

## **BREAST AUGMENTATION WITH MOTIVA IMPLANTS® INFORMATION FOR THE PATIENT**

### **1. Overview**

- Breast augmentation/reconstruction is an elective surgical procedure for enhancing the breast area in women of at least 18 years of age, using silicone implants. Generally, it is a cosmetic procedure performed to fulfill a woman's personal desire for fuller breasts, to restore volume lost after pregnancy and breast feeding or as a result of weight loss or aging, or to replace breast tissue that has been removed for some pathological condition, or that has failed to develop properly due to a breast anomaly.
- Breast augmentation with silicone implants or any other method is never an indispensable surgical procedure, but an elective one.
- Alternative treatments would consist of the use of external breast prostheses or padding, or the transfer of other body tissues to enlarge breast size. The use of other synthetic filling materials (liquid silicone, other fillers) is not recommended and can provoke serious health problems.
- The decision to have breast implants is a very personal one. This information addresses the risks and benefits of surgery using breast implants and help you to make an informed decision about your breast augmentation/ reconstruction (primary or replacement) surgery. You must decide if implants will achieve your goals and if the risks and potential complications are acceptable for you.
- A sterile silicone breast implant is an tearshaped sack, or outer shell, constructed from several layers of elastic silicone material, filled with silicone gel (a clear and cohesive material), which is surgically implanted above or below your pectoral muscle. Silicone has been extensively studied and proven safe in the medical device, pharmaceutical and food industries for decades, and is widely used in implantable medical devices such as artificial joints, catheters, facial implants and tissue expanders.
- Traditionally, breast implant surfaces have been either smooth or textured. Textured surfaces have been manufactured by projecting salt, sugar or other particles on the implant shell. Lately, these textures have been associated with secondary effects in women with active lifestyles. Motiva Implants® SilkSurface® and VelvetSurface® are proprietary surfaces obtained without the use of foreign materials like salt or sugar, with a controlled process that guarantees improved biocompatibility.
- Breast implants have either a round, oval or contoured shape and come in several different sizes and projections. Historically, round implants have been used to increase fullness of the breast upper-pole, while oval or teardrop shaped

implants were designed to best mimic the natural breast shape, with more fullness in the lower pole.

- The design of the Sterile Silicone Breast Implants Motiva Implant Matrix® family is conceived so that the gel properties adapt to the patient's needs and the implant profile, maintaining its shape over time. Your doctor will explain to you in detail all the characteristics of these modern breast implants, so you fully understand the product you will receive.
- You should be aware when choosing breast augmentation with implants that you may require additional procedures as well as further consultations with your surgeon. Breast implants are not lifetime devices but are subject to wear and tear like any other implant device. Breast implantation might not be a onetime surgery. Your implant (s) may have to be removed or replaced, which may imply revision surgery. Many of the changes to your breasts 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, wrinkling, sagging or other cosmetic changes of the breast area, which can be permanent. When you have your implants replaced (revision-augmentation), your risk of future complications increases compared to first time (primary) augmentation surgery.
- Rupture of a silicone gel-filled breast implant is most often silent. This means that neither you or your surgeon will know that your implants have a rupture most of the time. If displacement or rupture are suspected, you will need a screening MRI examination to determine if a rupture is present. If implant rupture is noted on MRI, you should have the implant removed, with or without replacement.

## **2. Selection of the implant and surgical considerations**

- If you desire a breast implant size that is too large for your tissue, the surgeon may warn you that implant edges may be visible or palpable postoperatively. The implant size should be consistent with your chest wall dimensions, including base width measurements, characteristics of the tissue and projection of the implant.
- Textured implants, larger implants, subglandular placement, and an insufficient amount of tissue available to cover the implant may cause implants to be more palpable.
- Also, excessively large implants may speed up the effects of gravity on the breasts, and can result in droop or sag. Larger sized implants increase the risk of developing complications such as extrusion, hematoma, infection, palpable implant folds, and visible skin wrinkling, sometimes requiring surgical intervention to correct these complications.

### 3. Incision, Position and Implant Surface

Your doctor will use his preferred surgical technique for placing your Sterile Silicone Breast Implant.

- The periareolar incision is usually more concealed, but may considerably reduce the possibility of future breast-feeding and may be associated with a higher risk of changes in nipple sensation as compared to other incision sites. The inframammary incision is generally less concealed than the periareolar, but it is associated with less breast feeding difficulties. The axillary incision is the least concealed of all incision sites.
- The possible benefits of submuscular placement are that it may result in less palpable implants, less likelihood of capsular contracture, and easier mammographies. However, submuscular placement is associated with a longer surgical procedure, a more prolonged recovery period and more pain.
- Also, it may make it more difficult to perform some reoperation procedures. Subglandular placement may make surgery and recovery shorter, be less painful, and provide easier access for reoperation than the submuscular placement. However, this placement may result in more palpable implants, greater risk of capsular contracture, ptosis and increased difficulty in mammographies.
- Dual plane placement has been associated with the benefits of submuscular placement with the advantages of a faster recovery and less pain and postoperative discomfort.

### 4. Informed Consent

Considering the risks inherent to breast area enhancement with silicone-filled breast implants and the possible complications related to it, Establishment Labs relies on your surgeon to explain the existing risk-benefit balance of the implantation to you, as well as to obtain your formal informed consent to perform the surgical procedure.

### 5. Relevant Topics

Some of the relevant topics patients need to be aware of when considering the use of silicone gel filled breast implants are:

- **Surgical Setting and Anesthesia**– Breast augmentation surgery is usually performed on an outpatient basis, in a specialized operating room which may be located in a hospital, a surgery center, or surgical suite in the surgeon's office. General anesthesia is commonly used, and local anesthesia with sedation is also an option. 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, pre-surgical examinations, and length of time you need to be without food or your routine medications prior to the surgical procedure.

- **Reoperation/ Explantation** – Rupture, unacceptable cosmetic outcomes (dimpling, wrinkling, and other potentially permanent cosmetic changes of the breast) and other complications may require additional surgeries to the patients’ breast. Patients should be advised that their risk of future complications increases with revision surgery as compared to primary augmentation or reconstruction surgery. For example, the risk of severe capsular contracture doubles for both augmentation and reconstruction patients with implant replacement compared to first time implantation. There is a risk of an accidental compromise of implant shell integrity during reoperation, potentially leading to product failure. Silicone-filled breast Implants are not lifetime devices, and there is a possibility that patients will undergo implant removal(s), with or without replacement, over the course of their life.
- **Avoiding Damage During Treatment**– Patients should inform other treating physicians of the presence of breast implants to minimize the risk of damage to the implants.
- **Topical Medications**– The patient should consult a physician or a pharmacist before the use of topical medicines (e.g. steroids) in the breast area.
- **Trauma**– The patient should consult her surgeon or a physician if she suspects any complications, in particular in the case of trauma or compression caused, for example, by extreme massaging of the breast region, by some sport activities or by using seat belts.
- **Smoking**– Smoking may interfere with the healing process.
- **Radiation to the Breast**– Establishment Labs S.A. 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 implant extrusion.
- **Insurance Coverage**– Patients should check with their insurance company regarding coverage issues before undergoing surgery.
- **Mental Health and Elective Surgery**– It is important that all patients seeking an elective procedure, such as breast augmentation, have realistic expectations that focus on improvement rather than perfection. Ask the patient to openly discuss, prior to surgery, any history of depression or other mental health disorders.
- **Breast Examination Techniques**– Patients should perform breast self-examinations monthly and be shown how to distinguish the implant from their breast tissue. The patient should not manipulate or squeeze the implant excessively. The patient should be told that the presence of lumps, persistent pain, swelling, hardening, or change in the implant shape could suggest

symptomatic rupture of the implant. If the patient has any of these signs, she should be advised to report them, and possibly have an MRI evaluation to screen for rupture.

- **Lactation**— Breast implant surgery may interfere with the ability to successfully breast feed, either by reducing or eliminating milk production. Particularly, periareolar incision may considerably reduce the possibility of breast-feeding.

## 6. General Postoperative Advice

**Postoperative Care**— Concerning the postoperative period, the recovery process depends on your particular profile and other variables. During the first 48 hours, you might have an elevated body temperature and your breasts may remain swollen and sensitive to physical contact for a month or longer. Both of these should fade away over time. You are likely to feel tired and sore for several days following the operation. You could experience a feeling of tightness in the breast area as the skin adjusts to the new breast size. You should avoid any strenuous activities for at least a couple of weeks but should be able to return to work within a few days. Breast massage may also be recommended as appropriate.

- Sleep or rest with your head slightly elevated, avoiding lateral positions. Keep your arms close to your body, and avoid lifting weights until allowed by your surgeon.
- Do not drive for at least 2 days after your surgery, and do not exercise until approved by your surgeon.
- Do not expose your breasts directly to sunlight until approved by your surgeon.
- Gently massage your breasts with a circular motion starting 48 hours after your surgery.
- Healing cream may be recommended by your surgeon.

## 7. Life expectancy of the breast implant

Sterile Silicone Breast Implants are not lifetime devices. However, the life expectancy of a silicone breast implant cannot be precisely estimated, as there are many factors beyond the manufacturer's control that can affect the longevity of a device. The time period varies from patient to patient. Some patients could need replacement surgery few years after the primary procedure while others can have their implants intact for 10 years or longer. Therefore, the life expectancy of the implant cannot be guaranteed. For safety, as well as the most beautiful and healthy outcome, it is important that you return to your plastic surgeon's office for the follow-up evaluations prescribed by your doctor.

Establishment Labs recommends yearly visits to verify the device integrity. During the 10- year follow-up visit the surgeon should assess whether or not it is advisable to remove and replace the implants.

## **8. Risks and Potential Complications**

Because breast implant surgery is more often performed using general anesthesia, it is associated with the same risks as other invasive surgical procedures.

After breast implant surgery, patients might experience swelling, hardness, discomfort, itching, bruising, twinges and pain over the first few weeks. Potential adverse events that may occur with silicone gel-filled breast implant surgery include:

### **Capsular Contracture**

Normally, capsules of collagen fibers form as an immune response around a foreign body, such as a breast implant, tending to isolate it. Capsular contracture occurs when the capsule tightens and squeezes the implant. This can cause the implant to turn rigid (from slightly firm to quite hard) and the firmest ones can cause varying degrees of discomfort, pain and palpability. In addition to the firmness, capsular contracture can result in a deformed breast, visible surface wrinkling and/or displacement of the implant. Detection of breast cancer by mammography may also be more difficult. Capsular contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time.

Capsular contracture occurs more commonly in patients undergoing revision surgery than in patients undergoing primary implantation surgery. Capsular contracture is a risk factor for implant rupture, and it is the most common reason for reoperation in augmentation and reconstruction patients.

Capsular contracture is graded into 4 levels depending on its severity. Baker Grade I: the breast is normally soft and looks natural; Baker Grade II: the breast is a little firm but looks normal; Baker Grade III: the breast is firm and looks abnormal; Baker Grade IV: the breast is hard, painful, and looks abnormal. Patients should also be advised that additional surgery might be needed in cases where pain and/or firmness are severe (Baker Grades III or IV) and that capsular contracture may happen again after additional surgeries.

Correction of capsular contracture may require surgical removal or release of the capsule, or removal and possible replacement of the implant itself.

### **Rupture**

Rupture— Breast implants can rupture when the shell develops a tear or hole. Rupture can occur at any time during/after implantation, but it is more likely to happen due to an intraoperative puncture or to excessive force excerpted when placing the implant into the surgical pocket. It can also associate with inadequate positioning or ulterior displacement (folded envelope), trauma, implant ageing, etc. The implant's rupture can

lead to some dissemination of the gel and provoke silicone granuloma formation. Rupture of a silicone gel-filled breast implant is most often silent (the patient does not experience any symptoms and there are no physical signs of changes with the implant) rather than symptomatic. Therefore, patients should be advised to have regular MRIs over their lifetime to screen for silent rupture even if they are not having any apparent problems. The first MRI is recommended to be performed 3 years postoperatively, then regularly at 2-year intervals, and submitted to the treating surgeon. Patients should be provided with a list of radiology centers with experience with breast implant MRI films to scan for signs of rupture. The importance of these MRI evaluations should be emphasized. If rupture is noted on an MRI, the patient should be strongly encouraged to have her implant removed and replaced.

- Local breast complications that were associated with rupture in the literature include breast firmness, a change in breast shape or size, and breast pain. These symptoms are not specific to rupture and may be also experienced by women who have capsular contracture.
- There have been rare reports of gel migration to nearby tissues such as the chest wall, armpit, or abdominal wall, and to more distant locations down the arm or into the groin. This has led to nerve damage, granuloma formation and/ or breakdown of tissues in direct contact with the gel in a few cases. There have been reports of silicone presence in the liver of patients with silicone breast implants. Movement of silicone gel material to lymph nodes in the armpit also has been reported, even in women without evidence of rupture, leading to lymphadenopathy.
- Concerns have been raised over whether ruptured implants are associated with the development of connective tissue or rheumatic diseases and/or symptoms such as fatigue and fibromyalgia. A number of epidemiology studies have evaluated large populations of women with breast implants from a variety of manufacturers and implant models. These studies do not support an association of breast implants and rheumatic disease.

### **Pain**

Most women undergoing augmentation or reconstruction with a mammary implant will experience some post-operative breast and/or chest pain. While this pain normally recedes in most women as they heal after surgery, it can become a chronic problem in other women.

Hematoma, migration, infection, implants that are too large, or capsular contracture can cause chronic pain. Sudden, severe pain may be associated with implant rupture. You must immediately report if there is significant pain or if pain persists.

### **Changes in Nipple and Breast Sensation**

Breast surgery can result in an increased/decreased breast and/or nipple sensitivity. Typically the sensation is lost after complete mastectomy where the nipple itself is removed, and can be severely lessened by partial mastectomy. 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 the patient's sexual response or ability to nurse.

### **Infection**

Infection can occur with any surgery or implant. 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. Signs of acute infection reported in association with breast implants include edema, erythema, tenderness, pain, and fever. 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.

As with other surgical procedures, toxic shock syndrome in rare instances has been noted in women after breast implant surgery. Toxic Shock Syndrome (TSS), a life-threatening condition, has been reported in rare instances following breast implant surgery. Symptoms of TSS occur suddenly and can include high fever (102°F, 38.8°C or higher), vomiting, diarrhea, sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches and drops in blood pressure, which may cause fainting. Patients should immediately contact their physician for diagnosis and treatment if any of these symptoms occur.

### **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, they can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, some will 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 procedure.

### **Breast-feeding**

Although most women with breast implants who attempt nursing have successfully breast-fed their babies, it is not known if there are increased risks for a woman with breast implants or if the children of women with breast implants are more likely to have health problems. At this time, it is not known if it is possible for a small amount of silicone to pass from the breast implant silicone shell into breast milk during breast-feeding, or what the potential consequences might be.

A periareolar surgical approach may further increase the chance of breast-feeding difficulties. However, the American Academy of Pediatrics has stated that there is no reason why a woman with implants should refrain from nursing.

### **Calcification**

Calcium deposits can form in scar tissue surrounding the implant and may cause pain and firmness, and be visible on a mammography. These deposits must be identified as different from calcium deposits that are a sign of breast cancer. Additional surgery may be necessary to remove and examine calcifications. 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 significantly increases with age.

### **Delayed Wound Healing**

Some patients may experience a prolonged wound healing time. Smoking may interfere with the healing process. Delayed wound healing may increase the risk of infection, extrusion, and necrosis. Wound healing times may vary depending on the type of surgery or incision.

### **Implant Extrusion**

Lack of adequate tissue coverage, local trauma or infection may result in exposure and extrusion of the implant. This has been reported with the use of steroid drugs or after radiation therapy of breast tissue. If tissue breakdown occurs and the implant becomes exposed, implant removal may be necessary, which may result in additional scarring and/or loss of breast tissue.

### **Necrosis**

Necrosis is the formation of dead tissue around the implant. This may prevent wound healing and require surgical correction and/or implant removal.

Permanent scar deformity may occur following necrosis. Factors associated with necrosis include infection, use of steroids in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

### **Granulomas**

These are benign lumps that can form when body cells surround foreign material such as silicone. Like any lump, it should be further evaluated to rule out a malignancy.

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

The pressure of the breast implant may cause the breast tissue to thin and shrink (with increased implant visibility and palpability), potentially leading to 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/ creasing of the breast.

### **Lymphadenopathy**

Literature reports associate lymphadenopathy with both intact and ruptured silicone breast implants. One study reported that armpit lymph nodes from women with both intact and ruptured silicone gel implants had abnormal tissue reactions, granulomas, and the presence of silicone. These reports occurred in cases of women who had implants from a variety of manufacturers and implant models.

### **Unsatisfactory Results**

Unsatisfactory results such as wrinkling, sagging, asymmetry, implant displacement/migration, incorrect size, implant palpability/visibility, scar deformity, and/or hypertrophic scarring, may occur.

Some of these results may cause discomfort. Preexisting asymmetry may not be entirely correctable by implant surgery. Revision surgery could be indicated to increase patient satisfaction, but this involves additional considerations and risks. Realistic expectations as well as careful preoperative planning and surgical technique can minimize but not always prevent unsatisfactory results.

### **Implant Rotation**

In the case of Sterile Silicone Breast Implants®, Anatomical TrueFixation™ rotation of an implant may occur. Proper placement and pocket dissection reduces the risk of occurrence. Revision surgery may be necessary to correct rotation. In case of rotation beyond 45°, it is advised to rotate the device back into its correct position in an open surgical procedure. Reshaping of the implant pocket may be necessary to avoid any further rotation in the future. For Breast Implants with TrueFixation™ the superior arch of the implant was designed for limiting the implant sliding inside the pocket, helping to maintain its position.

### **Gel Diffusion**

Small quantities of silicone may diffuse through the elastomer envelope of silicone gel-filled implants. The detection of small quantities of silicone in the periprosthetic capsule, axillary lymph nodes and other distal regions in patients with apparently intact gel-filled implants has been reported in the literature.

Some studies on long-term implants have suggested that gel-bleed may contribute to the development of capsular contracture and lymphadenopathy. On the other hand, evidence against gel-bleed being a significant contributing factor to capsular contracture and other local complications is provided by the fact that there are similar or lower complication rates for silicone gel-filled breast implants than for saline-filled breast implants.

### **Gel Fracture**

Gel fracture may occur with cohesive silicone as a result of handling during surgery or, alternatively, due to the development of capsular contracture, and may result in device

distortion. This can lead to both patient and surgeon dissatisfaction with the aesthetic outcome of surgery and may require a second procedure.

### **Interference with Mammography**

Mammography— Patients should be advised to have routine mammography exams performed according to their surgeon's recommendations. The importance of these exams should be emphasized. Patients should be instructed to inform their examiners about the presence, type, and placement of their implants, and to request a diagnostic mammography, rather than a screening mammography. Breast implants may complicate the interpretation of mammographic images by obscuring underlying breast tissue and/ or by compressing overlying tissue. Accredited mammography centers, technicians with experience in examining patients with breast implants, and the use of displacement techniques are needed to adequately visualize breast tissue in the implanted breast. The current recommendations for preoperative/screening mammograms are no different for women with breast implants than for those women without implants. Pre and post-surgical mammographies may be performed to determine a baseline for routine future studies in augmentation patients.

### **Interference with Magnetic Resonance Imaging (MRI)**

Patients should be advised to have regular MRIs over their lifetime to screen for silent rupture even if they are not having any apparent problems. As mentioned before, it is advised to have the first MRI 3 years postoperatively, then regularly at 2-year intervals.

Establishment Labs S.A. Sterile Silicone Breast Implants are MRI Conditional. It is important to note that Motiva Implants with Q Inside Safety Technology™ contain a ferrite component in the microtransponder that provides unique device identification data through an external reader. This microtransponder may create an imaging void during breast implant MRI (known as artifact effect) that can block visualization of a small area near the UDI.

Although the artifact effect is small, it may block the view of a minor breast tissue portion.

In selected cases, alternative imaging techniques can be used to better visualize the region affected by the implant UDI.

The patient implanted with Sterile Silicone Breast Implants Motiva Implants® can undergo MRI scan under the following conditions:

- Static magnetic field of 1.5-Tesla and 3 -Tesla only.
- Maximum spatial gradient magnetic field of 4.000-gauss/cm (40-T/m).
- Under the scan defined conditions, the Motiva Implant Matrix® Breast Implant with Qid™ is expected to produce a maximum temperature rise of 3.0 OC after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the magnetically induced displacement force and magnetically induced torque were tested and no clinically significant displacement or torque was detected.

In non-clinical testing, the image artifact caused by Sterile Silicone Breast Implants Motiva Implant Matrix® breast implants with Qid™ extends approximately 15 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

In selected cases, the following imaging techniques can be used as an alternative to better visualize the region affected by the implant UDI:

- Ultrasound.
- Tomosynthese.
- Digital compression mammogram.
- Subtraction contrast Mammography.
- Scintimammography.

### **Anaplastic Large Cell Lymphoma (ALCL)**

Anaplastic Large Cell Lymphoma (ALCL) Lymphomas, including anaplastic large T-cell lymphoma (ALCL) – The U.S. Food and Drug Administration in 2011 released a safety communication stating that women with breast implants may have a very small, but increased risk of developing anaplastic large cell lymphoma, or ALCL, in the scar tissue or fluid adjacent to a breast implant. ALCL is not breast cancer; it is a rare type of cancer involving the cells of the immune system.

Cases of ALCL in the breast have also been reported in women without breast implants. When occurring in association with breast implants, patients were diagnosed following symptoms such as pain, lumps, swelling, fluid accumulation, or asymmetry. In the cases reported, ALCL was most commonly diagnosed years after implant placement and usually located immediately surrounding the breast implant. ALCL associated with breast implants is distinct and separate from primary lymphoma of the breast, which has a worse prognosis and is a majority B-cell phenotype (Domchek, 2002). In contrast, ALCL is always a T-cell lymphoma, and in epidemiological studies occurs at a higher rate in women with breast implants compared to the general population (deJong, 2008).

Confirmed cases of ALCL may require surgery and chemotherapy as part of an individualized treatment plan by appropriate specialists. Women without symptoms do not require screening or implant removal and should continue with their normal breast health routine. The U.S. Food and Drug Administration and other regulatory bodies have confirmed that breast implants have a reasonable assurance of safety and efficacy.

## 9. Other Reported Conditions

There have been reports in the literature of other conditions in women with silicone breast implants.

Many of these conditions have been studied to evaluate their potential association with breast implants. However, no causal relationship has been established between breast implants and the conditions listed below.

- **Connective Tissue Disease (CTD):** Since the early 1990s, nearly a dozen comprehensive systemic reviews have been commissioned by government health ministries in several countries to examine the alleged links between silicone gel breast implants and systemic diseases. A clear consensus has emerged from these independent scientific reviews that there is no clear evidence of a causal link between the implantation of silicone breast implants and connective tissue disease.
- **Cancer:** Breast cancer reports in the medical literature reveal 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 medical literature indicate that breast implants do not significantly delay breast cancer detection or adversely affect cancer survival prognosis in implanted women. Some studies even suggest lower rates of breast cancer in women with breast implants.

### Neurological Disease, Signs, and Symptoms

- Some women with breast implants have experienced neurological disturbances (e.g., visual symptoms or alterations in sensation, muscle strength, walking, balance, thinking or memory) or diseases (e.g., multiple sclerosis) and they believe those symptoms are related to their implants. However, there is no evidence in published literature of a causal relationship between breast implants and neurological disease.

## 10. Follow-Up Examinations

### Symptomatic Rupture

Symptoms associated with rupture may include hard knots or lumps surrounding the implant, loss of size of the breast area, pain, tingling, swelling, numbness, burning, or hardening of the breast area. If you notice any of these changes, see your plastic surgeon so that he or she can examine the implants for rupture and determine whether you need to have an MRI examination to find out if your symptoms are due to rupture of the implant. If rupture has occurred, you should have your implant removed.

## **11. Additional Information**

### **Patient ID Card**

Every patient must have a record of her surgical procedure in case of future consultations or additional surgeries. Each implant is provided with a Patient ID card, which must be given to you by your surgeon for personal reference. Apart from the information stated on the Record Labels that should be affixed to the back of the card, the Patient ID card includes your name, position of the implant, date of implantation and name of the treating surgeon. This card is for your permanent record and should be kept with you at all times. 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.