

## SILICONE IMPLANT BREAST AUGMENTATION SURGERY

### ► INFORMED CONSENT FORM

Prof. Dr. Ferit Demirkan

Plastic, Reconstructive and Aesthetic Surgeon

Date..... / ..... /20.....

### Dear Patient, Dear Parent/Guardian

This form has been prepared to inform the patient and their relatives about the surgery to be performed. It is a legal obligation to read and approve it. The aim of informed consent forms are to explain the anticipated risks and undesirable situations (complications) of surgical treatments and to provide information about other options. The identified risks are defined in such a way as to meet the needs of most patients under many conditions. However, this form should not be considered as a document containing the risks of all forms of treatment. Depending on your own personal health status or medical information, your plastic surgeon may offer you different or additional information.

Do not sign the form on the last page until you have carefully read all the information written below and found the answers to all your questions.

### GENERAL INFORMATION

Among all forms of plastic surgery, there is no other that has generated as much scientific and political controversy as breast augmentation surgery. Presently, more than 2 million women in the United States have breast implants. This number is gradually increasing in our country as well. Breast augmentation surgery is a surgical operation performed for various reasons mentioned below:

- \* To correct the body contours of women who think that their breasts are small for personal reasons,
- \* To correct the loss of breast volume after pregnancy,
- \*To ensure symmetry in breast size,
- \*To rebuild the breast in various situations,
- \* To replace breast implants (protheses) placed for medical or cosmetic reasons.

The history of breast augmentation surgery is all about searching for the ideal prosthesis. The beginning of this process can be dated back to the 19th century, when fat glands called lipomas were used to enlarge the breasts. Today there are two main methods: implants and fat injections. This consent form is about breast augmentation surgeries performed with implants.

### BREAST IMPLANTS:

Implants used in breast augmentation are produced from chemically harmless, non-cancerous and easily obtainable polymer-based materials. Modern breast prostheses consist of medical-grade gel silicone (polydimethylsiloxane) placed in a sheath that also consists mainly of medical-grade silicone. The permeability of the silicone shell is minimized, and the gel inside does not flow out in case the silicone implant ruptures. Although saline filled implants (with salt water) were used in silicone shells in previous years, they were abandoned as they leaked some of the fluid inside and were harder in texture. There are also different types of silicone implants developed for specific needs: B-Lite® implants, in which a part of the silicone gel is filled with micro-spheres full of air for a lighter feeling, implants that change in shape (Ergonomix®) and silicone implants covered in polyurethane to reduce capsular contracture (Microthane®).

Breast prostheses are divided into two groups in terms of shape, content and surface structure. Breast prostheses according to shape are divided into two groups: round and anatomical (tear drop). The surface of round prostheses are spherical and they fill both the upper and lower parts of the breast evenly. Therefore, they create a more pronounced shape in the upper part of the breasts and cleavage. In anatomical (tear drop) prostheses, the vertical diameter is slightly longer than the horizontal diameter and the height of the prosthesis is higher in the lower pole of the breast than the upper pole. So, they enlarge the lower part of the breast more. The reason they are called anatomical is because they are more similar to the natural shape of

the breast. In the new Ergonomics® prostheses, although the surface is round and the appearance of the breast is round in a horizontal position, the fluid gel inside moves down with gravity in a vertical position and takes an anatomical shape. This allows the implant to behave more dynamically and naturally.

When it comes to surface structure, prostheses are divided into five categories: macro-textured, micro-textured, nano-textured, flat and polyurethane coated. While the implants made in the early years were all flat-surfaced, micro-textured prostheses were later developed in order to reduce capsular contracture. There is evidence that the textured surface reduces both the rotation of the implant and the formation of capsules around it. However, these results have made some manufacturers further reduce the smoothness of implants, causing macro-textured implants to rupture and remain in the tissue and leading to tissue reactions. For this reason, the firm Allergan removed their implants from the market. Although coating the upper surface of the silicone shell in order to reduce capsular contraction has been a long-term and effective method, the fact that polyurethane can cause tumors in animals (even though that hasn't been the case so far in humans) prevented it from receiving general acceptance. In the latest generation of implants, lighter textured shells called nanotextured or silk surface implants are used.

Some new implants may have microchips containing implant information and radio-opaque tapes that will help detect rotation through radiology from the outside. Some other new implants, described as fully filled implants are filled with 100% gel, unlike conventional implants. This complete filling process has become possible with the development of technology and aims to prevent the formation of ripples that occur after surgery in implants that are not fully filled with gel.

### **The Issue of the Removal of Silicones From the Market in the US**

Over the past 50 years, more than 2000 studies have been published on silicone and various prostheses containing silicone. Silicone has been used for the first time as a medical prosthesis in ventricular shunts applied in patients with hydrocephalus. Silicone was also used in the endotracheal tubes, intraocular lens prostheses, artificial heart valves and facial implants applied for congenital deficiencies that have come into use in later years. Syringes and intravenous catheters that are used daily in medicine also have silicone in them. Today in the US, in addition to breast prostheses, there are various prostheses made of silicone inside the bodies of more than 2 million people.

Over the past 20 to 25 years in the US, visual and print media, court lawyers, various social groups and the United States Food and Drug Administration launched a campaign against silicone breast implants and sparked debates on whether breast prostheses made of silicone gel has relation to certain rheumatic diseases and breast cancer; and whether it is harmful for breastfeeding mothers. In 1992, the FDA banned the use of silicone gel breast prostheses, except for breast reconstruction surgeries and a small number of breast augmentation patients participating in long-term clinical trials. Since then, studies have shown many times that there is no such relation. In 1999, a 2-year study conducted by the Institute of Medicine of the National Academy of Sciences found no link between silicone gel implants and breast cancer and rheumatic diseases, as well as concluding that it did not present a hazard for unborn or breastfed children. The FDA virtually lifted this ban in 2006 by allowing 2 breast implants with silicone gel to be carried out.

### **The Link Between Breast Prostheses and Breast Cancer:**

The issue of whether silicone prostheses increase the risk of developing breast cancer and make it harder to diagnose has been a subject of debate and curiosity for many years. In a study conducted on 11,000 patients in Canada in 1995, the incidence of breast cancer in patients who underwent breast augmentation surgery was compared with patients without breast prosthesis, and as a result, it was determined that there was no statistically significant difference in the incidence of breast cancer in patients who underwent breast augmentation surgery compared to the general population.

In a study conducted by the American National Academy of Sciences Institute of Medicine in 1999, it was seen that there was no increase in the incidence of first time or recurrent breast cancer in patients with breast prosthesis.

However, a type of lymphoma developing in the capsule around textured prostheses was reported in 1997. ALCL (Anaplastic Large Cell Lymphoma) is essentially a rare tumor on its own. The fact that it has not been reported before has been associated with recent changes in the implant surface and, in particular, implants with a macro-textured surface. For this reason, macro-textured implants and polyurethane-coated implants were first banned in France in 2018, and in 2019, the FDA decided to withdraw macro-textured implants from the market in the United States. However, the FDA has not previously requested the removal of implants in women who have had such implants before. There are 2 theories about macro-textured implants causing lymphoma: The first is that the textured surfaces break off from the surface of the implant with the movement of the surrounding tissues and get stuck in the capsule, where they attract lymphocytes; the other is that the

macro-textured structure has a much larger surface area for bacteria to settle, and that the tumor is of inflammatory origin. The incidence of this tumor ranges from 1/1000 to 1/3000 in women who have had a textured implant applied. However, as of 03/2022, there are fewer than 1000 cases and only 36 deaths worldwide. It is believed that the incidence of tumors may decrease with a reduction in the use of macro-textured implants.

Another source of doubt about breast prostheses is that these prostheses delay the diagnosis of breast cancer by blocking x-rays during mammography. However, studies on this subject have shown that the effectiveness of mammography in patients with prosthesis is almost the same as in patients without one. In breast prostheses that have been in existence for more than 10 years, thin calcium layers may form in the capsule around the it. Although it is believed that silicone implants do not hide small lesions or mimic cancer, it is still necessary to be careful, and mammograms should be examined by experienced radiologists, especially in patients with breast prostheses. It is also reported that mammographic examinations of patients who have prostheses placed under the pectoral muscle give better images compared to prostheses placed under the mammary gland. On the other hand, in patients who cannot undergo mammography, breast tissue can also be examined with breast ultrasonography and magnetic resonance imaging, and any suspicious lesion can be detected.

In summary, it can be said that there is no serious increase in the risk of developing breast cancer in patients with breast prostheses.

### **The Link Between Breast Prostheses and Pregnancy and Breastfeeding:**

According to a study by the British Ministry of Health in 1994, it was reported that breast prostheses in the mother do not pose any danger to the baby. As a result of this study, there was no evidence found that would prevent mothers with breast prostheses from breastfeeding. In a study conducted in 1991, low levels of silicon were found in the milk of mothers with breast prosthesis; however, this study revealed that the same amount of silicon was found in the milk of all mothers in the test group, with or without a breast prosthesis. In fact, a study conducted by the Institute of Medicine of the American National Academy of Sciences in 1999 showed that even cow's milk and baby food formulas contain more silicon than breast milk. In patients undergoing breast augmentation surgery, only technical reasons might affect breastfeeding. For example, in incisions made around the nipple, milk ducts up to the lower half of the nipples can be severed. However, as this kind of problem is not encountered in incisions made on the under-breast or under-arm; there is no harm done to the mammary gland since the prostheses are placed through the former areas.

### **The Link Between Breast Prostheses and Rheumatic Diseases:**

In 1988, scleroderma was reported in a patient with breast prosthesis, raising the question of whether silicone prostheses are linked to autoimmune diseases. In some female patients with breast implants, symptoms similar to immune system diseases such as systemic lupus erythematosus, rheumatoid arthritis, scleroderma, or other arthritis-like conditions were reported. The existence of a link between implanted silicone and connective tissue disorders is available in literature. Although there is no scientific evidence of an increased risk of these diseases in women with prostheses filled with silicone gel or physiological serum, this possibility has not been completely ruled out to this day. If a causal relationship had been identified, the theoretical risk of immune and unknown diseases would be low. The effect of breast prosthesis in patients who have previously had connective tissue disease is unknown. Unlike silicone gel-filled implants, physiological serum-filled ones contain saline (salted water). Still, both of them have a rubber surface containing silicone. The increased risk of autoimmune diseases also applies to implants filled with physiological serum. A link between anti-silicone antibodies and an autoimmune disease has not been found in patients with breast prosthesis. Currently, there is not enough information that suggests a connection between the removal of the breast prosthesis and the scar tissue capsule preventing or affecting the course of an autoimmune disease.

### **Asymmetry:**

In most women, there is an asymmetry between the breasts ranging from minimal to distinctive. These can be caused by differences in volume or shape between the two breasts, differences in the direction and level of the nipple and asymmetries of the bone structure of the chest wall. These should be taken into account before the operation and what to do should be discussed. Leaving the minimal asymmetries as they are may be the best solution. Assymetries in volume can be removed by using different implants or injecting fat in appropriate cases. Nipple asymmetries or larger assymetries can lead to additional breast augmentation/reduction procedures or a two-stage treatment plan. It may not be possible to correct the assymetries in the chest wall.

### **Tubular Breasts:**

This condition, which is colloquially called 'goat's breasts', is a congenital anomaly and can effect one or both of the breasts.

In these cases, typically the distance between the nipple and the line under the breast is narrow, breasts are small, the nipple is very wide and protruding, and sometimes pointed downwards. It is very difficult to correct, it has its own special surgical methods, and sometimes it may require more than one surgical session. It may not be possible to completely correct the asymmetry in patients with this condition.

## **SURGERY**

There are 4 incision options for breast prosthesis placement. These are transaxillary (armpits), periareolar (areas around the nipple), inframmary fold (under the breast) and periumbilical (abdomen) incisions. With the help of these incisions, a suitable sized pocket is created in the areas under the mammary gland or the chest muscle and the prosthesis is placed inside. Each incision has its own advantages and disadvantages. The most preferred one is the inframmary fold incision. The incision made around the nipple heals in time with a fairly small scar around the brown area called the areola, but it may require severing the milk ducts. In this case, the implant makes contact with the severed milk ducts while being moved from the nipple to the bottom of the breast, and these channels, which are filled with bacteria, cause the bacteria to stick to the implant. This increases capsular contracture in the long term. In inframmary fold incisions, there is no damage done to the mammary glands and milk ducts and healing occurs with a very vague scar on the crease below the breast. In transaxillary incisions, incision is not made on the breast but on the armpit. In transaxillary and periumbilical incisions, prostheses are endoscopically rolled and placed when they are empty and are filled with fluid inside the breast. Otherwise it is not possible to place a normal-sized silicone implant filled with gel through these incisions. However, water-filled implants have various drawbacks (drooping, sound of water, roughness), which is why these types of incision methods are not as common. In the early post-operative period, slightly red scars can be visible but they gradually fade and become indistinct over time.

This surgery is performed under general anesthesia. In general anesthesia, the patient is completely put to sleep and their breathing is monitored by the anesthesia team with a tube inserted into the windpipe. In order to avoid any problems, laboratory tests are performed before surgery. The anesthesiologist will evaluate the patient before the operation. In the operating room, the patient's heart rate and blood oxygen levels are constantly monitored with the help of electronic devices during the operation. Allergy or drug reactions are rarely encountered, but can be fatal. Moreover, these reactions cannot be detected in advance with routine tests. Fortunately, when these undesirable situations occur in hospital conditions, they can be successfully treated, and the probability of a complication arising that will harm the patient is extremely small. Before general anesthesia, nothing should be eaten or drunk for 6-8 hours, the patient's stomach must be empty.

After the operation, no food or drink is given orally to the patient for at least 3- 4 hours. The length of the time can be changed by the doctor. The operation lasts about 1.5 - 2.5 hours. During the operation, drains can be placed to let out the accumulated blood if the doctor finds it necessary. After the operation, the patient will be sent back to their room after 1 hour of being monitored in the recovery room. However, if nausea and similar problems occur due to anesthesia, the duration of the stay may be prolonged.

A set of bands surrounding the surgery area and a special bra is put on the patient. Usually in the first hours after surgery, dizziness, fatigue and nausea may occur. Some medications are used to relieve these conditions. In the fourth hour of the operation, the patient is usually allowed to have liquid food and get on their feet.

On the day of surgery or the next day, the patient is allowed to go home after their discharge procedures are done. The first two days should usually be spent resting. During this period, the patient may have different complaints depending on whether the prosthesis is placed behind the muscle or in front of the muscle. Usually, in prostheses placed behind the muscle, pain increases with the movement of the arm. This condition is usually limited to the first week. Edema (swelling), which gradually increases in the first two days, begins to decrease from the third day. The arm and torso are relieved. On the third or fourth day, the bands and drains in the patient's chest are removed. Only heat-resistant bands on the incision seams aren't removed. The patient is allowed to take showers.

After breast prosthesis operations, physical activities should be strictly restricted for the first three weeks and gradually increased after this period. Playing tennis or doing heavy sports is not allowed before the first month. In the 6-8 weeks following surgery, going to the sauna, solarium and steam baths must be avoided. It is recommended not to lie face down or on the side in the first 6 weeks.

Short-term pain in the form of stinging, burning, cramping may occur from time to time, which may last for months. The frequency and severity of these pains, which are not so severe as to affect daily life, gradually decrease. Painkillers may be used when they occur. It is natural for numbness and edema (swelling) to occur in the entire breast area. This is usually a temporary condition, and it can last up to 6-12 months. In some cases, bruises may occur that disappear in 1-2 weeks. Similarly, there may be numbness and/or excessive sensitivity in the nipple.

It can take 10-30 days for the patient to return to daily life, depending on the operation performed, healing time and body tolerance of the patient.

### **Other Treatment Options:**

Breast augmentation surgery is an optional surgical procedure. Other treatment options include fat injections, the use of external breast prostheses or pad support, or tissue transfer (in the case of flap surgery) from other parts of the body.

### **Risks of Breast Augmentation Surgery:**

Each surgical procedure has a certain amount of risk, and it is important that you understand which one is related to breast augmentation surgery. It is essential to compare the risks and benefits of each option when deciding on a surgical procedure. Even if many patients do not experience the following complications, you should discuss them all with your plastic surgeon until you are sure that you understand the risks, possible complications, and consequences. People who consider breast augmentation surgery should also be prepared for a possible correction surgery in the future. Breast implants may not stay in the same shape forever.

**Bleeding:** Although rare, it is possible to experience bleeding during or after surgery. If post-operative bleeding occurs, the accumulated blood (hematoma) needs to be drained urgently. Do not take aspirin or pain medications ten days before surgery, as they increase the risk of bleeding.

**Infection:** Infection after this type of surgery is not common, it can be observed in the immediate post-operative period or in the period following the placement of the implant. It can be difficult to diagnose subacute or chronic infections. If infection occurs, treatment may call for antibiotics and the possibility of removing the implant, or require additional surgery. It is more difficult to treat infection with breast implants than in normal body tissues. If the infection does not respond to antibiotics, the breast implant may have to be removed. After the infection is treated, a new implant can be placed. Although it is extremely rare for a bacterial infection that exists somewhere else in the body to surround the prosthesis, it is recommended to use protective antibiotics before dental or other surgical operations in the future.

**Capsular Contracture:** This is the complication that should be known best among the late complications. A capsule naturally forms around each foreign object that enters the body. This capsule is mostly thin and soft. Despite meticulous, careful surgery and precautions, the body can sometimes have reactions to these prostheses as they are foreign objects. These reactions are manifested by an increasingly thickening membrane around the prosthesis. In some patients, the capsule that develops around the implant may harden and thicken like a scar tissue, and cause deformity, stiffness, and pain in the breast. In this case, if there is an amount of capsular contracture in the early stage, the breast will become slightly unnatural looking and stiff. If there is a capsular contracture in more advanced stages, the natural look of the breast deteriorates, movement is limited, the implant moves up, and the breast acquires the appearance of a squeezed orange. Using certain medications in the early period may be useful. Excessive stiffness of the breasts may occur shortly after surgery or years later. It is usually observed in less than 7% of patients in varying degrees from mild to severe. Capsular contracture can be one sided or two sided, and the incidence rate increases over time. In advanced stages of capsular contracture, the capsule around the prosthesis must be removed, cleaned, the pocket where the prosthesis is placed must be expanded and the prosthesis must be replaced. There is no definitive information on who and under what conditions capsule contracture can occur. The most common theory is that the implant gathers a number of bacteria from the skin or the severed mammary glands during its placement in the prepared pocket, and these bacteria create a chronic inflammation by forming a layer called biofilm to escape the body's defense mechanism. To prevent this, both the implant and the pocket are washed with antibiotic solutions during the placement of the prosthesis, the operating room is cleaned, gloves are changed and the sterility of the implant is maintained. There is evidence that the incidence of capsular contracture decreases with these measures.

**Changes in Nipple and Skin Sensation:** It is normal to feel some change in nipple sensation immediately after the operation. After a few months, normal sensation returns in most patients. Partial or permanent nipple and skin sensory loss may rarely develop.

**Scarring:** Excessive scarring is not usual. In rare cases, abnormal scars may form. Scars can look unpleasant and in a different color from the surrounding skin. Additional surgical intervention may be required after surgery for abnormal scarring.

**Implants Damage:** Similar to other medical devices, breast implants can fail. They can rupture or leak. When an implant filled with physiological serum leaks, the salt water is absorbed by the body. The rupture can grow after an accident or during mammography. The implant can also be damaged during surgery. Damaged or ruptured implants are impossible to repair, they need to be removed or replaced. Breast implants cannot stay in the same shape forever. It is possible for small parts of the implant material to break off from the surface. The consequence of this is not known.

**Prosthesis Coming Out:** The prosthesis may be exposed as a result of infection or a lack of sufficient living tissue covering it. It has been reported that skin atrophy may develop after radiation therapy and steroid use. If tissue destruction occurs and the prosthesis becomes visible through the skin, the prosthesis may need to be removed. Smoking can have a negative effect on wound healing.

**Mammography:** Breast prostheses may cause mammography evaluation and cancer diagnosis to become more difficult. The implant may rupture due to compression during mammography. Informing the mammography technician about your prosthesis will allow a better evaluation of the results. In patients with advanced capsular contracture, imaging difficulty and pain increases in direct proportion to the contracture. Ultrasonography, specialized mammography and magnetic resonance imaging can be useful in detecting breast lumps. Since more x-rays are required with specialized mammography techniques, patients with prostheses are exposed to more radiation. Even so, the amount of x-rays received during mammography cannot be compared to the amount it takes for a risk of cancer.

**Movement:** In implants placed under the muscle, there may be a downward and outward movement of the implants with the contraction of chest muscles.

**Rotation:** Implants attach to the surrounding tissue in the first 3 weeks. However, there is a chance that the implants rotate around their axis or even flip over. If implants are touched or moved around too much (as in sexual activity), they may lose adhesion and start slipping or rotating. After a while, the implant can start moving around and rotating in a wider area. Another reason for rotation is the placement of submuscular anatomical implants for people who do arm-heavy sports (swimming, tennis, volleyball). Since the chest muscle covers only the upper and inner parts of the implant, the contractions that occur during sports trigger the anatomical implants to rotate outwards and to the side. If rotation occurs, additional surgery may be required.

**Asymmetry:** Asymmetries in the early stages may be due to the breasts swelling in different sizes. If the asymmetry persists after 2 months, it is necessary to know if it was pre-existing from before the surgery. Other reasons include the breasts being damaged or extended use of the arms (especially in mothers) during the adhesion period of the prosthesis. Another reason is different sized pockets being opened during surgery. In the long term, problems such as capsular contracture, implant rupture and rotation should be researched. The distinction can be made by physical examination, ultrasound and MRI if necessary. The solution is usually a surgical revision.

**Folding on the Skin:** It is possible that the crease of the implant shell becomes visible and palpable on the inner and outer sides of the breast, especially in skinny people or people with large implants. Some folding is normal and expected. This is more pronounced in patients with physiological serum-filled prostheses and those who have thin breast tissue. Silicone gel-filled implants are more resistant. It is possible to feel the shell of the prosthesis in some cases. Palpated implant shell, creases or folds can be confused with a tumor; in case of doubt, further research should be carried out. The prosthesis may become visible under the skin due to the force that pushes it between the skin layers.

**Calcification:** Calcium deposits formed in the scar tissue surrounding the implant can cause pain and stiffness; they can be observed on mammography. These deposits should be differentiated from signs of breast cancer. If calcification develops, additional surgical intervention may be required to remove or examine it.

**Implant Displacement:** The implant can slip in the breast due to poor initial placement or it may develop with discomfort in the breast. Difficult techniques used in implant placement (transaxillary or periumbilical) can increase the risk of poor implant placement and slippage, and correcting this condition may require additional surgery.

**Removal/Replacement of Breast Prostheses:** Removal or replacement of the breast prosthesis and the surrounding scar tissue is a surgical procedure with risks and potential complications.

**Complications in Anesthesia:** Both local and general anesthesia carry risks. In all surgical anesthesia and sedation procedures, there is a possibility of undesirable conditions from minor to fatal. Small areas in the lungs may shut down. This increases the risk of lung infection. Antibiotic use and respiratory physiotherapy may be required. There may be swelling and pain in the legs due to blood clots. These clots can rarely travel through the bloodstream to your lungs, which can lead to death. A heart attack/stroke or death may occur during the procedure. Wounds and respiratory tract infections, heart and lung problems, and intravascular coagulation may occur in obese patients and/or smokers.

**Chest Wall Deformity:** Chest wall deformity has been reported secondary to the use of tissue expanders and breast prostheses. There is no known reason for this.

**Unusual Activities and Occupation:** Some activities and occupations may pose a potential risk of breast trauma or bleeding.

**Allergic Reactions:** In rare cases, local allergic reactions to the bands, sewing materials or creams used as part of the surgical



**IF THE PATIENT IS CONSCIOUS;**

**Patient**

Name and Surname of the Patient:

.....

Address:.....

.....

Phone Number: (.....) .....

Signature:

**Doctor**

Name and Surname of the Doctor:

.....

Signature:

**Witness\*\*:**

Name and Surname:

.....

Signature:

**IF THE PATIENT IS NOT CONSCIOUS AND HAS A  
LEGAL REPRESENTATIVE;**

**Legal Representative\* or Guardian**

Name and Surname of the Patient:

.....

Address:.....

.....

Phone Number: (.....) .....

Signature:

**Doctor**

Name and Surname of the Doctor:

.....

Signature:

**Witness\*\*:**

Name and Surname:

.....

Signature: