

## **Recommended Minimum Requirements for Preoperative Informed Consent: Aesthetic Breast Augmentation with Implants**

### **1. Purpose and Scope of the Guideline**

This guideline defines the minimum mandatory elements required for a valid, ethical, and legally robust preoperative informed consent for aesthetic breast augmentation with implants.

Its primary objectives are:

- to enhance patient safety,
- to ensure clear understanding of procedure-specific risks,
- to promote international uniformity in consent standards,
- to reduce medico-legal disputes related to inadequate or incomplete information.

This guideline applies to all surgeons performing aesthetic breast augmentation, regardless of specialty background, and is intended as a baseline standard, not a maximal or exhaustive consent.

### **2. Discussion of Therapeutic Alternatives**

Patients must be informed that breast augmentation with implants is not the only option.

The following alternatives must be discussed, when clinically applicable:

- Autologous fat grafting (lipofilling), including its limitations and need for repeated sessions
- Mastopexy without implants
- Combined mastopexy–augmentation
- No surgical treatment (conservative option)

The advantages, limitations, durability, and specific risks of each alternative must be clearly explained.

### **3. Description of the Surgical Procedure**

The consent must include a clear and comprehensible description of:

- Type and location of incisions
- Implant pocket (sub glandular, subfascial, submuscular, dual plane)
- Implant characteristics: filling material
- Shape
- surface characteristics
- approximate volume and dimensions

It must be explicitly stated that implant choice is individualized and that intraoperative adjustments may be necessary for safety or anatomical reasons.

### **4. Purpose, Expected Outcome and Limitations**

The goals of surgery must be linked to the patient's preoperative anatomy and expectations.

Patients must understand that:

- exact symmetry cannot be guaranteed,
- aesthetic outcome is influenced by tissue quality and healing response,
- photographic simulations are illustrative and non-binding.

### **5. Mastopexy, Combined Procedures and Scarring**

When lifting procedures are performed, the consent must clearly describe:

- type of mastopexy
- extent and location of scars
- risk of scar widening, hypertrophy, or pigmentary changes

Patients must acknowledge that scarring is permanent, although it may fade over time.

## **6. Procedure -Specific Complications**

This section represents a central and non-negotiable component of the informed consent.

Patients must be explicitly informed, in clear and understandable language, about the following implant-specific complications:

### **i. Capsular Contracture**

- definition and clinical presentation
- potential impact on breast shape, consistency, and pain
- possibility of recurrence despite corrective surgery

It is strongly suggested to show pictures of the above conditions

### **ii. Implant Rupture and Deflation**

- differences between saline and silicone implants
- silent rupture
- need for imaging surveillance
- indication for implant removal or replacement

### **iii. Implant Malposition and Rotation**

- bottoming-out
- lateral or medial displacement
- double bubble deformity
- rotation of anatomical implants

It is strongly suggested to show pictures of the above conditions

### **iv. Infection and Biofilm Formation**

- early and late infections
- role of biofilm in chronic complications
- possible need for implant removal

### **v. Sensory Changes**

- nipple–areola complex hypoesthesia or hyperesthesia
- possible permanence of sensory alterations

### **vi. Rippling, Visibility and Palpability**

- influence of tissue thickness and implant type
- higher risk in low-BMI patients

It is strongly suggested to show pictures of the above conditions

## **vii. Need for Reoperation**

Patients must clearly understand that breast implants are not permanent devices and that:

- revision surgery is common over time
- multiple surgeries may be required during a patient's lifetime

The probability and timing of reoperations should be explained using available international data, without guaranteeing durability.

Visual aids (photographs or diagrams) are strongly recommended to improve patient comprehension

## **7. General Surgical and Anesthetic Risks**

General risks common to all surgical procedures must be addressed, including:

- bleeding and hematoma
- thromboembolic events
- cardiopulmonary complications
- allergic reactions

## **8. Long-Term Changes, Ageing and Pregnancy**

Patients must be informed that:

- ageing, weight changes, pregnancy and breastfeeding may alter results
- future corrective surgery may be necessary regardless of initial outcome

It is strongly suggested to show pictures of the above conditions,

## **9. BIA-ALCL and Breast Illness (BLL)**

The consent must include updated information on:

- current scientific knowledge regarding BIA-ALCL
- known incidence and warning signs
- diagnostic and therapeutic pathways

Breast Implant Illness (BII) must be discussed as a patient-reported condition, acknowledging ongoing scientific research and uncertainty.

## **10. Clinical and Imaging Follow-up**

The consent must specify recommended follow-up, including:

- clinical examinations
- ultrasound and/or MRI surveillance
- breast cancer screening protocols adapted to implant presence

## **11. Financial Aspects and Future Costs**

Patients must be informed that:

- future implant replacement or revision surgery may not be included in the initial fee
- additional costs may arise over time

Agreements about financial management of complications and unstable results should be detailed

## **12. Data Protection and Use of Images**

Explicit authorization must be obtained for:

- storage of medical data
- use of clinical photographs or videos

Patients must be informed of their rights to withdraw consent for image use, in accordance with applicable regulations.

This guideline defines minimum requirements and does not replace national legal obligations or professional judgment.

**Disclaimer**

*The information contained in this document is for general guidance and informational purposes only. It is highly recommended that you consult guidelines from your National/Regional Health Authority.*