

“RISKS OF MEDICAL INTERVENTION (SURGICAL PROCEDURE)” – APPENDIX No. 2

INFORMED CONSENT – BREAST IMPLANT REMOVAL

“RISKS OF MEDICAL INTERVENTION (SURGICAL PROCEDURE)”

Appendix No. 2: approved by “ARZ EST” on 02.05.2019 by Order No. 01/5.

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

INSTRUCTIONS

This informed consent document has been prepared to provide you with information about the procedure for removal of breast implant(s), the associated risks, and alternative treatment methods.

It is important to carefully and completely review this information. Please initial each page to confirm that you have read it and sign the consent for the surgery proposed by your plastic surgeon and agreed upon with you.

GENERAL INFORMATION

Removal of breast implants placed for cosmetic or reconstructive purposes is a surgical procedure.

Removal may be performed as a standalone procedure or in combination with additional procedures, such as:

- Simple removal of the implant without removal of the capsule
- Removal of the capsule (capsulectomy)
- Removal of silicone gel that has escaped beyond the capsule (breast biopsy)
- Breast lift (mastopexy) after removal of the implant and/or capsule

Damaged or ruptured implants cannot be repaired; their removal or replacement is recommended.

The procedure may be performed under general or local anesthesia.

This consent form is intended for permanent removal of the implants and/or capsule.

If re-placement of implants is planned, a separate consent form must be signed.

If mastopexy is performed, additional informed consent is required.

ALTERNATIVE METHODS

Alternatives include:

- Declining implant removal
- Replacement of implants or correction of their position

Any surgical method involves risks.

RISKS OF BREAST IMPLANT REMOVAL SURGERY

Any surgery involves certain risks. It is important to understand the possible complications.

SPECIFIC RISKS

Skin Wrinkling

Pronounced skin wrinkling may occur after implant removal. Additional surgery for a breast lift may be required.

Silicone Implant Rupture

- Gel leakage may occur
- Complete removal of silicone may be impossible
- Fragments of the implant shell may remain
- Calcifications may occur
- Additional surgery may be required

Delayed Healing and Necrosis

- Wound separation
- Death of areas of skin or the nipple
- Increased risk in smokers
- Repeat surgery may be required

Changes in Nipple Sensation

- Temporary reduction in sensation (usually 3–4 weeks)
- In rare cases, permanent loss of sensation

Contour Irregularities

- Asymmetry
- Differences in nipple shape
- Excess skin
- Surgical correction may be possible

GENERAL RISKS OF SURGERY

- Impaired healing
- Bleeding
- Infection
- Scarring
- Tissue firmness
- Changes in skin color
- Increased skin sensitivity
- Wound separation
- Damage to deep structures (nerves, blood vessels, lungs)
- Fat necrosis
- Seroma (fluid accumulation)
- Complications of anesthesia
- Shock (extremely rare)
- Pain (which may become chronic)
- Pulmonary embolism
- Thrombosis
- Allergic reactions
- Asymmetry
- Unsatisfactory result

Repeat surgery may sometimes be required.

ADDITIONAL WARNINGS

Smoking

Increases the risk of skin necrosis and complications.

Mammography

Regular breast examinations and breast self-examination should be continued.

Immune System Disorders

To date, there is no evidence that implants increase the risk of autoimmune diseases; however, risks cannot be completely excluded.

Breastfeeding

Most women may be able to breastfeed, but no guarantee can be provided.

Medications

Aspirin, NSAIDs, and certain medications increase the risk of bleeding. Medications such as Plavix must not be discontinued without medical advice.

Sun Exposure

May impair healing and increase scarring.

Psychological Changes

The following may occur after implant removal:

- Significant reduction in breast volume
- Pronounced deformity
- Worsening of appearance compared with the condition before the initial surgery
- Depression
- Reduced sexual interest

Implant removal may not result in an improvement in health in cases of suspected implant-related illnesses.

NEED FOR REPEAT SURGERY

In the future, the following may be required:

- Additional correction
- Repeat surgery

Medicine is not an exact science. No guarantees regarding the result can be provided.

PATIENT RESPONSIBILITIES

- Strictly follow the physician's recommendations
- Limit physical activity
- Do not remove dressings or drains yourself
- Attend follow-up examinations

DISCLAIMER

This document is intended to inform the patient about the nature of the surgery, its risks, and alternative treatment methods, including the option of declining surgery.

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.