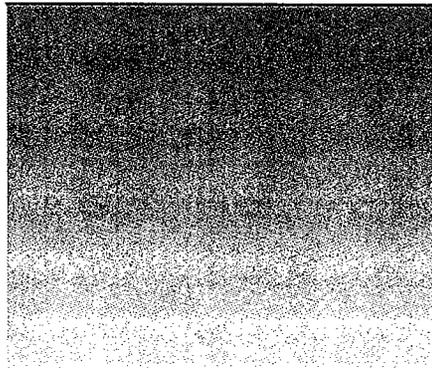


**Directions for Use**

**BIOCELL<sup>®</sup>**  
**Textured**  
**and**  
**Smooth**

SILICONE-FILLED  
BREAST IMPLANTS



**INAMED**  
AESTHETICS

**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician

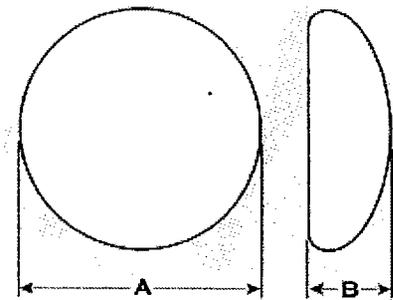
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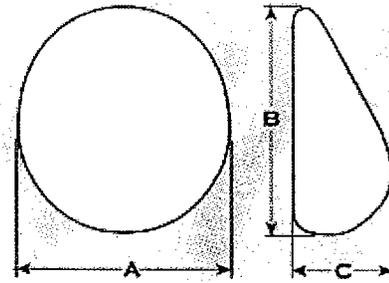
**Device Description**

INAMED Aesthetics' McGhan® Style Silicone-Filled Breast Implants are constructed with barrier shell technology resulting in a low diffusion silicone elastomer shell, and are filled with a soft, cohesive silicone. McGhan® Silicone Filled Breast Implants are available in both smooth and BIOCELL® surface texture.

<b>Round Breast Implants:</b>	
Style 10:	Smooth shell surface, moderate projection
Style 20:	Smooth shell surface, full projection
Style 40:	Smooth shell surface, standard projection
Style 45:	Smooth shell surface, full projection
Style 110:	BIOCELL® Textured shell surface, moderate projection
Style 120:	BIOCELL® Textured shell surface, full projection
<b>Shaped Breast Implants:</b>	
Style 153:	BIOCELL® Textured shell surface, double lumen, full height, full projection. <i>Style 153 has a ptotic shape to match an existing breast in unilateral reconstruction.</i>



A = Width; B = Projection  
**Round Breast Implant**



A = Width; B = Height; C = Projection  
**Shaped Breast Implant**

## INDICATIONS

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- **Breast Augmentation.** A woman must be at least 18 years old for breast augmentation.
- Breast Reconstruction
- Breast Revision

## CONTRAINDICATIONS

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### *Patient Groups in which the product is contraindicated:*

- Women with existing malignant or pre-malignant cancer of the breast without adequate treatment
- Women with an active infection anywhere in her body
- Augmentation in women who are currently pregnant or nursing

### *Surgical Practices in which product use is contraindicated due to compromise of product integrity:*

- **Alteration.** Do not alter the implant.
- **Stacking** of implants: Do not place more than one implant per breast pocket.

## Warnings

### 1. *Closed Capsulotomy*

**DO NOT** treat capsular contracture by forceful external compression, which will likely result in implant damage, rupture, folds, and/or hematoma.

### 2. *Reuse*

Breast implants are intended for single use only. Do not resterilize.

### 3. *Avoiding Damage during Surgery*

- Care should be taken not to damage the prosthesis with surgical instruments.
- Do not insert or attempt to repair a damaged prosthesis.
- Use care in subsequent procedures such as open capsulotomy, breast pocket revision, hematoma/seroma aspiration, and biopsy/lumpectomy to avoid damage to the implant.
- Do not contact the implant with disposable, capacitor-type cautery devices.

### 4. *Microwave Diathermy*

The use of microwave diathermy in patients with breast implants is not recommended, as it has been reported to cause tissue necrosis, skin erosion, and extrusion of the implant.

### 5. *Do not use endoscopic placement or periumbilical approach in placement of the implant.*

## Precautions

### 1. *Specific Populations*

Safety and Effectiveness has not been established in patients with:

- Autoimmune diseases such as lupus and scleroderma
- A compromised immune system (e.g., currently receiving immunosuppressive therapy)
- Patients with conditions or medications that interfere with wound healing ability (such as poorly controlled diabetes) or blood clotting (such as concurrent Coumadin® therapy).
- Reduced blood supply to breast tissue

### 2. *Mammography*

Breast implants may complicate the interpretation of mammographic images by obscuring underlying breast tissue and/or by compressing overlying tissue. Accredited mammography centers and use of displacement techniques are needed to adequately visualize breast tissue in the implanted breast. Radiologists should be experienced with the most current radiological techniques and equipment for imaging breasts with implants. Presurgical mammography with a follow-up mammogram 6 months to 1 year following surgery may be performed to establish a baseline for future routine mammography.

### 3. *Radiation to the Breast*

INAMED has not tested the *in vivo* effects of radiation therapy in patients who have breast implants. The literature suggests that radiation therapy may increase the likelihood of capsular contracture, necrosis, and extrusion.

#### 4. *Long Term Effects*

The long term safety and effectiveness of INAMED's McGhan® Silicone-Filled Breast Implants have not been established. INAMED is monitoring the long-term (i.e., 10 year) risk of implant rupture, reoperation, implant removal, and capsular contracture.

#### 5. *Instructions to Patients:*

- **Reoperation** – Patients should be advised that additional surgery to their breast and/or implant will be likely over the course of their life.
- **Explantation** – Patients should be advised that implants are not considered life time devices and they will likely undergo implant removal, with or without replacement, over the course of their life. Patients should also be advised that the changes to their breast following explantation are irreversible.
- **Mammography** - Patients should be instructed to inform their mammographers about the presence, type, and placement of their implants. Patients should be advised to request diagnostic mammography, rather than screening mammography.
- **Lactation** – Patients should be advised that breast implants may interfere with the ability to successfully breast feed.
- **Infection** – Signs of acute infection reported in association with breast implants include erythema, tenderness, fluid accumulation, pain and fever. In rare instances, Toxic Shock Syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms of TSS occur suddenly: a high fever (102°F, 38.8°C or higher), vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches and drops in blood pressure, which may cause fainting. Patients should be advised to contact a physician immediately for diagnosis and treatment for any of these symptoms.
- **Avoiding Damage during Treatment** – Patients should be instructed to inform other treating physicians of the presence of implants to minimize the risk of damage to the implants.
- **Smoking** – Patients should be informed that smoking may interfere with the healing process.
- **Cosmetic Dissatisfaction** – Patients should be informed that dissatisfaction with cosmetic results related to such things as scar deformity, hypertrophic scarring, asymmetry, displacement, incorrect size, unanticipated contour, and palpability may occur. Careful surgical planning and technique can minimize, but not preclude, the risk of such results. Preexisting asymmetry may not be entirely correctable. Physiological and behavioral differences among patients and variations in surgical techniques and medical treatments account for a wide variety of responses to silicone-filled breast implant surgery. Revision surgery may be indicated to maintain patient satisfaction, but carries additional considerations and risks.
- **Breast Examination Techniques** – Patients should be instructed to perform breast self-examinations monthly and be shown how to distinguish the implant from the breast tissue.

## Adverse Events

McGhan® Silicone-Filled Breast Implants were evaluated in three major open label, multicenter clinical studies: the 1990 Augmentation/Reconstruction Study (AR90), the Adjunct Study (which involved 25,346 patients), and the Core Study (which involved 940 patients). Because the AR90 Study utilized devices and surgical practices that are no longer current, these data are not reported below.

The cumulative Kaplan-Meier risk of first occurrence of adverse events (and 95% confidence interval) reported in greater than 1% of patients is shown in Tables 1 and 2 based on indication.

**Table 1**  
**Adjunct: 3-Year Cumulative First Occurrence Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient**

Complication	Reconstruction N = 15,465		Revision N = 9,881	
	Rate (%)	(95% CI)	Rate (%)	(95% CI)
Reoperation	44.1	(42.0, 46.2)	34.5	(31.9, 37.0)
Implant Replacement/Removal	28.2	(26.1, 30.3)	24.1	(21.7, 26.5)
Capsular Contracture*	17.6	(15.7, 19.4)	20.0	(17.6, 22.3)
Asymmetry*	16.3	(14.4, 18.2)	9.8	(7.9, 11.6)
Implant Palpability*	10.3	(8.7, 11.8)	12.1	(10.0, 14.2)
Wrinkling*	9.4	(7.9, 10.8)	10.6	(8.7, 12.5)
Implant Malposition*	8.5	(7.1, 9.9)	7.3	(5.6, 8.9)
Breast Pain*	7.9	(6.5, 9.3)	7.8	(6.1, 9.4)
Implant Visibility*	6.3	(5.1, 7.6)	6.9	(5.2, 8.6)
Loss of Nipple Sensation*	5.8	(4.6, 7.0)	3.7	(2.5, 4.8)
Hypertrophic Scarring*	3.4	(2.6, 4.3)	2.0	(1.3, 2.7)
Capsule Calcification*	3.2	(2.3, 4.2)	3.4	(2.3, 4.5)
Skin Paresthesia*	2.6	(1.9, 3.3)	1.4	(0.8, 2.1)
Swelling*	2.3	(1.8, 2.9)	1.9	(1.4, 2.5)
Other Complications*	2.0	(1.2, 2.7)	1.0	(0.5, 1.5)
Implant Rupture	1.6	(0.9, 2.4)	2.7	(1.4, 3.9)
Nipple Hypersensitivity*	1.4	(0.8, 2.1)	1.9	(1.1, 2.7)
Implant Extrusion	1.3	(0.6, 2.0)	0.6	(0.3, 1.0)
Redness*	1.2	(0.8, 1.7)	1.0	(0.6, 1.5)
Nipple Paresthesia*	1.1	(0.7, 1.6)	1.1	(0.4, 1.9)

\*These complications were assessed with severity ratings. Only the rates for moderate, severe, or very severe (excludes mild and very mild ratings) are shown in this table.

**Table 2**  
**Core: 2-Year Cumulative First Occurrence Kaplan-Meier Adverse Event Risk Rates**  
**(95% Confidence Interval), By Patient**

Complication	Augmentation N = 494		Reconstruction N = 221		Revision N = 225	
	Rate (%)	(95% CI)	Rate (%)	(95% CI)	Rate (%)	(95% CI)
Reoperation	17.1	(13.7, 20.5)	36.9	(30.5, 43.4)	29.4	(23.3, 35.6)
Swelling*	6.8	(4.5, 9.0)	3.7	(1.2, 6.2)	5.6	(2.5, 8.7)
Capsular Contracture*	6.7	(4.5, 9.0)	13.5	(8.8, 18.1)	9.9	(5.8, 14.0)
Breast Pain*	5.0	(3.0, 6.9)	3.3	(0.9, 5.7)	6.8	(3.3, 10.3)
Implant Replacement/Removal	4.7	(2.8, 6.6)	17.2	(12.1, 22.2)	10.7	(6.4, 14.9)
Loss of Nipple Sensation*	3.1	(1.6, 4.7)	0	—	0	—
Implant Malposition*	2.5	(1.1, 4.0)	5.8	(2.6, 8.9)	4.4	(1.6, 7.3)
Asymmetry*	2.1	(0.8, 3.4)	11.9	(7.5, 16.3)	5.0	(2.0, 8.1)
Hypertrophic Scarring*	1.7	(0.5, 2.8)	2.4	(0.3, 4.5)	<1	<1
Skin Rash*	1.6	(0.5, 2.8)	1.4	(0.0, 2.9)	<1	<1
Other Nipple Related Observation*	1.5	(0.4, 2.6)	4.4	(1.6, 7.3)	1.5	(0.0, 3.1)
Ptosis*	1.3	(0.3, 2.4)	1.0	(0.0, 2.3)	<1	<1
Loss of Skin Sensation*	1.2	(0.3, 2.2)	0	—	<1	<1
Bruising*	1.2	(0.3, 2.2)	1.4	(0.0, 2.9)	1.4	(0.0, 2.9)
Implant Rupture	<1	<1	4.8	(1.7, 7.9)	2.7	(0.4, 5.0)
Tissue or Skin Necrosis*	<1	<1	3.8	(1.2, 6.5)	1.9	(0.1, 3.8)
Wrinkling/Rippling*	<1	<1	2.9	(0.6, 5.2)	2.9	(0.6, 5.2)
Other Complications*	<1	<1	2.3	(0.3, 4.4)	2.0	(0.1, 4.0)
Infection*	0	—	2.3	(0.3, 4.3)	1.8	(0.1, 3.7)
Delayed Wound Healing*	<1	<1	2.3	(0.3, 4.3)	<1	<1
Seroma*	<1	<1	1.8	(0.1, 3.6)	4.7	(1.9, 7.6)

\*These complications were assessed with severity ratings. Only the rates for moderate, severe, or very severe (excludes mild and very mild ratings) are shown in this table.

Of the 494 augmentation patients in the Core Study, at least one additional operation after the initial implantation (reoperation) was performed on 81 patients (16.4%) through 2 years. A total of 91 reoperations was performed on augmentation patients over 2 years. Of the 221 reconstruction patients in the Core Study, at least one reoperation was performed on 80 patients (36.2%) through 2 years. A total of 104 reoperations were performed on reconstruction patients over 2 years, excluding planned procedures such as nipple reconstruction and nipple tattoo. Of the 225 revision patients in the Core Study, at least one reoperation was performed on 62 patients (27.6%) through 2 years. A total of 84 reoperations were performed on revision patients over 2 years. Table 3 shows the types of reoperations performed through 2 years in the Core Study based on the total number of reoperations.

**Table 3**  
**Core: Types of Reoperations through 2 Years**

Type of Reoperation <sup>1</sup>	Augmentation N = 91 Reoperations		Reconstruction N = 104 Reoperations		Revision N = 84 Reoperations	
	n	percent	n	percent	n	percent
Capsule Procedure <sup>2</sup>	25	28	13	13	18	21
Implant Replacement/Removal <sup>3</sup>	22	24	37	36	23	27
Mastopexy	12	13	1	1	6	7
Scar Revision	9	10	15	14	8	10
Biopsy	8	9	0	0	2	2
Aspiration of Hematoma/Seroma	5	6	7	7	6	7
Pocket Revision	3	3	5	5	6	7
Reposition Implant	3	3	3	3	3	4
Wound Repair	2	2	6	6	3	4
Revision of Nipple Reconstruction/Tattoo	1	1	4	4	5	6
Surgical Exploration of Breast Area/Implant	1	1	0	0	0	0
Removal of Excess Tissue/Lesion/Cyst	0	0	6	6	2	2
Liposuction	0	0	4	4	0	0
Flap Procedure	0	0	1	1	0	0
Breast Reduction	0	0	1	1	1	1

Other <sup>4</sup>	0	0	1	1	1	1
<b>Total</b>	<b>91</b>	<b>100</b>	<b>104</b>	<b>100</b>	<b>84</b>	<b>100</b>

<sup>1</sup>Primary procedure performed

<sup>2</sup>Capsule Procedure includes capsulectomy, capsulotomy, and capsulorrhaphy

<sup>3</sup>Some removals were replaced with a McGhan implant, while others were replaced with a non-McGhan implant.

<sup>4</sup>Reconstruction: Through 2 years, other reoperation was revision.

Revision: Through 2 years, other reoperation was removal of retained suture.

Of the 494 augmentation patients in the Core Study, there were 22 patients (4.5%) who had 41 implants removed through 2 years. Of the 221 reconstruction patients in the Core Study, there were 37 patients (16.7%) who had 45 implants removed through 2 years. Of the 225 revision patients in the Core Study, there were 22 patients (9.8%) who had 37 implants removed through 2 years. Of the 41 augmentation implants removed through 2 years, 95% were replaced; of the 45 reconstruction implants removed through 2 years, 87% were replaced; of the 37 revision implants removed through 2 years, 87% were replaced. The primary reason for implant removal is shown in Table 4 below based on the number of implants removed.

**Table 4**  
**Core: Reasons for Implant Removal Through 2 Years**

Primary Reason for Implant Removal	Augmentation N = 41 Implants		Reconstruction N = 45 Implants		Revision N = 37 Implants	
	n	percent	n	percent	n	percent
Capsular Contracture	19	46	12	27	4	11
Style/Size Change (Patient Request)	7	17	3	7	12	32
Malposition	6	15	8	18	7	19
Implant Rupture	2	5	0	0	2	5
Asymmetry	3	7	11	24	2	5
Media Anxiety (Patient Request)	3	7	0	0	0	0
Extrusion	1	2	1	2	0	0
Wrinkling	0	0	3	7	1	3
Hematoma/Seroma	0	0	2	4	0	0
Unsatisfactory Scar	0	0	1	2	2	5
Injury (Iatrogenic or Traumatic)	0	0	1	2	1	3
Breast Cancer	0	0	1	2	0	0
Breast Tissue Contour Deformity	0	0	1	2	0	0
Pain	0	0	1	2	0	0
Ptosis	0	0	0	0	4	11
Delayed Wound Healing	0	0	0	0	1	3
Infection	0	0	0	0	1	3
<b>Total</b>	<b>41</b>	<b>100</b>	<b>45</b>	<b>100</b>	<b>37</b>	<b>100</b>

### Potential Adverse Events

The following is a list of potential adverse events that may occur with breast implant surgery. Some of these adverse events have been reported in Tables 1 and 2 above. The risks include: implant rupture, additional surgery, capsular contracture, infection, Toxic Shock Syndrome, necrosis, hematoma, seroma, extrusion, breast pain, changes in nipple sensation, changes in breast sensation, dissatisfaction with cosmetic results (wrinkling, folding, displacement, asymmetry, palpability, visibility, ptosis), calcific deposits, irritation/inflammation, delayed wound healing, hypertrophic scarring, breast tissue

atrophy/chest wall deformity, difficulty/inability in breast feeding, and inability to adequately visualize breast lesions with mammography.

In addition to these potential adverse events, there have been concerns with certain systemic diseases.

- **Connective Tissue Disease**

Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma, or rheumatoid arthritis, was raised because of cases reported in the literature with small numbers of women with implants. A review of several large epidemiological studies of women with and without implants indicates that these diseases are no more common in women with implants than those in women without implants. Furthermore, basic animal toxicological studies do not find pathology that would support a causation of human connective tissue disease by silicone breast implants.

- **Cancer**

Published clinical studies indicate that breast cancer is no more common in women with implants than those without implants. Furthermore, basic animal toxicological studies do not find pathology that would support a causation of human carcinogenicity by silicone breast implants.

- **Second Generation Effects**

There have been concerns raised regarding potential damaging effects on children born of mothers with implants. A review of the published literature on this issue suggests that the information is insufficient to draw definitive conclusions. However, basic animal toxicological studies do not find pathology that would support a causation of human reproductive and developmental concerns from silicone breast implants.

## **Clinical Studies Overview**

### ***1. Study Design***

The safety and effectiveness of McGhan® Silicone-Filled Breast Implants were evaluated in three open label, multicenter clinical studies: the 1990 Augmentation/Reconstruction Study (AR90), the Adjunct Study, and the Core Study. Because the 1990 Study utilized devices and surgical practices that are no longer current, these data are not reported below.

The Adjunct Study was designed as a prospective 5-year study to assess safety outcomes for a large number of patients. Patients studied were those seeking breast reconstruction or revision of an existing implant for medical reasons. Follow-up was at 1, 3, and 5 years and is currently ongoing. Safety assessments consisted of adverse event rates and rates of secondary surgical treatment.

The Core Study was designed as a 10-year study to assess safety and effectiveness. Patients studied were those seeking implant surgery for breast augmentation, breast reconstruction, or revision of an existing breast implant. Follow-up was at 0-4 weeks, 6 months, and annually through 10 years, and is currently ongoing. Safety assessments consisted of adverse event rates and rates of secondary surgical treatment. Effectiveness assessments consist of patient satisfaction, breast size change, and measures of body esteem/self esteem/body image.

## **2. *Patient Accounting and Baseline Demographic Profile***

The Adjunct Study enrolled 15,465 reconstruction patients and 9,881 revision patients over a 5-year period. Of those reconstruction patients available to be seen, 5,537 (53.8%) returned for their 1-year follow-up visit and 670 (27.0%) returned for their 3-year follow-up visit. Of those revision patients available to be seen, 3,180 (43.9%) returned for their 1-year follow-up visit and 460 (19.9%) returned for their 3-year follow-up visit.

The Core Study enrolled 494 augmentation patients, 221 reconstruction patients, and 225 revision patients. Of those patients available to be seen, 90% of the augmentation patients, 95% of the reconstruction patients, and 87% of the revision patients were seen for their 2-year follow-up visit.

Demographic information obtained from the Adjunct Study revealed that approximately 60% of participants were married, more than 40% were employed in professional occupations, and more than 70% had at least some college education. The median patient age was 44 years for both reconstruction and revision patients.

Demographic information obtained from the Core Study revealed that over 80% of patients were Caucasian and most study participants were married (49% of augmentation patients, 75% of reconstruction patients, and 64% of revision patients). Approximately half were employed in professional occupations and more than three fourths had at least some college education. The median patient age was 34 years for augmentation patients, 50 years for reconstruction patients, and 44 years for revision patients.

With respect to surgical baseline factors in the Adjunct Study, for both reconstruction and revision patients, the most frequently used devices were round with a fairly equal distribution of smooth and textured surface.

With respect to surgical baseline factors in the Core Study, for augmentation patients, the most frequently used devices were round, with a smooth surface somewhat more common than textured. The most common incision sites were inframammary and periareolar, and the most frequent placement of the implant was submuscular. For reconstruction patients, the most frequently used devices were shaped with a textured surface, the most common incision site was the mastectomy scar, and the most

frequent placement of the implant was submuscular. For revision patients, the most frequently used devices were round, and the textured surface (round and shaped) was more common than smooth. The most common incision site was inframammary, and the most frequent placement of the implant was submuscular.

### 3. *Safety Outcomes*

The Adjunct Study safety outcomes are presented in Table 1 above.

The Core Study safety outcomes are presented in Tables 2-4 above.

#### **CTD and Breast Disease**

Tables 5 and 6 summarize post-implant observations from the Core Study pertaining to connective tissue/autoimmune disease (CTD) and breast disease (including breast carcinoma). These data should be interpreted with caution in that there was no comparison group of similar women without implants. CTD reports were based on a diagnosis by a physician.

**Table 5**  
**Core: Reports of CTD Through 2 Years, By Patient**

Rheumatic Disease	No. of Confirmed Reports in Patients		
	Augmentation	Reconstruction	Revision
Rheumatoid Arthritis	1	0	0
Systemic Sclerosis/Scleroderma	0	1	0
Fibromyalgia	0	0	1

**Table 6**  
**Core: Reports of Breast Disease Through 2 Years, By Patient**

Breast Disease Observation	No. of Confirmed Reports in Patients		
	Augmentation	Reconstruction	Revision
Benign	25	9	13
Malignant	1	4	0
Unknown Outcome	1	0	0

### 4. *Effectiveness Outcomes in the Adjunct Study*

Effectiveness of silicone-filled breast implants was assessed in the Adjunct Study by patient reports of satisfaction at 1 and 3 years post-implant. Because this study continued to enroll patients over a 5-year period, many of the enrolled patients have not yet reached their 3-year follow-up visit. Thus, satisfaction data was available from a much smaller number of patients at 3 years than at 1 year.

For reconstruction patients, 5,501 of the original 15,465 patients (36%) were included in an analysis of satisfaction at 1 year post-implant (64% were not included because these patients had not yet reached the 1-year follow-up time point, satisfaction data was not obtained at the 1-year visit, or implant replacement/removal occurred prior to 1 year). Of these 5,501 reconstruction patients, 93% indicated being satisfied with their breast implants at 1 year. Satisfaction data was obtained from 732 reconstruction patients at 3 years post-implant. 93% of these patients indicated they were satisfied with their breast implants at 3 years.

For revision patients, 3,150 of the original 9,881 patients (32%) were included in an analysis of satisfaction at 1 year post-implant. Of these 3,150 revision patients, 90% indicated being satisfied with their breast implants at 1 year. Satisfaction data was obtained from 498 revision patients at 3 years post-implant. 88% of these patients indicated they were satisfied with their breast implants at 3 years.

##### **5. Effectiveness Outcomes in the Core Study**

Effectiveness of silicone-filled breast implants was assessed in the Core Study by a variety of outcomes, including bra cup size change (augmentation patients only), patient satisfaction, body image, body esteem, and self concept. These outcomes were assessed for patients with both original and replacement silicone devices before implantation and at 2 years after surgery, except for bra size and satisfaction. Bra size was measured within the first year and a half after surgery. Satisfaction was measured at every follow-up visit through 2 years. Bra size and satisfaction analyses were based only on original silicone devices.

##### **Augmentation**

408 of the original 494 augmentation patients (83%) at 18 months were included in an analysis of cup size (17% did not provide data because pre/post measurements were not obtained or replacement/removal occurred prior to obtaining a post measurement). Of these 408 patients, the following shows the percentage of patients experiencing various changes in cup size:

- Increase by 1 cup size: 40%
- Increase by 2 cup sizes: 45%
- Increase by more than 2 cup sizes: 8%
- No Increase: 6%

425 of the original 494 augmentation patients (86%) were included in an analysis of satisfaction at 2 years (14% were not included because satisfaction data was not obtained or implant replacement/removal occurred prior to 2 years). Of these 425 patients, 95% indicated being satisfied with their breast implants at 2 years.

Before implantation, augmentation patients scored higher (better) than the general U.S. female population on the SF-36, which measures general health-related quality of life. After 2 years, patients showed a worsening of some SF-36 scores as well as some scores on the MOS-20, another survey of general health-related quality of life. The following three scales showed no change over the 2 years: the Rosenberg Self-Esteem Scale (which measures overall self-esteem), the Tennessee Self-Concept Scale (which measures overall self-concept), and the Semantic Differential Scale (which measures attitudes about one's breasts compared to attitudes about oneself). The Body Esteem Scale (which measures self-esteem related specifically to one's body) showed an improvement in patients' sexual attractiveness and a worsening in their physical condition. Measures of patients' expectation vs. their perceived results of breast implant surgery showed an improvement in self image, social relations, and daily living over the 2 years.

### **Reconstruction**

177 of the original 221 reconstruction patients (80%) were included in an analysis of satisfaction at 2 years (20% were not included because satisfaction data was not obtained or implant replacement/removal occurred prior to 2 years). Of these 177 patients, 94% indicated being satisfied with their breast implants at 2 years.

Before implantation, reconstruction patients scored higher (better) than the general U.S. female population on most scores on the SF-36, which measures general health-related quality of life. After 2 years, patients showed an improvement in physical functioning scores on both the SF-36 and the MOS-20, another survey of general health-related quality of life. The following four scales showed no change over the 2 years: the Rosenberg Self-Esteem Scale (which measures overall self-esteem), the Tennessee Self-Concept Scale (which measures overall self concept), the Body Esteem Scale (which measures self-esteem related specifically to one's body), and the Semantic Differential Scale (which measures attitudes about one's breasts compared to attitudes about oneself). Measures of patients' expectation vs. their perceived results of breast implant surgery showed an improvement in social relations and a worsening in daily living over the 2 years.

### **Revision**

173 of the original 225 revision patients (77%) were included in an analysis of satisfaction at 2 years (23% were not included because satisfaction data was not obtained or implant replacement/removal occurred prior to 2 years). Of these 173 patients, 88% indicated being satisfied with their breast implants at 2 years.

Before implantation, revision patients scored significantly higher (better) than the general U.S. female population on the SF-36, which measures general health-related quality of life. After 2 years, patients showed a worsening of some SF-36 scores as well as some scores on the MOS-20, another survey of general health-related quality of life. There was no change over the 2 years in the Semantic Differential Scale (which measures attitudes about one's breasts compared to attitudes about oneself). Patients showed a worsening on the Rosenberg Self-Esteem Scale (which measures overall self-esteem), the Tennessee Self-Concept Scale (which measures overall self

concept), and the physical condition subscale of the Body Esteem Scale (which measures self-esteem related specifically to one's body). Measures of patients' expectation vs. their perceived results of breast implant surgery showed an improvement in self image and social relations over the 2 years.

## **Instructions for Use**

**NOTE:** Back-up breast implants must be available during the procedure.

**DO NOT** Stack more than one implant per breast pocket.

### ***Single Use***

This product is intended for **single use only**. Do not reuse explanted implants.

### ***Product Identification***

Product identification stickers accompany each device within the internal product packaging. The stickers provide product-specific information. Product stickers may be attached to the patient's chart for identification purposes. The Device Identification Cards, which accompany each device within the internal product packaging, should be provided to the patient for personal reference. To complete the Device Identification Card, place one device identification sticker for each implant on the back of the card. If a sticker is unavailable, the lot number, catalog number and description of the device may be copied by hand from the device label.

### ***Medical Device Registration***

Successful device registration begins with the **Medical Device Registration Form** that is supplied with every breast implant. The Medical Device Registration Form should be completed and returned to INAMED by the physician or medical facility. Stickers with product specific information are provided for quick completion of the form and are located on the internal product packaging attached to the label. If stickers are unavailable, the lot number, catalog number and description of each device may be copied by hand from the device label.

### ***Surgical Planning***

INAMED relies on the surgeon to know and follow the proper surgical procedures with McGhan<sup>®</sup> Silicone-Filled Breast Implants. Proper surgical planning such as allowance for adequate tissue coverage, implant site (i.e., submuscular vs. subglandular), incision site, implant type, etc. should be made preoperatively. The surgeon must carefully evaluate breast implant size and contour, incision placement, pocket dissection and implant placement criteria with respect to the patient's anatomy and desired physical outcome. Planning should include clear delineation of aesthetic goals to ensure mutual understanding between surgeon and patient. The surgeon should observe current and accepted techniques to minimize the risk of adverse, and potentially disfiguring, reactions.

### ***Preliminary Product Examination***

*How to Open Sterile Product Package*

Remove the sterile breast implant from its package in an aseptic environment and using talc-free gloved hands. DO NOT expose the breast implant to lint, talc, sponge, towel, or other contaminants.

1. Peel open the lid of the outer thermoform package.
2. Invert the outer thermoform package over the sterile field, allowing the sealed inner thermoform package to gently fall into the field.
3. Peel open the lid of the inner thermoform package using the pull-tab.
4. Gently retrieve the breast implant. Prior to use, keep the breast implant in the inner thermoform package to prevent contact with airborne and surgical field particulate contaminants.

#### *Examination of Silicone-Filled Breast Implants*

Prior to use, examine the breast implant for evidence of any particulate contamination, damage, or loss of shell integrity. If satisfactory, return the breast implant to the inner thermoform tray and cover it with the lid until implanted to prevent contact with airborne contaminants.

**DO NOT** implant any device that may appear to have particulate contamination, damage, or loss of shell integrity. A sterile back-up implant must be readily available at the time of surgery.

**DO NOT** implant any device that may appear to have leaks or nicks.

**DO NOT** implant damaged or contaminated breast implants.

#### *Sterile Product*

Each sterile silicone-filled breast implant is supplied in a sealed, double primary package. Style-specific sterile product accessories are also supplied within the product packaging. Sterility of the implant is maintained only if the thermoform packages, including the package seals, are intact. Use standard procedures to maintain sterility during transfer of the breast implant to the sterile field. Remove the breast implant and accessories from their packages in an aseptic environment and using talc-free gloved hands.

**DO NOT** use the product if the thermoform packages or seals have been damaged.

**DO NOT** resterilize the product.

**NEVER**, under any circumstances, attempt to resterilize using ethylene oxide, which is known to cause adverse tissue reaction if not completely removed from the device. Avoid unnecessary exposure of the breast implant to lint, talc, sponge, towel, skin oils, and other contaminants.

Prior to use, keep the breast implant in the inner thermoform and covered to prevent contact with airborne and surgical field particulate contaminants.

1. Peel open the lid of the outer thermoform package.
2. Invert the outer thermoform over the sterile field, allowing the sealed inner thermoform to gently fall into the field.
3. Peel open the lid of the inner package using the pull-tab.
4. Gently retrieve the breast implant.

#### *Method for Removing Ruptured Silicone From the Surgical Pocket*

In the event of breast implant rupture, the following technique is useful for removal of the silicone mass. Wearing double talc-free surgical gloves on one hand, use the index finger to penetrate the silicone mass. With the other hand, exert pressure on the breast to facilitate manipulation of the silicone mass into the double-gloved hand. Once the silicone is in hand, pull the outer glove over the silicone mass and remove. To remove any residual silicone, blot the surgical pocket with gauze sponges. Avoid contact between surgical instruments and the silicone. If contact occurs, use isopropyl alcohol to remove the silicone from the instruments. Ruptured breast implants must be reported and should be returned to INAMED. In the event of breast implant rupture, contact INAMED Product Support Department at 800.624.4261.

### ***Surgical Procedure***

#### ***Placement***

Ensure incision is sufficiently large to facilitate insertion and to avoid damage to the device. Inadequate pocket dissection increases the risk of rupture and implant malposition.

A sterile BIOCELL® Delivery Assistance Sleeve is available separately and can be used to assist with placement of the breast implant. Use of this sleeve for insertion of BIOCELL® textured breast implants provides a shell/tissue interface with less friction. Insert the implant into one end of the sleeve. Insert the proximal end of the sleeve into the surgically prepared pocket. With the tissue retracted, the sleeve can be twisted at its distal end to gently guide the breast implant into the pocket. Once the breast implant is inserted, gently remove the sleeve.

**DO NOT** use lubricants to facilitate placement. Their use creates the risk of pocket contamination and may also affect the tissue-capsule interface.

**DO NOT** damage the breast implant with sharp surgical instruments such as needles and scalpels, blunt instruments such as clamps and forceps, or by overhandling and manipulation during introduction into the surgical pocket.

**DO NOT** use excessive force during breast implant placement.

**DO NOT** manipulate the implant for either radial expansion, compression or dissection of the pocket.

**Breast augmentation** with silicone-filled implants can be carried out through several different incisions including inframammary, periareolar, or transaxillary. The transumbilical incisional approach is not recommended. Some surgeons advocate a "no-touch" technique, which requires significant attention to minimizing contact between the patient's skin and the implant. Pocket dissection should be planned out preoperatively and be performed accurately and with minimal trauma. Excellent hemostasis is important to avoid postoperative hematoma. The implant may be placed subglandularly or subpectorally depending upon the balance of cosmetic and medical considerations in any given patient. The size and shape of the device may be determined preoperatively by means of dimensional planning or intraoperatively with the help of temporary sizer devices. It is important to maintain proper orientation of any BioDIMENSIONAL® shaped implant.

The incision for the placement of the implant should be securely closed and in several layers, whenever possible. Drains are optional.

**Breast Reconstruction** is generally carried out in the mastectomy scar. Special care must be used in breast reconstruction to make sure that appropriate amounts of healthy tissue be available to cover the implant and that the implant be properly sized and positioned based upon careful preoperative planning.

Educational materials are available through the Inamed Customer Care Department to supplement surgical knowledge of the dimensional techniques intended for use with BioDIMENSIONAL® styles.

#### ***Maintaining Hemostasis/Avoiding Fluid Accumulation***

Postoperative hematoma and seroma may be minimized by meticulous attention to hemostasis during surgery, and possibly also by postoperative use of a closed drainage system. Persistent, excessive bleeding must be controlled before implantation. Any postoperative evacuation of hematoma or seroma must be conducted with care to avoid breast implant contamination, or damage from sharp instruments.

### **Information the Physician Should Provide to the Patient**

Breast implantation is an elective procedure and the patient must be well counseled on the risk-benefit relationship. The surgeon should provide each prospective patient with the following:

- ***Making an Informed Decision: Silicone-Filled Breast Implant Surgery***  
This brochure can be used to facilitate patient education in the risks and benefits of silicone-filled breast implant surgery. The patient should be advised to wait a week after reviewing and considering this information before deciding whether to have augmentation surgery.
- ***Device Identification Card***  
Enclosed with each silicone-filled breast implant is a Device Identification Card. To complete the Device Identification Card, place one device identification sticker for each implant on the back of the card. Stickers are located on the internal product packaging attached to the label. If a sticker is unavailable, the lot number, catalog number and description of the device may be copied by hand from the device label. Patients should be provided with these cards for personal reference.

### **Specific Product Information**

#### ***BIOCELL® Delivery Assistance Sleeve***

Sterile BIOCELL® Delivery Assistance Sleeves are available from your INAMED Aesthetics Sales Representative or Customer Care Department at 800.766.0171.

#### ***Returned Goods Policy***

Product returns should be handled through an INAMED Aesthetics Sales Representative or through the Customer Care Department at 800.766.0171. Return value is based on time limitations. All package seals must be intact to be eligible for return. Returned products

may be subject to a restocking charge. Certain products are non-returnable, including Zyderm® and Zyplast®.

***Reporting and Return of Explanted Devices***

The reason for explantation should be reported and the explanted device returned to INAMED Corporation. In the event of such an explantation, please contact Product Support at 800.624.4261 for an Explant Kit and explant return instructions.

***ConfidencePlus™ Limited Warranties***

The ConfidencePlus™ Limited Warranties provide lifetime replacement and limited financial reimbursement in the event of loss of shell integrity resulting in implant deflation or rupture, subject to certain conditions as fully discussed in the ConfidencePlus™ literature. For more information, please contact Product Support at 800.624.4261.

***Product Ordering***

To order directly in the U.S.A or for product information, please contact your local INAMED Aesthetics Sales Representative or the INAMED Customer Care Department at 800.766.0171.

McGhan, BIOCELL, BioDIMENSIONAL, BIOSPAN, ZYDERM and ZYPLAST are registered trademarks of INAMED Corporation.

ConfidencePlus is a trademark of INAMED Corporation.

These products are covered by one or more of the following U.S. Patents: 5,480,430; 5,007,929; 4,889,744 and 4,859,712 and/or foreign patents corresponding thereto.



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5540 Ekwil Street  
Santa Barbara, CA 93111  
800.624.4261  
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[www.InamedAesthetics.com](http://www.InamedAesthetics.com)