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**CORE CLINICAL STUDY  
REVISION COHORT**

December 16, 2002

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REVISION 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 revision cohort through 2 years post-implant.

Data from 225 patients who received 432 silicone-filled breast implants for the purpose of unilateral or bilateral revision of existing breast implants are presented in this report. The extract date of the database used for this report is August 30, 2002. The revision patients were enrolled between January 19, 1999 and June 19, 2000. The majority of patients are Caucasian with a median age at study entry of 44 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, 12 (5.3%) of the 225 patients initially enrolled (implanted) have been discontinued from the study. Seven of the 12 patients were discontinued due to permanent removal of all study devices, 3 patients died, and 2 patients chose to discontinue. All 3 patient deaths were the result of cancer. Taking into account patients who died or had all study devices removed without replacement with other study devices, follow-up compliance was 78.8% at the 1-year follow-up visit and 86.6% 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-implantation, 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:

- General Breast Surgery Complications (e.g., breast pain)

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- 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 (9.9%), breast pain (6.8%), swelling (5.6%), and asymmetry (5.0%). All other complications occurred at a by-patient risk rate of less than 5.0%. Overall, nearly two thirds (63.7%) of complications were resolved within the period of this report. Of those complications that were resolved, the majority (69.4%) were resolved either without treatment or with non-surgical treatment.

A total of 11 devices were suspected of rupture through 2 years post-implant. Six (6) of the 11 devices have been explanted and the remaining 5 devices are still implanted. Of the 11 suspected device ruptures, 4 devices were found to be intact (i.e., false reports of rupture), 2 devices were confirmed ruptured, and 3 devices remain unconfirmed ruptures. Based on confirmed and unconfirmed ruptures, the 2-year by-patient risk of implant rupture was 2.7%.

A total of 62 patients underwent 84 reoperations through 2 years post-implant, with a 2-year by-patient risk of reoperation of 29.4%. Of the 84 reoperations, the most common procedures performed were implant removal with replacement (23.8%) and capsulotomy (16.7%).

By the end of the 2-year post-implant visit, 22 patients had 37 study devices removed, with a 2-year by-patient risk of implant replacement/removal for any reason of 10.7%. Of the 37 devices that were explanted, 12 (32.4%) were removed due to patient request for a style/size change and 7 (18.9%) were removed due to malposition. Most devices (86.5%) were replaced.

Forty-four (44) patients (19.6%) reported reproduction problems prior to implantation. The most prevalent problem was spontaneous abortion/miscarriage. Five (5) patients (2.2%) had 5 reports of post-implant reproduction problems through 2 years, of which 2 were spontaneous abortions/miscarriages, 2 were infertility, and 1 was another reproduction problem (hysterectomy done for unknown reasons). Two of the 5 patients who had a post-implant reproduction problem also had a pre-implant reproduction problem.

Twenty-four (24) patients (10.7%) reported lactation problems prior to implantation, most commonly pain and inadequate milk production. One patient (0.4%) had 1 report of a post-implant lactation problem through 2 years: inadequate milk production.

Sixty-seven (67) patients (29.8%) reported breast disease prior to implantation, of which 42 were confirmed malignant disease, 24 were benign breast disease, and 1 was unknown breast disease. Thirteen (13) patients (5.8%) had reports of post-implant breast disease

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through 2 years, all of which were benign breast disease. Two (2) of the 13 patients who had post-implant benign breast disease also had pre-implant benign breast disease.

One (1) patient reported a CTD (rheumatoid arthritis) pre-implant. One (1) patient reported a CTD through 2 years post implant. This 50-year old patient had a confirmed diagnosis of fibromyalgia with an onset date of 11 months after implant surgery.

More than 90% of physicians and more than 85% of 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 4.4 and 4.9 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. On each of the eight scales for which comparative values are available, the women in this study scored between 9 and 14 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. A number of the general health and self-related concept scales, which showed no change pre-implant vs. 1 year post-implant did show a significant decrease pre-implant vs. 2 years post-implant.

For approximately half of the general health and specific self-related concepts, average scores at 1 year or 2 years post-implant were statistically significantly lower vs. baseline. However, the magnitude of this difference was small and the general health-related post-implant quality of life scores remained at or above those of the general population. In contrast, all of the specific measures of breast-related concepts showed significantly higher scores at 1 year post-implant vs. baseline, and the magnitude of the difference was generally large. Patients' satisfaction with their breasts on a variety of assessments (e.g., breast shape, size, feel) showed substantial increases at 1 year vs. baseline.

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<b>Table 1. Core Clinical Study - Revision Cohort Summary of 2-Year Risk Rate for Specific Complications</b>		
<b>Complication</b>	<b>2-Year Risk By Patient</b>	<b>2-Year Risk By Implant</b>
Capsular Contracture	9.9%	5.4%
Breast Pain	6.8%	4.7%
Swelling	5.6%	4.1%
Asymmetry	5.0%	N/A
Seroma	4.7%	2.7%
Implant Malposition	4.4%	3.1%
Wrinkling/Rippling	2.9%	2.0%
Other Complications	2.0%	1.1%
Tissue or Skin Necrosis	1.9%	1.0%
Infection	1.8%	1.0%
Other Nipple Related Observation	1.5%	1.3%
Bruising	1.4%	0.9%
Irritation	1.0%	0.5%
Hematoma	0.9%	0.5%
Implant Palpability	0.9%	0.5%
Hypertrophic Scarring	0.5%	0.3%
Other Abnormal Scarring	0.5%	0.3%
Delayed Wound Healing	0.5%	0.2%
Implant Extrusion	0.5%	0.2%
Implant Visibility	0.5%	0.2%
Ptosis	0.5%	0.2%
Skin Rash	0.5%	0.2%
Loss of Skin Sensation	0.4%	0.2%
Capsule Calcification	0.0%	0.0%
Fluid Accumulation	0.0%	0.0%
Loss of Nipple 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%
Pneumothorax	0.0%	0.0%
Redness	0.0%	0.0%
Skin Hypersensitivity	0.0%	0.0%
Skin Paresthesia	0.0%	0.0%

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	<b>Scale Range</b>	<b>General Population</b>	<b>Baseline</b>	<b>1 Year</b>	<b>Significant</b>
<b>General Health Concepts</b>					
SF36: Role Limitations due to Emotional Problems	0 – 100	79.5	90.8	83.1	↓ *
SF36: Role Limitations due to Physical Health Problems	0 – 100	77.8	86.7	80.6	—
SF36: General Health	0 – 100	70.6	84.3	81.5	↓ *
SF36: Bodily Pain	0 – 100	73.6	84.4	84.0	—
SF36: Social Functioning	0 – 100	81.5	93.4	89.0	↓ *
SF36: Physical Functioning	0 – 100	81.5	94.2	91.0	—
SF36: Vitality	0 – 100	58.4	70.9	67.6	—
SF36: Mental Health	0 – 100	73.3	83.2	80.8	—
SF36: Reported Health Transition	0 – 100	—	40.3	42.9	—
MOS20: Health Perceptions	0 – 100	—	84.9	82.6	—
MOS20: Physical Functioning	0 – 100	—	91.9	89.5	—
MOS20: Role Functioning	0 – 100	—	92.4	91.1	—
MOS20: Social Functioning	0 – 100	—	95.5	93.2	—
MOS20: Mental Health	0 – 100	—	82.0	80.8	—
<b>Specific Self- and Breast-Related Concepts</b>					
Self Concept – Physical Self	18 – 90	—	74.6	73.8	—
Self Esteem	10 – 40	—	35.9	35.5	—
Self vs. Breast Semantic Differential	(-6) – (+6)	—	0.0	0.0	—
Body Esteem – Total Score	32 – 160	—	119.8	119.5	—
Body Esteem – Sexual Attractiveness	13 – 65	—	49.9	50.9	—
Body Esteem – Weight Concern	10 – 50	—	33.5	33.1	—
Body Esteem – Physical Condition	9 – 45	—	35.2	34.2	—
Personal Life Satisfaction	1 – 6	—	4.7	4.8	—
Satisfaction with Breasts	1 – 5	—	2.5	4.1	* ↑
How Well Breasts Matched	1 – 6	—	3.2	4.6	* ↑
Satisfaction with Breast Shape	1 – 5	—	2.3	3.9	* ↑
Satisfaction with Breast Size	1 – 5	—	2.7	4.2	* ↑
Satisfaction with Breast Feel or Touch	1 – 5	—	2.3	3.9	* ↑
Rowland Expectation: Improve Self Image	1 – 5	—	2.7	3.0	* ↑
Rowland Expectation: Improve Social Relations	1 – 5	—	1.3	1.4	* ↑
Rowland Expectation: Improve Daily Living	1 – 5	—	2.8	2.8	—

\* 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 revision 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 225 revision patients were enrolled in this study, where enrollment is defined as undergoing implant surgery. The first revision patient was enrolled on January 19, 1999, and the last revision patient was enrolled on June 19, 2000.

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

- Female, age 18 years or older
- Breast implant revision surgery (i.e., removal and replacement of breast implants) indicated for the following:
  - Previous augmentation or reconstruction with silicone-filled or saline-filled breast implants
- 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:

- 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<sub>1c</sub> > 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)

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- 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 22 Principal Investigators (PIs) at 27 sites (defined as a unique PI-IRB combination) enrolled revision patients in the Core Clinical Study. Additionally, there are currently 5 other non-implanting Principal Investigators at 5 sites who later joined the study for the purpose of following patients who were originally enrolled by a different physician (e.g., patients who relocated to another state). A number of the 22 implanting investigators had difficulty enrolling the target minimum of 10 revision patients indicated in the protocol, primarily due to a less than expected revision patient population at these sites. However, 18 of the 22 Principal Investigators did enroll 5 or more revision 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:

#### 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.

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**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 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

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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 revision patients. The major purpose of revision surgery is to replace an existing breast implant, either due to medical complications (e.g., capsular contracture) or due to patient request to change the style/size of the device. As such, only some revision surgeries are performed to change breast size (i.e., to increase or decrease size vs. initial breast implant placed). Thus, a measure of the change in pre- and post-implant breast size is not relevant or meaningful for the revision 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.

## C. GENERAL ANALYSIS APPROACH

### 1. Overview

Patients from all investigational sites were pooled together for analysis. Inamed believes that the 22 Principal Investigators (representing 27 enrolling sites) participating in the revision 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.

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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 49.3% of revision 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 19, 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 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

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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. Appendix H contains a summary of the medical complications listed in Methods Section D.3.b that occurred following explant and replacement in the revision 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).

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#### 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 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.

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**c. Primary Surgical Treatment Characteristics**

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

- Previous augmentation
- Previous reconstruction

The specific reason for the patient's revision surgery also is provided. The sum total of the reasons for revision surgery may be greater than the total number of enrolled patients due to the fact that all reasons for revision surgery are reported, including multiple reasons for the same patient.

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.

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**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).

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

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- 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
- 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, hospitalization for serious illness or injury, being in the military and assigned to active duty, 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.

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### 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
- 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

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

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

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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 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 device reoperation or 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' 1<sup>st</sup> 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

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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 implant was known to be intact (i.e., date of implantation). For example, if a patient had her 1<sup>st</sup> 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

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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
- 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

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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 a hierarchy:

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

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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 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 that 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

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- 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
- 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

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- 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
- 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.

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**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.

**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 was not performed for revision 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-

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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

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 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).

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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
- 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

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“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 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 implant revision 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 revision surgery 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

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cancer, helped me hide the mastectomy better). The revision patients answered the 13 generalized items, which comprise the following 3 scales:

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

The subscale Improve Well-Being was not measured among the revision patients because this subscale contains questions specific only to the reconstruction population.

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**

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 revision surgery 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:

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- 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 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

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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 ( $\leq 40$  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 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. 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 44 years, with a range from 18 to 80 years. Most patients were Caucasian (87.6%); several patients indicated more than one race, yielding a total percentage greater than 100%. Nearly two thirds of patients (63.6%) were married.

Table 2 reports occupation and education data for the revision patients. Nearly half of the patients (47.6%) were employed in professional jobs. The vast majority of patients (84.4%) had at least some college education.

As reported in Table 3, patients' median height was 5'5", with a range of 4'11" to 5'11", and their median weight was 125 pounds, with a range of 92 to 220 pounds.

#### 2. Product Styles and Sizes

##### Tables 4 – 9

Table 4 presents a distribution of the device styles used for the revision patients in this study. Four hundred and thirty-two (432) primary study devices were implanted in the 225 revision patients. Textured devices were more commonly used (61.1%) than were smooth devices (38.9%), and round devices were used more often (71.1%) than were shaped devices (28.9%).

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

#### 3. Surgical Treatment Characteristics

##### Tables 10 – 17

Table 10 presents a distribution of the indications for breast revision surgery. The majority of revision patients (76.0%) enrolled to revise a previous augmentation surgery, and the remaining patients (24.0%) enrolled to revise a previous reconstruction surgery. The most common reasons for revision were capsular contracture (52.4%), rippling (20.4%), and suspected rupture (18.2%).

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

Most patients were administered a general anesthetic (80.9%), with the remaining patients anesthetized solely using a local anesthetic (19.1%), (Table 11).

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Approximately one third of the revision patient surgeries (35.6%) were performed in a doctor's office, one third (32.4%) were performed in a free standing surgical facility, and one third (32.0%) were performed in a hospital.

The most common incision sites for implant placement were inframammary (58.1%) and periareolar (23.6%), (Table 12).

The majority of devices were placed submuscularly (64.4%) or subglandularly (30.8%), (Table 13).

More than half of devices were inserted without the use of drains (56.5%), (Table 14).

Concurrent breast procedures were performed for 348 (80.6%) of the 432 device surgeries. A total of 459 concurrent procedures were performed during the 348 device surgeries, most commonly full capsulectomy (56.3%), (Table 15). The sum across concurrent procedures is greater than 100% because some device surgeries involved more than one concurrent procedure.

The majority of the 432 device surgeries (91.0%) involved administration of some type of medication through pocket irrigation (Table 16). The medications used most frequently during device surgeries were antibiotics (77.1%) and betadine (42.0%). 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 225 patients (88.4%) were administered parenteral medication, most commonly antibiotics (99.5%), (Table 17). The sum across medications is greater than 100% because some patients were administered more than one type of medication by this route.

#### **4. Surgical Complications**

##### Table 18

Intraoperative complications were reported during 2 (0.5%) of the 432 primary implant surgeries (Table 18). Specifically, the doctor reported the intraoperative complications as: "calcified shell; silicone slick fragile implant" and "calcified shell; ruptured old implant".

#### **B. PATIENT COMPLIANCE AND DISCONTINUATION**

All of the 225 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 78.8% at the 1-year follow-up visit and 86.6% at the 2-year follow-up visit (Table 19).

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Based on data obtained through 2 years, 12 of the 225 revision patients (5.3%) were discontinued from the study (Table 20). Of these 12 discontinuations, 3 were due to death, 7 were due to removal of all study devices, and 2 were due to patient choice to discontinue from the study. All 3 patient deaths were the result of cancer.

## C. SAFETY ASSESSMENT

### 1. Unanticipated Adverse Events

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

<b>Complication</b>	<b>(Table #)</b>	<b>2-Year Risk By Patient % (95% CI)</b>	<b>2-Year Risk By Implant % (95% CI)</b>
Capsular Contracture	(37)	9.9% (5.8%, 14.0%)	5.4% (3.1%, 7.6%)
Breast Pain	(25)	6.8% (3.3%, 10.3%)	4.7% (2.7%, 6.8%)
Swelling	(141)	5.6% (2.5%, 8.7%)	4.1% (2.2%, 6.0%)
Asymmetry	(21)	5.0% (2.0%, 8.1%)	N/A
Seroma	(125)	4.7% (1.9%, 7.6%)	2.7% (1.1%, 4.3%)
Implant Malposition	(61)	4.4% (1.6%, 7.3%)	3.1% (1.4%, 4.8%)
Wrinkling/Rippling	(149)	2.9% (0.6%, 5.2%)	2.0% (0.6%, 3.4%)
Other Complications	(153)	2.0% (0.1%, 4.0%)	1.1% (0.0%, 2.1%)
Tissue or Skin Necrosis	(145)	1.9% (0.1%, 3.8%)	1.0% (0.0%, 2.0%)
Infection	(73)	1.8% (0.1%, 3.7%)	1.0% (0.0%, 1.9%)
Other Nipple Related Observation	(109)	1.5% (0.0%, 3.1%)	1.3% (0.2%, 2.4%)
Bruising	(29)	1.4% (0.0%, 2.9%)	0.9% (0.0%, 1.9%)
Irritation	(77)	1.0% (0.0%, 2.3%)	0.5% (0.0%, 1.2%)
Hematoma	(49)	0.9% (0.0%, 2.1%)	0.5% (0.0%, 1.1%)
Implant Palpability	(65)	0.9% (0.0%, 2.2%)	0.5% (0.0%, 1.2%)
Hypertrophic Scarring	(53)	0.5% (0.0%, 1.5%)	0.3% (0.0%, 0.8%)
Other Abnormal Scarring	(105)	0.5% (0.0%, 1.5%)	0.3% (0.0%, 0.8%)
Delayed Wound Healing	(41)	0.5% (0.0%, 1.4%)	0.2% (0.0%, 0.7%)
Implant Extrusion	(57)	0.5% (0.0%, 1.4%)	0.2% (0.0%, 0.7%)
Implant Visibility	(69)	0.5% (0.0%, 1.4%)	0.2% (0.0%, 0.7%)
Ptosis	(117)	0.5% (0.0%, 1.4%)	0.2% (0.0%, 0.7%)
Skin Rash	(137)	0.5% (0.0%, 1.4%)	0.2% (0.0%, 0.7%)
Loss of Skin Sensation	(85)	0.4% (0.0%, 1.3%)	0.2% (0.0%, 0.7%)
Capsule Calcification	(33)	0.0% —	0.0% —
Fluid Accumulation	(45)	0.0% —	0.0% —
Loss of Nipple Sensation	(81)	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% —
Pneumothorax	(113)	0.0% —	0.0% —
Redness	(121)	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 revision patients, the highest 2-year cumulative risk rates by patient were for capsular contracture (9.9%), breast pain (6.8%), swelling (5.6%), and asymmetry (5.0%). All other complications occurred at a by-patient risk rate of less than 5.0%.

The highest incidence rate across all complications was for swelling at 0-4 weeks post-implant (4.0%). The highest prevalence rate across all complications was for capsular contracture at 2 years post-implant (7.7%).

Median time to resolution among patients whose complications were resolved ranged from 3 days (hematoma) to 237 days (other complications). Among patients without resolution, median elapsed treatment time ranged from 1 day (other abnormal scarring) to 1006 days (implant palpability and wrinkling/rippling). 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, nearly two thirds (63.7%) of complications were resolved.

Complication	(Table #)	Resolution Status		
		Unresolved	Resolved	% Resolved
Asymmetry	(24)	3	7	70.0%
Breast Pain	(28)	3	11	78.6%
Bruising	(32)	0	3	100.0%
Capsule Calcification	(36)	0	0	N/A
Capsular Contracture	(40)	12	8	40.0%
Delayed Wound Healing	(44)	0	1	100.0%
Fluid Accumulation	(48)	0	0	N/A
Hematoma	(52)	0	2	100.0%
Hypertrophic Scarring	(56)	0	1	100.0%
Implant Extrusion	(60)	0	1	100.0%
Implant Malposition	(64)	2	7	77.8%
Implant Palpability	(68)	1	1	50.0%
Implant Visibility	(72)	1	0	0.0%
Infection	(76)	1	3	75.0%
Irritation	(80)	2	0	0.0%
Loss of Nipple Sensation	(84)	0	0	N/A
Loss of Skin Sensation	(88)	1	0	0.0%
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)	1	0	0.0%
Other Nipple Related Observation	(112)	1	2	66.7%
Pneumothorax	(116)	0	0	N/A
Ptosis	(120)	1	0	0.0%
Redness	(124)	0	0	N/A
Seroma	(128)	3	7	70.0%
Skin Hypersensitivity	(132)	0	0	N/A
Skin Paresthesia	(136)	0	0	N/A
Skin Rash	(140)	1	0	0.0%
Swelling	(144)	2	10	83.3%
Tissue or Skin Necrosis	(148)	1	3	75.0%
Wrinkling/Rippling	(152)	3	3	50.0%
Other Complications	(156)	2	2	50.0%
<b>Total (N=113)</b>		<b>41</b>	<b>72</b>	<b>63.7%</b>

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The following table summarizes the method of resolution for each complication that was resolved. More than one third (36.1%) of resolved complications were resolved without any type of treatment, and one third (33.3%) 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)	1	2	3	1
Breast Pain	(28)	0	0	4	7
Bruising	(32)	0	0	0	3
Capsule Calcification	(36)	N/A	N/A	N/A	N/A
Capsular Contracture	(40)	2	3	2	1
Delayed Wound Healing	(44)	0	1	0	0
Fluid Accumulation	(48)	N/A	N/A	N/A	N/A
Hematoma	(52)	0	2	0	0
Hypertrophic Scarring	(56)	0	1	0	0
Implant Extrusion	(60)	0	1	0	0
Implant Malposition	(64)	1	5	0	1
Implant Palpability	(68)	1	0	0	0
Implant Visibility	(72)	0	0	0	0
Infection	(76)	0	0	2	1
Irritation	(80)	0	0	0	0
Loss of Nipple Sensation	(84)	N/A	N/A	N/A	N/A
Loss of Skin Sensation	(88)	0	0	0	0
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	2	0
Pneumothorax	(116)	N/A	N/A	N/A	N/A
Ptosis	(120)	0	0	0	0
Redness	(124)	N/A	N/A	N/A	N/A
Seroma	(128)	1	1	3	2
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	0	0
Swelling	(144)	0	0	1	9
Tissue or Skin Necrosis	(148)	0	0	3	0
Wrinkling/Rippling	(152)	0	0	2	1
Other Complications	(156)	0	0	2	0
<b>Total (N=72)</b>		<b>6</b>	<b>16</b>	<b>24</b>	<b>26</b>

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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 level is associated with implant visibility ( $M = 4.0$ ,  $n = 1$ ). The lowest average severity levels are associated with loss of nipple sensation ( $M = 1.5$ ,  $n = 2$ ), redness ( $M = 1.6$ ,  $n = 10$ ), ptosis ( $M = 1.7$ ,  $n = 3$ ), skin rash ( $M = 1.8$ ,  $n = 5$ ), and delayed wound healing ( $M = 1.9$ ,  $n = 8$ ).

### 3. Implant Rupture

#### Tables 158 – 162

Tables 158-162 present the results pertaining to implant rupture. A total of 11 of the 432 primary implants (2.5%) showed evidence of rupture: 2 devices were identified as ruptured at explant, 4 devices were suspected of rupture via MRI, 1 device was suspected of rupture via ultrasound, and 4 devices were suspected of rupture via physician exam (Table 158). Of the 11 suspected implant ruptures, 2 were confirmed to be ruptured on explant, 6 were false reports of rupture whereby the devices were found to be intact (4 false reports were identified upon explant and 2 false reports were identified by follow-up MRI), and 3 devices have unconfirmed rupture status (Table 159).

Based on confirmed and unconfirmed ruptures, the 2-year risk of implant rupture was 2.7% by patient and 1.4% by implant (Table 160). The 2-year incidence of implant rupture was 2.6% and the 2-year prevalence of implant rupture was 2.6% by patient (Table 161). Of the 5 implant ruptures by patient through 2 years post-implant, 3 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 29.4% by patient and 23.3% by implant (Table 163).

A total of 84 reoperations were performed on 62 patients (27.6% of 225 enrolled revision patients) through 2 years post-implant (Table 164). Most of the 62 patients (80.6%) had one reoperation; 5 patients (8.1%) had two reoperations and 7 patients (11.3%) had three or more reoperations.

No intraoperative complications were reported for any of the 84 reoperations (Table 165).

Among the 84 reoperations, the primary reasons for reoperation were malposition (15.5%), capsular contracture (11.9%), scarring (11.9%), and ptosis (10.7%), (Table 166). The primary procedure performed during reoperation was most commonly implant removal with replacement (23.8%) or capsulotomy (16.7%), (Table 167). In sum, the most frequently performed reoperations were implant replacement/removal due to

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unsatisfactory cosmetic result (11.9%) and scar revision due to unsatisfactory cosmetic result (9.5%), (Table 168).

During the 84 reoperations, a total of 156 individual surgical procedures were performed (Table 169). The majority of reoperations (79.8%) involved only one or two surgical procedures (e.g., bilateral implant replacement/removal, which is counted as two procedures). Of the 156 procedures performed, the most common procedures were implant removal with replacement (20.5%), capsulotomy (14.1%), and mastopexy (13.5%), (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 10.7% by patient and 9.4% by implant (Table 171). The 2-year risk of implant removal with replacement was 9.8% by patient and 8.2% by implant (Table 172), and the 2-year risk of implant removal without replacement was 1.5% by patient and 1.3% by implant (Table 173).

Of the 37 primary explanted devices, the most common reasons for replacement/removal were patient request for a style/size change (32.4%) and malposition (18.9%), (Table 174).

Of the 37 explanted devices, 1 was confirmed ruptured upon explantation (Table 175). The ruptured device had an intact capsule and gel on the implant surface but no evidence of extracapsular gel. The physician indicated that removal was not difficult for the ruptured device. Of the 36 remaining non-ruptured devices, none had gel on the implant surface, extracapsular gel, or were difficult to remove. Two of the 36 non-ruptured implants had a torn capsule.

A total of 32 of the 37 explanted devices were replaced (86.5%), (Table 176). Of the devices replaced, most (75.0%) were replaced with another McGhan study device. Of the 24 implants replaced with McGhan study devices, more than half (54.2%) 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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30.7% (Table 178). The 2-year by-patient risk of any breast implant surgery – cosmetic complication is 13.9% (Table 179). The 2-year by-patient risk of any breast implant surgery – non-cosmetic complication is 7.1% (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. Forty-four (44) of the 225 revision patients (19.6%) experienced pre-implant reproduction problems, most frequently spontaneous abortion/miscarriage (Table 181). Through 2 years post-implant, 5 patients (2.2%) had a total of 5 reproduction problems: 2 spontaneous abortions/miscarriages, 2 infertility, and 1 other reproduction problem (hysterectomy done for unknown reasons), (Table 182). Two of the 5 patients who had a post-implant reproduction problem also had a pre-implant reproduction problem. Both patients had infertility pre- and post-implant.

Tables 183 and 184 report pre- and post-implant lactation problems. Twenty-four (24) of the 225 revision patients (10.7%) experienced pre-implant lactation problems, most frequently pain and inadequate milk production (Table 183). Through 2 years post-implant, 1 patient (0.4%) reported 1 lactation problem: inadequate milk production (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. Sixty-seven (67) of the 225 revision patients (29.8%) reported pre-implant breast disease, of which 42 were confirmed malignant disease, 24 were benign disease, and 1 was unknown breast disease (Table 185). Through 2 years post-implant, 13 patients (5.8%) had an occurrence of breast disease, all of which were benign (Table 186). Two (2) of the 13 patients who had post-implant benign breast disease also had pre-implant benign breast disease.

Tables 187 and 188 report the results of pre- and post-implant mammograms. Twenty-five (25) of the 225 revision patients (11.1%) had a pre-implant abnormal mammogram result (Table 187). Of these 25 abnormal results, 17 had no breast disease, 5 had confirmed malignant disease, 2 had benign breast disease, and 1 had unknown breast disease. Through 2 years post-implant, 82 patients had a mammogram, of which 5 showed an abnormal result (Table 188). Of the 5 patients with abnormal mammogram results, 1 had no breast disease and 4 had benign breast disease.

### **3. Connective Tissue/Autoimmune Disease**

#### Table 189 – 190

Tables 189 and 190 report pre- and post-implant occurrences of connective tissue/autoimmune disease (CTD). One (1) revision patient reported a CTD (rheumatoid arthritis) pre-implant (Table 189).

Through 2 years post-implant, one (1) patient reported a connective tissue/autoimmune disease (Table 190). Specifically, this 50-year-old patient had a confirmed report of fibromyalgia with an onset date of 11 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 revision 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 90% 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 4.9 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, approximately 80% were medical/procedural dissatisfactions at each follow-up interval (Table 197).

Tables 198-200 report patient satisfaction with the implant surgery based on primary study devices. More than 85% 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 4.4 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, 60.0% were aesthetic dissatisfactions and 40% were medical/procedural dissatisfactions at 0-4 weeks post-implant (Table 200). By 2 years post-implant, most patient dissatisfactions specified (80.0%) were medical/procedural in nature.

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Table 201 reports patient satisfaction with the implant surgery based on both primary and secondary study devices. Again, more than 85% 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 4.4 and 4.8 at each follow-up visit interval.

### 3. Quality of Life

The quality of life results reported are based on all revision 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. The majority of the revision patients (78.9%) 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 (89.7%) 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 ( $M = 4.7$ ), ( $p < .001$ ). However, at least 80.0% of revision patients indicated being "satisfied" or "very satisfied" with their breast implants post-operatively (87.6% at 1 year post-implant and 80.6% 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), and improve daily living (Table 208). Both the improve self image and improve social relations subscales showed statistically significant increases pre- vs. post-implant. Table 209 (Rowland Expectation: Improve Well-Being) was included and intentionally left blank to correspond with the table numbers in the Core Clinical Study - Reconstruction Cohort Report.

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

##### Table 210

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At baseline, revision patients scored significantly higher ( $p \leq .001$ ) than did the general U.S. female population on all 8 of the SF-36 scales for which comparative values are available (Table 210). The largest difference (21.4%) 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 some of the subscales showed scores that slightly, but statistically significantly, decreased after implantation: role limitations due to emotional problems (SF-36), general health (SF-36), social functioning (SF-36), mental health (SF-36), health perceptions (MOS-20), and mental health (MOS-20). However, the magnitude of the differences were small, and the post-implant quality of life scores (SF-36) remained at or above those of the general U.S. female population. Other general health scales did not show statistically significant differences: role limitations due to physical health problems (SF-36), bodily pain (SF-36), physical functioning (SF-36), vitality (SF-36), reported health transition (SF-36), physical functioning (MOS-20), role functioning (MOS-20), and social functioning (MOS-20).

**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 a statistically significant decrease pre vs. 2 years post-implant in the way patients view their bodies and state of health, and their attitude about appearance, skills, and sexuality ( $p = .002$ ), (Table 228).

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Results on the Rosenberg Self-Esteem Scale also revealed a statistically significant decrease pre-implant vs. 2 years post-implant in patients' self-esteem ( $p < .001$ ), (Table 229).

**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. The only effect observed was a significant decrease pre- vs. 2 years post-implant in the physical condition subscale ( $p = .002$ ), (Table 235).

**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 ( $M = 2.5$ ) 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 ( $M = 3.2$ ) to post-implant ( $M = 4.5/4.6$ ), on a 1 (very poor) to 6 (excellent) scale (Tables 241 and 242). Patient satisfaction with her breast shape increased significantly from pre-implant ( $M = 2.3$ ) to post-implant ( $M = 3.8/3.9$ ), 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 ( $M = 2.7$ ) to post-implant ( $M = 4.0/4.2$ ), 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 ( $M = 2.3$ ) to post-implant ( $M = 3.7/3.9$ ), 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

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

## F. RISK FACTOR ANALYSIS

### 1. Reoperation

Tables 253 – 254

Of the 432 primary study implants, 94 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 432 primary study implants, 37 have been explanted (Table 171). Results from the Cox proportional hazards regression analysis revealed that none of the 7 characteristics examined was significantly related to implant replacement/removal.

### 3. Implant Rupture

Tables 257 – 258

Of the 432 primary study implants, 5 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 432 primary study implants, 21 had capsular contracture (Table 37). Results from the Cox proportional hazards regression analysis revealed that none of the 7 characteristics examined was significantly related to capsular contracture.

### 5. Infection

Tables 261 – 262

Of the 432 primary study implants, 4 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 revision of existing breast implants. This conclusion is based on data from a total of 225 revision 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 78.8% at 1 year and 86.6% 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 (9.9%), breast pain (6.8%), swelling (5.6%), and asymmetry (5.0%). The lowest 2-year by-patient risk rates, all of which were 0%, were for capsule calcification, fluid accumulation, loss of nipple sensation, lymphadenopathy, lymphedema, nipple hypersensitivity, nipple paresthesia, pneumothorax, redness, 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.

The majority of 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 or had previously refused treatment. Of the complications that were resolved, more than one third were resolved without any type of treatment and one third were resolved with non-surgical 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. Six (6) of the 11 devices have been explanted and the remaining 5 devices remain implanted. Of the 11 suspected ruptures, 6 ruptures were false reports (i.e., the devices were found to be intact upon further follow-up), 2 devices were confirmed to be ruptured, and 3 devices are unconfirmed ruptures. Based on confirmed and unconfirmed ruptures, the 2-year by-patient risk of implant rupture was 2.7%.

The 2-year risk of reoperation was 29.4% by patient. Of all reoperations performed through 2 years post-implant, the most common were implant replacement/removal due to unsatisfactory cosmetic result (11.9%) and scar revision due to unsatisfactory cosmetic result (9.5%). The 2-year risk of implant replacement/removal was 10.7% by patient. The most common reason for implant replacement/removal was patient request for style/size change (32.4%).

Through 2 years post-implant, 5 patients (2.2%) reported a total of 5 reproduction problems and 1 patient reported 1 lactation problem. Through 2 years post-implant, 13 patients had reports of benign breast disease. One (1) 50-year-old patient (0.4%) reported

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a connective tissue disease through 2 years post-implant, specifically a confirmed diagnosis of fibromyalgia 11 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 approximately half of the general health concepts, average scores at 1 or 2 years post-implant were statistically significantly lower vs. baseline. However, the magnitude of this difference was small and the general health-related quality of life scores remained at or above those of the general U.S. female population. The small decreases that were observed in a number of the quality of life scales utilized in this study may be related to the very high scores that were observed among patients at baseline. Compared with the general U.S. female population, the patients who enrolled in this study had significantly higher quality of life scores pre-implant. Upon re-testing a group with very high scores initially, observing a decrease in scores is a common statistical phenomenon referred to as "regression to the mean" (Campbell & Stanley, 1963). A small change between pre- and post-implant scores cannot unambiguously be attributed to breast implant surgery without comparison to a control group of women with similar pre-implant characteristics who did not obtain breast implant surgery. Such a control group was not included in this study.

In terms of patients' expectation and perceived results of breast implant surgery, significant positive change was observed pre- vs. post-implant in subscales that measured self image and social relations. For specific self-related concepts, there were significant decreases pre-implant vs. 2 years post-implant in patient's self-esteem, body esteem, and physical self-concept. There was no significant difference in how patients rated themselves relative to their breasts pre- vs. post-implant.

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 physicians and more than 85% of 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 4.4 and 4.9 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 2.5 (out of 5) pre-implant to a mean score of 4.1/4.0 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 revision, including reoperations, is relatively low and that women who undergo revision 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

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al., 1993; Young et al., 1994; McGhan Medical RTV Saline-Filled Mammary Implant  
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**CORE REVISION TABLES**

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Table 1: Patient Age, Race, and Marital Status

Characteristic	Patients	
	n	%(N = 225)
<b>Age</b>		
18-19	1	0.4%
20-29	17	7.6%
30-39	59	26.2%
40-49	83	36.9%
50-59	48	21.3%
60-69	12	5.3%
70 & over	5	2.2%
	225	100.0%
Median = 44 years Range = 18 to 80 years		
<b>Race</b>		
Caucasian	197	87.6%
African-American	3	1.3%
Asian	3	1.3%
Hispanic	6	2.7%
Other	4	1.8%
Not Provided	14	6.2%
	227	100.9%
<b>Marital Status</b>		
Single	28	12.4%
Married	143	63.6%
Widowed	4	1.8%
Separated	4	1.8%
Divorced	46	20.4%
	225	100.0%

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Table 2: Patient Occupation and Education

Characteristic	Patients	
	n	%(N = 225)
<b>Occupation</b>		
Clerical	31	13.8%
Professional	107	47.6%
Trade	2	0.9%
Service	21	9.3%
Student	6	2.7%
Housewife	43	19.1%
Other	15	6.7%
	225	100.0%
<b>Education</b>		
Less Than High School	4	1.8%
High School Graduate	31	13.8%
Some College	86	38.2%
College Graduate	74	32.9%
Post College	30	13.3%
	225	100.0%

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Table 3: Pre-Implant Height and Weight

Characteristic	Patients	
	n	%(N = 225)
<b>Height</b>		
4'11" & under	1	0.4%
5'0" - 5'2.9"	37	16.4%
5'3" - 5'5.9"	92	40.9%
5'6" - 5'8.9"	80	35.6%
5'9" - 5'11.9"	15	6.7%
6'0" & over	0	0.0%
	225	100.0%

Median = 5'5"

Range = 4'11" to 5'11"

<b>Weight</b>		
99 lbs & under	4	1.8%
100 - 109	20	8.9%
110 - 119	49	21.8%
120 - 129	53	23.6%
130 - 139	39	17.3%
140 - 149	26	11.6%
150 - 159	14	6.2%
160 lbs & over	20	8.9%
	225	100.0%

Median = 125 lbs

Range = 92 to 220 lbs

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Table 4: Product Styles

Product Style	Implants	
	n	%(N = 432)
Smooth		
Style 40 (round)	136	31.5%
Style 45 (round)	32	7.4%
	<hr/> 168	<hr/> 38.9%
Textured		
Style 110 (round)	104	24.1%
Style 120 (round)	35	8.1%
Style 153 (shaped)	125	28.9%
	<hr/> 264	<hr/> 61.1%

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Table 5: Product Style 40

Size	Implants	
	n	%(N = 136)
80cc	0	0.0%
100cc	0	0.0%
120cc	0	0.0%
140cc	0	0.0%
160cc	4	2.9%
180cc	0	0.0%
200cc	5	3.7%
220cc	1	0.7%
240cc	7	5.1%
260cc	9	6.6%
280cc	16	11.8%
300cc	18	13.2%
320cc	13	9.6%
340cc	5	3.7%
360cc	9	6.6%
400cc	18	13.2%
460cc	16	11.8%
500cc	8	5.9%
560cc	7	5.1%
	136	100.0%

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Table 6: Product Style 45

Size	Implants	
	n	%(N = 32)
120cc	0	0.0%
160cc	0	0.0%
200cc	0	0.0%
240cc	1	3.1%
280cc	3	9.4%
320cc	2	6.3%
360cc	12	37.5%
400cc	12	37.5%
460cc	0	0.0%
500cc	0	0.0%
550cc	2	6.3%
600cc	0	0.0%
650cc	0	0.0%
700cc	0	0.0%
800cc	0	0.0%
	32	100.0%

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Table 7: Product Style 110

Size	Implants	
	n	%(N = 104)
90cc	0	0.0%
120cc	0	0.0%
150cc	1	1.0%
180cc	0	0.0%
210cc	5	4.8%
240cc	12	11.5%
270cc	6	5.8%
300cc	21	20.2%
330cc	22	21.2%
360cc	12	11.5%
390cc	6	5.8%
420cc	4	3.8%
450cc	6	5.8%
480cc	3	2.9%
510cc	6	5.8%
	104	100.0%

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Table 8: Product Style 120

Size	Implants	
	n	%(N = 35)
180cc	0	0.0%
220cc	0	0.0%
260cc	0	0.0%
300cc	5	14.3%
340cc	10	28.6%
400cc	10	28.6%
440cc	0	0.0%
500cc	5	14.3%
550cc	0	0.0%
600cc	5	14.3%
650cc	0	0.0%
	35	100.0%

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Table 9: Product Style 153

Size	Implants	
	n	%(N = 125)
360cc	35	28.0%
450cc	43	34.4%
540cc	18	14.4%
630cc	20	16.0%
720cc	9	7.2%
	125	100.0%

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Table 10: Indication for Implant Placement

Indication	Patients	
	n	%(N = 225)
Previous Augmentation	171	76.0%
Previous Reconstruction	54	24.0%
	225	100.0%

Reason for Revision	n	%(N=225)
Suspected Rupture	41	18.2%
Suspected Deflation	11	4.9%
Implant Malposition	31	13.8%
Infection	2	0.9%
Rippling	46	20.4%
Asymmetry	40	17.8%
Increase Size	38	16.9%
Decrease Size	16	7.1%
Capsular Contracture	119	52.9%
Pain	12	5.3%
Necrosis	1	0.4%
Extrusion	0	0.0%
Implant Palpability	1	0.4%
Ptosis	16	7.1%
Breast Cancer	7	3.1%
Implant Placement (High)	0	0.0%
Change Size - Unknown Size Direction	1	0.4%
Breast Deformity	1	0.4%
Fibrocystic Disease	1	0.4%
Media	1	0.4%
Other	2	0.9%
	387*	172.0%

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Table 10 (cont.): Indication for Implant Placement

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Other Reason Specified (N = 2)

Pt Seq#	Other Reason Specified
001	MASTECTOMY DONE& PREVIOUS IMPLANTS REMOVED DUE TO SURGICAL COMPLICATIONS WITH PREVIOUS IMPLANTS PLACED BY ANOTHER DOCTOR
001	MASTECTOMY DONE& PREVIOUS IMPLANTS REMOVED DUE TO SURGICAL COMPLICATIONS WITH PREVIOUS IMPLANTS PLACED BY ANOTHER DOCTOR
002	AGE OF IMPLANT CAUSES DOCTOR TO RECOMMEND REVISION DUE TO POSSIBLE LOSS OF IMPLANT INTEGRITY

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\* The sum of reasons for revision listed may exceed the total number of  
revision patients because a patient may have more than one reason for  
revision.

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Table 11: Anesthesia and Surgical Facility

Characteristic	Patients	
	n	%(N = 225)
Anesthesia		
General	182	80.9%
Local	43	19.1%
	<hr/>	<hr/>
	225	100.0%
Surgical Facility		
Doctor's Office	80	35.6%
Hospital	72	32.0%
Free Standing Surgical Facility	73	32.4%
	<hr/>	<hr/>
	225	100.0%

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Table 12: Incision Site

Incision Site	Implants	
	n	%(N = 432)
Periareolar	102	23.6%
Inframammary	251	58.1%
Mastectomy Scar	62	14.4%
Axillary	4	0.9%
Breast Scar	5	1.2%
Mastopexy Incision With Implant Placement	6	1.4%
Other	2	0.5%
	432	100.0%

Other Incision Site Specified (N = 2)

Imp  
 Seq# Other Incision Site Specified

001 LATERAL INCISION  
 002 LATERAL INCISION

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Table 13: Implant Location

Implant Location	Implants	
	n	%(N = 432)
Subcutaneous	12	2.8%
Subglandular	133	30.8%
Submuscular-Partial	226	52.3%
Submuscular-Complete	52	12.0%
Subtissue Flap	9	2.1%
	432	100.0%

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Table 14: Drains Placed

Drains Placed	Implants	
	n	%(N = 432)
Yes	188	43.5%
No	244	56.5%
	432	100.0%

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Table 15: Concurrent Breast Procedures

Concurrent Breast Procedures	Implants	
	n	%(N = 432)
No Concurrent Procedure	84	19.4%
Concurrent Procedure	348	80.6%
	432	100.0%

Type Of Concurrent Procedure	n	%(N = 348)
Biopsy	4	1.1%
Capsulectomy Unknown	4	1.1%
Capsulorrhaphy	10	2.9%
Capsulotomy	38	10.9%
Flap	7	2.0%
Full Capsulectomy	196	56.3%
Mastectomy	13	3.7%
Mastopexy	57	16.4%
Nipple Areolar Complex	16	4.6%
Partial Capsulectomy (Posterior)	26	7.5%
Partial Capsulectomy (Anterior)	64	18.4%
Revision of Nipple Reconstruction/Tattoo	2	0.6%
Revision of Pocket or Fold	6	1.7%
Scar Revision	10	2.9%
Tissue Expander Removal	2	0.6%
Other	4	1.1%
	459*	131.9%

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Table 15 (cont.): Concurrent Breast Procedures

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Other Procedure Specified (N = 4)

Imp Seq#	Other Procedure Specified
001	REVISION OF SCAR AND SKIN DEFORMITIES
002	REVISION OF SCAR AND SKIN DEFORMITIES
003	FAT INJECTIONS
004	CAPSULORRAPHY FAT INJECTIONS

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\* 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 = 432)
No Pocket Irrigation	39	9.0%
Pocket Irrigation	393	91.0%
	<u>432</u>	<u>100.0%</u>

  

Type Of Pocket Irrigation	n	%(N = 393)
Steroid	0	0.0%
Antibiotic	303	77.1%
Betadine	165	42.0%
Local Anesthetic	126	32.1%
	<u>594*</u>	<u>151.1%</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 = 225)
No Parenteral Medications	26	11.6%
Parenteral Medication	199	88.4%
	<u>225</u>	<u>100.0%</u>

  

Type Of Parenteral Medication	n	%(N = 199)
Antibiotics	198	99.5%
Steroid	58	29.1%
Anesthetic	1	0.5%
Sedative	13	6.5%
Other	5	2.5%
	<u>275*</u>	<u>138.2%</u>

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Table 17 (cont.): Intraoperative Medication - Parenteral Medication

---

Other Parenteral Medication Specified (N = 5)

Pt

Seq# Other Parenteral Medication Specified

---

001	REGLAN 10MG IU BEFORE SURGERY
002	REGLAN 10MG, KETALAR, VERSED
003	REGLAN
004	VERSED, KETALAR, REGLAN
005	REGLAN, VERSED, FENTANYL, KETALAR

---

\* 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 = 432)
Yes	2	0.5%
No	430	99.5%
	432	100.0%

Intraoperative Complication Specified (N = 2)

Imp

Seq# Intraoperative Complication Specified

001	CALCIFIED SHELL;SILICONE SLICK FRAGILE IMPLANT
002	CALCIFIED SHELL;RUPTURED OLD IMPLANT

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Table 19: Patient Compliance Through 2 Years

	0-4 Weeks	6 Months	1 Year	2 Years
Theoretically Due	225	225	225	225
Deaths*	0	0	0	2
Explant-Related Discontinuations*	0	1	3	7
Without Replacement	0	0	0	1
Replacement with Non-Study Device	0	1	2	3
Unknown Replacement Status	0	0	1	3
Expected	225	224	222	216
Actual Evaluated	221	172	175	187
Lost-to-Follow-Up	4	52	47	29
% Follow-Up	98.2%	76.8%	78.8%	86.6%

\* Deaths and Explant-Related Discontinuations are reported cumulatively.

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Table 20: Patient Discontinuation Through 2 Years

Discontinuation	Patients (N = 225)	
	n	%
Not Discontinued	213	94.7%
Discontinued		
Death	3	1.3%
Explanted of All Study Devices	7	3.1%
Patient Choice	2	0.9%
	225	100.0%

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

---

Death Reason Specified (N = 3)

Pt  
Seq# Death Reason Specified

---

001 CERVICAL CANCER  
002 BREAST CANCER-METASTASIS  
003 OVARIAN CARCINOMA

---

Patient Choice Discontinuation Specified (N = 2)

Pt  
Seq# Patient Choice Discontinuation

---

001 PT.UNHAPPY WITH RESULTS OF SCARS.WENT TO ANOTHER  
DOCTOR  
002 PT REFUSES TO TRAVEL FOR ANY RECHECK AND REFUSES  
TO SEE ANY OTHER DOCTOR. WANTS TO BE DISCONTINUED  
FROM THE STUDY

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Table 21: Risk of First Occurrence of Asymmetry

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
4 Weeks	1	208	0.5% ( 0.0%, 1.4%)		N/A	
6 Months	5	197	2.4% ( 0.3%, 4.5%)		N/A	
1 Year	6	190	2.9% ( 0.6%, 5.2%)		N/A	
2 Years	10	171	5.0% ( 2.0%, 8.1%)		N/A	

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Table 22: Incidence and Prevalence of Asymmetry

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 ( 0.4%)	1 ( 0.4%)	224		N/A	
6 Months	4 ( 1.9%)	5 ( 2.4%)	209		N/A	
1 Year	1 ( 0.5%)	2 ( 1.0%)	201		N/A	
2 Years	4 ( 2.1%)	6 ( 3.1%)	195		N/A	

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Table 23: Time to Resolution of Asymmetry

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 3)	Minimum	1
	Median	366
	Maximum	696
Resolved - Time To Resolution (N = 7)*	Minimum	1
	Median	75
	Maximum	280

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

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Table 24: Distribution of Asymmetry Resolution Status

Resolution Status	By Patient	
	n	%(N = 10)
Not Yet Resolved		
Undergoing Treatment	3	30.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>3</u>	<u>30.0%</u>
Resolved*		
With Reoperation and Explantation	1	10.0%
With Reoperation Without Explantation	2	20.0%
With Non-Surgical Treatment	3	30.0%
Without Treatment	1	10.0%
<u>Total</u>	<u>7</u>	<u>70.0%</u>

\* Includes 2 occurrences of Asymmetry that were resolved after explanation 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)
4 Weeks	7	203	3.2%	( 0.9%, 5.5%)	10	394	2.3%	( 0.9%, 3.8%)
6 Months	10	192	4.6%	( 1.8%, 7.4%)	15	373	3.6%	( 1.8%, 5.4%)
1 Year	11	185	5.2%	( 2.2%, 8.1%)	16	360	3.9%	( 2.0%, 5.8%)
2 Years	14	164	6.8%	( 3.3%, 10.3%)	19	319	4.7%	( 2.7%, 6.8%)

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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	7 ( 3.1%)	7 ( 3.1%)	224	10 ( 2.3%)	10 ( 2.3%)	431
6 Months	3 ( 1.4%)	6 ( 2.9%)	209	5 ( 1.2%)	9 ( 2.2%)	402
1 Year	1 ( 0.5%)	6 ( 3.0%)	201	1 ( 0.3%)	8 ( 2.1%)	386
2 Years	3 ( 1.5%)	8 ( 4.1%)	195	3 ( 0.8%)	9 ( 2.4%)	374

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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 = 3)	Minimum	1
	Median	621
	Maximum	1006
Resolved - Time To Resolution (N = 11)	Minimum	1
	Median	73
	Maximum	667

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Table 28: Distribution of Breast Pain Resolution Status

Resolution Status	By Patient	
	n	%(N = 14)
Not Yet Resolved		
Undergoing Treatment	3	21.4%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>3</u>	<u>21.4%</u>
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	4	28.6%
Without Treatment	7	50.0%
<u>Total</u>	<u>11</u>	<u>78.6%</u>

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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	206	1.4% ( 0.0%, 2.9%)	4	398	0.9% ( 0.0%, 1.9%)
6 Months	3	199	1.4% ( 0.0%, 2.9%)	4	383	0.9% ( 0.0%, 1.9%)
1 Year	3	193	1.4% ( 0.0%, 2.9%)	4	371	0.9% ( 0.0%, 1.9%)
2 Years	3	174	1.4% ( 0.0%, 2.9%)	4	332	0.9% ( 0.0%, 1.9%)

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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 ( 1.3%)	3 ( 1.3%)	224	4 ( 0.9%)	4 ( 0.9%)	431
6 Months	0 ( 0.0%)	1 ( 0.5%)	209	0 ( 0.0%)	1 ( 0.2%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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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		1
Median		13
Maximum		51

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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%
<b>Total</b>	<b>0</b>	<b>0.0%</b>
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%
<b>Total</b>	<b>3</b>	<b>100.0%</b>

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Table 33: Risk of First Occurrence of Capsule Calcification

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n	% (95% CI)	n	n	% (95% CI)		
4 Weeks	0	209	0.0%	--	0	402	0.0%	--
6 Months	0	201	0.0%	--	0	386	0.0%	--
1 Year	0	195	0.0%	--	0	374	0.0%	--
2 Years	0	176	0.0%	--	0	335	0.0%	--

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Table 34: Incidence and Prevalence of Capsule Calcification

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 ( 0.0%)	0 ( 0.0%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	0 ( 0.0%)	0 ( 0.0%)	209	0 ( 0.0%)	0 ( 0.0%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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Table 35: Time to Resolution of Capsule Calcification

THERE WAS NO CAPSULE CALCIFICATION OBSERVED AMONG REVISION PATIENTS

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Table 36: Distribution of Capsule Calcification Resolution Status

THERE WAS NO CAPSULE CALCIFICATION OBSERVED AMONG REVISION 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	5	204	2.3% ( 0.3%, 4.4%)	5	397	1.2% ( 0.2%, 2.3%)
6 Months	11	190	5.3% ( 2.2%, 8.3%)	12	375	3.0% ( 1.3%, 4.7%)
1 Year	17	179	8.3% ( 4.5%, 12.0%)	18	359	4.5% ( 2.5%, 6.6%)
2 Years	20	160	9.9% ( 5.8%, 14.0%)	21	319	5.4% ( 3.1%, 7.6%)

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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	5 ( 2.2%)	5 ( 2.2%)	224	5 ( 1.2%)	5 ( 1.2%)	431
6 Months	6 ( 2.9%)	11 ( 5.3%)	209	7 ( 1.7%)	12 ( 3.0%)	402
1 Year	6 ( 3.0%)	14 ( 7.0%)	201	6 ( 1.6%)	15 ( 3.9%)	386
2 Years	3 ( 1.5%)	15 ( 7.7%)	195	3 ( 0.8%)	15 ( 4.0%)	374

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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	119	
Median	620	
Maximum	1006	
Resolved - Time To Resolution (N = 8)*		
Minimum	1	
Median	77	
Maximum	518	

\* Includes 1 occurrence of Capsular Contracture that was resolved after explantation of the patient's primary study device.

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Table 40: Distribution of Capsular Contracture Resolution Status

Resolution Status	By Patient	
	n	%(N = 20)
Not Yet Resolved		
Undergoing Treatment	9	45.0%
Treatment Not Possible	0	0.0%
Refused Treatment	3	15.0%
<b>Total</b>	<b>12</b>	<b>60.0%</b>
Resolved*		
With Reoperation and Explantation	2	10.0%
With Reoperation Without Explantation	3	15.0%
With Non-Surgical Treatment	2	10.0%
Without Treatment	1	5.0%
<b>Total</b>	<b>8</b>	<b>40.0%</b>

\* Includes 1 occurrence of Capsular Contracture that was resolved after explantation of the patient's primary study device.

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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)
4 Weeks	0	209	0.0%	( 0.0%, 0.0%)	0	402	0.0%	( 0.0%, 0.0%)
6 Months	1	200	0.5%	( 0.0%, 1.4%)	1	385	0.2%	( 0.0%, 0.7%)
1 Year	1	194	0.5%	( 0.0%, 1.4%)	1	373	0.2%	( 0.0%, 0.7%)
2 Years	1	175	0.5%	( 0.0%, 1.4%)	1	334	0.2%	( 0.0%, 0.7%)

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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	0 ( 0.0%)	0 ( 0.0%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	1 ( 0.5%)	1 ( 0.5%)	209	1 ( 0.2%)	1 ( 0.2%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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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 = 1)		
Minimum		14
Median		14
Maximum		14

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Table 44: Distribution of Delayed Wound Healing 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%
<b>Total</b>	<b>0</b>	<b>0.0%</b>
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%
<b>Total</b>	<b>1</b>	<b>100.0%</b>

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Table 45: Risk of First Occurrence of Fluid Accumulation

Time	By Patient				By Implant			
	Number Affected		Cumulative Risk		Number Affected		Cumulative Risk	
	n	% (95% CI)						
4 Weeks	0	0.0%	209	0.0%	0	0.0%	402	0.0%
6 Months	0	0.0%	201	0.0%	0	0.0%	386	0.0%
1 Year	0	0.0%	195	0.0%	0	0.0%	374	0.0%
2 Years	0	0.0%	176	0.0%	0	0.0%	335	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%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	0 ( 0.0%)	0 ( 0.0%)	209	0 ( 0.0%)	0 ( 0.0%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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Table 47: Time to Resolution of Fluid Accumulation

THERE WAS NO FLUID ACCUMULATION OBSERVED AMONG REVISION PATIENTS

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Table 48: Distribution of Fluid Accumulation Resolution Status

THERE WAS NO FLUID ACCUMULATION OBSERVED AMONG REVISION 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)
4 Weeks	2	207	0.9%	( 0.0%, 2.1%)	2	400	0.5%	( 0.0%, 1.1%)
6 Months	2	199	0.9%	( 0.0%, 2.1%)	2	384	0.5%	( 0.0%, 1.1%)
1 Year	2	193	0.9%	( 0.0%, 2.1%)	2	372	0.5%	( 0.0%, 1.1%)
2 Years	2	174	0.9%	( 0.0%, 2.1%)	2	333	0.5%	( 0.0%, 1.1%)

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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	2 ( 0.9%)	2 ( 0.9%)	224	2 ( 0.5%)	2 ( 0.5%)	431
6 Months	0 ( 0.0%)	0 ( 0.0%)	209	0 ( 0.0%)	0 ( 0.0%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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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 = 2)		
Minimum		1
Median		3
Maximum		5

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Table 52: Distribution of Hematoma 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%
<u>Total</u>	<u>0</u>	<u>0.0%</u>
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	2	100.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
<u>Total</u>	<u>2</u>	<u>100.0%</u>

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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	% (95% CI)	n	n	% (95% CI)	n	% (95% CI)
4 Weeks	0	209	0.0%	--	0	402	0.0%	--
6 Months	0	201	0.0%	--	0	386	0.0%	--
1 Year	1	194	0.5% ( 0.0%, 1.5%)		1	373	0.3% ( 0.0%, 0.8%)	
2 Years	1	175	0.5% ( 0.0%, 1.5%)		1	334	0.3% ( 0.0%, 0.8%)	

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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%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	0 ( 0.0%)	0 ( 0.0%)	209	0 ( 0.0%)	0 ( 0.0%)	402
1 Year	1 ( 0.5%)	1 ( 0.5%)	201	1 ( 0.3%)	1 ( 0.3%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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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 = 0)		
Minimum	.	
Median	.	
Maximum	.	
Resolved - Time To Resolution (N = 1)		
Minimum		21
Median		21
Maximum		21

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Table 56: Distribution of Hypertrophic Scarring 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	1	100.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
<u>Total</u>	<u>1</u>	<u>100.0%</u>

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Table 57: Risk of First Occurrence of Implant Extrusion

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
	n	n			n	n		
4 Weeks	0	209	0.0%	0.0%	0	402	0.0%	0.0%
6 Months	1	200	0.5% (0.0%, 1.4%)	0.5%	1	385	0.2% (0.0%, 0.7%)	0.2%
1 Year	1	194	0.5% (0.0%, 1.4%)	0.5%	1	373	0.2% (0.0%, 0.7%)	0.2%
2 Years	1	175	0.5% (0.0%, 1.4%)	0.5%	1	334	0.2% (0.0%, 0.7%)	0.2%

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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%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	1 ( 0.5%)	1 ( 0.5%)	209	1 ( 0.2%)	1 ( 0.2%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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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	21	21
Median	21	21
Maximum	21	21

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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%
<u>Total</u>	<u>0</u>	<u>0.0%</u>
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%
<u>Total</u>	<u>1</u>	<u>100.0%</u>

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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)
4 Weeks	1	208	0.4% ( 0.0%, 1.3%)	2	400	0.5% ( 0.0%, 1.1%)
6 Months	5	196	2.4% ( 0.3%, 4.4%)	6	380	1.5% ( 0.3%, 2.6%)
1 Year	8	187	3.9% ( 1.2%, 6.5%)	10	364	2.5% ( 1.0%, 4.1%)
2 Years	9	169	4.4% ( 1.6%, 7.3%)	12	326	3.1% ( 1.4%, 4.8%)

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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	1 ( 0.4%)	1 ( 0.4%)	224	2 ( 0.5%)	2 ( 0.5%)	431
6 Months	4 ( 1.9%)	5 ( 2.4%)	209	4 ( 1.0%)	6 ( 1.5%)	402
1 Year	3 ( 1.5%)	7 ( 3.5%)	201	4 ( 1.0%)	9 ( 2.3%)	386
2 Years	1 ( 0.5%)	6 ( 3.1%)	195	2 ( 0.5%)	8 ( 2.1%)	374

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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 = 2)	Minimum	749
	Median	878
	Maximum	1006
Resolved - Time To Resolution (N = 7)*	Minimum	1
	Median	127
	Maximum	486

\* Includes 2 occurrences of Implant Malposition that were resolved after explanation 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 = 9)
Not Yet Resolved		
Undergoing Treatment	2	22.2%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>2</u>	<u>22.2%</u>
Resolved*		
With Reoperation and Explantation	1	11.1%
With Reoperation Without Explantation	5	55.6%
With Non-Surgical Treatment	0	0.0%
Without Treatment	1	11.1%
<u>Total</u>	<u>7</u>	<u>77.8%</u>

\* Includes 2 occurrences of Implant Malposition that were 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	208	0.4%	( 0.0%, 1.3%)	1	401	0.2%	( 0.0%, 0.7%)
6 Months	2	200	0.9%	( 0.0%, 2.2%)	2	385	0.5%	( 0.0%, 1.2%)
1 Year	2	194	0.9%	( 0.0%, 2.2%)	2	373	0.5%	( 0.0%, 1.2%)
2 Years	2	175	0.9%	( 0.0%, 2.2%)	2	334	0.5%	( 0.0%, 1.2%)

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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 ( 0.4%)	1 ( 0.4%)	224	1 ( 0.2%)	1 ( 0.2%)	431
6 Months	1 ( 0.5%)	2 ( 1.0%)	209	1 ( 0.2%)	2 ( 0.5%)	402
1 Year	0 ( 0.0%)	1 ( 0.5%)	201	0 ( 0.0%)	1 ( 0.3%)	386
2 Years	0 ( 0.0%)	1 ( 0.5%)	195	0 ( 0.0%)	1 ( 0.3%)	374

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Table 67: Time to Resolution of Implant Palpability

Measurement in Days	
Resolution	By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	1006
Median	1006
Maximum	1006
Resolved - Time To Resolution (N = 1)	
Minimum	7
Median	7
Maximum	7

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Table 68: Distribution of Implant Palpability 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 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)
	n	n	% (95% CI)	n	n	% (95% CI)		
4 Weeks	1	208	0.5% ( 0.0%, 1.4%)	1	401	0.2% ( 0.0%, 0.7%)		
6 Months	1	200	0.5% ( 0.0%, 1.4%)	1	385	0.2% ( 0.0%, 0.7%)		
1 Year	1	194	0.5% ( 0.0%, 1.4%)	1	373	0.2% ( 0.0%, 0.7%)		
2 Years	1	176	0.5% ( 0.0%, 1.4%)	1	335	0.2% ( 0.0%, 0.7%)		

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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 ( 0.4%)	1 ( 0.4%)	224	1 ( 0.2%)	1 ( 0.2%)	431
6 Months	0 ( 0.0%)	1 ( 0.5%)	209	0 ( 0.0%)	1 ( 0.2%)	402
1 Year	0 ( 0.0%)	1 ( 0.5%)	201	0 ( 0.0%)	1 ( 0.3%)	386
2 Years	0 ( 0.0%)	1 ( 0.5%)	195	0 ( 0.0%)	1 ( 0.3%)	374

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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 = 1)		
Minimum		525
Median		525
Maximum		525
Resolved - Time To Resolution (N = 0)		
Minimum		.
Median		.
Maximum		.

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Table 72: Distribution of Implant Visibility Resolution Status

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved	1	100.0%
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>1</u>	<u>100.0%</u>
Resolved	0	0.0%
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 73: Risk of First Occurrence of Infection

Time	By Patient				By Implant			
	Number Affected		Cumulative Risk		Number Affected		Cumulative Risk	
	n	n	% (95% CI)		n	n	% (95% CI)	
4 Weeks	3	206	1.4% ( 0.0%, 2.9%)		3	400	0.7% ( 0.0%, 1.5%)	
6 Months	4	197	1.8% ( 0.1%, 3.7%)		4	383	1.0% ( 0.0%, 1.9%)	
1 Year	4	191	1.8% ( 0.1%, 3.7%)		4	371	1.0% ( 0.0%, 1.9%)	
2 Years	4	172	1.8% ( 0.1%, 3.7%)		4	332	1.0% ( 0.0%, 1.9%)	

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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 ( 1.3%)	3 ( 1.3%)	224	3 ( 0.7%)	3 ( 0.7%)	431
6 Months	1 ( 0.5%)	3 ( 1.4%)	209	1 ( 0.2%)	3 ( 0.7%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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Table 75: Time to Resolution of Infection

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 1)		
Minimum		821
Median		821
Maximum		821
Resolved - Time To Resolution (N = 3)		
Minimum		7
Median		41
Maximum		44

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Table 76: Distribution of Infection Resolution Status

Resolution Status	By Patient	
	n	%(N = 4)
Not Yet Resolved		
Undergoing Treatment	1	25.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>1</u>	<u>25.0%</u>
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	2	50.0%
Without Treatment	1	25.0%
<u>Total</u>	<u>3</u>	<u>75.0%</u>

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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)
4 Weeks	1	208	0.5% ( 0.0%, 1.4%)	1	401	0.2% ( 0.0%, 0.7%)
6 Months	1	200	0.5% ( 0.0%, 1.4%)	1	385	0.2% ( 0.0%, 0.7%)
1 Year	2	193	1.0% ( 0.0%, 2.3%)	2	372	0.5% ( 0.0%, 1.2%)
2 Years	2	175	1.0% ( 0.0%, 2.3%)	2	334	0.5% ( 0.0%, 1.2%)

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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	1 ( 0.4%)	1 ( 0.4%)	224	1 ( 0.2%)	1 ( 0.2%)	431
6 Months	0 ( 0.0%)	1 ( 0.5%)	209	0 ( 0.0%)	1 ( 0.2%)	402
1 Year	1 ( 0.5%)	2 ( 1.0%)	201	1 ( 0.3%)	2 ( 0.5%)	386
2 Years	0 ( 0.0%)	2 ( 1.0%)	195	0 ( 0.0%)	2 ( 0.5%)	374

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Table 79: Time to Resolution of Irritation

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 2)		
Minimum		421
Median		641
Maximum		861
Resolved - Time To Resolution (N = 0)		
Minimum		.
Median		.
Maximum		.

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Table 80: Distribution of Irritation 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 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	209	0.0%	--	0	402	0.0%	--
6 Months	0	201	0.0%	--	0	386	0.0%	--
1 Year	0	195	0.0%	--	0	374	0.0%	--
2 Years	0	176	0.0%	--	0	335	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%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	0 ( 0.0%)	0 ( 0.0%)	209	0 ( 0.0%)	0 ( 0.0%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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Table 83: Time to Resolution of Loss of Nipple Sensation

THERE WAS NO LOSS OF NIPPLE SENSATION OBSERVED AMONG REVISION PATIENTS

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Table 84: Distribution of Loss of Nipple Sensation Resolution Status

THERE WAS NO LOSS OF NIPPLE SENSATION OBSERVED AMONG REVISION 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	1	208	0.4% ( 0.0%, 1.3%)	1	401	0.2% ( 0.0%, 0.7%)		
6 Months	1	200	0.4% ( 0.0%, 1.3%)	1	386	0.2% ( 0.0%, 0.7%)		
1 Year	1	194	0.4% ( 0.0%, 1.3%)	1	374	0.2% ( 0.0%, 0.7%)		
2 Years	1	176	0.4% ( 0.0%, 1.3%)	1	335	0.2% ( 0.0%, 0.7%)		

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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	1 ( 0.4%)	1 ( 0.4%)	224	1 ( 0.2%)	1 ( 0.2%)	431
6 Months	0 ( 0.0%)	1 ( 0.5%)	209	0 ( 0.0%)	1 ( 0.2%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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Table 87: Time to Resolution of Loss of Skin Sensation

Measurement in Days	
Resolution	By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	524
Median	524
Maximum	524
Resolved - Time To Resolution (N = 0)	
Minimum	.
Median	.
Maximum	.

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Table 88: Distribution of Loss of Skin Sensation Resolution Status

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	1	100.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>1</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 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			n	n		
4 Weeks	0	209	0.0%	--	0	402	0.0%	--
6 Months	0	201	0.0%	--	0	386	0.0%	--
1 Year	0	195	0.0%	--	0	374	0.0%	--
2 Years	0	176	0.0%	--	0	335	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%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	0 ( 0.0%)	0 ( 0.0%)	209	0 ( 0.0%)	0 ( 0.0%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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Table 91 : Time to Resolution of Lymphadenopathy

THERE WAS NO LYMPHADENOPATHY OBSERVED AMONG REVISION PATIENTS

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Table 92: Distribution of Lymphadenopathy Resolution Status

THERE WAS NO LYMPHADENOPATHY OBSERVED AMONG REVISION 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	209	0.0%	..	0	402	0.0%	..
6 Months	0	201	0.0%	..	0	386	0.0%	..
1 Year	0	195	0.0%	..	0	374	0.0%	..
2 Years	0	176	0.0%	..	0	335	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%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	0 ( 0.0%)	0 ( 0.0%)	209	0 ( 0.0%)	0 ( 0.0%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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Table 95: Time to Resolution of Lymphedema

THERE WAS NO LYMPHEDEMA OBSERVED AMONG REVISION PATIENTS

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Table 96: Distribution of Lymphedema Resolution Status

THERE WAS NO LYMPHEDEMA OBSERVED AMONG REVISION 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	209	0.0%	..	0	402	0.0%	..
6 Months	0	201	0.0%	..	0	386	0.0%	..
1 Year	0	195	0.0%	..	0	374	0.0%	..
2 Years	0	176	0.0%	..	0	335	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%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	0 ( 0.0%)	0 ( 0.0%)	209	0 ( 0.0%)	0 ( 0.0%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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Table 99: Time to Resolution of Nipple Hypersensitivity

THERE WAS NO NIPPLE HYPERSENSITIVITY OBSERVED AMONG REVISION PATIENTS

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Table 100: Distribution of Nipple Hypersensitivity Resolution Status

THERE WAS NO NIPPLE HYPERSENSITIVITY OBSERVED AMONG REVISION 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			n	n		
4 Weeks	0	209	0.0%	..	0	402	0.0%	..
6 Months	0	201	0.0%	..	0	386	0.0%	..
1 Year	0	195	0.0%	..	0	374	0.0%	..
2 Years	0	176	0.0%	..	0	335	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%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	0 ( 0.0%)	0 ( 0.0%)	209	0 ( 0.0%)	0 ( 0.0%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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Table 103: Time to Resolution of Nipple Paresthesia

THERE WAS NO NIPPLE PARESTHESIA OBSERVED AMONG REVISION PATIENTS

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Table 104: Distribution of Nipple Paresthesia Resolution Status

THERE WAS NO NIPPLE PARESTHESIA OBSERVED AMONG REVISION 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)
	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	209	0.0%	--	0	402	0.0%	--
6 Months	0	201	0.0%	--	0	386	0.0%	--
1 Year	0	195	0.0%	--	0	374	0.0%	--
2 Years	1	176	0.5%	( 0.0%, 1.5%)	1	335	0.3%	( 0.0%, 0.8%)

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Table 106: Incidence and Prevalence of Other Abnormal Scarring

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%)	431
6 Months	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.3%)	1 ( 0.3%)	374

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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 = 1)			
Minimum			1
Median			1
Maximum			1
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 = 1)
Not Yet Resolved		
Undergoing Treatment	1	100.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	1	100.0%
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%
Total	0	0.0%

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

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	209	0.0%	0.0%	0	402	0.0%	0.0%
6 Months	3	198	1.5% (0.0%, 3.1%)	1.5% (0.0%, 3.1%)	5	381	1.3% (0.2%, 2.4%)	1.3% (0.2%, 2.4%)
1 Year	3	192	1.5% (0.0%, 3.1%)	1.5% (0.0%, 3.1%)	5	369	1.3% (0.2%, 2.4%)	1.3% (0.2%, 2.4%)
2 Years	3	173	1.5% (0.0%, 3.1%)	1.5% (0.0%, 3.1%)	5	330	1.3% (0.2%, 2.4%)	1.3% (0.2%, 2.4%)

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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	0 ( 0.0%)	0 ( 0.0%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	3 ( 1.4%)	3 ( 1.4%)	209	5 ( 1.2%)	5 ( 1.2%)	402
1 Year	0 ( 0.0%)	3 ( 1.5%)	201	0 ( 0.0%)	5 ( 1.3%)	386
2 Years	0 ( 0.0%)	1 ( 0.5%)	195	0 ( 0.0%)	2 ( 0.5%)	374

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Table 111: Time to Resolution of Other Nipple Related Observation

Measurement in Days	
Resolution	By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	657
Median	657
Maximum	657
Resolved - Time To Resolution (N = 2)	
Minimum	161
Median	183
Maximum	205

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Table 112: Distribution of Other Nipple Related Observation Resolution Status

Resolution Status	By Patient	
	n	%(N = 3)
Not Yet Resolved		
Undergoing Treatment	1	33.3%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>1</u>	<u>33.3%</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	0	0.0%
<u>Total</u>	<u>2</u>	<u>66.7%</u>

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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	209	0.0%	--	0	402	0.0%	--
6 Months	0	201	0.0%	--	0	386	0.0%	--
1 Year	0	195	0.0%	--	0	374	0.0%	--
2 Years	0	176	0.0%	--	0	335	0.0%	--

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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%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	0 ( 0.0%)	0 ( 0.0%)	209	0 ( 0.0%)	0 ( 0.0%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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Table 115: Time to Resolution of Pneumothorax

THERE WAS NO PNEUMOTHORAX OBSERVED AMONG REVISION PATIENTS

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Table 116: Distribution of Pneumothorax Resolution Status

THERE WAS NO PNEUMOTHORAX OBSERVED AMONG REVISION PATIENTS

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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)
	n	n			n	n		
4 Weeks	0	209	0.0%	--	0	402	0.0%	--
6 Months	1	200	0.5% ( 0.0%, 1.4%)		1	385	0.2% ( 0.0%, 0.7%)	
1 Year	1	194	0.5% ( 0.0%, 1.4%)		1	373	0.2% ( 0.0%, 0.7%)	
2 Years	1	175	0.5% ( 0.0%, 1.4%)		1	334	0.2% ( 0.0%, 0.7%)	

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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	0 ( 0.0%)	0 ( 0.0%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	1 ( 0.5%)	1 ( 0.5%)	209	1 ( 0.2%)	1 ( 0.2%)	402
1 Year	0 ( 0.0%)	1 ( 0.5%)	201	0 ( 0.0%)	1 ( 0.3%)	386
2 Years	0 ( 0.0%)	1 ( 0.5%)	195	0 ( 0.0%)	1 ( 0.3%)	374

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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		696
Median		696
Maximum		696
Resolved - Time To Resolution (N = 0)		
Minimum		.
Median		.
Maximum		.

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Table 120 : Distribution of Ptosis Resolution Status

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	1	100.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	1	100.0%
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%
Total	0	0.0%

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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	209	0.0%	--	0	402	0.0%	--
6 Months	0	201	0.0%	--	0	386	0.0%	--
1 Year	0	195	0.0%	--	0	374	0.0%	--
2 Years	0	176	0.0%	--	0	335	0.0%	--

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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%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	0 ( 0.0%)	0 ( 0.0%)	209	0 ( 0.0%)	0 ( 0.0%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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Table 123: Time to Resolution of Redness

THERE WAS NO REDNESS OBSERVED AMONG REVISION PATIENTS

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Table 124: Distribution of Redness Resolution Status

THERE WAS NO REDNESS OBSERVED AMONG REVISION PATIENTS

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Table 125: Risk of First Occurrence of Seroma

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
4 Weeks	6	203	2.8% ( 0.6%, 4.9%)	7	395	1.7% ( 0.4%, 2.9%)
6 Months	8	193	3.7% ( 1.2%, 6.3%)	9	378	2.2% ( 0.8%, 3.6%)
1 Year	10	185	4.7% ( 1.9%, 7.6%)	11	364	2.7% ( 1.1%, 4.3%)
2 Years	10	170	4.7% ( 1.9%, 7.6%)	11	328	2.7% ( 1.1%, 4.3%)

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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	6 ( 2.7%)	6 ( 2.7%)	224	7 ( 1.6%)	7 ( 1.6%)	431
6 Months	2 ( 1.0%)	7 ( 3.3%)	209	2 ( 0.5%)	8 ( 2.0%)	402
1 Year	2 ( 1.0%)	4 ( 2.0%)	201	2 ( 0.5%)	5 ( 1.3%)	386
2 Years	0 ( 0.0%)	4 ( 2.1%)	195	0 ( 0.0%)	5 ( 1.3%)	374

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Table 127: Time to Resolution of Seroma

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 3)		
Minimum		524
Median		637
Maximum		838
Resolved - Time To Resolution (N = 7)		
Minimum		1
Median		63
Maximum		570

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Table 128: Distribution of Seroma Resolution Status

Resolution Status	By Patient	
	n	%(N = 10)
Not Yet Resolved		
Undergoing Treatment	3	30.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>3</u>	<u>30.0%</u>
Resolved		
With Reoperation and Explantation	1	10.0%
With Reoperation Without Explantation	1	10.0%
With Non-Surgical Treatment	3	30.0%
Without Treatment	2	20.0%
<u>Total</u>	<u>7</u>	<u>70.0%</u>

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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	209	0.0%	--	0	402	0.0%	--
6 Months	0	201	0.0%	--	0	386	0.0%	--
1 Year	0	195	0.0%	--	0	374	0.0%	--
2 Years	0	176	0.0%	--	0	335	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%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	0 ( 0.0%)	0 ( 0.0%)	209	0 ( 0.0%)	0 ( 0.0%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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Table 131: Time to Resolution of Skin Hypersensitivity

THERE WAS NO SKIN HYPERSENSITIVITY OBSERVED AMONG REVISION PATIENTS

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Table 132: Distribution of Skin Hypersensitivity Resolution Status

THERE WAS NO SKIN HYPERSENSITIVITY OBSERVED AMONG REVISION 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	% (95% CI)	n	n	% (95% CI)		
4 Weeks	0	209	0.0%	--	0	402	0.0%	--
6 Months	0	201	0.0%	--	0	386	0.0%	--
1 Year	0	195	0.0%	--	0	374	0.0%	--
2 Years	0	176	0.0%	--	0	335	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%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	0 ( 0.0%)	0 ( 0.0%)	209	0 ( 0.0%)	0 ( 0.0%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	0 ( 0.0%)	0 ( 0.0%)	195	0 ( 0.0%)	0 ( 0.0%)	374

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Table 135: Time to Resolution of Skin Paresthesia

THERE WAS NO SKIN PARESTHESIA OBSERVED AMONG REVISION PATIENTS

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Table 136: Distribution of Skin Paresthesia Resolution Status

THERE WAS NO SKIN PARESTHESIA OBSERVED AMONG REVISION 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)
4 Weeks	1	208	0.5% ( 0.0%, 1.4%)	1	401	0.2% ( 0.0%, 0.7%)
6 Months	1	200	0.5% ( 0.0%, 1.4%)	1	385	0.2% ( 0.0%, 0.7%)
1 Year	1	194	0.5% ( 0.0%, 1.4%)	1	373	0.2% ( 0.0%, 0.7%)
2 Years	1	175	0.5% ( 0.0%, 1.4%)	1	334	0.2% ( 0.0%, 0.7%)

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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	1 ( 0.4%)	1 ( 0.4%)	224	1 ( 0.2%)	1 ( 0.2%)	431
6 Months	0 ( 0.0%)	1 ( 0.5%)	209	0 ( 0.0%)	1 ( 0.2%)	402
1 Year	0 ( 0.0%)	1 ( 0.5%)	201	0 ( 0.0%)	1 ( 0.3%)	366
2 Years	0 ( 0.0%)	1 ( 0.5%)	195	0 ( 0.0%)	1 ( 0.3%)	374

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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 = 1)		
Minimum		861
Median		861
Maximum		861
Resolved - Time To Resolution (N = 0)		
Minimum		.
Median		.
Maximum		.

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Table 140: Distribution of Skin Rash Resolution Status

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	1	100.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	1	100.0%
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%
Total	0	0.0%

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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)
4 Weeks	9	200	4.1% ( 1.5%, 6.7%)	14	388	3.3% ( 1.6%, 5.0%)
6 Months	10	192	4.5% ( 1.8%, 7.3%)	15	373	3.5% ( 1.8%, 5.3%)
1 Year	11	186	5.0% ( 2.1%, 7.9%)	16	362	3.8% ( 2.0%, 5.6%)
2 Years	12	167	5.6% ( 2.5%, 8.7%)	17	322	4.1% ( 2.2%, 6.0%)

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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	9 ( 4.0%)	9 ( 4.0%)	224	14 ( 3.2%)	14 ( 3.2%)	431
6 Months	1 ( 0.5%)	6 ( 2.9%)	209	1 ( 0.2%)	8 ( 2.0%)	402
1 Year	1 ( 0.5%)	2 ( 1.0%)	201	1 ( 0.3%)	2 ( 0.5%)	386
2 Years	1 ( 0.5%)	2 ( 1.0%)	195	1 ( 0.3%)	2 ( 0.5%)	374

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Table 143: Time to Resolution of Swelling

Resolution	Measurement in Days	
	By Patient	
Not Yet Resolved - Elapsed Treatment Time (N = 2)		
Minimum		227
Median		683
Maximum		1139
Resolved - Time To Resolution (N = 10)*		
Minimum		5
Median		31
Maximum		61

\* 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 = 12)
Not Yet Resolved		
Undergoing Treatment	2	16.7%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>2</u>	<u>16.7%</u>
Resolved*		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	1	8.3%
Without Treatment	9	75.0%
<u>Total</u>	<u>10</u>	<u>83.3%</u>

\* 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	% (95% CI)	n	n	% (95% CI)		
4 Weeks	1	208	0.4% ( 0.0%, 1.3%)	1	401	0.2% ( 0.0%, 0.7%)		
6 Months	4	197	1.9% ( 0.1%, 3.8%)	4	382	1.0% ( 0.0%, 2.0%)		
1 Year	4	191	1.9% ( 0.1%, 3.8%)	4	370	1.0% ( 0.0%, 2.0%)		
2 Years	4	172	1.9% ( 0.1%, 3.8%)	4	331	1.0% ( 0.0%, 2.0%)		

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Table 146: Incidence and Prevalence of Tissue or Skin Necrosis

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 ( 0.4%)	1 ( 0.4%)	224	1 ( 0.2%)	1 ( 0.2%)	431
6 Months	3 ( 1.4%)	4 ( 1.9%)	209	3 ( 0.7%)	4 ( 1.0%)	402
1 Year	0 ( 0.0%)	1 ( 0.5%)	201	0 ( 0.0%)	1 ( 0.3%)	386
2 Years	0 ( 0.0%)	1 ( 0.5%)	195	0 ( 0.0%)	1 ( 0.3%)	374

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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	978
	Median	978
	Maximum	978
Resolved - Time To Resolution (N = 3)	Minimum	14
	Median	28
	Maximum	39

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Table 148: Distribution of Tissue or Skin Necrosis Resolution Status

Resolution Status	By Patient	
	n	%(N = 4)
Not Yet Resolved		
Undergoing Treatment	1	25.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>1</u>	<u>25.0%</u>
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	3	75.0%
Without Treatment	0	0.0%
<u>Total</u>	<u>3</u>	<u>75.0%</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)
4 Weeks	3	206	1.3% ( 0.0%, 2.9%)	4	398	0.9% ( 0.0%, 1.8%)
6 Months	4	197	1.8% ( 0.1%, 3.6%)	5	381	1.2% ( 0.2%, 2.2%)
1 Year	5	190	2.3% ( 0.3%, 4.4%)	7	367	1.7% ( 0.5%, 3.0%)
2 Years	6	172	2.9% ( 0.6%, 5.2%)	8	330	2.0% ( 0.6%, 3.4%)

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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	3 ( 1.3%)	3 ( 1.3%)	224	4 ( 0.9%)	4 ( 0.9%)	481
6 Months	1 ( 0.5%)	3 ( 1.4%)	209	1 ( 0.2%)	3 ( 0.7%)	402
1 Year	1 ( 0.5%)	4 ( 2.0%)	201	2 ( 0.5%)	5 ( 1.3%)	386
2 Years	1 ( 0.5%)	4 ( 2.1%)	195	1 ( 0.3%)	4 ( 1.1%)	374

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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 = 3)		
Minimum		242
Median		1006
Maximum		1169
Resolved - Time To Resolution (N = 3)*		
Minimum		14
Median		127
Maximum		360

\* 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	3	50.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>3</u>	<u>50.0%</u>
Resolved*		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	2	33.3%
Without Treatment	1	16.7%
<u>Total</u>	<u>3</u>	<u>50.0%</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)
4 Weeks	1	208	0.4%	( 0.0%, 1.3%)	1	401	0.2%	( 0.0%, 0.7%)
6 Months	2	199	0.9%	( 0.0%, 2.2%)	2	384	0.5%	( 0.0%, 1.2%)
1 Year	2	193	0.9%	( 0.0%, 2.2%)	2	372	0.5%	( 0.0%, 1.2%)
2 Years	4	172	2.0%	( 0.1%, 4.0%)	4	331	1.1%	( 0.0%, 2.1%)

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

Other Complications Specified (N = 4)

Pt  
Seq# Other Complications Specified

001 THINNESS  
002 FREE SILICON FROM PREV. RUPTURE  
003 MEDIAL PUCKERING  
004 AREA OF RESIDUAL DEPRESSION

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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	1 ( 0.4%)	1 ( 0.4%)	224	1 ( 0.2%)	1 ( 0.2%)	431
6 Months	1 ( 0.5%)	2 ( 1.0%)	209	1 ( 0.2%)	2 ( 0.5%)	402
1 Year	0 ( 0.0%)	1 ( 0.5%)	201	0 ( 0.0%)	1 ( 0.3%)	386
2 Years	2 ( 1.0%)	3 ( 1.5%)	195	2 ( 0.5%)	3 ( 0.8%)	374

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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 = 2)		
Minimum		242
Median		624
Maximum		1006
Resolved - Time To Resolution (N = 2)		
Minimum		32
Median		237
Maximum		441

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Table 156: Distribution of Other Complications Resolution Status

Resolution Status	By Patient	
	n	%(N = 4)
Not Yet Resolved		
Undergoing Treatment	2	50.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
<u>Total</u>	<u>2</u>	<u>50.0%</u>
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	2	50.0%
Without Treatment	0	0.0%
<u>Total</u>	<u>2</u>	<u>50.0%</u>

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

Complication	Patients	Severity Level*								Descriptive Statistics	
		Very Mild				Very Severe				Mean	SD
		Mild	Moderate	Severe	Severe	Mild	Moderate	Severe	Severe		
	N	%	%	%	%	%	%	%	%		
Asymmetry	25	32.0%	28.0%	16.0%	8.0%	16.0%	0.0%	0.0%	16.0%	2.5	1.4
Breast Pain	24	16.7%	25.0%	29.2%	16.7%	12.5%	0.0%	0.0%	12.5%	2.8	1.3
Bruising	8	25.0%	37.5%	37.5%	0.0%	0.0%	0.0%	0.0%	0.0%	2.1	0.8
Capsular Contracture***	35	0.0%	42.9%	31.4%	20.0%	5.7%	0.0%	0.0%	0.0%	2.9	0.9
Delayed Wound Healing	8	25.0%	62.5%	12.5%	0.0%	0.0%	0.0%	0.0%	0.0%	1.9	0.6
Fluid Accumulation	1	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	2.0	N/A**
Hematoma	6	0.0%	66.7%	0.0%	16.7%	16.7%	0.0%	0.0%	16.7%	2.8	1.3
Hypertrophic Scarring	7	28.6%	57.1%	0.0%	14.3%	0.0%	0.0%	0.0%	0.0%	2.0	1.0
Implant Extrusion	1	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	3.0	N/A**
Implant Malposition	10	10.0%	0.0%	20.0%	40.0%	30.0%	0.0%	0.0%	30.0%	3.8	1.2
Implant Palpability	5	40.0%	20.0%	40.0%	0.0%	0.0%	0.0%	0.0%	0.0%	2.0	1.0
Implant Visibility	1	0.0%	33.3%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	4.0	N/A**
Infection	6	0.0%	0.0%	16.7%	33.3%	16.7%	0.0%	0.0%	16.7%	3.3	1.2
Irritation	3	33.3%	0.0%	66.7%	0.0%	0.0%	0.0%	0.0%	0.0%	2.3	1.2
Loss of Nipple Sensation	2	50.0%	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.5	0.7
Loss of Skin Sensation	2	0.0%	50.0%	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%	2.5	0.7
Nipple Hypersensitivity	1	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	2.0	N/A**

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

Complication	Severity Level* (Allowable Range 1 - 5)										Descriptive Statistics			
	Patients		Very Mild		Mild		Moderate		Severe		Very Severe		Mean	SD
	N	%	%	%	%	%	%	%	%	%				
Other Abnormal Scarring	4	25.0%	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	25.0%	2.5	1.7	
Other Nipple Related Obs.	8	37.5%	25.0%	12.5%	12.5%	12.5%	0.0%	0.0%	0.0%	12.5%	12.5%	2.4	1.5	
Ptosis	3	66.7%	0.0%	33.3%	33.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.7	1.2	
Redness	10	40.0%	60.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.6	0.5	
Seroma	12	8.3%	8.3%	58.3%	58.3%	0.0%	0.0%	0.0%	0.0%	0.0%	25.0%	3.3	1.2	
Skin Rash	5	40.0%	40.0%	20.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.8	0.8	
Swelling	31	29.0%	32.3%	32.3%	32.3%	6.5%	6.5%	0.0%	0.0%	0.0%	0.0%	2.2	0.9	
Tissue or Skin Necrosis	5	0.0%	20.0%	40.0%	40.0%	20.0%	20.0%	20.0%	20.0%	20.0%	20.0%	3.4	1.1	
Wrinkling/Rippling	18	44.4%	22.2%	11.1%	11.1%	11.1%	11.1%	11.1%	11.1%	11.1%	11.1%	2.2	1.4	
Other Complications	11	9.1%	54.5%	18.2%	18.2%	0.0%	0.0%	0.0%	0.0%	0.0%	18.2%	2.6	1.3	

\* 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 = 432)
No Rupture	421	97.5%
Rupture Suspected Through:		
Explant	2	0.5%
MRI	4	0.9%
Reoperation	0	0.0%
Mammography	0	0.0%
Ultrasound	1	0.2%
Physician Exam	4	0.9%
	<u>432</u>	<u>100.0%</u>

Physician Exam - Symptom of Rupture	n	%(N = 4)
Lump/Mass/Nodules	0	0.0%
Implant Distortion	2	50.0%
Burning Sensation	0	0.0%
Softer Breast Texture	1	25.0%
Decreased Breast Size	1	25.0%
Pain/Tenderness	1	25.0%
	<u>5*</u>	<u>125.0%</u>

\* The sum of rupture symptoms listed may exceed the total number of implants identified as ruptured by physician exam because more than one symptom may be reported for the same implant.

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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	4	36.4%
Mammography* Indicated Non-Rupture	0	0.0%
Ultrasound* Indicated Non-Rupture	0	0.0%
MRI* Indicated Non-Rupture	2	18.2%
Unconfirmed Rupture Status	3	27.3%
	<u>11</u>	<u>100.2%</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	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
4 Weeks	0	209	0.0%	( 0.0%, 0.0%)	0	402	0.0%	( 0.0%, 0.0%)
6 Months	0	201	0.0%	( 0.0%, 0.0%)	0	386	0.0%	( 0.0%, 0.0%)
1 Year	0	195	0.0%	( 0.0%, 0.0%)	0	374	0.0%	( 0.0%, 0.0%)
2 Years	5	172	2.7%	( 0.4%, 5.0%)	5	331	1.4%	( 0.2%, 2.6%)

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Table 161: Incidence and Prevalence of Implant Rupture

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 ( 0.0%)	0 ( 0.0%)	224	0 ( 0.0%)	0 ( 0.0%)	431
6 Months	0 ( 0.0%)	0 ( 0.0%)	209	0 ( 0.0%)	0 ( 0.0%)	402
1 Year	0 ( 0.0%)	0 ( 0.0%)	201	0 ( 0.0%)	0 ( 0.0%)	386
2 Years	5 ( 2.6%)	5 ( 2.6%)	195	5 ( 1.3%)	5 ( 1.3%)	374

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Table 162: Distribution of Implant Rupture Resolution Status

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

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Table 163: Risk of First Occurrence of Reoperation

Time	By Patient				By Implant			
	Number Affected		Cumulative Risk		Number Affected		Cumulative Risk	
	n	% (95% CI)						
4 Weeks	9	4.1% ( 1.5%, 6.7%)	206	4.1% ( 1.5%, 6.7%)	12	2.8% ( 1.2%, 4.4%)	401	2.8% ( 1.2%, 4.4%)
6 Months	35	16.3% (11.4%,21.2%)	176	16.3% (11.4%,21.2%)	49	11.9% ( 8.8%,15.0%)	356	11.9% ( 8.8%,15.0%)
1 Year	49	23.0% (17.3%,28.6%)	160	23.0% (17.3%,28.6%)	71	17.4% (13.7%,21.0%)	330	17.4% (13.7%,21.0%)
2 Years	62	29.4% (23.3%,35.6%)	139	29.4% (23.3%,35.6%)	94	23.3% (19.2%,27.4%)	289	23.3% (19.2%,27.4%)

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Table 164: Number of Reoperations Per Patient

	Patients (N = 225)	
	n	%
No Reoperations	163	72.4%
At Least One Reoperation	62	27.6%
<b>Total</b>	<b>225</b>	<b>100.0%</b>

Breakdown of At Least One Reoperation	n	%(N = 62 )
1 Reoperation	50	80.6%
2 Reoperations	5	8.1%
3 or More Reoperations	7	11.3%
<b>Total</b>	<b>62</b>	<b>100.0%</b>
<b>Total Number of Reoperations</b>	<b>84*</b>	

\* Total number of reoperations is calculated as:  
 ( 50 \* 1 reoperation) + ( 5 \* 2 reoperations) +  
 ( 4 \* 3 reoperations) + ( 3 \* 4 reoperations)  
 = 84 reoperations.

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Table 165: Intraoperative Complications During Reoperation

Intraoperative Complications	Reoperations	
	n	%(N = 84)
Yes	0	0.0%
No	82	97.6%
Unknown*	2	2.4%
	84	100.0%

\* The implanting study physician did not perform the reoperation for these patients. No information regarding intraoperative complications was able to be obtained from the non-study surgeons who performed these reoperations.

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Table 166: Primary\* Reason for Reoperation

Reason	Patient Reoperations	
	n	%(N = 84)
Device Malfunction - Rupture	2	2.4%
Injury - Iatrogenic or Traumatic	2	2.4%
Breast Cancer	1	1.2%
Capsular Contracture	10	11.9%
Infection	1	1.2%
Healing Related		
Extrusion	3	3.6%
Necrosis	0	0.0%
Hematoma/Seroma	8	9.5%
Delayed Wound Healing	6	7.1%
Nipple Complications	5	6.0%
Pain	0	0.0%
Unsatisfactory Cosmetic Result		
Breast Tissue Contour Deformity	1	1.2%
Malposition	13	15.5%
Wrinkling/Rippling	1	1.2%
Implant Palpability/Visibility	0	0.0%
Asymmetry	4	4.8%
Ptosis	9	10.7%
Scarring	10	11.9%
Patient Request		
Style/Size Change	6	7.1%
Media Anxiety	0	0.0%
Need for Biopsy	1	1.2%
Other	1	1.2%
Total	84	100.0%

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

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Other Reason Specified (N = 1)

Reop Seq#	Other Reason Specified
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001	TO KEEP POCKET OPEN
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001	TO KEEP POCKET OPEN
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Table 167: Primary\* Procedure Performed

Procedure	Patient Reoperations	
	n	%(N = 84)
Implant Removal		
With Replacement**	20	23.8%
Without Replacement	3	3.6%
Capsule Procedure		
Capsulotomy	14	16.7%
Capsulorrhaphy	4	4.8%
Capsulectomy	0	0.0%
Flap Procedure	0	0.0%
Pocket Revision	6	7.1%
Reposition Implant	3	3.6%
Surgical Exploration of Breast Area or Implant	0	0.0%
Mastopexy	6	7.1%
Breast Reduction	1	1.2%
Wound Repair	3	3.6%
Aspiration of Hematoma/Seroma	6	7.1%
Liposuction	0	0.0%
Removal of Excess Tissue/Lesion/Cyst	2	2.4%
Revision of Nipple Reconstruction/Tattoo	5	6.0%
Scar Revision	8	9.5%
Biopsy	2	2.4%
Other	1	1.2%
<b>Total</b>	<b>84</b>	<b>100.0%</b>

\* 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.

\*\* Includes 1 patient who had delayed replacement. This patient had a device removal without replacement in 7/99, and then had a new device placed in 8/00.

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Table 167 (Cont.): Primary Procedure Performed

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Other Procedure Specified (N = 1)

Reop Seq#	Other Procedure Specified
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001	REMOVAL OF RETAINED SUTURE
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Table 168: Primary\* Reason For Reoperation and Primary Procedure Performed

Reason	Procedure	Patient Reoperations	
		n	%(N = 84)
Device Rupture	Implant Replacement/Removal	2	2.4%
Injury - Iatrogenic or Traumatic	Implant Replacement/Removal	1	1.2%
Breast Cancer	Capsule Procedure	1	1.2%
Capsular Contracture	Biopsy	1	1.2%
Infection	Implant Replacement/Removal	3	3.6%
Healing Related	Capsule Procedure	7	8.3%
	Implant Replacement/Removal	1	1.2%
	Capsule Procedure	2	2.4%
	Aspiration of Hematoma/Seroma	6	7.1%
	Wound Repair	3	3.6%
	Removal of Excess Tissue/Lesion/Cyst	2	2.4%
	Pocket Revision	3	3.6%
	Revision of Nipple Reconstruction/Tattoo	5	6.0%
	Other	1	1.2%
Unsatisfactory Cosmetic Result	Implant Replacement/Removal	10	11.9%
	Capsule Procedure	7	8.3%
	Pocket Revision	3	3.6%
	Scar Revision	8	9.5%
	Mastopexy	6	7.1%
	Reposition Implant	3	3.6%
	Breast Reduction	1	1.2%

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

Reason	Procedure	Patient Reoperations	
		n	%(N = 84)
Patient Request	Implant Replacement/Removal	6	7.1%
Need for Biopsy	Biopsy	1	1.2%
Other	Capsule Procedure	1	1.2%
Total		84	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 = 84)
1	43	51.2%
2	24	28.6%
3	7	8.3%
4	8	9.5%
5	0	0.0%
6	2	2.4%
Total	84	100.0%
Total Number of Procedures	156*	

\* Total number of procedures is calculated as:  
 ( 43 \* 1 procedure) + ( 24 \* 2 procedures) + ( 7 \* 3 procedures)  
 + ( 8 \* 4 procedures) + ( 2 \* 6 procedures) = 156 procedures.

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Table 170: Type of Procedure Performed During Reoperation

Type of Procedure	Procedures	
	n	%(N = 156)
Implant Removal		
With Replacement	32	20.5%
Without Replacement	5	3.2%
Capsule Procedure		
Capsulotomy	22	14.1%
Capsulorrhaphy	9	5.8%
Capsulectomy	8	5.1%
Flap Procedure	0	0.0%
Pocket Revision	9	5.8%
Reposition Implant	7	4.5%
Surgical Exploration of Breast Area or Implant	1	0.6%
Mastopexy	21	13.5%
Breast Reduction	1	0.6%
Wound Repair	4	2.6%
Aspiration of Hematoma/Seroma	8	5.1%
Liposuction	0	0.0%
Removal of Excess Tissue/Lesion/Cyst	5	3.2%
Revision of Nipple Reconstruction/Tattoo	7	4.5%
Scar Revision	13	8.3%
Biopsy	3	1.9%
Other	1	0.6%
<b>Total</b>	<b>156</b>	<b>100.0%</b>

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

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Other Procedure Specified (N = 1)

Reop Seq#	Other Procedure Specified
001	REMOVAL OF RETAINED SUTURE

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Table 171: Risk of First Occurrence of Implant Replacement/Removal

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	2	0.9% ( 0.0%, 2.2%)	213	0.9% ( 0.0%, 2.2%)	3	0.7% ( 0.0%, 1.5%)	410	0.7% ( 0.0%, 1.5%)
6 Months	9	4.2% ( 1.5%, 6.9%)	201	4.2% ( 1.5%, 6.9%)	14	3.4% ( 1.7%, 5.2%)	389	3.4% ( 1.7%, 5.2%)
1 Year	13	6.1% ( 2.9%, 9.4%)	194	6.1% ( 2.9%, 9.4%)	22	5.4% ( 3.2%, 7.6%)	375	5.4% ( 3.2%, 7.6%)
2 Years	22	10.7% ( 6.4%, 14.9%)	173	10.7% ( 6.4%, 14.9%)	37	9.4% ( 6.5%, 12.2%)	335	9.4% ( 6.5%, 12.2%)

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

Time	By Patient				By Implant			
	Number Affected		Cumulative Risk		Number Affected		Cumulative Risk	
	n	% (95% CI)						
4 Weeks	2	0.9% ( 0.0%, 2.2%)	212	0.9% ( 0.0%, 2.2%)	3	0.7% ( 0.0%, 1.5%)	408	0.7% ( 0.0%, 1.5%)
6 Months	8	3.7% ( 1.2%, 6.3%)	201	3.7% ( 1.2%, 6.3%)	13	3.2% ( 1.5%, 4.9%)	387	3.2% ( 1.5%, 4.9%)
1 Year	11	5.2% ( 2.2%, 8.2%)	195	5.2% ( 2.2%, 8.2%)	18	4.4% ( 2.4%, 6.5%)	375	4.4% ( 2.4%, 6.5%)
2 Years	20	9.8% ( 5.7%, 13.8%)	173	9.8% ( 5.7%, 13.8%)	32	8.2% ( 5.4%, 10.9%)	335	8.2% ( 5.4%, 10.9%)

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

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
4 Weeks	0	210	0.0%	0	404	0.0%
6 Months	1	201	0.5% ( 0.0%, 1.4%)	1	388	0.2% ( 0.0%, 0.7%)
1 Year	2	194	1.0% ( 0.0%, 2.4%)	4	374	1.0% ( 0.0%, 2.1%)
2 Years	2	176	1.0% ( 0.0%, 2.4%)	5*	335	1.3% ( 0.2%, 2.5%)

\* The By Implant "Number Affected" includes 1 implants from a bilateral patient who is NOT included in the By Patient "Number Affected" at 2 years because only one of the patient's two implants involved implant removal without replacement; the other implant involved implant removal with replacement. Thus this patient's primary reason for reoperation was implant removal with replacement, not implant removal without replacement.

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Table 174: Primary\* Reason for Implant Replacement/Removal

Reason	Implant Removals	
	n	%(N = 37)
Device Malfunction - Rupture	2	5.4%
Injury - Iatrogenic or Traumatic	1	2.7%
Breast Cancer	0	0.0%
Capsular Contracture	4	10.8%
Infection	1	2.7%
Healing Related		
Extrusion	0	0.0%
Necrosis	0	0.0%
Hematoma/Seroma	0	0.0%
Delayed Wound Healing	1	2.7%
Nipple Complications	0	0.0%
Pain	0	0.0%
Unsatisfactory Cosmetic Result		
Breast Tissue Contour Deformity	0	0.0%
Malposition	7	18.9%
Wrinkling	1	2.7%
Implant Palpability/Visibility	0	0.0%
Asymmetry	2	5.4%
Ptosis	4	10.8%
Unsatisfactory Scar	2	5.4%
Patient Request		
Style/Size Change	12	32.4%
Media Anxiety	0	0.0%
Biopsy	0	0.0%
Other	0	0.0%
<b>Total</b>	<b>37</b>	<b>100.0%</b>

\* 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 = 1*)		Intact (Non-Ruptured) Implants (n = 36)	
	Yes(%)	No(%)	Yes(%)	No(%)
Capsule Torn**	0 (0.0%)	1 (100.0%)	2 (5.6%)	34 (94.4%)
Extracapsular Gel	0 (0.0%)	1 (100.0%)	0 (0.0%)	36 (100.0%)
Gel on Implant Surface	1 (100.0%)	0 (0.0%)	0 (0.0%)	36 (100.0%)
Removal Difficult	0 (0.0%)	1 (100.0%)	0 (0.0%)	36 (100.0%)

\* The number of ruptured implants reported is less than the number of ruptures confirmed by explant on Table 159 because 1 rupture reported in Table 159 was identified as suspected rupture within 2 years post-implant, but was 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 = 32)
McGhan Study Device	24	75.0%
Non-McGhan Medical Device	6	18.8%
Unknown Device Type*	2	6.3%
Total	32	100.0%

\* The implanting study physician did not perform the implant replacement/removal procedure for these patients. No information regarding type of replacement implant was able to be obtained from the non-study surgeons who performed these implant replacement/removal procedures.

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Table 177: McGhan Replacement Implant Size vs. Primary Implant

Size Change	By Implant	
	n	%(N = 24)
Increase in Size	13	54.2%
No Change in Size	4	16.7%
Decrease in Size	7	29.2%
Total	24	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	26	185	11.8%	( 7.5%, 16.1%)	37	370	8.7%	( 6.0%, 11.4%)
6 Months	48	157	22.5%	(16.8%, 28.1%)	69	326	16.7%	(13.1%, 20.3%)
1 Year	55	147	26.0%	(20.0%, 31.9%)	78	310	19.1%	(15.2%, 22.9%)
2 Years	64	129	30.7%	(24.4%, 36.9%)	94	273	23.4%	(19.2%, 27.6%)

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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)
4 Weeks	5	209	2.3%	( 0.3%, 4.2%)	7	403	1.6%	( 0.4%, 2.9%)
6 Months	16	193	7.5%	( 3.9%, 11.0%)	23	376	5.6%	( 3.4%, 7.8%)
1 Year	24	181	11.4%	( 7.1%, 15.6%)	35	356	8.7%	( 5.9%, 11.4%)
2 Years	29	162	13.9%	( 9.2%, 18.6%)	44	318	11.1%	( 8.0%, 14.2%)

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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)
4 Weeks	1	208	0.4% ( 0.0%, 1.3%)	2	400	0.5% ( 0.0%, 1.1%)
6 Months	7	194	3.4% ( 0.9%, 5.8%)	8	379	2.0% ( 0.6%, 3.4%)
1 Year	9	187	4.4% ( 1.6%, 7.2%)	10	366	2.5% ( 1.0%, 4.0%)
2 Years	14	166	7.1% ( 3.5%, 10.7%)	17	324	4.5% ( 2.4%, 6.6%)

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Table 181: Pre-Implant Reproduction Problems

Reproduction Problems	Patients	
	n	%(N = 225)
No Reproduction Problem	181	80.4%
Reproduction Problem	44	19.6%
	225	100.0%

Type Of Reproduction Problem	n	%(N = 44)
Infertility	9	20.5%
Spontaneous Abortion (Miscarriage)	32	72.7%
Planned Abortion to Treat a Medical Problem	1	2.3%
Ectopic Pregnancy	4	9.1%
Stillbirth	0	0.0%
	46*	104.5%

\* 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 182: Post-Implant Reproduction Problems Through 2 Years

Reproduction Problems	Patients	
	n	%(N = 225)
No Reproduction Problem	220	97.8%
Reproduction Problem	5	2.2%
	<u>225</u>	<u>100.0%</u>

Type Of Reproduction Problem	n	%(N = 5)
Infertility	2	40.0%
Spontaneous Abortion (Miscarriage)	2	40.0%
Planned Abortion to Treat a Medical Problem	0	0.0%
Ectopic Pregnancy	0	0.0%
Stillbirth	0	0.0%
Other	1	20.0%
	<u>5</u>	<u>100.0%</u>

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

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Other Reproduction Problem Specified (N = 1)

Pt Seq#	Other Reproduction Problem Specified
001	HYSTERECTOMY DONE FOR UNKNOWN REASONS

---

Table 183: Pre-Implant Lactation Problems

Lactation Problems	Patients	
	n	%(N = 225)
No Lactation Problem	201	89.3%
Lactation Problem	24	10.7%
	<u>225</u>	<u>100.0%</u>

  

Type Of Lactation Problem	n	%(N = 24)
Mastitis Not Requiring Treatment	2	8.3%
Mastitis Requiring Treatment	6	25.0%
Inadequate Milk Production	7	29.2%
Excess Milk Production	2	8.3%
Pain	8	33.3%
Other	2	8.3%
	<u>27*</u>	<u>112.5%</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 183 (cont.): Pre-Implant Lactation Problems

---

Other Lactation Problem Specified (N = 2)

Pt

Seq# Other Lactation Problem Specified

---

001 BABY WOULDN'T NURSE

002 DUCT DISRUPTION FROM PREVIOUS SURGERY

---

Table 184: Post-Implant Lactation Problems Through 2 Years

Lactation Problems	Patients	
	n	%(N = 225)
No Lactation Problem	224	99.6%
Lactation Problem	1	0.4%
	225	100.0%

  

Type Of Lactation Problem	n	%(N = 1)
Mastitis Not Requiring Treatment	0	0.0%
Mastitis Requiring Treatment	0	0.0%
Inadequate Milk Production	1	100.0%
Excess Milk Production	0	0.0%
Pain	0	0.0%
	1	100.0%

Table 185: Pre-Implant Breast Disease

Breast Disease	Patients	
	n	%(N = 225)
No Breast Disease	158	70.2%
Breast Disease	67	29.8%
	<u>225</u>	<u>100.0%</u>

  

Type Of Breast Disease	n	%(N = 67)
Confirmed Malignant Disease	42	62.7%
Benign Disease	24	35.8%
Unknown Breast Disease*	1	1.5%
	<u>67</u>	<u>100.0%</u>

\* This patient had a right breast lesion and a possible implant rupture indicated on a pre-operative mammogram done in December, 1998; no further information has been provided by the site.

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Table 186: Post-Implant Breast Disease Through 2 Years

Breast Disease	Patients	
	n	%(N = 225)
No Breast Disease	212	94.2%
Breast Disease	13	5.8%
	<u>225</u>	<u>100.0%</u>

  

Type Of Breast Disease	n	%(N = 13)
Benign Disease	13	100.0%
	<u>13</u>	<u>100.0%</u>

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Table 187: Pre-Implant Mammogram Result

Mammogram Results	Patients	
	n	%(N = 225)
No Pre-Implant Mammogram	100	44.4%
Pre-Implant Mammogram		
Normal Mammogram	100	44.4%
Abnormal Mammogram	25	11.1%
	<u>225</u>	<u>100.0%</u>

Disposition Of Patients With Abnormal Mammogram Results	n		%(N = 25)	
	n	%(N = 25)		
No Breast Disease	17	68.0%		
Confirmed Malignant Disease	5	20.0%		
Benign Disease	2	8.0%		
Unknown Breast Disease*	1	4.0%		
	<u>25</u>	<u>100.0%</u>		

\* This patient had a right breast lesion and a possible implant rupture indicated on a pre-operative mammogram done in December, 1998; no further information has been provided by the site.

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Table 188: Post-Implant Mammogram Result Through 2 Years

Mammogram Results	Patients	
	n	%(N = 225)
No Post-Implant Mammogram	143	63.6%
Post-Implant Mammogram		
Normal Mammogram	77	34.2%
At Least One Abnormal Mammogram	5	2.2%
	<u>225</u>	<u>100.0%</u>

Disposition Of Patients With Abnormal Mammogram Results	n		%(N = 5)	
	n	%(N = 5)		
No Breast Disease	1	20.0%		
Benign Disease	4	80.0%		
	<u>5</u>	<u>100.0%</u>		

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

CTD	Patients	
	n	%(N = 225)
No CTD	224	99.6%
CTD		
Confirmed CTD	1	0.4%
Unconfirmed CTD	0	0.0%
	<u>225</u>	<u>100.0%</u>

CTD Specified (N = 1)

Pt Seq#	CTD Specified
001	Rheumatoid Arthritis

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

CTD	Patients	
	n	%(N = 225)
No CTD	224	99.6%
CTD		
Confirmed CTD	1	0.4%
Unconfirmed CTD	0	0.0%
	<u>225</u>	<u>100.0%</u>

Confirmed CTD Specified (N = 1)

Pt Seq#	CTD Specified	# of Months Between Implant Surgery and Onset
001	Fibromyalgia	11

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

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

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

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

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Table 195: Physician Assessment of Implants

Time	N	Satisfaction Level* (Allowable Range 1 - 5)						Mean	SD
		Definitely Somewhat		Somewhat		Definitely			
		Dissat- isfied	%	Dissat- isfied	%	Satisfied	%		
0-4 Weeks	218	0.5%	0.9%	0.0%	7.3%	91.3%	4.9	0.5	
6 Months	168	0.0%	3.6%	0.0%	16.1%	80.4%	4.7	0.6	
1 Year	168	1.8%	5.4%	1.2%	13.7%	78.0%	4.6	0.9	
2 Years	172	2.9%	4.7%	0.6%	15.1%	76.7%	4.6	0.9	

\* 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	4 (1.8%)	214 (98.2%)	419	5 (1.2%)	414 (98.8%)
6 Months	168	6 (3.6%)	162 (96.4%)	320	7 (2.2%)	313 (97.8%)
1 Year	168	12 (7.1%)	156 (92.9%)	319	14 (4.4%)	305 (95.6%)
2 Years	172	15 (8.7%)	157 (91.3%)	328	18 (5.5%)	310 (94.5%)

\* 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	Implants N	Type of Dissatisfaction Specified			
		Aesthetic	Implant Design	Medical/ Procedural	Other
		%	%	%	%
0-4 Weeks*	5	20.0%	0.0%	80.0%	0.0%
6 Months	7	14.3%	0.0%	85.7%	0.0%
1 Year*	14	28.6%	0.0%	78.6%	0.0%
2 Years*	18	27.8%	0.0%	83.3%	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 198: Patient Assessment of Implants

Time	N	Satisfaction Level* (Allowable Range 1 - 5)				Descriptive Statistics	
		Definitely Dissatisfied	Somewhat Dissatisfied	Satisfied	Definitely Satisfied	Mean	SD
0-4 Weeks	218	0.0%	1.4%	0.0%	11.5%	4.8	0.5
6 Months	168	1.2%	4.2%	1.2%	16.7%	4.6	0.8
1 Year	168	3.0%	10.1%	0.6%	12.5%	4.4	1.1
2 Years	173	3.5%	8.1%	1.2%	16.8%	4.4	1.1

\* 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	4 (1.8%)	214 (98.2%)	419	5 (1.2%)	414 (98.8%)
6 Months	168	13 (7.7%)	155 (92.3%)	320	17 (5.3%)	303 (94.7%)
1 Year	168	20 (11.9%)	148 (88.1%)	319	27 (8.5%)	292 (91.5%)
2 Years	173	20 (11.6%)	153 (88.4%)	330	25 (7.6%)	305 (92.4%)

\* 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	Aesthetic		Implant Design		Medical/Procedural		Other
		N	%	N	%	N	%	
0-4 Weeks	5	60.0%	0.0%	40.0%	0.0%	0.0%	0.0%	
6 Months*	17	52.9%	0.0%	58.8%	0.0%	0.0%	0.0%	
1 Year*	27	48.1%	0.0%	63.0%	7.4%	0.0%	0.0%	
2 Years*	25	24.0%	0.0%	80.0%	0.0%	0.0%	0.0%	

\* 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 = .2)

Imp Seq#	Side	Other Dissatisfaction Specified
-------------	------	---------------------------------

001	L	BECAUSE THEY ARE "NOT HER BREASTS"
002	R	BECAUSE THEY ARE "NOT HER BREASTS"

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

Time	Patients	Satisfaction Level*						Mean	SD
		(Allowable Range 1 - 5)							
		Definitely Dissatisfied	Somewhat Dissatisfied	Satisfied	Somewhat Satisfied	Definitely Satisfied	Descriptive Statistics		
N	%	%	%	%	%	%			
0-4 Weeks	219	0.0%	1.4%	0.0%	11.4%	87.2%	4.8	0.5	
6 Months	171	1.2%	4.7%	1.2%	17.0%	76.0%	4.6	0.8	
1 Year	175	2.9%	9.7%	0.6%	13.7%	73.1%	4.4	1.1	
2 Years	186	3.2%	8.1%	1.1%	16.1%	71.5%	4.4	1.1	

\* 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)								
	N	Not At All		A Little Bit		Moderately		Quite A Bit Extremely	
			N	%	N	%	N	%	N
To Please My Partner	208	43.3%	23.1%	21.6%	7.7%	4.3%			
To Improve My Sex Life	208	55.8%	22.6%	14.4%	4.8%	2.4%			
To Make Me Feel Better About My Physical Appearance	213	2.3%	5.6%	13.1%	42.7%	36.2%			
To Improve the Way I Feel About Myself	209	13.9%	14.4%	22.0%	25.8%	23.9%			
To Increase My Chance of Meeting A Partner	204	89.7%	5.9%	3.4%	0.5%	0.5%			
Other Reason	50	2.0%	2.0%	2.0%	22.0%	72.0%			

\* 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 = 50)

Pt Seq#	Other Reason Specified
001	TO MAKE MY BODY MORE BALANCED
002	ALREADY HAVE PARTNER
003	TO FIT MY CLOTHES BETTER
004	FOR MY WORK
005	LOOK BETTER IN CLOTHES& SWIMSUIT
006	RECONSTRUCTION
007	TO HAVE CLOTHING FIT WELL.
008	OCCUPATION
009	SYMMETRY
010	WORK
011	REDO-DUE TO CAPSULATION TO FEEL NATURAL
012	SO DRESSES WILL FIT
013	PAIN!
014	RUPTURED
015	THE FEEL OF THE IMPLANT
016	BALANCED HOURGLASS FIG.
017	RID MY DISCOMFORT
018	ORIGINAL ONES NEED TO BE REPLACED
019	PROVIDE MORE NATURAL FEEL

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

Other Reason Specified (N = 50)

Pt Seq#	Other Reason Specified
020	CHANGE OUT OLD ONES
021	I'VE GOTTEN USED TO HAVING THEM
022	CANCER PREVENTION
023	WORK
024	TO REPAIR PREVIOUS LEAK AND TO ADJUST SHAPE
025	RECONSTRUCTION
026	IMPROVE MY PROPORTION
027	FINDING CLOTHES THAT FIT.
028	TO FIX IT UP
029	WORK
030	BE MORE COMFORTABLE
031	REVISE PREVIOUS SURGERY
032	HAD SUBCUTAPEOUS MASTECTOMY & THIS IS RECONSTRUCTION
033	RECONSTRUCTION
034	HEALTH IMPROVMENT
035	RIGHT BREAST DID NOT DEVELOP
036	RECONSTRUCTION REVISION
037	NEED TO BE REPLACED
038	RECONSTRUCTION

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

Other Reason Specified (N = 50)

Pt	Other Reason Specified
039	FOR HEALTH/ PAIN IN RIGHT BREAST
040	CORRECT DEFORMITY
041	COMFORT
042	TO FIT INTO COSTUMES
043	NO NEED FOR A BRA
044	CORRECT DEFORMITY
045	SIZE
046	IMPLANTS CAPSULATED&MOVED APART (EXTREMELY)
047	TO FEEL MY BREASTS AGAIN AS MORE CLOSELY TO PRE-OP BILATERAL MESTECTOMY SOME YEARS AGO.
048	REPAIR
049	MORE COMFORTABLE BREASTS
050	B X CA REVISION

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

Satisfaction with Breast Implants  
 (Allowable Range 1-5)

Descriptive Statistics

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Pre-Operative Expectation*	4.7B	0.5	3.0 - 5.0	129	19.97	2	<0.001
1 Year	4.3A	0.9	2.0 - 5.0				
2 Years	4.2A	1.1	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 letters.

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

Rating	% (N = 129 Patients)		
	Pre-Op	1 Year	2 Years
Very Dissatisfied	0.0%	0.0%	3.1%
Dissatisfied	0.0%	8.5%	7.0%
Neither Satisfied nor Dissatisfied	0.8%	3.9%	9.3%
Satisfied	24.8%	33.3%	30.2%
Very Satisfied	74.4%	54.3%	50.4%
	100.0%	100.0%	100.0%

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Table 205: Rowland Expectation Summary

Scale	Mean Score					Effect Size
	Table	Post-Op			p	
		Pre-Op	1 Year	2 Years		
Improve Self Image	206	2.7A	3.0B	3.0B	*	0.32
Improve Social Relations	207	1.3A	1.4B	1.6B	**	0.36
Improve Daily Living	208	2.8	2.8	2.9	n.s.	--
Improve Well-Being	209	N/A	N/A	N/A	--	--

\* = 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	2.7A	0.7	1.0 - 5.0	132	5.75	2	0.004
1 Year	3.0B	1.0	1.0 - 5.0				
2 Years	3.0B	1.0	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 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letter.

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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	0.5	1.0 - 3.3	131	10.98	2	<0.001
1 Year	1.4B	0.7	1.0 - 5.0				
2 Years	1.6B	0.9	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 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

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Table 208: Rowland Expectation: Improve Daily Living

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

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	2.8	1.1	1.0 - 5.0	133	0.67	2	0.513
1 Year	2.8	1.1	1.0 - 5.0				
2 Years	2.9	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 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 209: Rowland Expectation: Improve Well-Being

N/A: ROWLAND EXPECTATION: IMPROVE WELL-BEING WAS NOT ASSESSED FOR REVISION PATIENTS

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

	Mean Score		t	df	p
	Revision Patients	General Population			
Role Limitations due to Emotional Problems	90.79	79.47	5.12	177	<0.001
Role Limitations due to Physical Problems	86.72	77.77	3.27	159	0.001
General Health	84.28	70.61	8.52	158	<0.001
Bodily Pain	84.42	73.59	6.20	171	<0.001
Social Functioning	93.39	81.54	8.45	191	<0.001
Physical Functioning	94.21	81.47	8.61	194	<0.001
Vitality	70.92	58.43	7.19	158	<0.001
Mental Health	83.19	73.25	8.47	186	<0.001
Reported Health Transition	40.30	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		
			1 Year	2 Years	
Role Limitations due to Emotional Problems	212	90.8B	83.1A	79.1A	* 0.35
Role Limitations due to Physical Health Problems	213	86.7	80.6	81.7	n.s. --
General Health	214	84.3B	81.5AB	79.7A	* 0.17
Bodily Pain	215	84.4	84.0	82.4	n.s. --
Social Functioning	216	93.4B	89.0A	86.1A	** 0.31
Physical Functioning	217	94.2	91.0	91.7	n.s. --
Vitality	218	70.9	67.6	65.6	n.s. --
Mental Health	219	83.2B	80.8AB	77.9A	** 0.20
Reported Health Transition	220	40.3	42.9	45.9	n.s. --

\* = p < .01

\*\* = 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	90.8B	22.3	0.0 - 100.0	123	6.62	2	0.002
1 Year	83.1A	32.4	0.0 - 100.0				
2 Years	79.1A	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 letters.

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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)

Descriptive Statistics				ANOVA Results		
Time	Mean	S.D.	Range	N	F	P
Baseline	86.7	28.4	0.0 - 100.0	123	2.30	0.102
1 Year	80.6	35.2	0.0 - 100.0			
2 Years	81.7	34.9	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 214: SF-36: General Health

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

Time	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	p
Baseline	84.3B	16.6	35.0 - 100.0	122	5.98	2 0.003
1 Year	81.5AB	19.3	10.0 - 100.0			
2 Years	79.7A	20.2	20.0 - 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 letters.

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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	84.4	18.4	22.5 - 100.0	129	0.76	2	0.469
1 Year	84.0	20.4	0.0 - 100.0				
2 Years	82.4	23.0	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.

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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	93.4B	13.9	25.0 - 100.0	123	8.76	2	<0.001
1 Year	89.0A	19.9	0.0 - 100.0				
2 Years	86.1A	22.6	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 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

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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	P
Baseline	94.2	15.0	10.0 - 100.0	127	4.32	0.014
1 Year	91.0	18.7	5.0 - 100.0			
2 Years	91.7	18.9	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 218: SF-36: Vitality

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

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	70.9	18.5	20.0 - 100.0	127	5.07	2	0.007
1 Year	67.6	20.1	10.0 ; 95.0				
2 Years	65.6	20.1	10.0 - 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	p
Baseline	83.2B	12.0	36.0 - 100.0	127	7.89	2
1 Year	80.8AB	15.7	24.0 - 100.0			<0.001
2 Years	77.9A	15.0	20.0 - 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 letters.

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Table 220: SF-36: Reported Health Transition

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

Descriptive Statistics ANOVA Results

Time	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	p
Baseline	40.3	20.3	0.0 - 75.0	116	2.55	0.080
1 Year	42.9	17.7	0.0 - 100.0			
2 Years	45.9	22.6	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 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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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	84.9B	82.6B	79.1A	**	0.14
Physical Functioning	223	91.9	89.5	89.0	n.s.	--
Role Functioning	224	92.4	91.1	88.6	n.s.	--
Social Functioning	225	95.5	93.2	90.9	n.s.	--
Mental Health	226	82.0B	80.8B	75.3A	**	0.10

\*\* = 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	P
Baseline	84.9B	16.9	35.0 - 100.0	122	9.25	2
1 Year	82.6B	19.5	0.0 - 100.0			<0.001
2 Years	79.1A	21.8	10.0 - 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 223: MOS-20: Physical Functioning

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

Descriptive Statistics

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	91.9	17.5	16.7 - 100.0	129	1.95	2	0.145
1 Year	89.5	20.0	0.0 - 100.0				
2 Years	89.0	22.9	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 224: MOS-20: Role Functioning

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

Time	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	p
Baseline	92.4	20.9	0.0 - 100.0	129	1.69	0.187
1 Year	91.1	25.2	0.0 - 100.0			
2 Years	88.6	30.1	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 0.01 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)

Time	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	p
Baseline	95.5	11.8	40.0 - 100.0	130	4.19	0.016
1 Year	93.2	18.1	0.0 - 100.0			
2 Years	90.9	21.4	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	P
Baseline	82.0B	12.1	32.0 - 100.0	130	13.14	2
1 Year	80.8B	16.0	24.0 - 100.0			<0.001
2 Years	75.3A	16.7	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. Significantly different means are indicated with different letters.

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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	31	23.1%	134	0.91	2	0.636
1 Year	35	26.1%				
2 Years	35	26.1%				
Two or more years at any time in the past						
Baseline	11	8.2%	134	5.25	2	0.072
1 Year	13	9.7%				
2 Years	20	14.9%				
Much of the time in the past year						
Baseline	8	5.9%	135	7.61	2	0.022
1 Year	17	12.6%				
2 Years	17	12.6%				

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			ANOVA Results				
Time	Mean	S.D.	Range	N	F	df	p
Baseline	74.6B	7.6	55.0 - 90.0	109	6.66	2	0.002
1 Year	73.8B	8.8	46.0 - 90.0				
2 Years	72.4A	8.4	51.0 - 90.0				

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. Significantly different means are indicated with different letters.

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Table 229: Rosenberg Self-Esteem

		Descriptive Statistics		ANOVA Results				
		Mean	S.D.	Range	N	F	df	p
		Rosenberg Self-Esteem (Allowable Range 10-40)						
Baseline		35.9B	4.4	18.0 - 40.0	127	8.61	2	<0.001
1 Year		35.5B	4.2	23.0 - 40.0				
2 Years		34.7A	4.5	22.0 - 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. Significantly different means are indicated with different letters.

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Table 230: Self vs. Breast Semantic Differential

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

ANOVA Results

Descriptive Statistics

Time	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	P
Baseline	0.0	0.5	-1.6 - 1.4	125	0.17	0.842
1 Year	0.0	0.4	-1.1 - 1.5			
2 Years	0.0	0.4	-1.4 - 1.8			

\* 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.

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Table 231: Body Esteem Summary

Scale	Mean Score					Effect Size
	Pre-Op	Post-Op			p	
		1 Year	2 Years	3 Years		
Body Esteem: Total Score	119.8	119.5	117.7	n.s.	**	
Body Esteem: Sexual Attractiveness	49.9	50.9	50.4	n.s.	**	
Body Esteem: Weight Concern	33.5	33.1	32.6	n.s.	**	
Body Esteem: Physical Condition	35.2B	34.2AB	33.4A	*	0.15	

\* = p < .01  
 n.s. = not significant  
 Significantly different means are indicated with different letters.

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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	p
Baseline	119.8	19.7	81.0 - 160.0	99	1.15	0.318
1 Year	119.5	17.8	72.0 - 160.0			
2 Years	117.7	19.5	63.0 - 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)

Time	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	P
Baseline	49.9	7.8	27.0 - 65.0	118	1.33	0.265
1 Year	50.9	7.5	33.0 - 65.0			
2 Years	50.4	7.7	32.0 - 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. Significantly different means are indicated with different subscripts.

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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	p
Baseline	33.5	9.5	10.0 - 50.0	113	0.88	2
1 Year	33.1	8.3	10.0 - 50.0			
2 Years	32.6	8.9	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)

Time	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	p
Baseline	35.2B	6.7	18.0 - 45.0	122	6.43	0.002
1 Year	34.2AB	7.1	9.0 - 45.0			
2 Years	33.4A	7.6	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. Significantly different means are indicated with different letters.

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Table 236: Satisfaction Summary

Scale	Mean Score					Effect Size
	Table	Post-Op			p	
		Pre-Op	1 Year	2 Years		
Personal Life Satisfaction	237	4.7	4.8	4.7	n.s.	**
Satisfaction with Breasts	239	2.5A	4.1B	4.0B	**	1.35
How Well Breasts Matched	241	3.2A	4.6B	4.5B	**	0.92
Satisfaction with Breast Shape	243	2.9A	3.9B	3.8B	**	1.28
Satisfaction with Breast Size	245	2.7A	4.2B	4.0B	**	1.26
Satisfaction with Breast Feel or Touch	247	2.9A	3.9B	3.7B	**	1.28

\*\* = p < .001

n.s. = not significant  
 Significantly different means are indicated with different letters.

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Table 237: Personal Life Satisfaction

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	4.7	0.9	1.0 - 6.0	127	0.68	2	0.510
1 Year	4.8	1.0	2.0 - 6.0				
2 Years	4.7	1.1	1.0 - 6.0				

Personal Life Satisfaction Score  
 (Allowable Range 1-6)

- 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 = 127 Patients)		
	Pre-Op	Post-Op	
		1 Year	2 Years
Very Dissatisfied, Unhappy Most Of the Time	0.8%	0.0%	1.6%
Generally Dissatisfied, Unhappy	0.8%	0.8%	3.9%
Sometimes Fairly Satisfied, Sometimes Fairly Unhappy	7.9%	11.8%	8.7%
Generally Satisfied, Pleased	23.6%	19.7%	18.1%
Very Happy Most Of The Time	49.6%	45.7%	48.8%
Extremely Happy, Could Not Be More Satisfied	17.3%	22.0%	18.9%
	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	2.5A	1.2	1.0 - 5.0	128	118.9	2	<0.001
1 Year	4.1B	1.1	1.0 - 5.0				
2 Years	4.0B	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 0.05 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 240: Patient Rating of Satisfaction With Breasts

Rating	% (N = 128 Patients)		
	Pre-Op	Post-Op	
		1 Year	2 Years
Very Dissatisfied	20.3%	1.6%	5.5%
Dissatisfied	43.0%	12.5%	7.0%
Neither Satisfied nor Dissatisfied	7.0%	8.6%	10.2%
Satisfied	26.6%	31.3%	39.1%
Very Satisfied	3.1%	46.1%	38.3%
	100.0%	100.0%	100.0%

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Table 241: How Well Breasts Matched

How Well Breasts Matched  
 (Allowable Range 1-6)

Descriptive Statistics

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	3.2A	1.6	1.0 - 6.0	128	65.83	2	<0.001
1 Year	4.6B	1.3	1.0 - 6.0				
2 Years	4.5B	1.4	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 letters.

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Table 242: Patient Rating of How Well Breasts Matched

Rating	% (N = 128 Patients)		
	Pre-Op	1 Year	2 Years
Very Poor	19.5%	1.6%	4.7%
Poor	18.0%	6.3%	5.5%
Fair	19.5%	10.2%	10.9%
Good	19.5%	22.7%	17.2%
Very Good	15.6%	29.7%	32.8%
Excellent	7.8%	29.7%	28.9%
	100.0%	100.0%	100.0%

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Table 243: Satisfaction with Breast Shape

Satisfaction with Breast Shape  
 (Allowable Range 1-5)

ANOVA Results

Descriptive Statistics

Time	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	p
Baseline	2.3A	1.2	1.0 - 5.0	130	93.58	<0.001
1 Year	3.9B	1.2	1.0 - 5.0			
2 Years	3.8B	1.3	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 letters.

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Table 244: Patient Rating of Satisfaction With Breast Shape

Rating	% (N = 130 Patients)		
	Pre-Op	Post-Op	
		1 Year	2 Years
Very Dissatisfied	27.7%	3.1%	8.5%
Dissatisfied	40.0%	14.6%	11.5%
Neither Satisfied nor Dissatisfied	6.9%	9.2%	6.9%
Satisfied	20.8%	34.6%	33.8%
Very Satisfied	4.6%	38.5%	39.2%
	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	2.7A	1.2	1.0 - 5.0	129	89.63	2	<0.001
1 Year	4.2B	1.0	1.0 - 5.0				
2 Years	4.0B	1.2	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 letters.

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Table 246: Patient Rating of Satisfaction With Breast Size

Rating	Pre-Op		Post-Op	
	1 Year	2 Years	1 Year	2 Years
Very Dissatisfied	17.8%	6.2%	3.1%	6.2%
Dissatisfied	33.3%	10.9%	3.9%	10.9%
Neither Satisfied nor Dissatisfied	16.3%	7.0%	7.8%	7.0%
Satisfied	28.7%	33.3%	44.2%	33.3%
Very Satisfied	3.9%	42.6%	41.1%	42.6%
	100.0%	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)

ANOVA Results

Descriptive Statistics

Time	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	p
Baseline	2.3A	1.2	1.0 - 5.0	129	78.64	<0.001
1 Year	3.9B	1.2	1.0 - 5.0			
2 Years	3.7B	1.3	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 letters.

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

Rating	% (N = 129 Patients)		
	Pre-Op	Post-Op	
		1 Year	2 Years
Very Dissatisfied	31.0%	5.4%	7.8%
Dissatisfied	38.8%	13.2%	17.1%
Neither Satisfied nor Dissatisfied	5.4%	10.9%	7.8%
Satisfied	19.4%	28.7%	31.0%
Very Satisfied	5.4%	41.9%	36.4%
	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	0.6	1.0 - 4.0	140	0.69	1	0.408
2 Years	3.5	0.6	1.0 - 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	Descriptive Statistics			ANOVA Results		
	Mean	S.D.	Range	N	F	P
1 Year	3.4	0.8	1.0 - 4.0	141	1.11	1
2 Years	3.3	0.8	1.0 - 4.0			0.294

- 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	4.7	0.7	1.0 - 5.0	138	1.53	1	0.218
2 Years	4.7	0.7	1.0 - 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	P
1 Year	4.8	0.5	2.0 - 5.0	139	1.20	1	0.275
2 Years	4.9	0.4	2.0 - 5.0				

Problems  
 (Allowable Range 1-5)

- 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

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Risk Factor	Total Enrolled Implants (N = 432)	Reop- erations (N = 94)	Reop- erations (%)
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---

No significant risk factors were found.

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Table 254: Relative Risk of Reoperation for Significant Risk Factors

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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

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Risk Factor	Total		
	Enrolled Implants (N = 432)	Explants (N = 37)	Explants (%)

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No significant risk factors were found.

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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)
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No significant risk factors were found.

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Table 257: Frequency of Implant Rupture for Significant Risk Factors

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Risk Factor	Total Enrolled Implants (N = 432)	Ruptures (N = 5)	Ruptures (%)
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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)
No significant risk factors were found.				

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Table 259: Frequency of Capsular Contracture  
for Significant Risk Factors

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Risk Factor	Total	Capsular	Capsular
	Enrolled Implants (N = 432)	Contracture (N = 21)	Contracture (%)
<hr/>			

No significant risk factors were found.

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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)
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No significant risk factors were found.

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Table 261: Frequency of Infection for Significant Risk Factors

---

Risk Factor	Total	In-	In-
	Enrolled Implants (N = 432)	fection (N = 4)	fection (%)

---

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 REVISION APPENDICES**

# APPENDIX B

## Distribution of Patient Enrollment By Implanting Physician

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Appendix B: Distribution of Patient Enrollment by Implanting Physician

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Principal Investigator	Patients (N = 225)	
	n	%
	13	5.8%
	7	3.1%
	5	2.2%
	16	7.1%
	11	4.9%
	9	4.0%
	10	4.4%
	13	5.8%
	14	6.2%
	12	5.3%
	8	3.6%
	1	0.4%
	3	1.3%
	17	7.6%
	9	4.0%
	20	8.9%
	4	1.8%
	12	5.3%
	11	4.9%
	14	6.2%
	15	6.7%
	1	0.4%

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# 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			Shaped
		Round	Round	Round	Round	Round	Round	
		n	%	%	n	%	%	
	26	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
	14	42.9%	57.1%	0.0%	0.0%	0.0%	0.0%	0.0%
	10	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%
	31	0.0%	0.0%	32.3%	0.0%	0.0%	67.7%	9.1%
	22	0.0%	0.0%	90.9%	0.0%	0.0%	0.0%	0.0%
	17	47.1%	0.0%	52.9%	0.0%	0.0%	0.0%	0.0%
	20	60.0%	10.0%	30.0%	0.0%	0.0%	0.0%	0.0%
	26	0.0%	0.0%	0.0%	23.1%	0.0%	76.9%	0.0%
	25	8.0%	12.0%	4.0%	16.0%	0.0%	60.0%	0.0%
	22	9.1%	9.1%	40.9%	0.0%	0.0%	40.9%	0.0%
	16	37.5%	62.5%	0.0%	0.0%	0.0%	0.0%	0.0%
	2	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%
	6	0.0%	0.0%	0.0%	66.7%	0.0%	33.3%	0.0%
	34	52.9%	2.9%	5.9%	0.0%	0.0%	38.2%	0.0%
	18	66.7%	0.0%	11.1%	0.0%	0.0%	22.2%	0.0%
	39	0.0%	0.0%	20.5%	43.6%	0.0%	35.9%	0.0%

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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	%
	n	40	%	110	%
		45	%	120	%
				153	%
	6	0.0%	0.0%	50.0%	0.0%
	19	21.1%	0.0%	47.4%	21.1%
	22	100.0%	0.0%	0.0%	0.0%
	28	50.0%	0.0%	35.7%	0.0%
	27	14.8%	22.2%	11.1%	0.0%
	2	0.0%	0.0%	100.0%	0.0%

# 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 = 15)	Implants (N = 18)
Asymmetry	0	0
Breast Pain	1	1
Bruising	0	0
Capsule Calcification	0	0
Capsular Contracture	4	4
Delayed Wound Healing	0	0
Fluid Accumulation	1	1
Hematoma	0	0
Hypertrophic Scarring	2	3
Implant Extrusion	0	0
Implant Malposition	0	0
Implant Palpability	1	1
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	1	2
Other Nipple Related Observation	0	0

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

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Complication	# of Post 2-Year Occurrences	
	Patients (N = 15)	Implants (N = 18)
Pneumothorax	0	0
Ptosis	0	0
Redness	0	0
Seroma	0	0
Skin Hypersensitivity	0	0
Skin Paresthesia	0	0
Skin Rash	1	1
Swelling	1	1
Tissue or Skin Necrosis	0	0
Wrinkling/Rippling	2	3
Other Complications	2	2

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# APPENDIX G

**2-Year Complication Rates:  
Silicone-Filled Breast Implant  
Core Clinical Study - Revision Cohort  
&  
1995 Saline Clinical Study**

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Appendix G: 2-Year Complication Rates for Revision Patients in Core  
Study and 1995 Saline Study

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N/A: THE 1995 SALINE STUDY DID NOT INCLUDE A REVISION COHORT

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# 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 = 6)	Implants (N = 8)
Asymmetry	0	0
Breast Pain	3	4
Breast Ptosis	0	0
Bruising	1	1
Capsule Calcification	0	0
Capsular Contracture	0	0
Delayed Wound Healing	1	1
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	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	2	3
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 = 6)	Implants (N = 8)
Pneumothorax	0	0
Redness	0	0
Seroma	1	1
Skin Hypersensitivity	0	0
Skin Paresthesia	0	0
Skin Rash	0	0
Swelling	3	4
Tissue or Skin Necrosis	0	0
Wrinkling/Rippling	0	0
Other Complications	0	0

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

Satisfaction Level\*  
 (Allowable Range 1 - 5)

Time	N	Definitely Somewhat				Definitely		Mean	SD
		Dissat- isfied	Dissat- isfied	Somewhat Satisfied	Somewhat Satisfied	Satisfied	Satisfied		
6 Months	1	0.0%	0.0%	0.0%	0.0%	0.0%	100%	5.0	N/A**
1 Year	4	0.0%	0.0%	0.0%	0.0%	25.0%	75.0%	4.8	0.5
2 Years	10	0.0%	0.0%	0.0%	0.0%	10.0%	90.0%	4.9	0.3

\* Satisfaction level could range from 1 (definitely dissatisfied) to 5 (definitely satisfied).  
 \*\* Standard Deviation (SD) is N/A (Not Applicable) because N = 1.