

“RISKS OF MEDICAL INTERVENTION (SURGICAL PROCEDURE)”

Appendix No. 2

INFORMED CONSENT – BREAST AUGMENTATION

WITH SILICONE GEL-FILLED IMPLANTS

“RISKS OF MEDICAL INTERVENTION (SURGICAL PROCEDURE)” Appendix No. 2: approved by “ARZ EST” on May 2, 2019, by Order No. 01/5.

This document constitutes an integral part of the Agreement concluded between LLC “ARZ EST” and the Client/Patient.

INSTRUCTIONS

This informed consent document has been prepared to familiarize you with breast augmentation surgery using silicone gel-filled implants, its associated risks, and alternative treatment methods.

It is important to carefully and fully review this information.

GENERAL INFORMATION

Breast augmentation is a surgical procedure performed to increase the size of the female breasts for the following reasons:

- To improve the body contours of a woman who, for personal reasons, considers her breast size insufficient.
- To correct loss of breast volume following pregnancy.
- To equalize breast size in cases of significant asymmetry.
- To restore breast shape following partial or complete loss resulting from various diseases.
- To correct developmental abnormalities of the breasts.
- To correct or improve the results of previously placed implants for aesthetic or reconstructive indications.

The procedure is contraindicated in women with untreated breast cancer or precancerous breast conditions, active infection in the body, as well as in pregnant or breastfeeding women.

Individuals with a weakened immune system (receiving chemotherapy or immunosuppressive therapy), impaired blood clotting or wound healing, or impaired blood supply to breast tissue following previous surgery or radiation therapy have an increased risk of complications.

Silicone breast implants are FDA-approved for use in women over 22 years of age. There are no age restrictions for reconstructive procedures.

Breast augmentation is achieved by placing the implant:

- Behind the breast tissue;
- Partially or completely beneath the chest muscle.

Incisions are made in locations intended to make scars as inconspicuous as possible:

- Beneath the breast;
- Along the edge of the areola;
- In the armpit.

The FDA does not recommend the periumbilical approach for gel-filled implants.

Implants vary in shape, size, and surface type (smooth or textured). Selection depends on the patient's anatomy, preferences, and the surgeon's recommendations.

If the breasts differ in shape or size before surgery, a completely symmetrical result may not be achieved.

In cases of significant ptosis or reduced skin tone, an additional procedure—breast lift (mastopexy)—may be required.

IMPORTANT CONSIDERATIONS

- Surgery may not be the only breast surgery you undergo during your lifetime.
- Implants are not lifetime devices. Replacement or removal may be required.
- Changes resulting from implant placement are irreversible.
- The use of large-volume implants (>350 cc) increases the risk of complications:
 - Implant displacement or extrusion;
 - Hematoma;
 - Infection;
 - Skin rippling and wrinkling;
 - The need for repeat surgery.

ALTERNATIVE TREATMENT

Alternatives include:

- Choosing not to undergo surgery;

- External prostheses or breast inserts;
- Saline-filled implants;
- Autologous tissue transfer.

Each method also carries its own risks.

RISKS OF BREAST AUGMENTATION

Any surgical procedure involves risks. The following are possible complications.

RISKS ASSOCIATED WITH SILICONE IMPLANTS

Implant Rupture

- Rupture may be intracapsular or extracapsular.
- Gel migration may occur.
- Rupture may be “silent” (without symptoms).
- A damaged implant cannot be repaired.
- Regular MRI examinations are recommended (3 years after surgery and subsequently every 2 years).

Capsular Contracture

- Thickening/hardening of scar tissue around the implant.
- May cause pain and deformity.
- Repeat surgery may be required.
- Recurrence is possible.

Implant Extrusion / Tissue Necrosis

- Insufficient tissue coverage or infection may cause the implant to protrude through the skin.
- Irreversible scarring may occur.

Skin Rippling

- May be visible or palpable.
- May sometimes require additional evaluation.

Calcification

- Calcium deposits may form around the implant.
- Surgical removal may be required.

Implant Displacement

- Rotation or migration may occur.
- Corrective surgery may be required.

Seroma

- Accumulation of fluid around the implant.
- Drainage may be required.

GENERAL RISKS OF SURGERY

- Healing problems
- Bleeding
- Infection
- Scarring
- Changes in nipple sensation
- Pain
- Thrombosis
- Pulmonary embolism
- Allergic reactions
- Asymmetry
- Unsatisfactory aesthetic result
- Need for repeat surgery

ADDITIONAL WARNINGS

Smoking

Increases the risk of complications and impaired healing.

Mammography

Implants may make the detection of breast cancer more difficult. You must inform your physician that you have breast implants.

Breastfeeding

Most women are able to breastfeed. However, limitations may occur.

Medications

Aspirin and NSAIDs increase the risk of bleeding. You must inform your physician about all medications you are taking.

Psychological Aspects

Expectations should be realistic. Perfection cannot be guaranteed.

NEED FOR REPEAT SURGERY

In the future, the following may be required:

- Implant replacement;
- Implant removal;
- Correction of the result.

Medicine is not an exact science, and absolute guarantees regarding the outcome cannot be provided.

PATIENT RESPONSIBILITIES

- Strictly follow the physician's recommendations.
- Limit physical activity during the recovery period.
- Attend follow-up examinations.

DISCLAIMER

This document is intended to inform the patient about the nature of the surgery, its risks, and alternative treatment options. It does not cover absolutely all possible complications.

Standards of medical care may change as science and technology develop.

Please carefully read the information provided and make sure that you have received answers to all questions you may have.