

Important Information for  
Women about Breast  
Reconstruction with  
**INAMED** Silicone-Filled  
Breast Implants

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# 1. Considering Silicone Gel-Filled Breast Implant Surgery

You may be considering breast implant surgery to restore your breast shape after a mastectomy or an injury that resulted in either partial or total loss of the breast(s) or to correct a birth defect. This is referred to as breast reconstruction. Whether you decide to have breast reconstruction depends on your own individual case, medical condition, general health, lifestyle, emotional state, and breast size and shape. You may wish to speak with your family, friends, breast implant support groups, and breast cancer support groups to help you in making this decision.

If you are considering breast reconstruction and do not have a plastic surgeon, ask your general surgeon for a referral for the names of experienced, board certified plastic surgeons in your area. Your general surgeon, plastic surgeon, and oncologist should work together to plan your mastectomy and reconstruction procedure to give you the best possible result.

INAMED Aesthetics has prepared this information to help you better understand the breast implant procedure and assist you in making an informed decision about breast reconstruction surgery. It will help to answer some of the questions you may have about the surgery and about breast implants in general. It will also provide you with specific information about the risks and benefits of INAMED Silicone-Filled Breast Implants.

This information cannot and should not take the place of discussing your surgery with your plastic surgeon. Your decision whether or not to get breast implants should be based on realistic expectations of the outcome. There is no guarantee that your results will match those of other women. Your results will depend on many individual factors, such as your overall health (including age), chest structure, breast/nipple shape and position, skin texture, healing capabilities (which may be slowed by radiation and

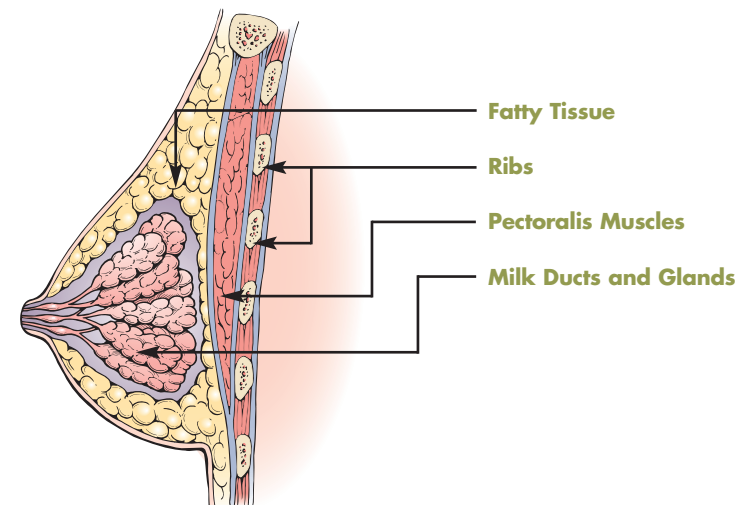
chemotherapy treatment, smoking, alcohol, and various medications), tendency to bleed, prior breast surgery, surgical team's skill and experience, type of surgical procedure, and type and size of implant. Make sure you speak with your surgeon about your expectations of the results, as well as what you can expect regarding the length of the surgery, your recovery, and any risks and potential complications of the surgery. Ask questions. You and your surgeon will work together to help you achieve the body image you desire.

As part of your decision, both you and your surgeon will be required to sign INAMED's consent to surgery form that confirms your understanding of what you have read and what you have learned from your surgeon. This INAMED consent document will be provided to you by your surgeon.

Review and consider this information before deciding whether to have primary breast reconstruction or revision-reconstruction surgery.

## 1.1 What Gives The Breast Its Shape?

The breast consists of milk ducts and glands, surrounded by fatty tissue that provides its shape and feel. Beneath the breast is the chest muscle (pectoralis major muscle).



Factors such as pregnancy (when milk glands are temporarily enlarged), rapid weight loss, and the effects of gravity as you age, combine to stretch the skin, which may cause the breast to droop or sag. However, it is important to realize that implants are used to make the breast larger. The implants alone may not adequately lift the breast, or correct the effects of pregnancy, weight loss, or skin stretching. Your surgeon may suggest additional procedures at the time of the breast reconstruction, such as mastopexy, to help achieve improved breast lift.

## 1.2 What Is A Silicone Gel-Filled Breast Implant?

- 4 A silicone gel-filled breast implant is a sac (implant shell) of silicone “rubber” (elastomer) filled with silicone gel. It is surgically implanted either under (and within) your breast tissue or under your chest muscle.



## 1.3 Are Silicone Gel-filled Breast Implants Right For You?

Breast implants are indicated for females for the following uses (procedures):

- **Breast augmentation for women at least 22 years old –**

Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of

an original primary breast augmentation surgery. (A separate patient brochure is available for those women considering breast augmentation surgery and should be read prior to reaching a decision to undergo breast augmentation.)

- **Breast reconstruction** – Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of an original primary breast reconstruction surgery.

### Contraindications

Breast implant surgery should not be performed in:

- Women with active infection anywhere in their body.
- Women with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions.
- Women who are currently pregnant or nursing.

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### Precautions

Safety and effectiveness have not been established in patients with the following:

- Autoimmune diseases (for example, lupus and scleroderma).
- A weakened immune system (for example, currently taking drugs that weaken the body’s natural resistance to disease).
- Conditions that interfere with wound healing and blood clotting.
- Reduced blood supply to breast tissue.
- Radiation to the breast following implantation.
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders with your surgeon prior to surgery. Patients with a diagnosis of depression or other mental health disorders should wait to schedule surgery until these conditions resolve.

## 1.4 Important Factors You Should Consider In Choosing Silicone Gel-Filled Breast Implants

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- Breast implants are not lifetime devices. Either because of rupture, other complications, or unacceptable cosmetic outcomes, you will likely need to have your implants removed at least once over your lifetime. When you have your implants replaced (revision-reconstruction), your risk of future complications may increase compared to first time (primary) reconstruction surgery. Because you will likely have revision-reconstruction over the course of your lifetime, you should also review the complication rates for revision-reconstruction patients to see what future risk rates you may experience.
  - Whether you are undergoing primary reconstruction or revision-reconstruction, breast implantation is likely not a one-time surgery. You will likely need additional surgeries. These additional surgeries can include implant removal with or without replacement of the implant, or they can include other surgical procedures.
  - Many of the changes to your breast following implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed and not replaced, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast, which can be permanent.
  - Breast implants may affect your ability to breastfeed, either by reducing or eliminating milk production. However, if you undergo a mastectomy, removal of the breast tissue eliminates the ability to breastfeed with the removed breast.
  - Rupture of a silicone gel-filled breast implant is most often silent. This means that most of the time neither you nor your surgeon will know that your implants have a rupture
  - It is recommended that you take a multi-step approach to monitor the integrity of the implant throughout the lifetime of the device beginning

with a patient self examination. Obtain an ultrasound or mammogram if a new symptom or sign is suspected or as part of a periodic review with a physician. If the ultrasound is negative or inconclusive, obtain an MRI. If MRI results suggest a rupture, discuss explantation of the implant with your plastic surgeon.

- With breast implants, routine screening mammography will be more difficult. You should continue to perform monthly breast examinations for cancer screening; however, this may be more difficult. The implant may interfere with finding breast cancer during mammography. Because the breast and implant is squeezed during mammography, an implant may rupture during the procedure. More x-ray views are necessary for women with breast implants; therefore, you will receive more exposure to radiation. However, the benefit of having the mammogram to find cancer outweighs the risk of the additional x-rays. Be sure to inform the mammography technologist that you have implants.
- You should perform an examination of your implants every month. You should ask your surgeon to help you distinguish the implant from your breast tissue. The presence of lumps, persistent pain, swelling, hardening, or change in implant shape may be signs of rupture of the implant. These should be reported to your surgeon and possibly evaluated with an MRI to screen for rupture.
- You should inform any other doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.
- Closed capsulotomy (use of pressure or force to “break up” the capsule) should not be used to treat capsular contracture. Closed capsulotomy can cause implant rupture.
- Smoking may interfere with the healing process after surgery.
- The long-term safety and effectiveness of INAMED Silicone-Filled Breast Implants has not been established. INAMED’s Core Study is ongoing and is not concluded. The Core Study will continue to evaluate the long-term (10 years) performance of these products. Unanswered questions remain regarding breast implants long-term. INAMED will continue to further address other long-term issues postapproval.

- It is important that you read this entire brochure because you need to understand the risks and benefits and to have realistic expectations of the outcome of your surgery.

## 2. Breast Implant Complications

8 Undergoing any type of surgical procedure involves risks (some serious) such as the effects of anesthesia, infection, swelling, redness, bleeding, pain, and even death, which need to be balanced against the benefits of the breast reconstruction surgery. There are potential complications specific to breast implant surgery and breast implants, as described below. It should also be noted that the published studies mentioned include augmentation and/or reconstruction patients.

### 2.1 What Are The Potential Complications?

#### **Rupture**

All implants, including breast implants, can fail over time and need to be removed or replaced. They are not to be considered lifetime devices. Breast implants can rupture when the shell develops a hole or a tear. Some implants may rupture in the first few months after being implanted and some may rupture after several years. Rupture may be caused by damage to the implant from surgical instruments, some other trauma to the implant during surgery, capsular contracture, closed capsulotomy (compressing the breast to relieve contracture), and stresses such as trauma or intense physical manipulation, excessive compression during mammographic imaging and for unknown/unexplained reasons.

#### **Health Consequences Of Rupture**

Sometimes when an implant ruptures, the silicone gel fill is released from the implant shell. INAMED's clinical studies have shown that when this takes place the silicone gel is typically contained within the scar capsule that has formed around the implant. However, a ruptured implant may allow silicone to migrate through the tissues. Although rare, there have been reports in the scientific literature providing evidence that the silicone gel fill may move beyond the fibrous capsule and into the breast tissue or away from the breast (gel migration), particularly if the scar capsule is ruptured, causing local complications such as pain and neuropathy. A report in a scientific journal compared women with intact implants to women with ruptured implants and found a significantly increased frequency of non-specific breast changes, changes in breast shape, and breast pain. The relationship of free silicone to development or progression of disease is unknown. You should also be aware of the potential for an intracapsular rupture (within the tissue capsule surrounding the implant) to progress to an extracapsular rupture (outside the tissue capsule surrounding the implant).

If an implant ruptures, your physician will likely recommend removal or replacement of the implant because the implant is no longer performing as intended. Along with the rupture, patients may experience local complications, such as hard knots in the breast, uneven appearance of the breasts, pain or tenderness, tingling, swelling, numbness, burning, or changes in breast sensation. These complications may also be experienced by patients with non-ruptured implants. The decision to remove a ruptured or suspected ruptured implant should be undertaken following review of all available clinical information and after careful consideration between you and your surgeon.

#### **Silent Rupture**

In some cases there may be no detectable evidence of rupture. There may be no change in the shape or size of the breast or any other physical symptoms. This is referred to as a silent rupture. Because of the possibility

of silent rupture, women with breast implants should periodically have their breast implants evaluated to determine if the implants have ruptured.

### **Capsular Contracture**

The scar tissue or capsule that normally forms around the implant may tighten and squeeze the implant making your breast feel firmer and sometimes painful. This is called capsular contracture. Capsular contracture may be more common following infection, hematoma, and seroma. It is also more common with subglandular placement (behind the mammary gland and on top of the chest muscle). Symptoms range in severity from mild firmness and mild discomfort to hardness and severe pain, distorted breast shape, and/or movement of the implant.

*IC* Capsular contracture may occur on one breast side, both sides, or not at all. In severe cases, the disfigurement or discomfort resulting from capsular contracture may require surgery to remove the scar tissue around the implant and/or implant replacement. In some cases, the contracture may not be correctable and removal of the implant and capsule tissue may be necessary. Closed capsulotomy, or tightly compressing the breast in order to break open the scar capsule, is not recommended due to concerns about implant rupture and localized bleeding. The occurrence of capsular contracture is not predictable, however, the chance of it happening increases with time. Capsular contracture may occur again or at any time after additional surgeries.

### **Additional Surgeries (Reoperations)**

You should assume that you will need to have additional surgeries (reoperations). Patients may decide to change the size or type of their implants, requiring additional surgery. Problems such as rupture, capsular contracture, hypertrophic scarring (irregular, raised scar), asymmetry, infection, and shifting can require additional surgery. For women receiving primary reconstruction implants, the three most common reasons for reoperation were implant malposition, capsular contracture, and asymmetry. For women receiving revision-reconstruction implants, the three most common reasons for additional surgery were nipple complications, scarring, and capsular contracture.

### **Implant Removal**

Because these are not lifetime devices, the longer you have your implants, the more likely it will be for you to have them removed for any reason, either because of dissatisfaction, an unacceptable cosmetic result, or a complication such as severe capsular contracture. Having your implants removed and replaced may increase your chances of getting future complications.

Most women who have their implants removed, have them replaced with new implants, but some women do not. If you choose not to replace your implants, you may have cosmetically unacceptable dimpling, puckering, wrinkling, and/or other potentially permanent cosmetic changes of the breast following removal of the implant. Even if you have your implants replaced, implant removal may result in loss of your breast tissue. *II* Also, implant replacement may increase your risks of future complications. For example, the risks of severe capsular contracture and reoperation may increase for patients with implant replacement compared to first time placement. You should consider the possibility of having your implants replaced and its consequences when making your decision to have implants.

### **Unsatisfactory Results**

Unsatisfactory results such as wrinkling, asymmetry, implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, and/or hypertrophic scarring, may occur. Some of these results may cause discomfort. Pre-existing asymmetry may not be entirely correctable by implant surgery. Revision surgery may be recommended to maintain patient satisfaction, but carries additional considerations and risks. Selecting an experienced plastic surgeon may minimize, but not necessarily prevent, unsatisfactory results.

### **Pain**

Pain of varying intensity and length of time may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain. You should tell your surgeon about significant pain or if your pain persists.

## Changes In Nipple And Breast Sensation

Feeling in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. While some of these changes can be temporary, they can also be permanent, and may affect your sexual response or your ability to nurse a baby. (See the paragraph on breastfeeding below.)

## Infection

Infection occurs rarely following breast implant surgery. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. In addition, breast and nipple piercing procedures may increase the possibility of infection. Infections in tissue with an implant present are harder to treat than infections in tissue without an implant. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved (cleared up). As with many other surgical procedures, in rare instances, toxic shock syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. You should contact a doctor immediately for diagnosis and treatment if you have these symptoms.

## Hematoma/Seroma

Hematoma is a collection of blood within the space around the implant, and a seroma is a build-up of fluid around the implant. Having a hematoma and/or seroma following surgery may result in infection and/or capsular contracture later on. Symptoms from a hematoma or seroma may include swelling, pain, and bruising. If a hematoma or seroma occurs, it will usually be soon after surgery. However, this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, large ones sometimes occur and may require surgery, typically involving draining and potentially placing a surgical drain in the wound

temporarily for proper healing. A small scar can result from surgical draining. Implant rupture also can occur from surgical draining if there is damage to the implant during the draining procedure.

## Breastfeeding

Breastfeeding difficulties have been reported following breast surgery, including breast reduction and breast reconstruction. If your surgeon uses a periareolar surgical approach (an incision around the colored portion surrounding the nipple), it may further increase the chance of breastfeeding difficulties.

## Calcium Deposits In The Tissue Around The Implant

Calcium deposits can form in the tissue capsule surrounding the implant. Symptoms may include pain and firmness. Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish calcium deposits from cancer. If additional surgery is necessary to examine and/or remove calcifications, this may cause damage to the implants. Calcium deposits also occur in women who undergo breast reduction procedures, in patients who have had hematoma formation, and even in the breasts of women who have not undergone any breast surgery. The occurrence of calcium deposits increases significantly with age.

## Extrusion

Extrusion is when the breast implant comes through your skin. This may occur, for example, when your wound has not closed or when breast tissue covering your implants weakens. Radiation therapy has been reported to increase the likelihood of extrusion. Extrusion requires additional surgery and possible removal of the implant, which may result in additional scarring and/or loss of your breast tissue.

## Necrosis

Necrosis is the death of cells or tissues. This may prevent or delay wound healing and require surgical correction, which may result in additional

scarring and/or loss of your breast tissue. Implant removal may also be necessary. Factors associated with increased necrosis include infection, use of steroids, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

### **Delayed Wound Healing**

Some patients may experience a prolonged wound healing time. Delayed wound healing may increase the risk of infection, extrusion, and necrosis. Depending on the type of surgery or the incision, wound healing times may vary. You should contact your surgeon immediately if your wound does not heal within the period of time he/she has discussed with you.

### **Breast Tissue Atrophy/Chest Wall Deformity**

<sup>14</sup> The pressure of the breast implant may cause breast tissue thinning (with increased implant visibility and palpability) and chest wall deformity. This can occur while implants are still in place or following implant removal without replacement. Either of these conditions may result in additional surgeries and/or unacceptable dimpling/puckering of the breast.

### **Lymphadenopathy**

Lymphadenopathy is a chronic enlargement of the lymph nodes. A lymph node is a round mass of tissue which makes cells as part of your immune system. The lymph nodes in the armpit (axilla) drain the breast area of fluid. Some patients with breast implants report having enlarged lymph nodes in the armpit(s). Some reports associate lymphadenopathy with both intact and ruptured silicone gel-filled breast implants. There is information in the literature that shows that armpit lymph nodes from women with silicone gel-filled breast implants had abnormal tissue reactions, granulomas, and the presence of silicone. This occurred in women both with ruptured and intact implants. These reports were in women who had implants from a variety of manufacturers and implant models.

Sometimes the enlarged lymph nodes are painful. If they become too large or painful, the lymph node(s) may need to be surgically removed. Painful and/or enlarged lymph nodes should be reported to your doctor.

## **2.2 What Are Other Reported Conditions?**

There have been reports of other conditions in women with breast implants. Many of these conditions have been studied to evaluate their potential association with breast implants. Although no cause and effect relationship has been established between breast implants and the conditions listed below, you should be aware of these reports. Furthermore, there is the possibility of risks, yet unknown, which in the future could be determined to be associated with breast implants.

### **Connective Tissue Disease**

Connective tissue diseases include diseases such as lupus, scleroderma, and rheumatoid arthritis. Fibromyalgia is a disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue. There have been a number of published epidemiological studies which have looked at whether having a breast implant is associated with having a typical or defined connective tissue disease. The study size needed to conclusively rule out the risk of a rare connective tissue disease would need to be very large. Published studies taken together show that breast implants are not significantly associated with a risk of developing a specific connective tissue disease. These studies do not distinguish between women with intact and ruptured implants. Only one study evaluated specific CTD diagnoses and symptoms in women with silent ruptured versus intact implants, but the study was too small to rule out a small risk.

### **Cancer**

- **Breast Cancer** – Reports in the medical literature indicate that patients with breast implants are not at a greater risk than those without breast implants for developing breast cancer. Some reports have suggested that breast implants may interfere with or delay breast cancer detection by mammography and/or biopsy; however, other reports in the published medical literature indicate that breast implants neither

significantly delay breast cancer detection nor adversely affect cancer survival of women with breast implants.

- **Brain Cancer** – One recent study has reported an increased incidence of brain cancer in women with breast implants as compared to the general population. The incidence of brain cancer, however, was not significantly increased in women with breast implants when compared to women who had other plastic surgeries. Another recently published review of four large studies in women with cosmetic implants concluded that the evidence does not support an association between brain cancer and breast implants.

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- **Respiratory/Lung Cancer** – One study has reported an increased incidence of respiratory/lung cancer in women with breast implants. Other studies of women in Sweden and Denmark have found that women who get breast implants are more likely to be current smokers than women who get breast reduction surgery or other types of cosmetic surgery.

- **Cervical/Vulvar Cancer** – One study has reported an increased incidence of cervical/vulvar cancer in women with breast implants. The cause of this increase is unknown.

- **Other Cancers** – One study has reported an increased incidence of stomach cancer and leukemia in women with breast implants compared to the general population. This increase was not significant when compared to women who had other types of plastic surgeries.

## Neurological

Some women with breast implants have complained of neurological symptoms (such as difficulties with vision, sensation, muscle strength, walking, balance, thinking or remembering things) or diseases (such as multiple sclerosis), which they believe are related to their implants. A scientific expert panel report found that the evidence for a neurological disease or syndrome caused by or associated with breast implants is insufficient or flawed.

## Suicide

In several studies, a higher incidence of suicide was observed in women with breast implants. The reason for the observed increase is unknown, but it was found that women with breast implants had higher rates of hospital admission due to psychiatric causes prior to surgery, as compared with women who had breast reduction or in the general population of Danish women.

## Effects On Children

At this time, it is not known if a small amount of silicone may pass through from the breast implant silicone shell into breast milk during breastfeeding. Although there are no current established methods for accurately detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone gel-filled breast implants when compared to women without implants.

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In addition, concerns have been raised regarding potential damaging effects on children born to mothers with implants. Two studies in humans have found that the risk of birth defects overall is not increased in children born after breast implant surgery. Although low birth weight was reported in a third study, other factors (for example, lower pre-pregnancy weight) may explain this finding. One of the authors of these human studies recommended further research on infant health.

## Gel Bleed

A concern related specifically to silicone gel-filled breast implants is that small amounts of the silicone fluid or oil may bleed through the shell and travel into the surrounding tissue. This escaped silicone fluid or oil might cause local complications. There is inadequate information to determine whether or not gel bleed is a problem because there have been no studies that measure the amount of gel bleed and relate it to complications. Laboratory testing conducted by INAMED has shown that only minimal amounts of the silicone gel filler bleed across an intact silicone shell over time and that the make-up of this gel does not pose a health concern.

Clinically, there has been no evidence in the medical literature or from INAMED's own testing associating gel bleed (gel elements moving through the implant shell) with complications in breast implant patients.

### **Delayed-Type Hypersensitivity**

While there is no scientific evidence that silicone can cause hypersensitivity reactions in humans, some animal testing reports in the literature suggest evidence of a delayed-type hypersensitivity to silicone. The biological mechanism and outcome for these findings in animal models remain unknown.

## 18 **3. INAMED's Clinical Studies**

This section of the brochure summarizes the results of the INAMED Core Study conducted on INAMED Silicone-Filled Breast Implants for primary reconstruction and revision-reconstruction. The results of the Core Study give you useful information on the experience of other women with INAMED Silicone-Filled Breast Implants. While the results cannot be used to predict your individual outcome, they can be used as a general guide of what you may expect. Your own complications and benefits depend on many individual factors.

### **3.1 Overview Of INAMED's Core Study**

The INAMED Core Study is a 10-year study to assess safety and effectiveness in augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients. Patient follow-up is at 0–4 weeks, 6 months, 12 months, 24 months, and annually through 10 years. Safety is assessed by complications, such as implant rupture, capsular contracture, and reoperation. Benefit (effectiveness) is assessed by patient satisfaction and measures of body image/esteem and self esteem.

The INAMED Core Study consisted of 715 patients. This includes 455 reconstruction patients, 147 revision-reconstruction patients,

98 reconstruction patients, and 15 revision-reconstruction patients. The study is currently ongoing, with the results through 4 years reported in this brochure. INAMED will periodically update this brochure as more information becomes available.

INAMED's Core Study results indicate that the risk of any complication at some point through 4 years after implant surgery is 58.3% for primary reconstruction patients and 60.0% for revision-reconstruction patients. However, the majority of women were satisfied with their implants. The results also indicate that the chance of additional surgery (reoperation) through the first 4 years is 2 in 5 for primary reconstruction patients (with implant removal and replacement as the most common type of additional surgery), and 1 in 3 for revision-reconstruction patients (with the most common type of additional surgery being revision of nipple reconstruction/tattoo). The information below provides more details about the complications and benefits you may experience.

INAMED also conducted another study called the Adjunct Study, which reports complications for a large number of reconstruction and revision patients at 1, 3, and 5 years. Because of the low follow-up rates, which make the data of limited value, Adjunct Study data are not provided in this brochure.

Described below are the benefits and complications reported in the INAMED Core Study for reconstruction patients. The findings are described separately for primary reconstruction and revision-reconstruction patients.

### **3.2 What Were The 4-Year Follow-Up Rates?**

The Core Study enrolled 98 reconstruction patients. Of the women expected to be seen at the 4-year follow-up visit, 89% were seen.

The Core Study enrolled 15 revision-reconstruction patients. Of the women expected to be seen at the 4-year follow-up visit, 100% were seen.

### 3.3 What Were The Benefits?

The benefits of silicone gel-filled breast implants were assessed by a variety of outcomes, including bra cup size change and assessments of patient satisfaction, body image, body esteem, and self concept. Data were collected before implantation and at scheduled follow-up visits for those patients who still had their original implants and who came back for these visits.

#### **Primary Reconstruction Patients**

INAMED's satisfaction assessment was based on patients' ratings of satisfaction with their implants at the time of the follow-up visits. 67 (68%) of the original 98 patients provided a satisfaction rating at 4 years after implantation with 94% of these patients indicating that they were satisfied with their breast implants.

For primary reconstruction patients, the SF-36, which measures mental and physical health, showed no changes after 4 years compared to before breast implantation. For patient responses to questions regarding overall self-concept/self-esteem, there was no change in self-concept on the Tennessee Self Concept Scale and no change in overall self esteem on the Rosenberg Self Esteem Scale 4 years after receiving implants. Patient responses to questions on the Body Esteem Scale regarding overall body image also did not show a change 4 years after receiving implants.

#### **Revision-Reconstruction Patients:**

INAMED's satisfaction assessment was based on patients' ratings of satisfaction with their implants at the time of the follow-up visits. 13 (87%) of the original 15 revision-reconstruction patients provided a satisfaction rating at 4 years. Of these 13 patients, 92% indicated that they were satisfied with their breast implants.

For revision-reconstruction patients, responses were similar pre- and post-implantation on the SF-36, Tennessee Self Concept Scale, Rosenberg Self Esteem Scale and Body Esteem Scale.

### 3.4 What Were The 4-Year Complication Rates?

#### **Complications Reported In The Core Study For Primary Reconstruction**

The complications observed in women through 4 years are presented in Table 1. The rates reflect the number of reconstruction patients out of 100 who experienced the listed complication at least once within the first 4 years after their implantation. Some complications occurred more than once for some patients. The most common complications experienced within the first 4 years of implantation was reoperation (40.9% or approximately 41 patients out of 100). *Please refer to the Glossary at the back of this brochure for the definition of any complication you may not understand.*

TABLE 1

## Primary Reconstruction: Complications

**Complication\*** **4-Year Complication Rate by Patient**

Reoperation 40.9%

Implant Removal with Replacement 18.3%

Asymmetry 16.4%

Capsular Contracture III/IV 14.1%

Implant Removal without Replacement 7.8%

Swelling 7.2%

Wrinkling/Rippling 6.0%

Infection 4.2%

Implant Malposition 3.3%

Breast Pain 3.1%

Implant Extrusion 2.3%

Tissue/Skin Necrosis 2.3%

Hypertrophic Scarring 2.1%

Skin Rash 2.0%

Redness 1.1%

Bruising 1.0%

Nipple Sensation Changes 1.0%

Ptosis 1.0%

Capsule Calcification, Delayed Wound Healing, Hematoma, Implant Palpability/Visibility, Implant Rupture (MRI cohort), Irritation, Lymphadenopathy, Lymphedema, Other Complications, Other Nipple Related Observation, Pneumothorax, Seroma/Fluid Accumulation, Skin Sensation Changes 0%

\*Most events were assessed with severity ratings, and the rates shown in the table include only complications rated moderate, severe or very severe (excludes mild and very mild ratings). All occurrences of reoperation, implant removal, implant rupture, implant extrusion and pneumothorax are included.

## Complications Reported In The Core Study For Revision-Reconstruction

The complications observed in women through 4 years are presented in Table 2. The rates reflect the number of revision-reconstruction patients out of the 15 enrolled who experienced the listed complication at least once within the first 4 years after their implantation. Some complications occurred more than once for some patients. The most common complication experienced within the first 4 years of implantation was reoperation (33.3%). Please refer to the Glossary at the back of this brochure for the definition of any complication you may not understand.

TABLE 2

## Revision-Reconstruction: Complications

**Complication\*** **4-Year Complication Rate by Patient**

Reoperation 33.3%

Asymmetry 13.3%

Implant Malposition 13.3%

Breast Pain 6.7%

Bruising 6.7%

Capsular Contracture III/IV 6.7%

Delayed Wound Healing 6.7%

Hypertrophic Scarring 6.7%

Implant Palpability/Visibility 6.7%

Seroma/Fluid Accumulation 6.7%

Wrinkling/Rippling 6.7%

Capsule Calcification, Hematoma, Implant Extrusion, Implant Removal, Implant Rupture (MRI cohort), Infection, Irritation, Lymphadenopathy, Lymphedema, Nipple Sensation Changes, Other Complications, Other Nipple Related Observation, Pneumothorax, Ptosis, Redness, Skin Rash, Skin Sensation Changes, Swelling, Tissue/Skin Necrosis 0%

\*Most events were assessed with severity ratings, and the rates shown in the table include only complications rated moderate, severe or very severe (excludes mild and very mild ratings). All occurrences of reoperation, implant removal, implant rupture, implant extrusion and pneumothorax are included.

## Other Events

Through 4 years, events other than the complications described in the previous tables were collected in the Core Study for reconstruction and revision-reconstruction patients. Some of these events, such as breast cancer and CTD, can occur in non-implanted patients. Therefore, without a comparison group of women with similar characteristics (such as age, race, etc.) and without breast implants, no conclusions can be made about the relationship between breast implants and some of these other events. Events equal to or greater than 1% are described in Tables 3 and 4.

TABLE 3

### Primary Reconstruction: Other Events

Other Event	4-Year Rate by Patient
Benign Breast Disease	15%
Malignant Breast Cancer	8%
Biopsy Procedure	6%
CTD - Systemic Sclerosis/Scleroderma	1%

TABLE 4

### Revision-Reconstruction: Other Events

Other Event	4-Year Rate by Patient
Benign Breast Disease	13%

## 3.5 What Were The Main Reasons For Reoperation?

There may be one or more reasons identified for having a reoperation (additional surgery after the primary or revision breast reconstruction). Furthermore, there may be multiple surgical procedures (for example, implant removal with or without replacement, capsule procedures,

incision and drainage, implant reposition, scar revision, etc.) performed during a reoperation.

There were 121 additional surgical procedures performed during 54 reoperations involving 39 primary reconstruction patients. The most common reason for reoperation through 4 years in primary reconstruction patients was because of implant malposition (22.2% of 54 reoperations). The most common type of additional surgery through 4 years was implant removal/replacement to treat unsatisfactory cosmetic result (18.5% of 54 reoperations).

Table 5 below provides the main reason for each reoperation performed through 4 years in primary reconstruction patients.

TABLE 5

### Primary Reconstruction: Main Reason For Reoperation Through 4 Years

Reason for Reoperation	n	% (of 54 Reoperations)
Implant Malposition	12	22.2%
Capsular Contracture	10	18.5%
Asymmetry	8	14.8%
Hematoma/Seroma	6	11.1%
Need for Biopsy	3	5.6%
Ptosis	3	5.6%
Scarring	3	5.6%
Breast Tissue Contour Deformity	2	3.7%
Implant Extrusion	2	3.7%
Patient Request for Style/Size Change	2	3.7%
Delayed Wound Healing	1	1.9%
Implant Rupture	1	1.9%
Necrosis	1	1.9%

There were 8 additional surgical procedures performed during 7 reoperations involving 5 revision-reconstruction patients. The most common reason for reoperation through 4 years in revision-reconstruction patients was because of nipple complications (57.1% of 7 reoperations). The most common type of additional surgery through 4 years was revision of nipple reconstruction/tattoo (4 of 7 reoperations).

Table 6 below provides the main reason for each reoperation performed through 4 years in revision-reconstruction patients.

TABLE 6

### Revision-Reconstruction: Main Reason For Reoperation through 4 Years

Reason for Reoperation	n	% (of 7 Reoperations)
Nipple Complications	4	57.1%
Scarring	2	28.6%
Capsular Contracture	1	14.3%

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## 3.6 What Were The Main Reasons For Implant Removal?

The main reasons for implant removal among primary reconstruction patients in the Core Study over the 4 years are shown in Table 7 below. There were 28 implants removed in 23 patients. Of these 28 implants, 21 (75.0%) were replaced. The most common reason for implant removal was implant malposition (28.6% of the 28 implants removed).

TABLE 7

### Primary Reconstruction: Main Reason For Implant Removal through 4 Years

Reason for Removal	n	% (of 28 Explants)
Implant Malposition	8	28.6%
Capsular Contracture	7	25.0%
Asymmetry	4	14.3%
Patient Request for Style/Size Change	4	14.3%
Hematoma/Seroma	2	7.1%
Implant Extrusion	1	3.6%
Implant Rupture	1	3.6%
Necrosis	1	3.6%

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There were no implant removals among revision-reconstruction patients in the Core Study over 4 years.

## 4. Surgical Considerations For Breast Reconstruction

### 4.1 What Are The Alternatives To Breast Reconstruction With Silicone Gel-Filled Breast Implants?

For primary reconstruction patients, alternatives may include:

- Accept your breasts as they are and have no surgery.
- Wear a padded bra or external prostheses.
- Have mastopexy surgery (breast lift) without an implant.
- Have reconstruction using your own tissue (flap procedure).

- Have surgery with saline implants.

For revision-reconstruction patients, alternatives may include:

- No revision.
- Removal with or without replacement.

## 4.2 Choosing A Surgeon

When choosing a surgeon who is experienced with breast reconstruction, you should know the answers to the following types of questions:

- How many breast reconstruction implantation procedures does he/she perform per year?
- How many years has he/she performed breast reconstruction procedures?
- Has he/she completed INAMED's Physician Education Program for the use of its silicone gel-filled breast implants?
- Is he/she board certified, and if so, with which board?
- In which province(s) is he/she licensed to practice surgery? (Note that some provinces provide information on disciplinary action and malpractice claims/settlements to prospective patients, either by request or on the Internet.)
- What is the most common complication he/she encounters with breast reconstruction?
- What is his/her reoperation rate with breast reconstruction, and what is the most common type of reoperation he/she performs?
- Can he/she perform this surgery in a hospital, as well as in the surgeon's independent surgery center? (Note that hospitals require evidence of appropriate training in specific procedures before allowing surgeons to operate in their facilities.)

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## 4.3 What Are Other Choices And Options Associated With The Surgery?

### Implant Shape And Size

Depending on the desired shape you wish to achieve, you and your surgeon have implants with three different profiles, or styles, from which to choose. Generally, the larger you want your cup size, the larger the breast implant the surgeon will consider (measured in cubic centimeters, or cc's), not in cup sizes, because this depends on the size and shape of the individual woman's chest.

Your surgeon will also evaluate your existing breast and skin tissue to determine if you have enough tissue to cover the breast implant you are considering, or, in some cases such as after pregnancy, too much extra skin. If you desire a breast implant size that is too large for your tissue, the surgeon may warn you that breast implant edges may be visible or palpable postoperatively. Also, excessively large breast implants may speed up the effects of gravity on the breast, and can result in droop or sag at an earlier age. A recent report indicates that larger sized implants (greater than 350 cc) may be too large for many women, increasing the risk of developing complications such as extrusion, hematoma, infection, palpable implant folds, and visible skin wrinkling requiring surgical intervention to correct these complications.

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### Surface Texturing

Some studies suggest that surface texturing reduces the chance of severe capsular contracture, while other studies do not. INAMED's Core Study did not show a difference in the likelihood of developing capsular contracture with textured implants compared to smooth-surfaced implants.

A textured implant may require a larger incision because the rougher textured surface may make it harder to place into the pocket without undue stress, which might damage the implant or decrease its durability.

## Incision Sites

Most implants in breast reconstruction use the mastectomy scar either immediately (during the mastectomy procedure) or after tissue expansion.

## Surgical Approach

Women with small or medium sized breasts are the best candidates for breast reconstruction. Reconstruction patients commonly undergo additional surgeries to improve breast symmetry and appearance. For example, because the nipple and areola are usually removed with the breast tissue in mastectomy, the nipple is usually reconstructed by using a skin graft from another area of the body or the opposite breast, in addition to tattooing the area. Nipple reconstruction is usually done as a separate outpatient procedure after the initial reconstruction surgery is complete.

Your surgeon will decide whether your health and medical condition makes you an appropriate candidate for breast implant reconstruction. Women with larger breasts may require reconstruction with a combination of a tissue flap and an implant. Your surgeon may recommend breast implantation of the opposite, uninvolved breast in order to make your breasts more alike (maximize symmetry) or he/she may suggest breast reduction (reduction mammoplasty) or a breast lift (mastopexy) to improve symmetry. Mastopexy involves removing a strip of skin from under the breast or around the nipple and using it to lift and tighten the skin over the breast. Reduction mammoplasty involves removal of breast tissue and skin. If it is important to you not to alter the unaffected breast, you should discuss this with your plastic surgeon, as it may affect the breast reconstruction methods considered for your case.

## Palpability

Implants may be more palpable or noticeable if there is an insufficient amount of skin/tissue available to cover the implant and/or when the implant is placed subglandularly.

## Surgical Setting And Anesthesia

Reconstruction surgery is usually performed on an inpatient basis in an operating room. General anesthesia is most often used. You should be sure to check with your surgeon and with the facility where the surgery will take place, to become aware of the tests, presurgical examinations, and length of time you need to be without food or your routine medications prior to the surgical procedure.

## Timing Of Breast Reconstruction

The following description applies to reconstruction following mastectomy, but similar considerations apply to reconstruction following breast trauma or for reconstruction for congenital defects. The breast reconstruction process may begin at the time of your mastectomy (immediate reconstruction) or weeks to years afterwards (delayed reconstruction). Immediate reconstruction may involve placement of a breast implant but typically involves placement of a tissue expander, which will eventually be replaced with a breast implant. It is important to know that any type of surgical breast reconstruction may take several steps to complete.

Two potential advantages to immediate reconstruction are that your breast reconstruction starts at the time of your mastectomy and that there may be cost savings in combining the mastectomy procedure with the first stage of the reconstruction. However, there may be a higher risk of complications with immediate reconstruction, and your initial operative time and recuperative time may be longer.

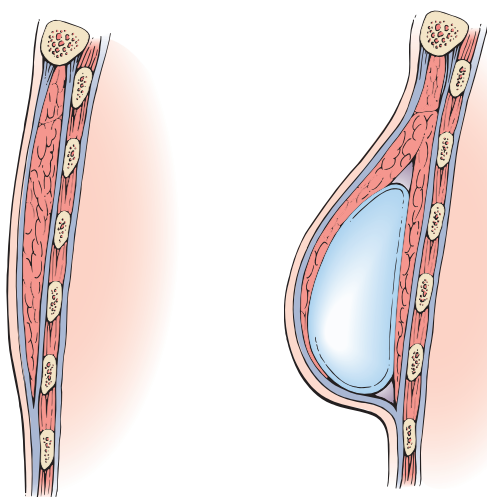
A potential advantage to delayed reconstruction is that you can delay your reconstruction decision and surgery until other treatments, such as radiation therapy and chemotherapy, are completed. Delayed reconstruction may be advisable if your surgeon anticipates healing problems with your mastectomy or if you just need more time to consider your options. There are medical, financial, and emotional considerations to choosing immediate versus delayed reconstruction. You should discuss with your surgeon, plastic surgeon, and oncologist, the advantages and disadvantages of immediate reconstruction with a breast implant, expander-assisted immediate reconstruction, and delayed reconstruction.

## Immediate Or Delayed Breast Implant Reconstruction

Breast reconstruction using only a breast implant may be done immediately at the time of your mastectomy or sometime thereafter. After the general surgeon removes your breast tissue, the plastic surgeon will then implant a breast implant that completes the reconstruction. In reconstruction following mastectomy, a breast implant is most often placed submuscularly.

## Expander-Assisted (Immediate Or Delayed) Breast Implant Reconstruction

Breast reconstruction usually occurs as a multistage procedure, starting with the placement of a breast tissue expander, which is replaced several months later with a breast implant. The tissue expander placement may be done immediately, at the time of your mastectomy, or be delayed until months or years later.



Side View,  
Breast Tissue Removed

Side View,  
Expander Inserted and Filled

## Tissue Expansion

During a mastectomy, the general surgeon removes skin as well as breast tissue, leaving the chest tissues flat and tight. To create a breast shaped space for the breast implant, a tissue expander is placed under the remaining chest tissues.

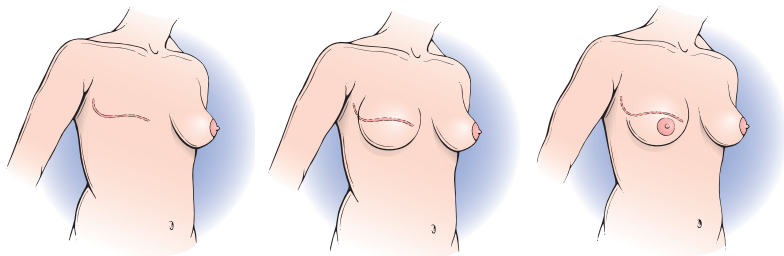
The tissue expander is a balloon-like device made from elastic silicone rubber. It is inserted unfilled, and over time, sterile saline fluid is added by inserting a small needle through the skin to the filling port of the device. As the tissue expander fills, the tissues over the expander begin to stretch, similar to the gradual expansion of a woman's abdomen during pregnancy. The tissue expander creates a new breast-shaped pocket for a breast implant.

Tissue expander placement usually occurs under general anesthesia in an operating room. Operative time is generally 1 to 2 hours. The procedure may require a brief hospital stay or be done on an outpatient basis. Typically, you can resume normal daily activity after 2 to 3 weeks.

Because the chest skin is usually numb from the mastectomy surgery, it is possible that you may not experience pain from the placement of the tissue expander. However, you may experience feelings of pressure, tightness or discomfort after each filling of the expander, which subsides as the tissue expands but may last for a week or more. Tissue expansion typically takes four to six months.

## Placing The Breast Implant

After the tissue expander is removed, the breast implant is placed in the pocket. In reconstruction, following mastectomy, a breast implant is most often placed submuscularly. The surgery to replace the tissue expander with a breast implant (implant exchange) is usually done under general anesthesia in an operating room. It may require a brief hospital stay or be done on an outpatient basis.



Post Mastectomy

Stage 1: Tissue Expander Placed and Expansion Underway

Stage 2: Breast Implant and Nipple/Areola Reconstruction

## Postoperative Care

You will probably feel somewhat tired and sore for several days following the operation, and your breasts may remain swollen and sensitive to physical contact for a month or longer. You may also experience a feeling of tightness in the breast area as your skin adjusts to your new breast size. The feeling in the breasts and nipple area also may be diminished during this time of swelling and immediate post surgery recovery. Other possible complications have been described above.

Postoperative care depends on each patient's situation, may involve the use of a special postoperative bra, compression bandage, or jog bra for extra support and positioning while you heal. Some surgeons may not want you to wear a bra at all for a period of time following the surgery. At your surgeon's recommendation, you will most likely be able to return to work within a few days, although for at least a couple of weeks you should avoid any strenuous activities that could raise your pulse and blood

pressure, or require strenuous use of your arms and chest. Your surgeon may also recommend breast massage exercises.

*Note: If you experience fever, do not feel well, or see noticeable swelling and/or redness or drainage in your implanted breast(s), you should contact your surgeon immediately.*

## Other Factors To Consider In Revision-Reconstruction Surgery

Some revision surgeries require removal of an intact implant (for example, capsulotomy and pocket adjustments), while others do not require removal of the implant. Any device that has been removed during revision surgery should not be reimplanted. INAMED breast implants are "for single use only."

## 4.4 Follow-Up Examinations

### Breast Self-Examinations

Following breast reconstruction you should continue to perform breast self-examinations monthly. This may be more difficult with a breast implant in place. To continue to perform monthly breast self examinations efficiently, you should ask your surgeon to help you identify the difference between the implant and your breast tissue. Being able to identify the implant from breast tissue will decrease the necessity of excessive squeezing of the implant during examination. Any new lumps should be evaluated with a biopsy, as appropriate. If a biopsy is performed, be sure to inform the medical professional performing the biopsy that you have breast implants so that care will be taken to avoid injuring the implant.

### Screening For Silent Rupture

Because most ruptures of silicone gel-filled breast implants are silent, in most cases neither you nor your surgeon will be able to find evidence of rupture. Therefore, evaluation of your implants is needed to screen for implant rupture.

It is recommended that you take a multi-step approach to monitor the integrity of the implant throughout the lifetime of the device beginning with a patient self examination. Obtain an ultrasound or mammogram if a new symptom or sign is suspected or as part of a periodic review with a physician. If the ultrasound is negative or inconclusive obtain an MRI. If MRI results suggest a rupture discuss explantation of the implant with your plastic surgeon.

### Symptomatic Rupture

Symptoms associated with rupture may include hard knots or lumps surrounding the implant or in the armpit, loss of size of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast. If you notice any of these changes, see your plastic surgeon so that he or she can examine the implants for rupture or other changes. You may need to have an MRI examination to determine whether your symptoms are due to rupture of the implant. If rupture has occurred, you should consider having your implant removed. Consult with your doctor regarding this and any other medical decisions related to your implants. More information on rupture is provided on page 8 of this brochure.

### Mammography

The current recommendations for getting screening/preoperative mammograms are no different for women with breast implants than for those without implants. Mammography exams should be interpreted by radiologists experienced in the evaluation of women with breast implants. It is essential that you tell your mammography technologist before the procedure that you have an implant, and you should request a diagnostic mammogram, rather than a screening mammogram. The technologist can use special techniques to reduce the possibility of rupture and to get the best possible views of the breast tissue.

## 5. Additional Information

### 5.1 Types Of Silicone Gel-Filled Breast Implants Available From INAMED

INAMED's Silicone-Filled Breast Implants come in a variety of profiles and sizes with either a textured shell or smooth surface shell.

The table below shows the INAMED implants that were approved by Health Canada. Your plastic surgeon will discuss with you the implant design that will best help you achieve the result you desire.

#### Approved INAMED Implant Styles

Style Number	Breast Implant Description	Size Range
Style 10	Smooth shell surface, moderate profile	120cc – 800cc
Style 15	Smooth shell surface, mid-range profile	155cc – 752cc
Style 20	Smooth shell surface, high profile	120cc – 800cc
Style 40	Smooth shell surface, moderate profile	80cc – 560cc
Style 45	Smooth shell surface, full profile	120cc – 800cc
Style 110	BIOCELL® Textured shell surface, moderate profile	90cc – 510cc
Style 115	BIOCELL® Textured shell surface, mid-range profile	150cc – 716cc
Style 120	BIOCELL® Textured shell surface, high profile	180cc – 650cc

## 5.2 If You Experience A Problem

You should immediately report any problems that you notice with your implants to your plastic surgeon. If you believe that you have experienced a serious problem(s) related to your breast implants, you should have your health professional report the problem(s) to INAMED.

### Device Identification Card

You will also be given a device identification card with the style and serial number of your breast implant(s). This card is for your permanent record and should be kept in a safe place. In the event you have a concern or problem with your implant you can use this card to describe the implant to your health care provider or to INAMED.

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## 5.3 ConfidencePlus™ Limited Warranties

The ConfidencePlus™ Limited Warranties provide lifetime replacement and limited financial reimbursement in the event of shell leakage or breakage resulting in implant rupture, subject to certain conditions as fully discussed in the ConfidencePlus™ literature. INAMED offers two levels of coverage under its warranty program. Our standard ConfidencePlus™ Limited Warranty program applies automatically to every INAMED breast implant recipient subject to the conditions discussed in the ConfidencePlus™ literature. The optional ConfidencePlus™ Platinum Limited Warranty program is available for a low enrollment fee and increases the financial benefit in the event of implant rupture, subject to the conditions discussed in the ConfidencePlus™ literature. For more information, please contact INAMED's Product Support Department at 800.962.8728.

## 5.4 How To Receive More Information

Upon request, you will be provided with a copy of the package insert (Information for Physicians/"Directions for Use" document). You can request a copy from your surgeon or from INAMED. The package insert has many undefined medical and technical terms because it contains information directed only to the surgeon.

For more detailed information on the preclinical and clinical studies conducted by INAMED, you are referred to the Summary Basis for Decision (SBD) document on Health Canada's website ([www.hc-sc.gc.ca](http://www.hc-sc.gc.ca)).

If, after reading this information, you have additional questions about breast implants or breast implant surgery, there are a number of resources available to you. 39

### Toll-Free Number

If you are a patient or a prospective patient and wish to speak to an INAMED Aesthetics Breast Implant Support Specialist to inquire about breast implants, discuss any concerns, or request a copy of the patient labeling or package insert (Directions for Use), call toll free at 800.962.8728.

### Additional Resources

INAMED Aesthetics

1.800.624.4261

[www.INAMED.com](http://www.INAMED.com)

Health Canada

[www.hc-sc.gc.ca](http://www.hc-sc.gc.ca)

Institute of Medicine Report on the Safety of Silicone Implants

[www.nap.edu/catalog/9618.html](http://www.nap.edu/catalog/9618.html)

Food and Drug Administration

1.888.INFO-FDA or 301.827.3990

[www.fda.gov/cdrh/breastimplants/](http://www.fda.gov/cdrh/breastimplants/)

# Glossary

Areola	The pigmented or darker colored area of skin surrounding the nipple of the breast.
Asymmetry	Lack of proportion of shape, size, and/or position between the two breasts.
Autoimmune Disease	A disease in which the body mounts an “attack” response to its own tissues or cell types. Normally, the body’s immune mechanism is able to distinguish clearly between what is a normal substance and what is foreign. In autoimmune diseases, this system becomes defective and mounts an attack against normal parts of the body, causing tissue injury. Certain diseases such as rheumatoid arthritis, lupus, and scleroderma are considered to be autoimmune diseases.
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Axillary	Pertaining to the armpit area.
Biocompatible	The condition of being compatible with living tissues or systems without being toxic.
Biopsy	The removal and examination of tissues, cells, or fluid from the body.
Body Esteem Scale	A questionnaire which asks about a person’s body image.
Breast Augmentation	A surgical procedure to increase breast size. For this document, it refers to placement of a breast implant.
Breast Implant	An internal artificial device or implant intended to replace the breast.
Breast Mass	A lump or body in the breast.

**Breast Reconstruction** A surgical procedure to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. For this document, it refers to placement of a breast implant. The first time a breast implant is placed, it is called primary reconstruction. All subsequent times the implant is replaced, it is called revision-reconstruction.

**Calcification** Process of hardening by calcium salts.

**Capsule** Scar tissue which forms around the breast implant. Sometimes this capsule squeezes the implant, resulting in capsular contracture (below).

**Capsular Contracture** A tightening of the tissue capsule surrounding an implant, resulting in firmness or hardening of the breast and in squeezing of the implant if severe. Capsular contracture is classified by Baker Grades. Grades III or IV are the most severe. Grade III may result in the need for additional surgery (reoperation) because of pain and possibly abnormal appearance. Grade IV usually results in the need for additional surgery (reoperation) because of pain and unacceptable appearance. Capsular contracture is a risk for implant rupture. Below is a description of each Baker Grade.

Baker Grade I – Normally soft and natural appearance

Baker Grade II – A little firm, but breast looks normal

Baker Grade III – More firm than normal, and looks abnormal (change in shape)

Baker Grade IV – Hard, obvious distortion, and tenderness with pain

Capsulectomy	Surgical removal of the scar tissue capsule around the implant.		effectiveness data are collected yearly through 10 years, with the follow-up from years 5 through 10 being performed as part of a postapproval Core Study.
Capsulorrhaphy	Surgical stitching of a tear in the scar tissue capsule around the implant.		
Capsulotomy (Closed)	An attempt to break the scar tissue capsule around the implant by pressing or pushing on the outside of the breast. This method does not require surgery but is a known risk for rupture of the implant and is contraindicated.	Delayed Wound Healing	Delayed progress in the healing of an opened wound.
		Displacement	Movement of the implant from the usual or proper place.
Capsulotomy (Open)	Surgical incision into the scar tissue capsule around the implant.	Epidemiological	Relating to the science of explaining the relationships of factors that determine disease frequency and distribution.
42 Congenital Anomaly	An abnormal development in part of the body.	Extracapsular Rupture	A type of rupture in which the silicone gel is outside of the scar tissue capsule surrounding the implant. 43
Connective Tissue Disease/Disorder (CTD)	A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc. and/or the immune system. Connective tissue diseases ("CTDs") that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma. Although not a disease, fibromyalgia is generally considered a CTD because it involves pain in the connective tissues.	Extrusion	Skin breakdown with the pressing out of the implant through the surgical wound or skin.
		Fibromyalgia	A disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue.
Contraindication	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.	Fibrous Tissues	Connective tissues composed mostly of fibers.
		Granuloma	A lump or mass made of inflammatory cells surrounding a foreign substance due to longstanding inflammation.
Contralateral	Opposite side.	Hematoma	A collection of blood within a space.
Core Study	The primary clinical study of augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients that supported the approval of the premarket approval (PMA) application. Safety and	Hypertrophic Scarring	An enlarged scar remaining after the healing of a wound.
		Immune Response	A bodily response to the presence of a foreign substance.

44	<p>Infection                    Invasion with microorganisms (for example, bacteria, viruses). An infection usually results in fever, swelling, redness and/or pain.</p> <p>Inflammation                The response of the body to infection or injury that is characterized by redness, swelling, warmth, pain, and/or loss of function.</p> <p>Inframammary                Below the breast.</p> <p>Inframammary Incision     An incision made in the fold below the breast.</p> <p>Inpatient Surgery            A surgical procedure in which the patient is required to stay overnight in the hospital.</p> <p>Intracapsular Rupture      A type of rupture in which the silicone gel remains inside the scar tissue capsule surrounding the implant.</p> <p>Lactation                     The production and secretion of milk by the breast glands.</p> <p>Lymphadenopathy            Enlargement of the lymph node(s).</p> <p>MRI                            Magnetic resonance imaging. A radiographic examination that currently has the best ability to detect rupture of silicone gel-filled breast implants.</p> <p>Mammary                     Pertaining to the breast.</p> <p>Mammography                A type of X-ray examination of the breasts used for detection of cancer.</p> <p>Mammoplasty                Plastic surgery of the breast.</p> <p>Mastopexy                    Plastic surgery to move sagging breasts into a more elevated position.</p> <p>Metastatic Disease            Spreading of cancer cells from the original site to other parts of the body.</p> <p>Migration                     Movement of silicone materials outside the breast implant.</p>	<p>Necrosis                      Death of cells or tissues.</p> <p>Outpatient Surgery            A surgical procedure in which the patient is not required to stay in the hospital overnight.</p> <p>Palpate                        To feel with the hand.</p> <p>Palpability                    The ability to feel the implant.</p> <p>Pectoralis                     Major muscle of the chest.</p> <p>Periareolar                    Around the darkened or pigmented area surrounding the nipple of the breast.</p> <p>Plastic Surgery                Surgery intended for the improvement of appearance of the body.</p> <p>Postoperatively                After surgery.</p> <p>Primary Breast Reconstruction     The first time a breast implant is placed for the purpose of breast reconstruction.</p> <p>Ptosis                         Breast sagging that is usually the result of normal aging, pregnancy, or weight loss.</p> <p>Reoperation                    An additional surgery after your first breast implantation.</p> <p>Revision-Reconstruction     Refers to the correction or improvement of an original primary reconstruction. In the context of this document, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast reconstruction.</p> <p>Rheumatological Disease/Disorder     A variety of diseases involving connective tissue structures of the body, especially the joints and fibrous tissue. These diseases are often associated with pain, inflammation, stiffness, and/or limitation of motion of the affected parts. Can include autoimmune diseases. Fibromyalgia is a rheumatological disorder.</p>	45
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Rosenberg Self Esteem Scale A questionnaire which measures overall self esteem.

Rupture An opening in the implant shell. Silicone gel-filled implant ruptures may be silent or symptomatic. Ruptures can be intracapsular or extracapsular.

Saline A solution that is made up of water and a small amount of salt.

Scar Revision A surgical procedure to improve the appearance of a scar.

Seroma A build-up of the watery portion of the blood in a tissue location.

SF-36 Scale A questionnaire intended to measure physical, mental, and social health.

Silent Rupture A rupture without symptoms and which is not apparent except through appropriate imaging techniques such as MRI. Most silicone gel-filled breast implant ruptures are silent. (see symptomatic rupture below).

Silicone Elastomer A type of silicone that has elastic properties similar to rubber.

Subglandular Placement Placement of a breast implant underneath and within the breast glands but on top of the chest muscle.

Submuscular Placement Placement of a breast implant wholly or partially underneath the chest muscle.

Surgical Incision A cut made to body tissue during surgery.

Symptom Any perceptible change in the body or its functions that indicates disease or a phase of a disease.

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Symptomatic Any evidence or sign of disease or disorder reported by the patient.

Symptomatic Rupture A breast implant rupture that is associated with symptoms (such as lumps, persistent pain, swelling, hardening, or change in implant shape). Some silicone-gel breast implant ruptures are symptomatic, but most are silent.

Systemic Pertaining to or affecting the body as a whole.

Tennessee Self Concept Concept Scale A questionnaire that evaluates how the patient sees herself and what she does, likes, and feels.

Umbilical Pertaining to the belly button.

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110 Cochrane Drive  
Markham, ON L3R 9S1  
800.962.8728

5540 Ekwil Street  
Santa Barbara, CA 93111  
800.624.4261

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