVISION OF TRAM SCAR AND RESECTION FAT NECROSIS

* The sum of concurrent procedures listed may exceed the total number of implants with concurrent procedures because an implant surgery may have involved more than one concurrent procedure.

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Table 16: Intraoperative Medication - Pocket Irrigation

Pocket Irrigation	Implants	
	n	%(N = 361)
No Pocket Irrigation	49	13.6%
Pocket Irrigation	312	86.4%
	<u>361</u>	<u>100.0%</u>

Type Of Pocket Irrigation	n	%(N = 312)
Steroid	0	0.0%
Antibiotic	220	70.5%
Betadine	194	62.2%
Local Anesthetic	93	29.8%
Unknown	3	1.0%
	<u>510*</u>	<u>163.5%</u>

* The sum of pocket irrigations listed may exceed the total number of implants with pocket irrigation because an implant surgery may have involved more than one type of pocket irrigation.

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Table 17: Intraoperative Medication - Parenteral Medication

Parenteral Medication	Patients	
	n	%(N = 221)
No Parenteral Medications	11	5.0%
Parenteral Medication	210	95.0%
	<u>221</u>	<u>100.0%</u>

Type Of Parenteral Medication	n	%(N = 210)
Antibiotics	209	99.5%
Steroid	52	24.8%
Anesthetic	1	0.5%
	<u>262*</u>	<u>124.8%</u>

* The sum of parenteral medications listed may exceed the total number of patients with parenteral medication because a patient may have had more than one type of parenteral medication.

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Table 18: Intraoperative Complications

Intraoperative Complication	Implants	
	n	%(N = 361)
Yes	1	0.3%
No	360	99.7%
	361	100.0%

Intraoperative Complication Specified (N = 1)

Imp
 Seq# Intraoperative Complication Specified

001 REOPENED TO VERIFY HEMOSTISIS - NO HEMATOMA

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Table 19: Patient Compliance Through 2 Years

	0-4 Weeks	6 Months	1 Year	2 Years
Theoretically Due	221	221	221	221
Deaths*	0	1	1	5
Explant-Related Discontinuations*	0	3	5	11
Without Replacement	0	2	3	5
Replacement with Non-Study Device	0	1	1	4
Unknown Replacement Status	0	0	1	2
Expected	221	217	215	205
Actual Evaluated	219	209	201	194
Lost-to-Follow-Up	2	8	14	11
% Follow-Up	99.1%	96.3%	93.5%	94.6%

* Deaths and Explant-Related Discontinuations are reported cumulatively.

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Table 20: Patient Discontinuation Through 2 Years

Discontinuation	Patients (N = 221)	
	n	%
Not Discontinued	200	90.5%
Discontinued		
Death	6	2.7%
Explanted of All Study Devices	12	5.4%
Patient Choice	1	0.5%
Other	2	0.9%
	221	100.0%

Patient Choice Discontinuation Specified (N = 1)

Pt

Seq# Patient Choice Discontinuation

001 PATIENT WAS DISCONTINUED DUE TO PATIENT CHOICE, BECAUSE SHE WANTED TO SEE ANOTHER DOCTOR DUE TO SCHEDULING CONFLICT WITH PRINCIPAL INVESTIGATOR

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Table 20 (cont.): Patient Discontinuation Through 2 Years

Death Reason Specified (N = 6)

Pt

Seq# Death Reason Specified

001	BREAST CANCER
002	CANCER
003	BREAST CANCER-METASTATIC ENDOCARCINOMA PROGRESSIVE
004	CAR ACCIDENT
005	METASTATIC LARGE CELL CARCINOMA OF BREAST
006	CANCER RECURRENCE AND METASTASIS

Other Discontinuation Specified (N = 2)

Pt

Seq# Other Discontinuation Reason Specified

001	CONFLICT BETWEEN PATIENT&PHYSICIAN
002	CONFLICT BETWEEN PATIENT&PHYSICIAN

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Table 21: Risk of First Occurrence of Asymmetry

Time	By Patient				By Implant			
	Number Affected		Cumulative Risk		Number Affected		Cumulative Risk	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
4 Weeks	9	4.1% (1.5%, 6.7%)	209	N/A	9	4.1% (1.5%, 6.7%)	209	N/A
6 Months	18	8.3% (4.6%, 12.0%)	189	N/A	18	8.3% (4.6%, 12.0%)	189	N/A
1 Year	21	9.8% (5.8%, 13.8%)	178	N/A	21	9.8% (5.8%, 13.8%)	178	N/A
2 Years	25	11.9% (7.5%, 16.3%)	159	N/A	25	11.9% (7.5%, 16.3%)	159	N/A

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Table 22: Incidence and Prevalence of Asymmetry

Time	By Patient		By Implant	
	Incidence	Prevalence	Incidence	Prevalence
4 Weeks	9 (4.1%)	9 (4.1%)		N/A
6 Months	9 (4.1%)	18 (8.3%)		N/A
1 Year	3 (1.5%)	11 (5.4%)		N/A
2 Years	4 (2.1%)	9 (4.7%)		N/A
			Number Evaluated	Number Evaluated
			221	
			218	
			204	
			193	

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Table 23: Time to Resolution of Asymmetry

Measurement in Days	
Resolution	By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 9)	
Minimum	189
Median	383
Maximum	749
Resolved - Time To Resolution (N = 16)*	
Minimum	1
Median	70
Maximum	365

* Includes 3 occurrences of Asymmetry that were resolved after explantation of the patient's primary study device.

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Table 24: Distribution of Asymmetry Resolution Status

Resolution Status	By Patient	
	n	%(N = 25)
Not Yet Resolved		
Undergoing Treatment	7	28.0%
Treatment Not Possible	0	0.0%
Refused Treatment	2	8.0%
<u>Total</u>	<u>9</u>	<u>36.0%</u>
Resolved*		
With Reoperation and Explantation	9	36.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	5	20.0%
Without Treatment	2	8.0%
<u>Total</u>	<u>16</u>	<u>64.0%</u>

* Includes 3 occurrences of Asymmetry that were resolved after explantation of the patient's primary study device.

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Table 25: 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)
	n	n			n	n		
4 Weeks	3	215	1.4%	(0.0%, 2.9%)	4	351	1.1%	(0.0%, 2.2%)
6 Months	5	201	2.3%	(0.3%, 4.3%)	6	327	1.7%	(0.3%, 3.0%)
1 Year	7	188	3.3%	(0.9%, 5.7%)	9	306	2.6%	(0.9%, 4.3%)
2 Years	7	173	3.3%	(0.9%, 5.7%)	9	284	2.6%	(0.9%, 4.3%)

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Table 26: Incidence and Prevalence of Breast Pain

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	3 (1.4%)	3 (1.4%)	221	4 (1.1%)	4 (1.1%)	361
6 Months	2 (0.9%)	3 (1.4%)	218	2 (0.6%)	4 (1.1%)	355
1 Year	2 (1.0%)	3 (1.5%)	204	3 (0.9%)	4 (1.2%)	330
2 Years	0 (0.0%)	3 (1.6%)	193	0 (0.0%)	4 (1.3%)	312

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Table 27: Time to Resolution of Breast Pain

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 1)		
Minimum		546
Median		546
Maximum		546
Resolved - Time To Resolution (N = 6)*		
Minimum		6
Median		52
Maximum		308

* Includes 2 occurrences of Breast Pain that were resolved after explantation of the patient's primary study device.

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Table 28: Distribution of Breast Pain Resolution Status

Resolution Status	By Patient	
	n	%(N = 7)
Not Yet Resolved		
Undergoing Treatment	1	14.3%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	1	14.3%
Resolved*		
With Reoperation and Explantation	1	14.3%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	3	42.9%
Without Treatment	2	28.6%
Total	6	85.7%

* Includes 2 occurrences of Breast Pain that were resolved after explanation of the patient's primary study device.

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Table 29: 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)
4 Weeks	3	215	1.4%	(0.0%, 2.9%)	4	351	1.1%	(0.0%, 2.2%)
6 Months	3	202	1.4%	(0.0%, 2.9%)	4	327	1.1%	(0.0%, 2.2%)
1 Year	3	191	1.4%	(0.0%, 2.9%)	4	309	1.1%	(0.0%, 2.2%)
2 Years	3	175	1.4%	(0.0%, 2.9%)	4	285	1.1%	(0.0%, 2.2%)

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Table 30: Incidence and Prevalence of Bruising

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	3 (1.4%)	3 (1.4%)	221	4 (1.1%)	4 (1.1%)	361
6 Months	0 (0.0%)	1 (0.5%)	218	0 (0.0%)	1 (0.3%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 31: Time to Resolution of Bruising

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 0)	Minimum	.
	Median	.
	Maximum	.
Resolved - Time To Resolution (N = 3)	Minimum	6
	Median	10
	Maximum	14

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Table 32: Distribution of Bruising Resolution Status

Resolution Status	By Patient	
	n	%(N = 3)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>0</u>	<u>0.0%</u>
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	3	100.0%
<u>Total</u>	<u>3</u>	<u>100.0%</u>

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Table 33: Risk of First Occurrence of Capsule Calcification

Time	By Patient				By Implant			
	Number		Cumulative Risk		Number		Cumulative Risk	
	Affected	Remaining	n	% (95% CI)	Affected	Remaining	n	% (95% CI)
4 Weeks	0	218	0.0%	..	0	355	0.0%	..
6 Months	0	204	0.0%	..	0	330	0.0%	..
1 Year	0	193	0.0%	..	0	312	0.0%	..
2 Years	0	177	0.0%	..	0	288	0.0%	..

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Table 34: Incidence and Prevalence of Capsule Calcification

Time	By Patient				By Implant			
	Incidence	Prevalence	Number Evaluated	Number	Incidence	Prevalence	Number Evaluated	
4 Weeks	0 (0.0%)	0 (0.0%)	221	361	0 (0.0%)	0 (0.0%)	361	
6 Months	0 (0.0%)	0 (0.0%)	218	355	0 (0.0%)	0 (0.0%)	355	
1 Year	0 (0.0%)	0 (0.0%)	204	330	0 (0.0%)	0 (0.0%)	330	
2 Years	0 (0.0%)	0 (0.0%)	193	312	0 (0.0%)	0 (0.0%)	312	

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Table 35: Time to Resolution of Capsule Calcification

THERE WAS NO CAPSULE CALCIFICATION OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 36: Distribution of Capsule Calcification Resolution Status

THERE WAS NO CAPSULE CALCIFICATION OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 37: 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)
4 Weeks	7	211	3.2%	(0.9%, 5.5%)	8	347	2.2%	(0.7%, 3.8%)
6 Months	16	191	7.5%	(3.9%, 11.0%)	18	315	5.2%	(2.8%, 7.5%)
1 Year	23	175	10.9%	(6.7%, 15.1%)	26	291	7.6%	(4.8%, 10.4%)
2 Years	28	158	13.5%	(8.8%, 18.1%)	31	267	9.2%	(6.1%, 12.3%)

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Table 38: Incidence and Prevalence of Capsular Contracture

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	7 (3.2%)	7 (3.2%)	221	8 (2.2%)	8 (2.2%)	361
6 Months	9 (4.1%)	16 (7.3%)	218	10 (2.8%)	18 (5.1%)	355
1 Year	7 (3.4%)	17 (8.3%)	204	8 (2.4%)	20 (6.1%)	330
2 Years	5 (2.6%)	17 (8.8%)	193	5 (1.6%)	20 (6.4%)	312

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Table 39: Time to Resolution of Capsular Contracture

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 12)	Minimum	105
	Median	507
	Maximum	897
Resolved - Time To Resolution (N = 16)	Minimum	1
	Median	109
	Maximum	553

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Table 40: Distribution of Capsular Contracture Resolution Status

Resolution Status	By Patient	
	n	%(N = 28)
Not Yet Resolved		
Undergoing Treatment	10	35.7%
Treatment Not Possible	0	0.0%
Refused Treatment	2	7.1%
<u>Total</u>	<u>12</u>	<u>42.9%</u>
Resolved		
With Reoperation and Explantation	6	21.4%
With Reoperation Without Explantation	1	3.6%
With Non-Surgical Treatment	6	21.4%
Without Treatment	3	10.7%
<u>Total</u>	<u>16</u>	<u>57.1%</u>

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Table 41: 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)
	n	n			n	n		
4 Weeks	2	216	0.9%	(0.0%, 2.2%)	2	353	0.6%	(0.0%, 1.3%)
6 Months	5	200	2.3%	(0.3%, 4.3%)	5	326	1.4%	(0.2%, 2.7%)
1 Year	5	189	2.3%	(0.3%, 4.3%)	5	308	1.4%	(0.2%, 2.7%)
2 Years	5	173	2.3%	(0.3%, 4.3%)	5	284	1.4%	(0.2%, 2.7%)

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Table 42: Incidence and Prevalence of Delayed Wound Healing

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	2 (0.9%)	2 (0.9%)	221	2 (0.6%)	2 (0.6%)	361
6 Months	3 (1.4%)	4 (1.8%)	218	3 (0.8%)	4 (1.1%)	355
1 Year	0 (0.0%)	1 (0.5%)	204	0 (0.0%)	1 (0.3%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 43: Time to Resolution of Delayed Wound Healing

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 0)	Minimum	.
	Median	.
	Maximum	.
Resolved - Time To Resolution (N = 5)	Minimum	1
	Median	26
	Maximum	39

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Table 44: Distribution of Delayed Wound Healing Resolution Status

Resolution Status	By Patient	
	n	%(N = 5)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>0</u>	<u>0.0%</u>
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	3	60.0%
With Non-Surgical Treatment	2	40.0%
Without Treatment	0	0.0%
<u>Total</u>	<u>5</u>	<u>100.0%</u>

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Table 45: Risk of First Occurrence of Fluid Accumulation

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n	% (95% CI)	n	n	% (95% CI)	n	% (95% CI)
4 Weeks	0	218	0.0%	--	0	355	0.0%	--
6 Months	0	204	0.0%	--	0	330	0.0%	--
1 Year	0	193	0.0%	--	0	312	0.0%	--
2 Years	0	177	0.0%	--	0	288	0.0%	--

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Table 46: Incidence and Prevalence of Fluid Accumulation

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	0 (0.0%)	0 (0.0%)	218	0 (0.0%)	0 (0.0%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 47: Time to Resolution of Fluid Accumulation

THERE WAS NO FLUID ACCUMULATION OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 48: Distribution of Fluid Accumulation Resolution Status

THERE WAS NO FLUID ACCUMULATION OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 49: Risk of First Occurrence of Hematoma

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		
4 Weeks	1	217	0.4% (0.0%, 1.3%)		1	354	0.3% (0.0%, 0.8%)	
6 Months	1	203	0.4% (0.0%, 1.3%)		1	329	0.3% (0.0%, 0.8%)	
1 Year	1	192	0.4% (0.0%, 1.3%)		1	311	0.3% (0.0%, 0.8%)	
2 Years	1	176	0.4% (0.0%, 1.3%)		1	287	0.3% (0.0%, 0.8%)	

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Table 50: Incidence and Prevalence of Hematoma

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.5%)	1 (0.5%)	221	1 (0.3%)	1 (0.3%)	361
6 Months	0 (0.0%)	0 (0.0%)	218	0 (0.0%)	0 (0.0%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 51: Time to Resolution of Hematoma

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 0)		
Minimum	.	.
Median	.	.
Maximum	.	.
Resolved - Time To Resolution (N = 1)		
Minimum		7
Median		7
Maximum		7

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Table 52: Distribution of Hematoma Resolution Status

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	1	100.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	1	100.0%

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Table 53: 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)
	n	n			n	n		
4 Weeks	0	218	0.0%	--	0	355	0.0%	--
6 Months	3	201	1.4% (0.0%, 2.9%)		4	327	1.1% (0.0%, 2.2%)	
1 Year	5	188	2.4% (0.3%, 4.5%)		6	307	1.8% (0.4%, 3.2%)	
2 Years	5	172	2.4% (0.3%, 4.5%)		6	283	1.8% (0.4%, 3.2%)	

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Table 54: Incidence and Prevalence of Hypertrophic Scarring

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	3 (1.4%)	3 (1.4%)	218	4 (1.1%)	4 (1.1%)	355
1 Year	2 (1.0%)	5 (2.5%)	204	2 (0.6%)	5 (1.5%)	330
2 Years	0 (0.0%)	5 (2.6%)	193	0 (0.0%)	5 (1.6%)	312

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Table 55: Time to Resolution of Hypertrophic Scarring

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 4)	Minimum	527
	Median	702
	Maximum	716
Resolved - Time To Resolution (N = 1)*	Minimum	546
	Median	546
	Maximum	546

* Includes 1 occurrence of Hypertrophic Scarring that was resolved after explantation of the patient's primary study device.

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Table 56: Distribution of Hypertrophic Scarring Resolution Status

Resolution Status	By Patient	
	n	%(N = 5)
Not Yet Resolved		
Undergoing Treatment	3	60.0%
Treatment Not Possible	1	20.0%
Refused Treatment	0	0.0%
Total	4	80.0%
Resolved*		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	1	20.0%
Without Treatment	0	0.0%
Total	1	20.0%

* Includes 1 occurrence of Hypertrophic Scarring that was resolved after explantation of the patient's primary study device.

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Table 57: Risk of First Occurrence of Implant Extrusion

Time	By Patient				By Implant			
	Number Affected		Cumulative Risk		Number Affected		Cumulative Risk	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
4 Weeks	0	0.0%	218	0.0%	0	0.0%	355	0.0%
6 Months	1	0.5% (0.0%, 1.4%)	203	0.5% (0.0%, 1.4%)	1	0.3%	330	0.3% (0.0%, 0.8%)
1 Year	1	0.5% (0.0%, 1.4%)	192	0.5% (0.0%, 1.4%)	1	0.3%	312	0.3% (0.0%, 0.8%)
2 Years	1	0.5% (0.0%, 1.4%)	176	0.5% (0.0%, 1.4%)	1	0.3%	288	0.3% (0.0%, 0.8%)

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Table 58: Incidence and Prevalence of Implant Extrusion

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	1 (0.5%)	1 (0.5%)	218	1 (0.3%)	1 (0.3%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 59: Time to Resolution of Implant Extrusion

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 0)		
Minimum	.	
Median	.	
Maximum	.	
Resolved - Time To Resolution (N = 1)		
Minimum		1
Median		1
Maximum		1

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Table 60: Distribution of Implant Extrusion Resolution Status

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	1	100.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	1	100.0%

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Table 61: 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)
	n	n			n	n		
4 Weeks	3	215	1.4%	(0.0%, 2.9%)	3	352	0.8%	(0.0%, 1.8%)
6 Months	9	196	4.2%	(1.5%, 6.9%)	12	319	3.5%	(1.5%, 5.4%)
1 Year	10	186	4.7%	(1.9%, 7.6%)	14	302	4.1%	(2.0%, 6.2%)
2 Years	12	170	5.8%	(2.6%, 8.9%)	16	278	4.7%	(2.5%, 7.0%)

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Table 62: Incidence and Prevalence of Implant Malposition

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	3 (1.4%)	3 (1.4%)	221	3 (0.8%)	3 (0.8%)	361
6 Months	6 (2.8%)	9 (4.1%)	218	9 (2.5%)	12 (3.4%)	355
1 Year	1 (0.5%)	6 (2.9%)	204	2 (0.6%)	10 (3.0%)	330
2 Years	2 (1.0%)	3 (1.6%)	193	2 (0.6%)	4 (1.3%)	312

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Table 63: Time to Resolution of Implant Malposition

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 3)		
Minimum		30
Median		383
Maximum		525
Resolved - Time To Resolution (N = 9)*		
Minimum		1
Median		89
Maximum		249

* Includes 1 occurrence of Implant Malposition that was resolved after explantation of the patient's primary study device.

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Table 64: Distribution of Implant Malposition Resolution Status

Resolution Status	By Patient	
	n	%(N = 12)
Not Yet Resolved		
Undergoing Treatment	2	16.7%
Treatment Not Possible	0	0.0%
Refused Treatment	1	8.3%
<u>Total</u>	<u>3</u>	<u>25.0%</u>
Resolved*		
With Reoperation and Explantation	3	25.0%
With Reoperation Without Explantation	4	33.3%
With Non-Surgical Treatment	2	16.7%
Without Treatment	0	0.0%
<u>Total</u>	<u>9</u>	<u>75.0%</u>

* Includes 1 occurrence of Implant Malposition that was resolved after explantation of the patient's primary study device.

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Table 65: 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)
4 Weeks	1	217	0.4% (0.0%, 1.3%)	1	354	0.3% (0.0%, 0.8%)
6 Months	1	204	0.4% (0.0%, 1.3%)	1	330	0.3% (0.0%, 0.8%)
1 Year	1	193	0.4% (0.0%, 1.3%)	1	312	0.3% (0.0%, 0.8%)
2 Years	1	177	0.4% (0.0%, 1.3%)	1	288	0.3% (0.0%, 0.8%)

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Table 66: Incidence and Prevalence of Implant Palpability

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.5%)	1 (0.5%)	221	1 (0.3%)	1 (0.3%)	361
6 Months	0 (0.0%)	1 (0.5%)	218	0 (0.0%)	1 (0.3%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 67: Time to Resolution of Implant Palpability

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 0)		
Minimum	.	.
Median	.	.
Maximum	.	.
Resolved - Time To Resolution (N = 1)		
Minimum		26
Median		26
Maximum		26

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Table 68: Distribution of Implant Palpability Resolution Status

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>0</u>	<u>0.0%</u>
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	1	100.0%
Without Treatment	0	0.0%
<u>Total</u>	<u>1</u>	<u>100.0%</u>

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Table 69: 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)
4 Weeks	1	217	0.4% (0.0%, 1.3%)	1	354	0.3% (0.0%, 0.8%)
6 Months	1	204	0.4% (0.0%, 1.3%)	1	330	0.3% (0.0%, 0.8%)
1 Year	1	193	0.4% (0.0%, 1.3%)	1	312	0.3% (0.0%, 0.8%)
2 Years	1	177	0.4% (0.0%, 1.3%)	1	288	0.3% (0.0%, 0.8%)

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Table 70: Incidence and Prevalence of Implant Visibility

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.5%)	1 (0.5%)	221	1 (0.3%)	1 (0.3%)	361
6 Months	0 (0.0%)	1 (0.5%)	218	0 (0.0%)	1 (0.3%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 71: Time to Resolution of Implant Visibility

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 0)	Minimum	.
	Median	.
	Maximum	.
Resolved - Time To Resolution (N = 1)	Minimum	26
	Median	26
	Maximum	26

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Table 72: Distribution of Implant Visibility Resolution Status

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>0</u>	<u>0.0%</u>
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	1	100.0%
Without Treatment	0	0.0%
<u>Total</u>	<u>1</u>	<u>100.0%</u>

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Table 73: Risk of First Occurrence of Infection

Time	By Patient				By Implant			
	Number Affected		Number Remaining		Number Affected		Number Remaining	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
4 Weeks	3	1.4% (0.0%, 2.9%)	215	1.4% (0.0%, 2.9%)	4	1.1% (0.0%, 2.2%)	351	1.1% (0.0%, 2.2%)
6 Months	5	2.3% (0.3%, 4.3%)	199	2.3% (0.3%, 4.3%)	6	1.7% (0.4%, 3.1%)	324	1.7% (0.4%, 3.1%)
1 Year	5	2.3% (0.3%, 4.3%)	188	2.3% (0.3%, 4.3%)	6	1.7% (0.4%, 3.1%)	306	1.7% (0.4%, 3.1%)
2 Years	5	2.3% (0.3%, 4.3%)	172	2.3% (0.3%, 4.3%)	6	1.7% (0.4%, 3.1%)	282	1.7% (0.4%, 3.1%)

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Table 74: Incidence and Prevalence of Infection

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	3 (1.4%)	3 (1.4%)	221	4 (1.1%)	4 (1.1%)	361
6 Months	2 (0.9%)	3 (1.4%)	218	2 (0.6%)	3 (0.8%)	355
1 Year	0 (0.0%)	2 (1.0%)	204	0 (0.0%)	2 (0.6%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 75: Time to Resolution of Infection

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 0)	Minimum	.
	Median	.
	Maximum	.
Resolved - Time To Resolution (N = 5)	Minimum	3
	Median	29
	Maximum	91

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Table 76: Distribution of Infection Resolution Status

Resolution Status	By Patient	
	n	%(N = 5)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	3	60.0%
Without Treatment	2	40.0%
Total	5	100.0%

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Table 77: Risk of First Occurrence of Irritation

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		
4 Weeks	0	218	0.0%	--	0	355	0.0%	--
6 Months	0	204	0.0%	--	0	330	0.0%	--
1 Year	0	193	0.0%	--	0	312	0.0%	--
2 Years	0	177	0.0%	--	0	288	0.0%	--

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Table 78: Incidence and Prevalence of Irritation

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	0 (0.0%)	0 (0.0%)	218	0 (0.0%)	0 (0.0%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 79: Time to Resolution of Irritation

THERE WAS NO IRRITATION OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 80: Distribution of Irritation Resolution Status

THERE WAS NO IRRITATION OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 81: 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)
	n	n	% (95% CI)	n	n	% (95% CI)	n	% (95% CI)
4 Weeks	0	218	0.0%	--	0	355	0.0%	--
6 Months	0	204	0.0%	--	0	330	0.0%	--
1 Year	0	193	0.0%	--	0	312	0.0%	--
2 Years	0	177	0.0%	--	0	288	0.0%	--

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Table 82: Incidence and Prevalence of Loss of Nipple Sensation

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	0 (0.0%)	0 (0.0%)	218	0 (0.0%)	0 (0.0%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 83: Time to Resolution of Loss of Nipple Sensation

THERE WAS NO LOSS OF NIPPLE SENSATION OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 84: Distribution of Loss of Nipple Sensation Resolution Status

THERE WAS NO LOSS OF NIPPLE SENSATION OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 85: Risk of First Occurrence of Loss of Skin Sensation

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n	% (95% CI)		n	n	% (95% CI)	
4 Weeks	0	218	0.0%	--	0	355	0.0%	--
6 Months	0	204	0.0%	--	0	330	0.0%	--
1 Year	0	193	0.0%	--	0	312	0.0%	--
2 Years	0	177	0.0%	--	0	288	0.0%	--

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Table 86: Incidence and Prevalence of Loss of Skin Sensation

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	0 (0.0%)	0 (0.0%)	218	0 (0.0%)	0 (0.0%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 87: Time to Resolution of Loss of Skin Sensation

THERE WAS NO LOSS OF SKIN SENSATION OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 88: Distribution of Loss of Skin Sensation Resolution Status

THERE WAS NO LOSS OF SKIN SENSATION OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 89: 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)
	n	n	% (95% CI)		n	n	% (95% CI)	
4 Weeks	0	218	0.0%	--	0	355	0.0%	--
6 Months	0	204	0.0%	--	0	330	0.0%	--
1 Year	0	193	0.0%	--	0	312	0.0%	--
2 Years	0	177	0.0%	--	0	288	0.0%	--

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Table 90: Incidence and Prevalence of Lymphadenopathy

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	0 (0.0%)	0 (0.0%)	218	0 (0.0%)	0 (0.0%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 91: Time to Resolution of Lymphadenopathy

THERE WAS NO LYMPHADENOPATHY OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 92: Distribution of Lymphadenopathy Resolution Status

THERE WAS NO LYMPHADENOPATHY OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 93: Risk of First Occurrence of Lymphedema

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		
4 Weeks	0	218	0.0%	--	0	355	0.0%	--
6 Months	0	204	0.0%	--	0	330	0.0%	--
1 Year	0	193	0.0%	--	0	312	0.0%	--
2 Years	0	177	0.0%	--	0	288	0.0%	--

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Table 94: Incidence and Prevalence of Lymphedema

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	0 (0.0%)	0 (0.0%)	218	0 (0.0%)	0 (0.0%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 95: Time to Resolution of Lymphedema

THERE WAS NO LYMPHEDEMA OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 96: Distribution of Lymphedema Resolution Status

THERE WAS NO LYMPHEDEMA OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 97: 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)
	n	n	% (95% CI)	n	n	% (95% CI)		
4 Weeks	0	218	0.0%	--	0	355	0.0%	--
6 Months	0	204	0.0%	--	0	330	0.0%	--
1 Year	0	193	0.0%	--	0	312	0.0%	--
2 Years	0	177	0.0%	--	0	288	0.0%	--

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Table 98: Incidence and Prevalence of Nipple Hypersensitivity

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	0 (0.0%)	0 (0.0%)	218	0 (0.0%)	0 (0.0%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 99: Time to Resolution of Nipple Hypersensitivity

THERE WAS NO NIPPLE HYPERSENSITIVITY OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 100: Distribution of Nipple Hypersensitivity Resolution Status

THERE WAS NO NIPPLE HYPERSENSITIVITY OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 101: 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)
	n	n	% (95% CI)	n	n	% (95% CI)		
4 Weeks	0	218	0.0%	--	0	355	0.0%	--
6 Months	0	204	0.0%	--	0	330	0.0%	--
1 Year	0	193	0.0%	--	0	312	0.0%	--
2 Years	0	177	0.0%	--	0	288	0.0%	--

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Table 102: Incidence and Prevalence of Nipple Paresthesia

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	0 (0.0%)	0 (0.0%)	218	0 (0.0%)	0 (0.0%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 103: Time to Resolution of Nipple Paresthesia

THERE WAS NO NIPPLE PARESTHESIA OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 104: Distribution of Nipple Paresthesia Resolution Status

THERE WAS NO NIPPLE PARESTHESIA OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 105: Risk of First Occurrence of Other Abnormal Scarring

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
4 Weeks	0	218	0.0% --	0	355	0.0% --
6 Months	1	203	0.5% (0.0%, 1.4%)	1	329	0.3% (0.0%, 0.8%)
1 Year	1	192	0.5% (0.0%, 1.4%)	1	311	0.3% (0.0%, 0.8%)
2 Years	2	175	1.0% (0.0%, 2.4%)	2	286	0.6% (0.0%, 1.5%)

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Table 106: Incidence and Prevalence of Other Abnormal Scarring

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	1 (0.5%)	1 (0.5%)	218	1 (0.3%)	1 (0.3%)	355
1 Year	0 (0.0%)	1 (0.5%)	204	0 (0.0%)	1 (0.3%)	330
2 Years	1 (0.5%)	2 (1.0%)	193	1 (0.3%)	2 (0.6%)	312

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Table 107: Time to Resolution of Other Abnormal Scarring

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 2)	Minimum	189
	Median	489
	Maximum	789
Resolved - Time To Resolution (N = 0)	Minimum	.
	Median	.
	Maximum	.

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Table 108: Distribution of Other Abnormal Scarring Resolution Status

Resolution Status	By Patient	
	n	%(N = 2)
Not Yet Resolved		
Undergoing Treatment	2	100.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>2</u>	<u>100.0%</u>
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
<u>Total</u>	<u>0</u>	<u>0.0%</u>

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Table 109: Risk of First Occurrence of Other Nipple Related Observation

Time	By Patient				By Implant			
	Number Affected	Number Remaining	n	% (95% CI)	Number Affected	Number Remaining	n	% (95% CI)
4 Weeks	1	217	217	0.5% (0.0%, 1.4%)	2	353	353	0.6% (0.0%, 1.3%)
6 Months	4	200	200	1.9% (0.1%, 3.7%)	7	323	323	2.0% (0.5%, 3.5%)
1 Year	7	187	187	3.4% (0.9%, 5.8%)	10	303	303	2.9% (1.1%, 4.7%)
2 Years	9	171	171	4.4% (1.6%, 7.3%)	13	279	279	3.9% (1.8%, 6.0%)

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Table 110: Incidence and Prevalence of Other Nipple Related Observation

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.5%)	1 (0.5%)	221	2 (0.6%)	2 (0.6%)	361
6 Months	3 (1.4%)	4 (1.8%)	218	5 (1.4%)	7 (2.0%)	355
1 Year	3 (1.5%)	6 (2.9%)	204	3 (0.9%)	8 (2.4%)	330
2 Years	2 (1.0%)	7 (3.6%)	193	3 (1.0%)	10 (3.2%)	312

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Table 111: Time to Resolution of Other Nipple Related Observation

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 5)	Minimum	526
	Median	623
	Maximum	707
Resolved - Time To Resolution (N = 4)*	Minimum	1
	Median	34
	Maximum	112

* Includes 1 occurrence of Other Nipple Related Observation that was resolved after explantation of the patient's primary study device.

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Table 112: Distribution of Other Nipple Related Observation Resolution Status

Resolution Status	By Patient	
	n	%(N = 9)
Not Yet Resolved		
Undergoing Treatment	4	44.4%
Treatment Not Possible	1	11.1%
Refused Treatment	0	0.0%
<u>Total</u>	<u>5</u>	<u>55.6%</u>
Resolved*		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	4	44.4%
Without Treatment	0	0.0%
<u>Total</u>	<u>4</u>	<u>44.4%</u>

* Includes 1 occurrence of Other Nipple Related Observation that was resolved after explantation of the patient's primary study device.

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Table 113: 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)
	n	n			n	n		
4 Weeks	0	218	0.0%	--	0	355	0.0%	--
6 Months	0	204	0.0%	--	0	330	0.0%	--
1 Year	1	192	0.5% (0.0%, 1.5%)		1	311	0.3% (0.0%, 0.9%)	
2 Years	1	176	0.5% (0.0%, 1.5%)		1	287	0.3% (0.0%, 0.9%)	

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Table 114: Incidence and Prevalence of Pneumothorax

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	0 (0.0%)	0 (0.0%)	218	0 (0.0%)	0 (0.0%)	355
1 Year	1 (0.5%)	1 (0.5%)	204	1 (0.3%)	1 (0.3%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 115: Time to Resolution of Pneumothorax

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 0)		
Minimum	.	
Median	.	
Maximum	.	
Resolved - Time To Resolution (N = 1)		
Minimum		7
Median		7
Maximum		7

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Table 116: Distribution of Pneumothorax Resolution Status

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>0</u>	<u>0.0%</u>
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	1	100.0%
Without Treatment	0	0.0%
<u>Total</u>	<u>1</u>	<u>100.0%</u>

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Table 117: Risk of First Occurrence of Ptosis

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
4 Weeks	1	217	0.4% (0.0%, 1.3%)	1	354	0.3% (0.0%, 0.8%)
6 Months	1	203	0.4% (0.0%, 1.3%)	1	330	0.3% (0.0%, 0.8%)
1 Year	1	192	0.4% (0.0%, 1.3%)	1	312	0.3% (0.0%, 0.8%)
2 Years	2	175	1.0% (0.0%, 2.3%)	2	287	0.6% (0.0%, 1.4%)

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Table 118: Incidence and Prevalence of Ptosis

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.5%)	1 (0.5%)	221	1 (0.3%)	1 (0.3%)	361
6 Months	0 (0.0%)	1 (0.5%)	218	0 (0.0%)	1 (0.3%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	1 (0.5%)	1 (0.5%)	193	1 (0.3%)	1 (0.3%)	312

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Table 119: Time to Resolution of Ptosis

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 1)		
Minimum		576
Median		576
Maximum		576
Resolved - Time To Resolution (N = 1)		
Minimum		98
Median		98
Maximum		98

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Table 120: Distribution of Ptosis Resolution Status

Resolution Status	By Patient	
	n	%(N = 2)
Not Yet Resolved		
Undergoing Treatment	1	50.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	1	50.0%
Resolved		
With Reoperation and Explantation	1	50.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	1	50.0%

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Table 121: Risk of First Occurrence of Redness

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		
4 Weeks	0	218	0.0%	--	0	355	0.0%	--
6 Months	2	202	1.0% (0.0%, 2.3%)		2	328	0.6% (0.0%, 1.4%)	
1 Year	2	191	1.0% (0.0%, 2.3%)		2	310	0.6% (0.0%, 1.4%)	
2 Years	2	175	1.0% (0.0%, 2.3%)		2	286	0.6% (0.0%, 1.4%)	

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Table 122: Incidence and Prevalence of Redness

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	2 (0.9%)	2 (0.9%)	218	2 (0.6%)	2 (0.6%)	355
1 Year	0 (0.0%)	2 (1.0%)	204	0 (0.0%)	2 (0.6%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 123: Time to Resolution of Redness

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 0)		
Minimum	.	.
Median	.	.
Maximum	.	.
Resolved - Time To Resolution (N = 2)		
Minimum	39	
Median	41	
Maximum	42	

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Table 124: Distribution of Redness Resolution Status

Resolution Status	By Patient	
	n	%(N = 2)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	2	100.0%
Without Treatment	0	0.0%
Total	2	100.0%

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Table 125: Risk of First Occurrence of Seroma

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)
4 Weeks	3	1.4% (0.0%, 2.9%)	215	1.4% (0.0%, 2.9%)	3	0.8% (0.0%, 1.8%)	352	0.8% (0.0%, 1.8%)
6 Months	4	1.8% (0.1%, 3.6%)	200	1.8% (0.1%, 3.6%)	4	1.1% (0.0%, 2.2%)	326	1.1% (0.0%, 2.2%)
1 Year	4	1.8% (0.1%, 3.6%)	189	1.8% (0.1%, 3.6%)	4	1.1% (0.0%, 2.2%)	308	1.1% (0.0%, 2.2%)
2 Years	4	1.8% (0.1%, 3.6%)	173	1.8% (0.1%, 3.6%)	4	1.1% (0.0%, 2.2%)	284	1.1% (0.0%, 2.2%)

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Table 126: Incidence and Prevalence of Seroma

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	3 (1.4%)	3 (1.4%)	221	3 (0.8%)	3 (0.8%)	361
6 Months	1 (0.5%)	3 (1.4%)	218	1 (0.3%)	3 (0.8%)	355
1 Year	0 (0.0%)	1 (0.5%)	204	0 (0.0%)	1 (0.3%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 127: Time to Resolution of Seroma

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 0)	Minimum	.
	Median	.
	Maximum	.
Resolved - Time To Resolution (N = 4)	Minimum	1
	Median	59
	Maximum	196

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Table 128: Distribution of Seroma Resolution Status

Resolution Status	By Patient	
	n	%(N = 4)
Not Yet Resolved	0	0.0%
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved	0	0.0%
With Reoperation and Explantation	1	25.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	3	75.0%
Without Treatment	0	0.0%
Total	4	100.0%

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Table 129: 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)
	n	n			n	n		
4 Weeks	0	218	0.0%	--	0	355	0.0%	--
6 Months	0	204	0.0%	--	0	330	0.0%	--
1 Year	0	193	0.0%	--	0	312	0.0%	--
2 Years	0	177	0.0%	--	0	288	0.0%	--

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Table 130: Incidence and Prevalence of Skin Hypersensitivity

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	0 (0.0%)	0 (0.0%)	218	0 (0.0%)	0 (0.0%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 131: Time to Resolution of Skin Hypersensitivity

THERE WAS NO SKIN HYPERSENSITIVITY OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 132: Distribution of Skin Hypersensitivity Resolution Status

THERE WAS NO SKIN HYPERSENSITIVITY OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 133: 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)
	n	n			n	n		
4 Weeks	0	218	0.0%	..	0	355	0.0%	..
6 Months	0	204	0.0%	..	0	330	0.0%	..
1 Year	0	193	0.0%	..	0	312	0.0%	..
2 Years	0	177	0.0%	..	0	288	0.0%	..

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Table 134: Incidence and Prevalence of Skin Paresthesia

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	0 (0.0%)	0 (0.0%)	218	0 (0.0%)	0 (0.0%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 135: Time to Resolution of Skin Paresthesia

THERE WAS NO SKIN PARESTHESIA OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 136: Distribution of Skin Paresthesia Resolution Status

THERE WAS NO SKIN PARESTHESIA OBSERVED AMONG RECONSTRUCTION PATIENTS

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Table 137: 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)
	n	n			n	n		
4 Weeks	3	215	1.4%	(0.0%, 2.9%)	4	351	1.1%	(0.0%, 2.2%)
6 Months	3	201	1.4%	(0.0%, 2.9%)	4	326	1.1%	(0.0%, 2.2%)
1 Year	3	190	1.4%	(0.0%, 2.9%)	4	308	1.1%	(0.0%, 2.2%)
2 Years	3	174	1.4%	(0.0%, 2.9%)	4	284	1.1%	(0.0%, 2.2%)

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Table 138: Incidence and Prevalence of Skin Rash

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	3 (1.4%)	3 (1.4%)	221	4 (1.1%)	4 (1.1%)	361
6 Months	0 (0.0%)	0 (0.0%)	218	0 (0.0%)	0 (0.0%)	355
1 Year	0 (0.0%)	0 (0.0%)	204	0 (0.0%)	0 (0.0%)	330
2 Years	0 (0.0%)	0 (0.0%)	193	0 (0.0%)	0 (0.0%)	312

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Table 139: Time to Resolution of Skin Rash

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 0)	Minimum	.
	Median	.
	Maximum	.
Resolved - Time To Resolution (N = 3)	Minimum	2
	Median	6
	Maximum	15

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Table 140: Distribution of Skin Rash Resolution Status

Resolution Status	By Patient	
	n	%(N = 3)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>0</u>	<u>0.0%</u>
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	2	66.7%
Without Treatment	1	33.3%
<u>Total</u>	<u>3</u>	<u>100.0%</u>

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Table 141: 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)
	n	n			n	n		
4 Weeks	7	211	3.2%	(0.9%, 5.5%)	8	347	2.2%	(0.7%, 3.8%)
6 Months	8	199	3.7%	(1.2%, 6.2%)	10	324	2.8%	(1.1%, 4.5%)
1 Year	8	188	3.7%	(1.2%, 6.2%)	10	306	2.8%	(1.1%, 4.5%)
2 Years	8	172	3.7%	(1.2%, 6.2%)	10	282	2.8%	(1.1%, 4.5%)

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Table 142: Incidence and Prevalence of Swelling

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	7 (3.2%)	7 (3.2%)	221	8 (2.2%)	8 (2.2%)	361
6 Months	1 (0.5%)	5 (2.3%)	218	2 (0.6%)	6 (1.7%)	355
1 Year	0 (0.0%)	1 (0.5%)	204	0 (0.0%)	1 (0.3%)	330
2 Years	0 (0.0%)	1 (0.5%)	193	0 (0.0%)	1 (0.3%)	312

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Table 143: Time to Resolution of Swelling

Measurement in Days	
By Patient	
Resolution	
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Maximum	.
Resolved - Time To Resolution (N = 8)*	
Minimum	1
Median	16
Maximum	379

* Includes 1 occurrence of Swelling that was resolved after explanation of the patient's primary study device.

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Table 144: Distribution of Swelling Resolution Status

Resolution Status	By Patient	
	n	%(N = 8)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved*		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	2	25.0%
Without Treatment	6	75.0%
Total	8	100.0%

* Includes 1 occurrence of Swelling that was resolved after explanation of the patient's primary study device.

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Table 145: 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)
	n	n			n	n		
4 Weeks	0	218	0.0%	0.0%	0	355	0.0%	0.0%
6 Months	6	198	2.8%	(0.6%, 5.0%)	7	324	2.0%	(0.5%, 3.5%)
1 Year	7	187	3.3%	(0.9%, 5.7%)	8	306	2.3%	(0.7%, 3.9%)
2 Years	8	170	3.8%	(1.2%, 6.5%)	9	282	2.7%	(0.9%, 4.4%)

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Table 146: Incidence and Prevalence of Tissue or Skin Necrosis

Time	By Patient			By Implant			Number Evaluated
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated	
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361	
6 Months	6 (2.8%)	6 (2.8%)	218	7 (2.0%)	7 (2.0%)	355	
1 Year	1 (0.5%)	3 (1.5%)	204	1 (0.3%)	3 (0.9%)	330	
2 Years	1 (0.5%)	4 (2.1%)	193	1 (0.3%)	4 (1.3%)	312	

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Table 147: Time to Resolution of Tissue or Skin Necrosis

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 1)	Minimum	770
	Median	770
	Maximum	770
Resolved - Time To Resolution (N = 7)	Minimum	1
	Median	42
	Maximum	260

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Table 148: Distribution of Tissue or Skin Necrosis Resolution Status

Resolution Status	By Patient	
	n	%(N = 8)
Not Yet Resolved		
Undergoing Treatment	1	12.5%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>1</u>	<u>12.5%</u>
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	6	75.0%
Without Treatment	1	12.5%
<u>Total</u>	<u>7</u>	<u>87.5%</u>

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Table 149: Risk of First Occurrence of Wrinkling / Rippling

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	218	0.0%	--	0	355	0.0%	--
6 Months	4	200	1.9%	(0.1%, 3.8%)	6	324	1.8%	(0.4%, 3.2%)
1 Year	6	189	2.9%	(0.6%, 5.2%)	8	308	2.4%	(0.8%, 4.0%)
2 Years	6	173	2.9%	(0.6%, 5.2%)	8	284	2.4%	(0.8%, 4.0%)

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Table 150: Incidence and Prevalence of Wrinkling / Rippling

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	4 (1.8%)	4 (1.8%)	218	6 (1.7%)	6 (1.7%)	355
1 Year	2 (1.0%)	6 (2.9%)	204	2 (0.6%)	8 (2.4%)	330
2 Years	0 (0.0%)	3 (1.6%)	193	0 (0.0%)	4 (1.3%)	312

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Table 151: Time to Resolution of Wrinkling / Rippling

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 4)	Minimum	109
	Median	715
	Maximum	891
Resolved - Time To Resolution (N = 2)*	Minimum	112
	Median	117
	Maximum	122

* Includes 1 occurrence of Wrinkling / Rippling that was resolved after explantation of the patient's primary study device.

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Table 152: Distribution of Wrinkling / Rippling Resolution Status

Resolution Status	By Patient	
	n	%(N = 6)
Not Yet Resolved		
Undergoing Treatment	2	33.3%
Treatment Not Possible	2	33.3%
Refused Treatment	0	0.0%
<u>Total</u>	<u>4</u>	<u>66.7%</u>
Resolved*		
With Reoperation and Explantation	1	16.7%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	1	16.7%
Without Treatment	0	0.0%
<u>Total</u>	<u>2</u>	<u>33.3%</u>

* Includes 1 occurrence of Wrinkling / Rippling that was resolved after explantation of the patient's primary study device.

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Table 153: Risk of First Occurrence of Other Complications

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n	% (95% CI)		n	n	% (95% CI)	
4 Weeks	0	218	0.0% (0.0%, 0.0%)		0	355	0.0% (0.0%, 0.0%)	
6 Months	5	199	2.3% (0.3%, 4.4%)		5	325	1.4% (0.2%, 2.7%)	
1 Year	5	188	2.3% (0.3%, 4.4%)		5	307	1.4% (0.2%, 2.7%)	
2 Years	5	172	2.3% (0.3%, 4.4%)		5	283	1.4% (0.2%, 2.7%)	

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Table 153 (Cont.): Risk of First Occurrence of Other Complications

Other Complications Specified (N = 5)

Pt	Other Complications Specified
001	INADEQUATE INFRAMAMMARY CREASE
002	FX INFRAMAMMARY FOLD
003	MILD TO MODERATE VENOUS CONGESTION
004	EPIDERMOLYSIS OF LEFT NIPPLE
005	PUCKERING

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Table 154: Incidence and Prevalence of Other Complications

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	221	0 (0.0%)	0 (0.0%)	361
6 Months	5 (2.3%)	5 (2.3%)	218	5 (1.4%)	5 (1.4%)	355
1 Year	0 (0.0%)	2 (1.0%)	204	0 (0.0%)	2 (0.6%)	330
2 Years	0 (0.0%)	2 (1.0%)	193	0 (0.0%)	2 (0.6%)	312

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Table 155: Time to Resolution of Other Complications

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 1)	Minimum	623
	Median	623
	Maximum	623
Resolved - Time To Resolution (N = 4)*	Minimum	1
	Median	19
	Maximum	1009

* Includes 1 occurrence of Other Complication that was resolved after explanation of the patient's primary study device.

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Table 156: Distribution of Other Complications Resolution Status

Resolution Status	By Patient	
	n	%(N = 5)
Not Yet Resolved		
Undergoing Treatment	1	20.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>1</u>	<u>20.0%</u>
Resolved*		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	3	60.0%
Without Treatment	1	20.0%
<u>Total</u>	<u>4</u>	<u>80.0%</u>

* Includes 1 occurrence of Other Complication that was resolved after explanation of the patient's primary study device.

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Table 157: Worst Case Severity Levels of Complications Through 2 Years

Complication	Patients	Severity Level* (Allowable Range 1 - 5)					Descriptive Statistics		
		Very Mild		Mild	Moderate	Severe	Very Severe	Mean	SD
		%	%	%	%	%	%		
Asymmetry	46	17.4%	28.3%	23.9%	13.0%	17.4%	2.8	1.3	
Breast Pain	21	38.1%	28.6%	14.3%	9.5%	9.5%	2.2	1.3	
Bruising	9	44.4%	22.2%	33.3%	0.0%	0.0%	1.9	0.9	
Capsular Contracture***	39	7.7%	20.5%	53.8%	12.8%	5.1%	2.9	0.9	
Delayed Wound Healing	10	30.0%	20.0%	30.0%	20.0%	0.0%	2.4	1.2	
Fluid Accumulation	2	0.0%	100.0%	0.0%	0.0%	0.0%	2.0	0.0	
Hematoma	2	0.0%	50.0%	50.0%	0.0%	0.0%	2.5	0.7	
Hypertrophic Scarring	7	14.3%	14.3%	28.6%	28.6%	14.3%	3.1	1.3	
Implant Extrusion	1	0.0%	0.0%	0.0%	0.0%	100.0%	5.0	N/A**	
Implant Malposition	19	5.3%	31.6%	47.4%	5.3%	10.5%	2.8	1.0	
Implant Palpability	1	0.0%	0.0%	0.0%	0.0%	100.0%	5.0	N/A**	
Implant Visibility	1	0.0%	0.0%	0.0%	0.0%	100.0%	5.0	N/A**	
Infection	5	0.0%	0.0%	40.0%	40.0%	20.0%	3.8	0.8	
Lymphadenopathy	1	100.0%	0.0%	0.0%	0.0%	0.0%	1.0	N/A**	
Nipple Hypersensitivity	1	0.0%	100.0%	0.0%	0.0%	0.0%	2.0	N/A**	
Other Abnormal Scarring	3	33.3%	0.0%	66.7%	0.0%	0.0%	2.3	1.2	
Other Nipple Related Obs.	17	17.6%	29.4%	41.2%	0.0%	11.8%	2.6	1.2	
Pneumothorax	1	0.0%	0.0%	0.0%	0.0%	100.0%	5.0	N/A**	

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Table 157 (Cont.): Worst Case Severity Levels of Complications Through 2 Years

Complication	N	Severity Level*					Descriptive Statistics		
		Very Mild		Mild	Moderate	Severe	Very Severe	Mean	SD
		%	%	%	%	%			
Ptosis	3	0.0%	33.3%	33.3%	0.0%	0.0%	33.3%	3.3	1.5
Redness	11	36.4%	45.5%	0.0%	0.0%	18.2%		2.2	1.5
Seroma	10	30.0%	30.0%	40.0%	0.0%	0.0%		2.1	0.9
Skin Rash	6	16.7%	33.3%	50.0%	0.0%	0.0%		2.3	0.8
Swelling	34	32.4%	44.1%	14.7%	5.9%	2.9%		2.0	1.0
Tissue or Skin Necrosis	10	0.0%	20.0%	50.0%	20.0%	10.0%		3.2	0.9
Wrinkling/Rippling	16	31.3%	31.3%	25.0%	12.5%	0.0%		2.2	1.1
Other Complications	10	10.0%	40.0%	40.0%	0.0%	10.0%		2.6	1.1

* Severity level ranged from 1 (very mild) to 5 (very severe).
 ** Standard Deviation (SD) is N/A (Not Applicable) because N = 1.
 *** Includes capsular contracture and breast firmness; Baker Grade I-IV for capsular contracture are indicated above as severity levels 1 to 4; severity for firmness ranged from 1 to 5.

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Table 158: Implant Rupture

Implant Rupture	Implants	
	n	%(N = 361)
No Rupture	350	97.0%
Rupture Suspected Through:		
Explant	0	0.0%
MRI	9	2.5%
Reoperation	0	0.0%
Mammography	0	0.0%
Ultrasound	2	0.6%
Physician Exam	0	0.0%
	<u>361</u>	<u>100.0%</u>

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Table 159: Suspected Implant Ruptures

Suspected Implant Ruptures	Implant Ruptures Identified	
	n	%(N = 11)
Confirmed Rupture by Explant	2	18.2%
False Report: Device Intact		
Explant Indicated Non-Rupture	1	9.1%
Mammography* Indicated Non-Rupture	0	0.0%
Ultrasound* Indicated Non-Rupture	0	0.0%
MRI* Indicated Non-Rupture	0	0.0%
Unconfirmed Rupture Status	8	72.7%
	<u>11</u>	<u>100.0%</u>

* Follow-up diagnostic test

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Table 160: Risk of First Occurrence of Implant Rupture

Time	By Patient				By Implant			
	Number Affected		Cumulative Risk		Number Affected		Cumulative Risk	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
4 Weeks	0	0.0% (0.0%, 0.0%)	218	0.0% (0.0%, 0.0%)	0	0.0%	355	0.0% (0.0%, 0.0%)
6 Months	0	0.0% (0.0%, 0.0%)	204	0.0% (0.0%, 0.0%)	0	0.0%	330	0.0% (0.0%, 0.0%)
1 Year	0	0.0% (0.0%, 0.0%)	193	0.0% (0.0%, 0.0%)	0	0.0%	312	0.0% (0.0%, 0.0%)
2 Years	9	4.8% (1.7%, 7.9%)	168	4.8% (1.7%, 7.9%)	10	3.3%	278	3.3% (1.3%, 5.3%)

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Table 161: Incidence and Prevalence of Implant Rupture

Time	By Patient		By Implant		Number Evaluated
	Incidence	Prevalence	Incidence	Prevalence	
4 Weeks	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	361
6 Months	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	355
1 Year	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	330
2 Years	9 (4.7%)	9 (4.7%)	10 (3.2%)	10 (3.2%)	312

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Table 162: Distribution of Implant Rupture Resolution Status

Resolution Status	By Patient	
	n	%(N = 9)
Not Yet Resolved		
Undergoing Treatment	7	77.8%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>7</u>	<u>77.8%</u>
Resolved		
With Reoperation and Explantation	2	22.2%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
<u>Total</u>	<u>2</u>	<u>22.2%</u>

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Table 163: 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		
4 Weeks	9	209	4.1%	(1.5%, 6.7%)	9	346	2.5%	(0.9%, 4.1%)
6 Months	52	166	23.8%	(18.2%,29.5%)	69	286	19.4%	(15.3%,23.5%)
1 Year	69	147	31.7%	(25.5%,37.9%)	92	259	26.0%	(21.4%,30.5%)
2 Years	80	126	36.9%	(30.5%,43.4%)	106	231	30.1%	(25.3%,34.8%)

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Table 164: Number of Reoperations Per Patient

	Patients (N = 221)	
	n	%
No Reoperations	141	63.8%
At Least One Reoperation	80	36.2%
Total	221	100.0%

Breakdown of At Least One Reoperation	n	%(N = 80)
1 Reoperation	62	77.5%
2 Reoperations	13	16.3%
3 or More Reoperations	5	6.3%
Total	80	100.0%
Total Number of Reoperations	104*	

* Total number of reoperations is calculated as:
 (62 * 1 reoperation) + (13 * 2 reoperations) +
 (4 * 3 reoperations) + (1 * 4 reoperations) =
 104 reoperations.

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Table 165: Intraoperative Complications During Reoperation

Intraoperative Complications	Reoperation	
	n	%(N =104)
Yes	0	0.0%
No	104	100.0%
	<u>104</u>	<u>100.0%</u>

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Table 166: Primary* Reason for Reoperation

Reason	Patient Reoperations	
	n	%(N = 104)
Device Malfunction - Rupture	0	0.0%
Injury - Iatrogenic or Traumatic	1	1.0%
Breast Cancer	1	1.0%
Capsular Contracture	13	12.5%
Infection	0	0.0%
Healing Related		
Extrusion	1	1.0%
Necrosis	2	1.9%
Hematoma/Seroma	9	8.7%
Delayed Wound Healing	7	6.7%
Nipple Complications	4	3.8%
Pain	1	1.0%
Unsatisfactory Cosmetic Result		
Breast Tissue Contour Deformity	7	6.7%
Malposition	21	20.2%
Wrinkling/Rippling	2	1.9%
Implant Palpability/Visibility	0	0.0%
Asymmetry	12	11.5%
Ptosis	1	1.0%
Scarring	18	17.3%
Patient Request		
Style/Size Change	2	1.9%
Media Anxiety	0	0.0%
Need for Biopsy	0	0.0%
Other	2	1.9%
Total	104	100.0%

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Table 166 (cont.): Primary* Reason for Reoperation

Other Reason Specified (N = 2)

Reop Seq#	Other Reason Specified
001	SCARING TIGHTNESS FROM RADIATION
002	CYST

* Some reoperations were performed for multiple reasons; only the primary reason is provided in the table. In cases where multiple reasons for reoperation were given, the primary reason was determined using a hierarchy as defined by the listed ordering of reasons.

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Table 167: Primary* Procedure Performed

Procedure	Patient Reoperations	
	n	%(N = 104)
Implant Removal		
With Replacement	32	30.8%
Without Replacement	5	4.8%
Capsule Procedure		
Capsulotomy	13	12.5%
Capsulorrhaphy	0	0.0%
Capsulectomy	0	0.0%
Flap Procedure	1	1.0%
Pocket Revision	5	4.8%
Reposition Implant	3	2.9%
Surgical Exploration of Breast Area or Implant	0	0.0%
Mastopexy	1	1.0%
Breast Reduction	1	1.0%
Wound Repair	6	5.8%
Aspiration of Hematoma/Seroma	7	6.7%
Liposuction	4	3.8%
Removal of Excess Tissue/Lesion/Cyst	6	5.8%
Revision of Nipple Reconstruction/Tattoo	4	3.8%
Scar Revision	15	14.4%
Biopsy	0	0.0%
Other	1	1.0%
Total	104	100.0%

* Some reoperations involved multiple procedures. Only the primary procedure is provided in the table. In cases where multiple procedures were performed, the primary procedure was determined using a hierarchy as defined by the listed ordering of procedures.

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Table 167 (cont.): Primary* Procedure Performed

Other Procedure Specified (N = 1)

Reop Seq#	Other Procedure Specified
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001	REVISION
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Table 168: Primary* Reason For Reoperation and Primary Procedure Performed

Reason	Procedure	Patient Reoperations	
		n	%(N = 104)
Injury - Iatrogenic or Traumatic	Implant Replacement/Removal	1	1.0%
	Implant Replacement/Removal	1	1.0%
	Implant Replacement/Removal	9	8.7%
Capsular Contracture	Capsule Procedure	4	3.8%
	Implant Replacement/Removal	3	2.9%
Healing Related	Capsule Procedure	1	1.0%
	Wound Repair	6	5.8%
	Revision of Nipple Reconstruction/Tattoo	4	3.8%
	Removal of Excess Tissue/Lesion/Cyst	1	1.0%
	Aspiration of Hematoma/Seroma	7	6.7%
	Flap Procedure	1	1.0%
	Implant Replacement/Removal	1	1.0%
	Implant Replacement/Removal	20	19.2%
	Capsule Procedure	8	7.7%
	Removal of Excess Tissue/Lesion/Cyst	4	3.8%
Pain	Liposuction	4	3.8%
	Scar Revision	15	14.4%
	Pocket Revision	5	4.8%
	Breast Reduction	1	1.0%
	Reposition Implant	3	2.9%
	Mastopexy	1	1.0%
	Unsatisfactory Cosmetic Result		
	Implant Replacement/Removal		
	Implant Replacement/Removal		
	Capsule Procedure		

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Table 168 (cont.): Primary* Reason For Reoperation and Primary Procedure Performed

Reason	Patient Reoperations	
	n	%(N = 104)
Patient Request	2	1.9%
Other	1	1.0%
	1	1.0%
Total	104	100.0%

* Some reoperations involved multiple reasons for reoperation and/or multiple procedures performed. Only the primary reason/procedure is provided in the table. In cases where multiple reasons/procedures were given, the primary reason/procedure was determined using a hierarchy.

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Table 169: Number of Procedures Performed Per Reoperation

Number of Procedures	Reoperations	
	n	%(N = 104)
1	47	45.2%
2	35	33.7%
3	8	7.7%
4	11	10.6%
5	2	1.9%
6	0	0.0%
7	1	1.0%
Total	104	100.0%
Total Number of Procedures	202*	

* Total number of procedures is calculated as:
 (47 * 1 procedure) + (35 * 2 procedures) + (8 * 3 procedures)
 + (11 * 4 procedures) + (2 * 5 procedures) +
 (1 * 7 procedures) = 202 procedures.

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Table 170: Type of Procedure Performed During Reoperation

Type of Procedure	Procedures	
	n	%(N = 202)
Implant Removal		
With Replacement	39	19.3%
Without Replacement	6	3.0%
Capsule Procedure		
Capsulotomy	28	13.9%
Capsulorrhaphy	2	1.0%
Capsulectomy	11	5.4%
Flap Procedure	2	1.0%
Pocket Revision	13	6.4%
Reposition Implant	13	6.4%
Surgical Exploration of Breast Area or Implant	0	0.0%
Mastopexy	3	1.5%
Breast Reduction	2	1.0%
Wound Repair	7	3.5%
Aspiration of Hematoma/Seroma	8	4.0%
Liposuction	9	4.5%
Removal of Excess Tissue/Lesion/Cyst	10	5.0%
Revision of Nipple Reconstruction/Tattoo	9	4.5%
Scar Revision	31	15.3%
Biopsy	1	0.5%
Other	8	4.0%
Total	202	100.0%

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Table 170 (cont.): Type of Procedure Performed During Reoperation

Other Procedure Specified (N = 8)

Procedure Seq#	Other Procedure Specified
001	CORRECT DOG EAR,LIPO RECONTOUR
002	CORRECT DOG EAR,LIPO RECONTOUR
003	REVISION
004	(R)AUTOGENOUS LATISS DORSI BREAST RECONSTR
005	SKIN&SUBCUTANEOUS TISSUE WAS REMOVED TO TH
006	SKIN AND SUBCUTANEOUS TISSUE WAS REMOVED T
007	RECONTOURING AND REDUCTION OF AXILLARY BRE
008	REMOVAL RT.PORT-A-CATH REV.RT.SUBMUSCULAR

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Table 171: 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)
4 Weeks	0	218	0.0%	--	0	355	0.0%	--
6 Months	19	198	8.8%	(5.0%, 12.5%)	23	331	6.5%	(3.9%, 9.1%)
1 Year	30	185	13.9%	(9.3%, 18.5%)	37	313	10.5%	(7.3%, 13.7%)
2 Years	37	166	17.2%	(12.1%, 22.2%)	45	288	12.8%	(9.3%, 16.3%)

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Table 172: Risk of First Occurrence of Implant Removal With Replacement

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		
4 Weeks	0	218	0.0%	0.0%	0	355	0.0%	--
6 Months	16	199	7.4%	(3.9%, 10.9%)	20	331	5.7%	(3.3%, 8.1%)
1 Year	25	186	11.7%	(7.4%, 15.9%)	31	313	8.9%	(5.9%, 11.8%)
2 Years	32	167	15.0%	(10.2%, 19.9%)	39	288	11.2%	(7.9%, 14.6%)

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Table 173: Risk of First Occurrence of Implant Removal Without Replacement

Time	By Patient				By Implant			
	Number Affected		Cumulative Risk		Number Affected		Cumulative Risk	
	n	% (95% CI)						
4 Weeks	0	0.0%	218	0.0%	0	0.0%	355	0.0% (0.0%, 0.0%)
6 Months	3	1.4% (0.0%, 3.0%)	203	1.4% (0.0%, 3.0%)	3	0.9% (0.0%, 1.8%)	330	0.9% (0.0%, 1.8%)
1 Year	5	2.4% (0.3%, 4.5%)	192	2.4% (0.3%, 4.5%)	6	1.8% (0.4%, 3.2%)	312	1.8% (0.4%, 3.2%)
2 Years	5	2.4% (0.3%, 4.5%)	176	2.4% (0.3%, 4.5%)	6	1.8% (0.4%, 3.2%)	288	1.8% (0.4%, 3.2%)

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Table 174: Primary* Reason for Implant Replacement/Removal

Reason	Implant Removals	
	n	%(N = 45)
Device Malfunction - Rupture	0	0.0%
Injury - Iatrogenic or Traumatic	1	2.2%
Breast Cancer	1	2.2%
Capsular Contracture	12	26.7%
Infection	0	0.0%
Healing Related		
Extrusion	1	2.2%
Necrosis	0	0.0%
Hematoma/Seroma	2	4.4%
Delayed Wound Healing	0	0.0%
Nipple Complications	0	0.0%
Pain	1	2.2%
Unsatisfactory Cosmetic Result		
Breast Tissue Contour Deformity	1	2.2%
Malposition	8	17.8%
Wrinkling	3	6.7%
Implant Palpability/Visibility	0	0.0%
Asymmetry	11	24.4%
Ptosis	0	0.0%
Unsatisfactory Scar	1	2.2%
Patient Request		
Style/Size Change	3	6.7%
Media Anxiety	0	0.0%
Biopsy	0	0.0%
Other	0	0.0%
Total	45	100.0%

* Some implant replacements/removals were performed for multiple reasons. Only the primary reason is provided in the table. In cases where multiple reasons were given, the primary reason was determined using a hierarchy as defined by the listed ordering of reasons.

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Table 175: Physician Evaluation of Explanted Devices

Characteristic	Ruptured Implants (n = 0*)		Intact (Non-Ruptured) Implants (n = 45)	
	Yes (%)	No (%)	Yes (%)	No (%)
Capsule Torn**	0 (0.0%)	0 (0.0%)	2 (4.4%)	43 (95.6%)
Extracapsular Gel	0 (0.0%)	0 (0.0%)	0 (0.0%)	45 (100.0%)
Gel on Implant Surface	0 (0.0%)	0 (0.0%)	0 (0.0%)	45 (100.0%)
Removal Difficult	0 (0.0%)	0 (0.0%)	0 (0.0%)	45 (100.0%)

* The number of ruptured implants reported is less than the number of ruptures confirmed by explant on Table 159 because the 2 ruptures reported in Table 159 were identified as suspected ruptures within 2 years post-implant, but were explanted after 2 years post-implant. Table 175 reports the status of devices that were explanted within 2 years post-implant.

** Capsule not intact

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Table 176: Distribution of Type of Replacement Implant

Type of Replacement Implant	By Implant	
	n	%(N= 39)
McGhan Study Device	35	89.7%
McGhan Non-Study Device	1	2.6%
Non-McGhan Medical Device	3	7.7%
Total	39	100.0%

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Table 177: McGhan Replacement Implant Size vs. Primary Implant

Size Change	By Implant	
	n	%(N = 35)
Increase in Size	12	34.3%
No Change in Size	3	8.6%
Decrease in Size	20	57.1%
Total	35	100.0%

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Table 178: Risk of First Occurrence of Any General Breast Surgery Complication

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		
4 Weeks	27	191	12.3%	(7.9%, 16.6%)	30	325	8.4%	(5.5%, 11.2%)
6 Months	61	150	28.1%	(22.1%, 34.0%)	74	267	20.9%	(16.7%, 25.2%)
1 Year	70	132	32.5%	(26.2%, 38.8%)	86	239	24.6%	(20.1%, 29.2%)
2 Years	76	114	35.7%	(29.2%, 42.2%)	96	213	27.9%	(23.1%, 32.6%)

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Table 179: Risk of First Occurrence of Any Breast Implant Surgery - Cosmetic Complication

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		
4 Weeks	13	205	5.9%	(2.8%, 9.1%)	13	342	3.6%	(1.7%, 5.6%)
6 Months	38	177	17.5%	(12.4%, 22.5%)	46	302	13.0%	(9.5%, 16.5%)
1 Year	48	164	22.2%	(16.6%, 27.7%)	56	287	15.9%	(12.1%, 19.8%)
2 Years	54	146	25.1%	(19.3%, 30.9%)	62	263	17.7%	(13.7%, 21.7%)

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Table 180: Risk of First Occurrence of Any Breast Implant Surgery – Non-Cosmetic Complication

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n	% (95% CI)	n	n	% (95% CI)		
4 Weeks	2	216	0.9% (0.0%, 2.2%)	2	353	0.6% (0.0%, 1.3%)		
6 Months	7	200	3.3% (0.9%, 5.7%)	8	327	2.3% (0.7%, 3.9%)		
1 Year	14	185	6.7% (3.3%, 10.2%)	15	306	4.4% (2.2%, 6.7%)		
2 Years	18	168	8.8% (4.9%, 12.7%)	20	282	6.1% (3.5%, 8.6%)		

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Table 181: Pre-Implant Reproduction Problems

Reproduction Problems	Patients	
	n	%(N = 221)
No Reproduction Problem	170	76.9%
Reproduction Problem	51	23.1%
	221	100.0%

Type Of Reproduction Problem	n	%(N = 51)
Infertility	15	29.4%
Spontaneous Abortion (Miscarriage)	32	62.7%
Planned Abortion to Treat a Medical Problem	7	13.7%
Ectopic Pregnancy	2	3.9%
Stillbirth	1	2.0%
Other	5	9.8%
	62*	121.6%

* The sum of reproduction problems listed may exceed the total number of patients with reproduction problems because a patient may have had more than one reproduction problem.

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Table 181 (cont.): Pre-Implant Reproduction Problems

Other Reproduction Problem (N = 5)

Pt

Seq# Other Reproduction Problem Specified

001	UTERUS-SEPTUM
002	LEVEL II ENDO.
003	ENDOMETREOSIS
004	ENDOMETRIOSIS
005	MOLAR PREGNANCY

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Table 182: Post-Implant Reproduction Problems Through 2 Years

Reproduction Problems	Patients	
	n	%(N = 221)
No Reproduction Problem	219	99.1%
Reproduction Problem	2	0.9%
	221	100.0%

Type Of Reproduction Problem	n	%(N = 2)
Infertility	0	0.0%
Spontaneous Abortion (Miscarriage)	0	0.0%
Planned Abortion to Treat a Medical Problem	1	50.0%
Ectopic Pregnancy	0	0.0%
Stillbirth	0	0.0%
Other	1	50.0%
	2	100.0%

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Table 182 (cont.): Post-Implant Reproduction Problems
Through 2 Years

Other Reproduction Problem (N = 1)

Pt	
Seq#	Other Reproduction Problem Specified

001	NO MENSES
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Table 183: Pre-Implant Lactation Problems

Lactation Problems	Patients	
	n	%(N = 221)
No Lactation Problem	195	88.2%
Lactation Problem	26	11.8%
	<u>221</u>	<u>100.0%</u>

Type Of Lactation Problems	n	%(N = 26)
Mastitis Not Requiring Treatment	4	15.4%
Mastitis Requiring Treatment	7	26.9%
Inadequate Milk Production	14	53.8%
Excess Milk Production	1	3.8%
Pain	6	23.1%
	<u>32*</u>	<u>123.1%</u>

* The sum of lactation problems listed may exceed the total number of patients with lactation problems because a patient may have had more than one lactation problem.

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Table 184: Post-Implant Lactation Problems Through 2 Years

Lactation Problems	Patients	
	n	%(N = 221)
No Lactation Problem	221	100.0%
Lactation Problem	0	0.0%
	221	100.0%

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Table 185: Pre-Implant Breast Disease

Breast Disease	Patients	
	n	%(N = 221)
No Breast Disease	3	1.4%
Breast Disease	218	98.6%
	<u>221</u>	<u>100.0%</u>

Type Of Breast Disease	n	%(N = 218)
Confirmed Malignant Disease	207	95.0%
Benign Disease	11	5.0%
	<u>218</u>	<u>100.0%</u>

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Table 186: Post-Implant Breast Disease Through 2 Years

Breast Disease	Patients	
	n	%(N = 221)
No Breast Disease	208	94.1%
Breast Disease*	13	5.9%
	<u>221</u>	<u>100.0%</u>

Type Of Breast Disease	n	%(N = 13)
Confirmed Malignant Disease	4	30.8%
Benign Disease	9	69.2%
	<u>13</u>	<u>100.0%</u>

* Includes 5 patients with breast disease on non-enrolled/non-implanted sides.

Table 187: Pre-Implant Mammogram Result

Mammogram Results	Patients	
	n	%(N = 221)
No Pre-Implant Mammogram	21	9.5%
Pre-Implant Mammogram		
Normal Mammogram	63	28.5%
Abnormal Mammogram	137	62.0%
	<u>221</u>	<u>100.0%</u>

Disposition Of Patients With Abnormal Mammogram Results	Patients	
	n	%(N = 137)
Confirmed Malignant Disease	131	95.6%
Benign Disease	6	4.4%
	<u>137</u>	<u>100.0%</u>

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Table 188: Post-Implant Mammogram Result Through 2 Years

Mammogram Results	Patients	
	n	%(N = 221)
No Post-Implant Mammogram	116	52.5%
Post-Implant Mammogram		
Normal Mammogram	95	43.0%
At Least One Abnormal Mammogram	10	4.5%
	<u>221</u>	<u>100.0%</u>

Disposition Of Patients With Abnormal Mammogram Results	n	
	n	%(N = 10)
No Breast Disease	2	20.0%
Confirmed Malignant Disease	2	20.0%
Benign Disease	6	60.0%
	<u>10</u>	<u>100.0%</u>

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Table 189: Pre-Implant Connective Tissue/Autoimmune Disease (CTD)

CTD	Patients	
	n	%(N = 221)
No CTD	221	100.0%
CTD		
Confirmed CTD	0	0.0%
Unconfirmed CTD	0	0.0%
<u>Total</u>	<u>221</u>	<u>100.0%</u>

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Table 190: Post-Implant Connective Tissue/Autoimmune Disease (CTD) Through 2 Years

CTD	Patients	
	n	%(N = 221)
No CTD	220	99.5%
CTD		
Confirmed CTD	1	0.5%
Unconfirmed CTD	0	0.0%
	221	100.0%

Confirmed CTD Specified (N = 1)

Pt Seq#	CTD Specified	# of Months Between Implant Surgery and Onset
001	Systemic Sclerosis/Scleroderma	4

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Table 191: Change in Pre- vs. Post-Implant Bra Cup Size

N/A: CHANGE IN BRA CUP SIZE WAS NOT ASSESSED FOR
RECONSTRUCTION PATIENTS

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Table 192: Comparison of Pre- vs. Post-Implant Bra Cup Size

N/A: COMPARISON OF PRE- VS. POST-IMPLANT BRA CUP SIZE WAS NOT ASSESSED
FOR RECONSTRUCTION PATIENTS

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Table 193: Pre- vs. Post-Implant Bra Size

N/A: PRE- VS. POST-IMPLANT BRA SIZE WAS NOT ASSESSED FOR RECONSTRUCTION PATIENTS

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Table 194: Pre- vs. Post-Implant Lateral Breast Measurement, By Breast

N/A: PRE- VS. POST-IMPLANT LATERAL BREAST MEASUREMENT WAS NOT ASSESSED FOR RECONSTRUCTION PATIENTS

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Table 195: Physician Assessment of Implants

Time	Satisfaction Level* (Allowable Range 1 - 5)										Mean	SD
	Definitely Somewhat					Definitely						
	Patients	N	%	%	%	Patients	N	%	%	%		
0-4 Weeks		218	0.0%	0.5%	1.4%			12.8%	17.5%	85.3%	4.8	0.4
6 Months		194	1.0%	3.1%	0.5%			17.5%	17.3%	77.8%	4.7	0.7
1 Year		185	1.6%	2.7%	1.6%			17.3%	19.8%	76.8%	4.6	0.8
2 Years		177	1.1%	3.4%	2.3%			19.8%		73.4%	4.6	0.8

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

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Table 196: Physician Dissatisfaction with Implants

Time	Physician Dissatisfaction Specified					
	Patients			Implants		
	n	Yes (%)*	No (%)	n	Yes (%)*	No (%)
0-4 Weeks	218	7 (3.2%)	211 (96.8%)	354	8 (2.3%)	346 (97.7%)
6 Months	194	11 (5.7%)	183 (94.3%)	317	14 (4.4%)	303 (95.6%)
1 Year	185	10 (5.4%)	175 (94.6%)	300	13 (4.3%)	287 (95.7%)
2 Years	177	9 (5.1%)	168 (94.9%)	285	10 (3.5%)	275 (96.5%)

* Includes all patients/implants for which a specific dissatisfaction was indicated, regardless of the satisfaction rating (1-5) provided.

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Table 197: Type of Physician Dissatisfaction with Implants

Time	N	Type of Dissatisfaction Specified				
		Implants	Aesthetic	Implant		Other
				Design	Medical/ Procedural	
			%	%	%	
0-4 Weeks	8		37.5%	0.0%	62.5%	0.0%
6 Months	14		35.7%	0.0%	64.3%	0.0%
1 Year*	13		53.8%	0.0%	69.2%	15.4%
2 Years	10		10.0%	0.0%	90.0%	0.0%

* The sum of the percentages across types of dissatisfaction may exceed 100% because a physician may have specified more than one type of dissatisfaction for an implant.

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Table 197 (cont.): Type of Physician Dissatisfaction with Implants

Other Physician Dissatisfactions Specified (N = 2)

Imp Seq#	Side	Other Dissatisfaction Specified
001	R	SEE NOTES PT IS VERY ANGRY WITH DIAGNOSES OF BREAST CANCER WANTS A "D" CUP BREAST UNABLE TO ACHIEVE WX
002	L	RADIATED SOFT TISSUE ON(L) IS THE PROBLEM NOT THE IMPLANT

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Table 198: Patient Assessment of Implants

Time	Patients	Satisfaction Level* (Allowable Range 1 - 5)								Descriptive Statistics	
		Definitely Somewhat				Definitely				Mean	SD
		Dissat- isfied	Dissat- isfied	Somewhat Satisfied	Somewhat Satisfied	Definitely Satisfied	Definitely Satisfied	%	%		
0-4 Weeks	218	0.5%	1.4%	2.8%	11.9%	83.5%	4.8	0.6			
6 Months	195	1.5%	5.1%	1.0%	20.0%	72.3%	4.6	0.9			
1 Year	186	2.7%	2.2%	2.2%	23.7%	69.4%	4.5	0.9			
2 Years	177	1.7%	4.0%	3.4%	23.7%	67.2%	4.5	0.9			

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

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Table 199: Patient Dissatisfaction with Implants

Time	Patient Dissatisfaction Specified					
	Patients			Implants		
	n	Yes (%)*	No (%)	n	Yes (%)*	No (%)
0-4 Weeks	218	6 (2.8%)	212 (97.2%)	353	7 (2.0%)	346 (98.0%)
6 Months	195	15 (7.7%)	180 (92.3%)	318	19 (6.0%)	299 (94.0%)
1 Year	186	12 (6.5%)	174 (93.5%)	301	16 (5.3%)	285 (94.7%)
2 Years	177	15 (8.5%)	162 (91.5%)	285	17 (6.0%)	268 (94.0%)

* Includes all patients/implants for which a specific dissatisfaction was indicated, regardless of the satisfaction rating (1-5) provided.

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Table 200: Type of Patient Dissatisfaction with Implants

Time	Type of Dissatisfaction Specified						
	Implants	N	Implant				Other
			Aesthetic	Design	Medical/ Procedural		
			%	%	%	%	%
0-4 Weeks		7	100.0%	0.0%	0.0%	0.0%	0.0%
6 Months		19	52.6%	0.0%	36.8%	10.5%	
1 Year*		16	62.5%	0.0%	37.5%	12.5%	
2 Years		17	41.2%	0.0%	29.4%	29.4%	

* The sum of the percentages across types of dissatisfaction may exceed 100% because a patient may have specified more than one type of dissatisfaction for an implant.

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Table 200 (cont.): Type of Patient Dissatisfaction with Implants

Other Patient Dissatisfactions Specified (N = 9)

Imp Seq#	Side	Other Dissatisfaction Specified
001	L	DOESN'T FEEL RIGHT
002	R	NOT IN RIGHT PLACE UNCOMFORTABLE
003	L	UNCOMPROTABLE
004	R	UNCOMPROTABLE
005	R	SEE NOTES PT IS VERY ANGRY WITH DIAGNOSES OF BREAST CANCER WANTS A "D" CUP BREAST UNABLE TO ACHIEVE EX
006	L	COLD SENSATION IN BREASTS IN WINTER
007	R	COLD SENSATION IN BREASTS IN WINTER
008	L	FEEL FOREIGN
009	R	FEEL FOREIGN

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Table 201: Patient Assessment of Implants, with Both Primary and Secondary Study Devices Included

Time	Satisfaction Level* (Allowable Range 1 - 5)										Mean	SD
	Definitely Dissatisfied		Somewhat Dissatisfied		Somewhat Satisfied		Definitely Satisfied		Descriptive Statistics			
	N	%	N	%	N	%	N	%	Mean	SD		
0-4 Weeks	218	0.5%	1.4%	2.8%	11.9%	83.5%	4.8	0.6				
6 Months	207	1.4%	5.8%	1.0%	21.7%	70.0%	4.5	0.9				
1 Year	200	3.0%	3.0%	2.0%	26.0%	66.0%	4.5	0.9				
2 Years	192	2.6%	4.2%	3.6%	24.0%	65.6%	4.5	0.9				

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

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Table 202: Motivations for Having Breast Implant Surgery

Reason	Level of Importance* (Allowable Range 1 - 5)							
	Not At All		A Little Bit		Moderately		Quite A Bit	
	N	%	N	%	N	%	N	%
To Please My Partner	214	42.1%	17.8%	23.8%	12.6%	3.7%		
To Improve My Sex Life	214	57.0%	11.2%	23.4%	7.9%	0.5%		
To Make Me Feel Better About My Physical Appearance	213	5.2%	6.6%	15.5%	37.1%	35.7%		
To Improve the Way I Feel About Myself	215	13.0%	6.0%	29.3%	24.7%	27.0%		
To Increase My Chance of Meeting A Partner	208	85.6%	2.9%	8.2%	1.4%	1.9%		
Other Reason	62	1.6%	0.0%	1.6%	17.7%	79.0%		

* Level of importance could range from 1 (not at all important) to 5 (extremely important).

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Table 202 (cont.) : Motivations for Having Breast Implant Surgery

Other Reason Specified (N = 62)

Pt Seq#	Other Reason Specified
001	TO PREVENT BREAST CA
002	MASTECTOMY
003	LOOK NICE IN CLOTHES
004	BREAST CANCER
005	MEDICALLY NECESSARY
006	RECTIFY BILATERAL MASTECTOMY
007	AFTER BREAST SURGERY
008	TO AVOID CANCER
009	TALKED TO OTHER PATIENTS WHO SAID THEY EVENTUALLY WANTED IMPLANTS
010	RECONSTRUCTION AFTER MASTECTOMY
011	COMFORT
012	RECONSTRUCTION
013	BREAST CANCER RECONSTR.
014	REPLACE AFTER BREAST CANCER
015	2 HAD COACLS-REPLACE BREST.
016	TO HAVE BREASTS
017	BREAST CANCER
018	CORRECT APPEARANCE POST MASTECTOMY
019	DOUBLE MASTECTOMY RECONSTRUCTION

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Table 202 (cont.): Motivations for Having Breast Implant Surgery

Other Reason Specified (N = 62)

Pt
 Seq# Other Reason Specified

020	RECONSTRUCT AFTER BREAST CANCER
021	BREAST CANCER
022	MASTECTOMY
023	MASECTOMY
024	CLOTHING
025	TO MATCH OTHER BREAST
026	DUE TO CANCER-FIX DEFORMED BREAST
027	COMFORT&CLOTHES
028	MASTECTOMY RECONSTRUCTION
029	MASTECTOMIES
030	PROTHESIS HASSLE
031	CANCER
032	RECONSTRUCTION
033	AFTER A MASTECTOMY MY NEW BREASTS REPRESENT AN ASSERTION OF "LIFE "
034	TO REMOVE TISSUE EXPANDERS TO FEEL MORE COMFORTABLE
035	Other Reason not Specified
036	TO FORGET MASTECTOMY
037	RECONSTRUCTION
038	REDUCE CHANCES FOR BREAST CA

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Table 202 (cont.): Motivations for Having Breast Implant Surgery

Other Reason Specified (N = 62)

Pt Seq#	Other Reason Specified
039	Other Reason not Specified
040	RECONSTRUCTION
041	COMFORT FOR NOT HAVING PAD
042	CONVENIENCE
043	MEDICAL NECESS.
044	RECONSTRUCTION
045	TO BE WHOLE AGAIN
046	TO FEEL "NORMAL" AFTER BC
047	MASTECTOMY
048	CONVENIENCE
049	BREAST CANCER
050	RECONSTRUCTION
051	ALL MY LIFE WANTED BIGER
052	TO LOOK MORE NORMAL
053	BREAST CANCER
054	RECONSTRUCTION/CANCER
055	EASE CHOICE OF MASTECTOMY
056	CANCER
057	MASTECTOMY

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Table 202 (cont.): Motivations for Having Breast Implant Surgery

Other Reason Specified (N = 62)

Pt Seq#	Other Reason Specified
058	MASTECTOMY-CANCER
059	MASTECTOMY
060	DUE TO CANCER
061	TO FEEL & LOOK BETTER DRESSED
062	RECONSTRUCTION TO "NORMAL"

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Table 203: Comparison of Patient Pre-Operative Expectation With Post-Implant Satisfaction With Breast Implants

Satisfaction with Breast Implants
 (Allowable Range 1-5)

Time	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	p
Pre-Operative Expectation*	4.6B	0.5	3.0 - 5.0	166	18.26	<0.001
1 Year	4.3A	0.8	2.0 - 5.0			
2 Years	4.2A	1.0	1.0 - 5.0			

* Pre-Operative Expectation is assessed at baseline to measure how much a patient expects to be satisfied with her implants after implantation.

- Score: 1 = Very Dissatisfied
 2 = Dissatisfied
 3 = Neither Satisfied nor Dissatisfied
 4 = Satisfied
 5 = Very Satisfied

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different subscripts.

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Table 204: Patient Satisfaction Rating: Pre-Operative Expectation vs. Post-Implant Satisfaction with Breast Implants

Rating	% (N = 166 Patients)		
	Pre-Op	Post-Op	
		1 Year	2 Years
Very Dissatisfied	0.0%	0.0%	1.2%
Dissatisfied	0.0%	3.6%	7.8%
Neither Satisfied nor Dissatisfied	2.4%	9.6%	6.0%
Satisfied	31.9%	36.1%	38.6%
Very Satisfied	65.7%	50.6%	46.4%
	100.0%	100.0%	100.0%

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Table 205: Rowland Expectation Summary

Scale	Mean Score					Effect Size
	Pre-Op	Post-Op			p	
		1 Year	2 Years	3 Years		
Improve Self Image	3.1	3.1	3.1	3.1	n.s.	..
Improve Social Relations	1.3A	1.7B	1.7B	1.7B	**	0.46
Improve Daily Living	3.3B	2.9A	2.9A	3.1A	*	0.30
Improve Well-Being	3.3	3.4	3.4	3.5	n.s.	..

* = p < .01

** = p < .001

n.s. = not significant

Significantly different means are indicated with different letters.

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Table 206: Rowland Expectation: Improve Self Image

Rowland Expectation: Improve Self Image
 (Allowable Range 1-5)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	3.1	0.8	1.3 - 5.0	166	0.46	2	0.633
1 Year	3.1	1.0	1.1 - 5.0				
2 Years	3.1	1.1	1.0 - 5.0				

- Score: 1 = Not At All
 2 = Slightly
 3 = Moderately
 4 = Considerably
 5 = Absolutely 100%

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0125 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

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Table 207: Rowland Expectation: Improve Social Relations

Rowland Expectation: Improve Social Relations
 (Allowable Range 1-5)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	1.3A	0.7	1.0 - 4.3	162	11.91	2	<0.001
1 Year	1.7B	1.1	1.0 - 5.0				
2 Years	1.7B	1.2	1.0 - 5.0				

- Score: 1 = Not At All
 2 = Slightly
 3 = Moderately
 4 = Considerably
 5 = Absolutely 100%

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0125 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

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Table 208: Rowland Expectation: Improve Daily Living

Rowland Expectation: Improve Daily Living
 (Allowable Range 1-5)

Descriptive Statistics

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	P
Baseline	3.3B	1.2	1.0 - 5.0	166	6.73	2	0.001
1 Year	2.9A	1.3	1.0 - 5.0				
2 Years	3.1A	1.3	1.0 - 5.0				

- Score: 1 = Not At All
 2 = Slightly
 3 = Moderately
 4 = Considerably
 5 = Absolutely 100%

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0125 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letter.

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Table 209: Rowland Expectation: Improve Well-Being

Rowland Expectation: Improve Well-Being
 (Allowable Range 1-5)

Descriptive Statistics

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	P
Baseline	3.3	1.2	1.0 - 5.0	154	1.46	2	0.233
1 Year	3.4	1.1	1.0 - 5.0				
2 Years	3.5	1.2	1.0 - 5.0				

- Score: 1 = Not At All
 2 = Slightly
 3 = Moderately
 4 = Considerably
 5 = Absolutely 100%

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0125 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

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Table 210: Comparison of Baseline SF-36 Scores to General Population

	Mean Score		t	df	p
	Reconstruction Patients	General Population			
Role Limitations due to Emotional Problems	80.81	79.47	0.47	1575	0.637
Role Limitations due to Physical Problems	70.61	77.77	2.38	1575	0.017
General Health	78.68	70.61	5.64	231	<0.001
Bodily Pain	77.65	73.59	2.37	219	0.019
Social Functioning	87.65	81.54	3.72	222	<0.001
Physical Functioning	87.14	81.47	3.61	239	<0.001
Vitality	65.04	58.43	4.20	217	<0.001
Mental Health	79.85	73.25	5.64	231	<0.001
Reported Health Transition	43.51	N/A	N/A	N/A	N/A

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Table 211: SF-36 Summary

Scale	Table	Mean Score			Effect Size	
		Pre-Op	Post-Op			p
			1 Year	2 Years		
Role Limitations due to Emotional Problems	212	80.8	86.1	86.9	n.s. --	
Role Limitations due to Physical Health Problems	213	70.6A	82.6B	78.9B	** 0.31	
General Health	214	78.7	78.2	76.9	n.s. --	
Bodily Pain	215	77.7	82.8	80.6	n.s. --	
Social Functioning	216	87.7	91.3	91.1	n.s. --	
Physical Functioning	217	87.1	90.2	88.7	n.s. --	
Vitality	218	65.0	66.4	65.2	n.s. --	
Mental Health	219	79.8	80.7	80.7	n.s. --	
Reported Health Transition	220	43.5B	22.6A	41.2B	** 0.68	

** = p < .001

n.s. = not significant

Significantly different means are indicated with different letters.

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Table 212: SF-36: Role Limitations Due to Emotional Problems

SF-36: Role Limitations Due to Emotional Problems
 (Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	80.8	34.8	0.0 - 100.0	165	2.63	2	0.074
1 Year	86.1	29.9	0.0 - 100.0				
2 Years	86.9	27.5	0.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 213: SF-36: Role Limitations Due to Physical Health Problems

SF-36: Role Limitations Due to Physical Health Problems
 (Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	70.6A	39.1	0.0 - 100.0	165	7.43	2	<0.001
1 Year	82.6B	33.4	0.0 - 100.0				
2 Years	78.9B	34.0	0.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different subscripts.

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Table 214: SF-36: General Health

SF-36: General Health
 (Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	78.7	16.8	25.0 - 100.0	165	1.07	2	0.344
1 Year	78.2	18.0	10.0 - 100.0				
2 Years	76.9	18.1	15.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 215: SF-36: Bodily Pain

SF-36: Bodily Pain
 (Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	77.7	20.3	20.0 - 100.0	163	4.01	2	0.019
1 Year	82.8	18.6	10.0 - 100.0				
2 Years	80.6	20.2	0.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 216: SF-36: Social Functioning

SF-36: Social Functioning
 (Allowable Range 1-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	87.7	19.3	25.0 - 100.0	163	3.15	2	0.044
1 Year	91.3	16.3	25.0 - 100.0				
2 Years	91.1	18.7	0.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 217: SF-36: Physical Functioning

SF-36: Physical Functioning
 (Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	87.1	18.3	5.0 - 100.0	165	3.27	2	0.039
1 Year	90.2	14.8	20.0 - 100.0				
2 Years	88.7	15.5	25.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 218: SF-36: Vitality

SF-36: Vitality
 (Allowable Range 0-100)

Descriptive Statistics ANOVA Results

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	65.0	18.8	0.0 - 100.0	165	0.60	2	0.547
1 Year	66.4	18.9	5.0 - 100.0				
2 Years	65.2	19.0	5.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 219: SF-36: Mental Health

SF-36: Mental Health
 (Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	P
Baseline	79.8	14.9	24.0 - 100.0	166	0.44	2	0.642
1 Year	80.7	14.2	32.0 - 100.0				
2 Years	80.7	13.2	16.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 220: SF-36: Reported Health Transition

SF-36: Reported Health Transition
 (Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	P
Baseline	43.5B	30.9	0.0 - 100.0	154	31.75	<0.001
1 Year	22.6A	24.7	0.0 - 100.0			
2 Years	41.2B	23.1	0.0 - 100.0			

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different subscripts.

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Table 221: MOS-20 Summary

Scale	Mean Score					Effect Size
	Table	Pre-Op	Post-Op		p	
			1 Year	2 Years		
Health Perceptions	222	78.3	80.6	78.2	n.s.	--
Physical Functioning	223	76.8A	82.1B	84.8B	**	0.24
Role Functioning	224	82.3	87.9	87.3	n.s.	--
Social Functioning	225	90.7	93.9	95.1	n.s.	--
Mental Health	226	79.0	80.0	79.5	n.s.	--

** = p < .001
 n.s. = not significant
 Significantly different means are indicated with different letters.

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Table 222: MOS-20: Health Perceptions

MOS-20: Health Perceptions
 (Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	78.3	18.2	15.0 - 100.0	165	2.21	2	0.111
1 Year	80.6	17.7	0.0 - 100.0				
2 Years	78.2	19.1	5.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.01 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 223: MOS-20: Physical Functioning

MOS-20: Physical Functioning
 (Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	p
Baseline	76.8A	22.3	0.0 - 100.0	167	8.99	2 <0.001
1 Year	82.1B	22.9	8.3 - 100.0			
2 Years	84.8B	21.7	0.0 - 100.0			

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.01 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

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Table 224: MOS-20: Role Functioning

MOS-20: Role Functioning
 (Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	82.3	29.3	0.0 - 100.0	167	3.27	2	0.039
1 Year	87.9	25.0	0.0 - 100.0				
2 Years	87.3	27.6	0.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.01 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 225: MOS-20: Social Functioning

MOS-20: Social Functioning
 (Allowable Range 0-100)

Descriptive Statistics

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	90.7	18.8	20.0 - 100.0	168	3.75	2	0.025
1 Year	93.9	16.8	0.0 - 100.0				
2 Years	95.1	16.2	0.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.01 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 226: MOS-20: Mental Health

MOS-20: Mental Health
 (Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	79.0	15.4	24.0 - 100.0	168	0.40	2	0.673
1 Year	80.0	14.7	24.0 - 100.0				
2 Years	79.5	14.3	28.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.01 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 227: Burnam Depression Screening Questions

Time	Patients Reporting Symptoms		Cochran-Mantel-Haenszel Results			
	n	%	N	Q (MH)	df	p
Two or more weeks in the past year						
Baseline	52	30.8%	169	6.42	2	0.040
1 Year	44	26.0%				
2 Years	35	20.7%				
Two or more years at any time in the past						
Baseline	18	10.7%	169	0.96	2	0.618
1 Year	21	12.4%				
2 Years	17	10.1%				
Much of the time in the past year						
Baseline	20	11.8%	169	5.41	2	0.067
1 Year	11	6.5%				
2 Years	10	5.9%				

Mantel-Haenszel Results: Results from repeated measures using the Cochran-Mantel-Haenszel General Association Statistic. When the Q(MH) statistic is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of proportions using Scheffe's multiple comparison technique.

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Table 228: TSCS: Physical Self

TSCS: Physical Self
 (Allowable Range 18-90)

Descriptive Statistics

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	p	
Baseline	69.8	8.6	44.0 - 90.0	140	2.20	2	0.113
1 Year	70.0	8.7	51.0 - 90.0				
2 Years	68.9	9.4	40.0 - 89.0				

TSCS: Tennessee Self Concept Scale
 Score: 90 indicates best possible physical self score

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 229: Rosenberg Self-Esteem

Rosenberg Self-Esteem
 (Allowable Range 10-40)

Descriptive Statistics			ANOVA Results				
Time	Mean	S.D:	Range	N	F	df	p
Baseline	35.0	4.3	21.0 - 40.0	169	1.06	2	0.349
1 Year	35.3	4.1	21.0 - 40.0				
2 Years	34.9	4.0	24.0 - 40.0				

Score: 40 indicates best possible self-esteem

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 230: Self vs. Breast Semantic Differential

Semantic Differential
 (Allowable Range (-6*) to +6)

ANOVA Results

Time	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	p
Baseline	0.0	0.5	-1.3 - 2.1	159	0.45	2
1 Year	-0.1	0.5	-2.2 - 1.3			
2 Years	-0.1	0.5	-2.5 - 1.1			0.637

* Score: a negative number indicates a patient rates her breasts more positively than she rates herself.

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

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Table 231: Body Esteem Summary

Scale	Mean Score					Effect Size
	Pre-Op	Post-Op		p		
		1 Year	2 Years			
Body Esteem: Total Score	232	112.2	110.9	111.4	n.s.	--
Body Esteem: Sexual Attractiveness	233	48.4	48.0	48.6	n.s.	--
Body Esteem: Weight Concern	234	30.9	30.3	30.8	n.s.	--
Body Esteem: Physical Condition	235	32.8	32.7	32.0	n.s.	--

n.s. = not significant

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Table 232: Body Esteem: Total Score

Body Esteem: Total Score
 (Allowable Range 32-160)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	P
Baseline	112.2	20.0	63.0 - 160.0	137	0.58	2	0.558
1 Year	110.9	20.2	57.0 - 159.0				
2 Years	111.4	21.3	72.0 - 160.0				

Score: 160 indicates best possible total body esteem

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 233: Body Esteem: Sexual Attractiveness

Body Esteem: Sexual Attractiveness
 (Allowable Range 13-65)

Descriptive Statistics				ANOVA Results		
Time	Mean	S.D.	Range	N	F	p
Baseline	48.4	7.8	33.0 - 65.0	152	0.76	2
1 Year	48.0	7.9	31.0 - 65.0			
2 Years	48.6	8.1	34.0 - 65.0			

Score: 65 indicates best possible sexual attractiveness body esteem.

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 234: Body Esteem: Weight Concern

Body Esteem: Weight Concern
 (Allowable Range 10-50)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	30.9	8.8	10.0 - 50.0	154	0.55	2	0.575
1 Year	30.3	8.9	11.0 - 50.0				
2 Years	30.8	9.3	10.0 - 50.0				

Score: 50 indicates best possible weight concern body esteem

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 235: Body Esteem: Physical Condition

Body Esteem: Physical Condition
 (Allowable Range 9-45)

Descriptive Statistics

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	32.8	6.7	11.0 - 45.0	159	2.21	2	0.111
1 Year	32.7	6.2	15.0 - 45.0				
2 Years	32.0	6.9	12.0 - 45.0				

Score: 45 indicates best possible physical condition body esteem

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 236: Satisfaction Summary

Scale	Table	Mean Score					Effect Size
		Pre-Op	Post-Op			p	
			1 Year	2 Years	3 Years		
Personal Life Satisfaction	237	4.5	4.5	4.6	4.6	n.s.	--
Satisfaction with Breasts	239	2.8A	4.1B	4.0B	4.0B	**	1.11
How Well Breasts Matched	241	2.8A	4.6B	4.4B	4.4B	**	1.22
Satisfaction with Breast Shape	243	2.5A	3.9B	3.7B	3.7B	**	1.21
Satisfaction with Breast Size	245	2.6A	4.0B	3.9B	3.9B	**	1.23
Satisfaction with Breast Feel or Touch	247	2.5A	3.7B	3.6B	3.6B	**	0.99

** = p < .001
 n.s. = not significant
 Significantly different means are indicated with different letters.

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Table 237: Personal Life Satisfaction

Personal Life Satisfaction Score
 (Allowable Range 1-6)

Descriptive Statistics

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	4.5	0.9	2.0 - 6.0	165	1.42	2	0.243
1 Year	4.5	0.9	1.0 - 6.0				
2 Years	4.6	0.9	2.0 - 6.0				

Score: 1 = Very Dissatisfied, Unhappy Most Of The Time

2 = Generally Dissatisfied, Unhappy

3 = Sometimes Fairly Satisfied, Sometimes Fairly Unhappy

4 = Generally Satisfied, Pleased

5 = Very Happy Most Of The Time

6 = Extremely Happy, Could Not Be More Satisfied Or Pleased

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 238: Patient Rating of Personal Life Satisfaction

Rating	% (N = 165 Patients)		
	Pre-Op	Post-Op	
		1 Year	2 Years
Very Dissatisfied, Unhappy Most Of the Time	0.0%	0.6%	0.0%
Generally Dissatisfied, Unhappy	1.8%	1.2%	1.2%
Sometimes Fairly Satisfied, Sometimes Fairly Unhappy	10.3%	12.1%	9.1%
Generally Satisfied, Pleased	33.3%	29.1%	29.1%
Very Happy Most Of The Time	41.2%	47.3%	47.3%
Extremely Happy, Could Not Be More Satisfied	13.3%	9.7%	13.3%
	100.0%	100.0%	100.0%

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Table 239: Satisfaction with Breasts

Satisfaction with Breasts Score
 (Allowable Range 1-5)

ANOVA Results

Descriptive Statistics

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	P
Baseline	2.8A	1.2	1.0 - 5.0	164	120.3	2	<0.001
1 Year	4.1B	0.9	1.0 - 5.0				
2 Years	4.0B	1.0	1.0 - 5.0				

- Score: 1 = Very Dissatisfied
 2 = Dissatisfied
 3 = Neither Satisfied nor Dissatisfied
 4 = Satisfied
 5 = Very Satisfied

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different subscripts.

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Table 240: Patient Rating of Satisfaction With Breasts

Rating	% (N = 164 Patients)		
	Pre-Op	Post-Op	
		1 Year	2 Years
Very Dissatisfied	14.6%	1.2%	1.2%
Dissatisfied	27.4%	7.3%	11.0%
Neither Satisfied nor Dissatisfied	24.4%	7.3%	6.1%
Satisfied	26.8%	44.5%	47.0%
Very Satisfied	6.7%	39.6%	34.8%
	100.0%	100.0%	100.0%

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Table 241: How Well Breasts Matched

How Well Breasts Matched
 (Allowable Range 1-6)

ANOVA Results

Descriptive Statistics

Time	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	p
Baseline	2.8A	1.5	1.0 - 6.0	151	139.6	2
1 Year	4.6B	1.2	1.0 - 6.0			<0.001
2 Years	4.4B	1.3	1.0 - 6.0			

- Score: 1 = Very Poor
 2 = Poor
 3 = Fair
 4 = Good
 5 = Very good
 6 = Excellent

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different subscripts.

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Table 242: Patient Rating of How Well Breasts Matched

Rating	% (N = 151 Patients)			
	Pre-Op	Post-Op		2 Years
		1 Year	2 Years	
Very Poor	26.5%	0.7%	2.0%	
Poor	17.9%	3.3%	6.6%	
Fair	20.5%	13.9%	13.2%	
Good	21.2%	23.8%	27.8%	
Very Good	9.9%	31.1%	26.5%	
Excellent	4.0%	27.2%	23.8%	
	100.0%	100.0%	100.0%	100.0%

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Table 243: Satisfaction with Breast Shape

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	2.5A	1.2	1.0 - 5.0	160	120.1	2	<0.001
1 Year	3.9B	1.1	1.0 - 5.0				
2 Years	3.7B	1.1	1.0 - 5.0				

Score: 1 = Very Dissatisfied
 2 = Dissatisfied
 3 = Neither Satisfied nor Dissatisfied
 4 = Satisfied
 5 = Very Satisfied

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different subscripts.

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Table 244: Patient Rating of Satisfaction With Breast Shape

Rating	% (N = 160 Patients)		
	Pre-Op	Post-Op	
		1 Year	2 Years
Very Dissatisfied	22.5%	2.5%	3.8%
Dissatisfied	28.8%	11.3%	15.0%
Neither Satisfied nor Dissatisfied	25.6%	11.9%	10.0%
Satisfied	18.8%	38.8%	47.5%
Very Satisfied	4.4%	35.6%	23.8%
	100.0%	100.0%	100.0%

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Table 245: Satisfaction with Breast Size

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	P
Baseline	2.6A	1.2	1.0 - 5.0	161	138.8	2	<0.001
1 Year	4.0B	1.0	1.0 - 5.0				
2 Years	3.9B	1.0	1.0 - 5.0				

Score: 1 = Very Dissatisfied
 2 = Dissatisfied
 3 = Neither Satisfied nor Dissatisfied
 4 = Satisfied
 5 = Very Satisfied

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different subscripts.

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Table 246: Patient Rating of Satisfaction With Breast Size

Rating	% (N = 161 Patients)		
	Pre-Op	Post-Op	
		1 Year	2 Years
Very Dissatisfied	22.4%	1.2%	0.6%
Dissatisfied	28.6%	8.1%	11.8%
Neither Satisfied nor Dissatisfied	22.4%	13.7%	11.2%
Satisfied	22.4%	39.8%	48.4%
Very Satisfied	4.3%	37.3%	28.0%
	100.0%	100.0%	100.0%

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Table 247: Satisfaction with Breast Feel or Touch

Satisfaction with Breast Feel or Touch
 (Allowable Range 1-5)

Time	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	p
Baseline	2.5A	1.2	1.0 - 5.0	160	94.64	2 <0.001
1 Year	3.7B	1.0	1.0 - 5.0			
2 Years	3.6B	1.1	1.0 - 5.0			

- Score: 1 = Very Dissatisfied
 2 = Dissatisfied
 3 = Neither Satisfied nor Dissatisfied
 4 = Satisfied
 5 = Very Satisfied

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different subscripts.

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Table 248: Patient Rating of Satisfaction With Breast Feel or Touch

Rating	% (N = 160 Patients)		
	Pre-Op	Post-Op	
		1 Year	2 Years
Very Dissatisfied	24.4%	2.5%	5.0%
Dissatisfied	24.4%	10.0%	11.9%
Neither Satisfied nor Dissatisfied	28.1%	25.6%	17.5%
Satisfied	18.8%	38.1%	45.0%
Very Satisfied	4.4%	23.8%	20.6%
	100.0%	100.0%	100.0%

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Table 249: Worry About Implants At Follow-Up

Worry About Implants At Follow-Up
 (Allowable Range 1-4)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
1 Year	3.5	0.5	1.0 - 4.0	171	0.02	1	0.893
2 Years	3.5	0.5	2.0 - 4.0				

Score: 1 = Extremely Worried
 2 = Very Worried
 3 = Somewhat Worried
 4 = Not Worried At All

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 250: Interference of Worry about Implants on Daily Activities

Interference of Worry about Implants on Daily Activities
 (Allowable Range 1-4)

Descriptive Statistics				ANOVA Results		
Time	Mean	S.D.	Range	N	F	p
1 Year	3.4	0.7	2.0 - 4.0	169	0.89	1
2 Years	3.5	0.7	2.0 - 4.0			0.347

- Score: 1 = Worry Interferes A Lot With Daily Activities
 2 = Worry Interferes A Little With Daily Activities
 3 = Worry Does Not Interfere With Daily Activities
 4 = Not Worried At All

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 251: Bodily Pain Due to Implants

Bodily Pain
(Allowable Range 1-5)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
1 Year	4.6	0.8	1.0 - 5.0	163	0.26	1	0.609
2 Years	4.5	0.8	2.0 - 5.0				

- Score: 1 = Extremely
 2 = Quite a Bit
 3 = Moderately
 4 = A Little Bit
 5 = Not at All

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 252: Problems with Work/Activities Due to Implants

Time	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	df
1 Year	4.9	0.4	3.0 - 5.0	170	0.61	1
2 Years	4.8	0.5	2.0 - 5.0			

- Score: 1 = Extremely
 2 = Quite a Bit
 3 = Moderately
 4 = A Little Bit
 5 = Not at All

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 253: Frequency of Reoperation for Significant Risk Factors

Risk Factor	Total Enrolled Implants (N = 361)	Reop- erations (N = 106)	Reop- erations (%)
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No significant risk factors were found.

Table 254: Relative Risk of Reoperation for Significant Risk Factors

Risk Factor	Unadjusted Risk Ratio	p-value	Adjusted Risk Ratio RR (95% CI)
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No significant risk factors were found.

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Table 255: Frequency of Implant Replacement/Removal
for Significant Risk Factors

Risk Factor	Total Enrolled Implants (N = 361)	Explants (N = 45)	Explants (%)
Device Shape			
Round	127	24	18.9%
Shaped	234	21	9.0%

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Table 256: Relative Risk of Implant Replacement/Removal
for Significant Risk Factors

Risk Factor	Unadjusted Risk Ratio	p-value	Adjusted Risk Ratio RR (95% CI)
Device Shape Round vs. Shaped	2.1	0.006	2.3 (1.3, 4.1)

Table 257: Frequency of Implant Rupture for Significant Risk Factors

Risk Factor	Total Enrolled Implants (N = 361)	Ruptures (N = 10)	Ruptures (%)
	<hr/>		

No significant risk factors were found.

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Table 258: Relative Risk of Implant Rupture
for Significant Risk Factors

Risk Factor	Unadjusted Risk Ratio	p-value	Adjusted Risk Ratio RR (95% CI)
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No significant risk factors were found.

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Table 259: Frequency of Capsular Contracture
for Significant Risk Factors

Risk Factor	Total	Capsular	Capsular
	Enrolled Implants (N = 361)	Contracture (N = 31)	Contracture (%)
Pocket Irrigation - Betadine			
Yes	194	7	3.6%
No	167	24	14.4%
Implant Placement			
Submuscular	320	25	7.8%
Other	41	6	14.6%

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Table 260: Relative Risk of Capsular Contracture
 for Significant Risk Factors

Risk Factor	Unadjusted Risk Ratio	p-value	Adjusted Risk Ratio RR (95% CI)
Pocket Irrigation - Betadine			
Yes vs. No	0.3	<0.001	0.1 (0.1, 0.4)
No vs. Yes	4.0		6.8 (2.7, 17.6)
Implant Placement			
Other vs. Submuscular	1.9	0.001	5.4 (1.9, 14.7)

* A risk ratio < 1.0 indicates a protective risk factor.

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Table 261: Frequency of Infection for Significant Risk Factors

Risk Factor	Total Enrolled Implants (N = 361)	In- fection (N = 6)	In- fection (%)
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No significant risk factors were found.

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Table 262: Relative Risk of Infection for Significant Risk Factors

Risk Factor	Unadjusted Risk Ratio	p-value	Adjusted Risk Ratio RR (95% CI)
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No significant risk factors were found.

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CORE RECONSTRUCTION APPENDICES

APPENDIX B

Distribution of Patient Enrollment By Implanting Physician

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Appendix B: Distribution of Patient Enrollment by Implanting Physician

Principal Investigator	Patients (N = 221)	
	n	%
	7	3.2%
	21	9.5%
	9	4.1%
	13	5.9%
	2	0.9%
	4	1.8%
	20	9.0%
	4	1.8%
	1	0.5%
	4	1.8%
	28	12.7%
	9	4.1%
	5	2.3%
	12	5.4%
	10	4.5%
	24	10.9%
	7	3.2%
	3	1.4%
	4	1.8%
	5	2.3%
	7	3.2%
	6	2.7%
	6	2.7%
	8	3.6%
	2	0.9%

APPENDIX C

Distribution of Product Styles By Implanting Physician

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Appendix C: Distribution of Product Styles by Implanting Physician

Implanting Physician	Total Implants Enrolled	Smooth Styles				Textured Styles			
		Round		Shaped		Round		Shaped	
		n	%	n	%	n	%	n	%
	13	0.0%	0.0%	0.0%	0.0%	7.7%	0.0%	0.0%	92.3%
	34	0.0%	0.0%	0.0%	0.0%	50.0%	0.0%	0.0%	50.0%
	17	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
	21	4.8%	4.8%	0.0%	0.0%	19.0%	4.8%	0.0%	66.7%
	3	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	4	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
	33	0.0%	0.0%	0.0%	0.0%	6.1%	0.0%	0.0%	93.9%
	6	66.7%	0.0%	0.0%	0.0%	33.3%	0.0%	0.0%	0.0%
	1	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%
	5	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	44	11.4%	2.3%	2.3%	11.4%	11.4%	2.3%	2.3%	72.7%
	14	0.0%	0.0%	0.0%	42.9%	42.9%	35.7%	0.0%	21.4%
	10	0.0%	0.0%	0.0%	30.0%	30.0%	0.0%	0.0%	70.0%
	22	0.0%	0.0%	0.0%	4.5%	4.5%	0.0%	0.0%	95.5%
	17	0.0%	11.8%	11.8%	17.6%	17.6%	5.9%	5.9%	64.7%

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Appendix C (Cont.): Distribution of Product Styles by Implanting Physician

Implanting Physician	Total Implants Enrolled	Smooth Styles			Textured Styles		
		Round	Round	Shaped	Round	Round	Shaped
		n	%	%	n	%	%
	46	19.6%	2.2%	4.3%	0.0%	73.9%	
	14	14.3%	0.0%	28.6%	0.0%	57.1%	
	5	0.0%	0.0%	0.0%	0.0%	100.0%	
	7	0.0%	0.0%	42.9%	0.0%	57.1%	
	6	0.0%	0.0%	16.7%	0.0%	83.3%	
	8	0.0%	0.0%	0.0%	75.0%	25.0%	
	9	0.0%	0.0%	11.1%	0.0%	88.9%	
	10	10.0%	0.0%	10.0%	0.0%	80.0%	
	9	0.0%	0.0%	77.8%	0.0%	22.2%	
	3	0.0%	0.0%	33.3%	0.0%	66.7%	

APPENDIX D

List of Complications Occurring Beyond 2 Years (730 Days) Post-Implant

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Appendix D: List of Complications Occurring Beyond 2 Years (730 Days)
 Post-Implant

Complication	# of Post 2-Year Occurrences	
	Patients (N = 12)	Implants (N = 15)
Asymmetry	3	3
Breast Pain	2	2
Bruising	0	0
Capsule Calcification	0	0
Capsular Contracture	6	8
Delayed Wound Healing	0	0
Fluid Accumulation	0	0
Hematoma	0	0
Hypertrophic Scarring	0	0
Implant Extrusion	0	0
Implant Malposition	1	2
Implant Palpability	0	0
Implant Visibility	0	0
Infection	0	0
Irritation	0	0
Loss of Nipple Sensation	0	0
Loss of Skin Sensation	0	0
Lymphadenopathy	0	0
Lymphedema	0	0
Nipple Hypersensitivity	0	0
Nipple Paresthesia	0	0
Other Abnormal Scarring	0	0
Other Nipple Related Observation	0	0

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Appendix D (cont.): List of Complications Occurring Beyond 2 Years
(730 Days) Post-Implant

Complication	# of Post 2-Year Occurrences	
	Patients (N = 12)	Implants (N = 15)
Pneumothorax	0	0
Ptosis	0	0
Redness	0	0
Seroma	0	0
Skin Hypersensitivity	0	0
Skin Paresthesia	0	0
Skin Rash	0	0
Swelling	0	0
Tissue or Skin Necrosis	0	0
Wrinkling/Rippling	1	1
Other Complications	0	0

APPENDIX G

**2-Year Complication Rates:
Silicone-Filled Breast Implant
Core Clinical Study - Reconstruction Cohort
&
1995 Saline Reconstruction Clinical Study (R95)**

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Appendix G: 2-Year Complication Rates for Reconstruction Patients in Core Study and 1995 Saline Study (R95)

Complication	Core 2-Year Risk By Patient	R95* 2-Year Risk By Patient
Reoperation	36.9% (30.5%, 43.4%)	34.9% (28.7%, 41.1%)
Implant Replacement/Removal	17.2% (12.1%, 22.2%)	21.1% (15.8%, 26.4%)
Capsular Contracture	13.5% (8.8%, 18.1%)	24.8% (19.0%, 30.6%)
Asymmetry	11.9% (7.5%, 16.3%)	27.1% (21.1%, 33.0%)
Implant Malposition	5.8% (2.6%, 8.9%)	11.6% (7.3%, 15.9%)
Implant Rupture/Deflation	4.8% (1.7%, 7.9%)	5.7% (2.5%, 8.8%)
Other Nipple Related Observation	4.4% (1.6%, 7.3%)	N/A
Tissue or Skin Necrosis	3.8% (1.2%, 6.5%)	3.6% (1.1%, 6.0%)
Swelling	3.7% (1.2%, 6.2%)	N/A
Breast Pain	3.3% (0.9%, 5.7%)	13.6% (9.0%, 18.2%)
Wrinkling/Rippling	2.9% (0.6%, 5.2%)	20.5% (15.0%, 25.9%)
Hypertrophic Scarring	2.4% (0.3%, 4.5%)	4.8% (1.9%, 7.8%)**
Infection	2.3% (0.3%, 4.3%)	4.8% (2.0%, 7.5%)
Other Complications	2.3% (0.3%, 4.4%)	2.5% (0.3%, 4.6%)
Delayed Wound Healing	2.3% (0.3%, 4.3%)	2.7% (0.6%, 4.9%)
Seroma	1.8% (0.1%, 3.6%)	3.9% (1.4%, 6.4%)
Bruising	1.4% (0.0%, 2.9%)	N/A
Skin Rash	1.4% (0.0%, 2.9%)	3.3% (0.9%, 5.7%)
Other Abnormal Scarring	1.0% (0.0%, 2.4%)	4.8% (1.9%, 7.8%)**
Ptosis	1.0% (0.0%, 2.3%)	N/A
Redness	1.0% (0.0%, 2.3%)	N/A
Implant Extrusion	0.5% (0.0%, 1.4%)	2.6% (0.6%, 4.7%)
Pneumothorax	0.5% (0.0%, 1.5%)	0.0% --
Hematoma	0.4% (0.0%, 1.3%)	1.3% (0.0%, 2.8%)
Implant Palpability	0.4% (0.0%, 1.3%)	16.6% (11.6%, 21.7%)***
Implant Visibility	0.4% (0.0%, 1.3%)	16.6% (11.6%, 21.7%)***
Capsule Calcification	0.0% --	4.7% (1.9%, 7.6%)
Fluid Accumulation	0.0% --	N/A
Irritation	0.0% --	6.6% (3.3%, 9.8%)
Loss of Nipple Sensation	0.0% --	8.0% (4.2%, 11.7%)
Loss of Skin Sensation	0.0% --	N/A
Lymphadenopathy	0.0% --	0.0% --
Lymphedema	0.0% --	N/A
Nipple Hypersensitivity	0.0% --	N/A

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Appendix G (cont.): 2-Year Complication Rates for Reconstruction Patients in Core Study and 1995 Saline Study (R95)

(Continued) Complication	Core 2-Year Risk By Patient	R95* 2-Year Risk By Patient
Nipple Paresthesia	0.0% --	0.4% (0.0%, 1.3%)
Skin Hypersensitivity	0.0% --	N/A
Skin Paresthesia	0.0% --	5.6% (2.5%, 8.6%)

- * From Original PMA Submission (PMA #P990074, November 15, 1999)
- ** Hypertrophic Scarring and Other Abnormal Scarring were combined and reported generally as Scarring in the 1995 Saline Study
- *** Implant Visibility and Implant Palpability were combined in the 1995 Saline Study

APPENDIX H

Summary of Outcomes Following Primary Implant Removal with Replacement

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Appendix H1: Summary of Complications Following
 Primary Implant Removal With Replacement

Complication	# of Occurrences	
	Patients (N = 10)	Implants (N = 11)
Asymmetry	3	3
Breast Pain	1	1
Breast Ptosis	0	0
Bruising	1	1
Capsule Calcification	0	0
Capsular Contracture	0	0
Delayed Wound Healing	0	0
Fluid Accumulation	0	0
Hematoma	0	0
Hypertrophic Scarring	0	0
Implant Extrusion	0	0
Implant Malposition	2	2
Implant Palpability	0	0
Implant Visibility	0	0
Infection	0	0
Irritation	1	1
Loss of Nipple Sensation	0	0
Loss of Skin Sensation	0	0
Lymphadenopathy	0	0
Lymphedema	0	0
Nipple Hypersensitivity	0	0
Nipple Paresthesia	0	0
Other Abnormal Scarring	0	0
Other Nipple Related Observation	0	0

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Appendix H1 (cont.): Summary of Complications Following
Primary Implant Removal With Replacement

Complication	# of Occurrences	
	Patients (N = 10)	Implants (N = 11)
Pneumothorax	0	0
Redness	1	1
Seroma	1	1
Skin Hypersensitivity	0	0
Skin Paresthesia	0	0
Skin Rash	0	0
Swelling	1	1
Tissue or Skin Necrosis	1	1
Wrinkling/Rippling	2	3
Other Complications	0	0

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Appendix H2: Patient Assessment of Secondary Implants Following Replacement
 of All Primary Study Devices

Time	N	Satisfaction Level* (Allowable Range 1 - 5)						Mean	SD
		Definitely Somewhat		Definitely		Descriptive Statistics			
		Dissat- isfied	%	Somewhat Satisfied	%	Satisfied	%		
6 Months	3	0.0%	33.3%	0.0%	33.3%	33.3%	3.7	1.5	
1 Year	5	20.0%	0.0%	0.0%	40.0%	40.0%	3.8	1.6	
2 Years	6	16.7%	0.0%	0.0%	33.3%	50.0%	4.0	1.5	

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