



ISAPS® PATIENT SAFETY

INFORMED CONSENT OF THE INTERNATIONAL SOCIETY
OF AESTHETIC PLASTIC SURGERY

INFORMED CONSENT FOR BREAST AUGMENTATION

November 12, 2024

Breast augmentation or placement of a breast prosthesis is a surgical procedure to increase the size of the breast(s), for various reasons: to improve the body contour of women, to correct a loss in breast volume, to correct a breast asymmetry between them, as breast reconstruction.

The shape and size of the breasts prior to surgery can influence the recommended treatment and the final result. If your breasts are not the same size or shape before surgery, it is unlikely that they will be completely symmetrical afterward. The incision, type and location of the prosthesis will depend on your anatomy, preferences and recommendation of your surgeon.

GENERAL RISKS AND COMPLICATIONS

Any surgery or procedure has general risks of complications:

- Postoperative bleeding
- Wound infection, respiratory (cold, pneumonia, bronchopneumonia), urinary, others
- Deep vein thrombosis in the lower extremities
- Pulmonary: atelectasis, pulmonary thromboembolism, others
- Cardiac: arrhythmia, acute myocardial infarction, problems associated with elevated or decreased blood pressure, others
- Neurological: vascular accidents, transient or permanent alterations in sensitivity or motility
- Anesthetics: allergic reaction to some medication. Both local anesthesia and general anesthesia carry a risk. There is the possibility of complications, and even death, from any form of anesthesia or sedation

COMPLICATIONS OF BREAST AUGMENTATION

Every surgical procedure involves risk and eventual complications. Although most patients do not experience the following complications of BREAST AUGMENTATION, you should discuss each of them with your plastic surgeon:

- **BLEEDING:** It is possible, although uncommon, to experience a bleeding episode during or after surgery. If postoperative bleeding occurs, treatment to drain accumulated blood or blood transfusion may be required.
- **INFECTION:** Infection is uncommon after this type of intervention. If infection occurs, treatment includes possible removal of the implant, antibiotics or additional surgery.
- **CAPSULAR CONTRACTURE:** Scar tissue that forms internally around the implant can contract and cause the prosthesis to become round, firm and possibly painful. Excessive breast hardness can occur shortly after surgery or after years. Capsular contracture can occur on one side, both or neither. Treatment for capsular contracture may sometimes require surgery.
- **MALPOSITION OF THE PROTHESIS:** It may occur that the scar tissue around the prosthesis determines a malposition of the prosthesis and/or asymmetry in relation to the contralateral breast. Treatment may require additional surgery. Depending

on the healing processes, malposition may occur again.

- **CHANGES IN NIPPLE AND SKIN SENSIBILITY:** There may be an alteration in sensation immediately after surgery. After several months, most patients have normal sensitivity. In some cases, a partial or complete loss of nipple and skin sensation may occur.
- **SKIN SCARRING:** Abnormal scars may occur. They can be also of a different color than the surrounding skin. Additional treatments may be needed to manage abnormal scars after surgery.
- **DELAYED HEALING:** There is a possibility of wound opening or delayed healing. Some areas may not heal normally and may take a long time to heal. Patients who smoke have a higher risk of skin loss and healing complications.
- **RUPTURE:** Breast prostheses can break or leak. The rupture can occur as a result of trauma, an injury, during a mammogram or without apparent cause. Prostheses do not have an unlimited life and will eventually require replacement surgery.
- **PROTHESIS EXTRUSION:** Lack of adequate coverage by the patient's tissues or an infection can result in exposure and extrusion of the prosthesis.
- **SKIN FOLDS:** There may be visible and palpable folds in the skin. This may be more pronounced in patients with little breast tissue. In some cases, additional surgery may be required. The folds may fade, disappear or recur depending on the local tissue.
- **PREGNANCY AND BREAST FEEDING:** Although there is no evidence of any special danger of implants for the pregnant woman or her child, studies continue to look for possible problems.
- **PAIN:** Chronic pain is very rare. Additional procedures may be required to rule out other causes and treat it.
- **SKIN NECROSIS:** There may be a partial or total lack of blood flow in some areas, the skin can turn black and become a wound that will require management with dressings or eventually surgery and that can leave noticeable scars.
- **ASSYMETRY:** Normally there is an asymmetry between both breasts in position and/or volume. After augmentation mammoplasty, this asymmetry may be more noticeable.
- **FAT NECROSIS:** Areas of fat nodules may occur in the breast that may be palpable and cause pain. Surgery may be required to remove it.
- **CALCIFICATION:** Calcium deposits can form in the tissue surrounding the prosthesis, which can cause pain, increased consistency and may be visible on mammography. If this occurs, additional surgery may be necessary to correct the problem.
- **BREAST IMPLANT ILLNESS:** Current medical literature does not demonstrate an increased risk of breast disease or breast cancer in women who have breast prostheses for aesthetic or reconstructive reasons. Symptoms of breast implant illness can appear regardless of the presence of a prosthesis.
- **BREAST IMPLANTS - ASSOCIATED ANAPLASTIC LARGE CELL LYMPHOMA:** A rare form of lymphoma can develop around the breast implants. Additional surgery or other therapies may be needed to treat this illness.
- **SQUAMOUS CELL CARCINOMA (SCC) ASSOCIATED WITH BREAST IMPLANTS (BIA-SCC):** A rare and aggressive cancer that can occur in the capsule around the breast implant. It can occur in both smooth and textured implants, and in both saline and silicone implants. Treatments include implant removal, mastectomy, chemotherapy and radiotherapy.

NEED FOR ADDITIONAL SURGERY

There are many variable conditions that can influence the long-term results of breast augmentation. Secondary surgery may be needed to make additional corrections. If complications occur, additional surgery or other treatments may be necessary.

ADDITIONAL COSTS

There may be additional costs associated with complications arising from surgery, secondary surgery or surgical revision.

CONTROLS

Since the plastic surgeon is in charge of a team of medical professionals who will be at his/her disposal, subsequent controls, procedures or cures may be carried out by one of the other members of the work team.

INFORMED CONSENT FOR PROCEDURE FORM

IT IS IMPORTANT THAT YOU READ THE ATTACHED INFORMATION CAREFULLY AND HAVE ALL YOUR QUESTIONS ANSWERED BEFORE YOU SIGN THE CONSENT BELOW:

INFORMED CONSENT FOR BREAST AUGMENTATION

1. I hereby authorize DR.
and the assistants who are selected to perform the following procedure or treatment:

BREAST AUGMENTATION

2. I have read, understood and signed the pages of the attached information: "Informed Consent for Breast Augmentation,,"

3. I have not omitted or altered data when presenting my history and clinical-surgical history, especially those referring to allergies and illnesses or personal risks.

4. I am aware that, during the course of the operation and medical treatment or anesthesia, unforeseen conditions may arise that require procedures other than those proposed. I hereby authorize him/her and his/her assistants to perform these other procedures in the exercise of their professional judgment. The authorization will include any condition requiring treatment that was not known to the surgeon at the time the procedure was started.

5. I agree that no guarantee has been given to me by anyone as to the result that may be obtained.

6. I give consent for the administration of anesthetics that are considered necessary or advisable. I understand that any form of anesthesia presents a risk and the possibility of complications, injuries and very rarely, death.

7. I give consent to the photographing or filming of the operation to be performed, including any part of my body, and the subsequent use of the material for medical, scientific or educational purposes, since my identity will not be revealed in the images:

YES NO

8. For the purpose of advancing medical education, I give consent for observers to enter the operating room:

YES NO

9. The treatment mentioned above and the complications of the procedure have been explained to me in an understandable way.

10. LOCATION OF SCARS:

- Around the areola
- Vertical scar
- In the inframammary fold
- In the axillary fold

I give consent for the treatment and the points cited above (1 to 10):
(Identification and signature of the patient or authorized person)

Name:

Identification:

Signature:

Date:

Disclaimer

*This medical informed consent form is offered as a guide to ISAPS members and as an aid to drafting consent forms for their patients and their practice. Whilst it provides a framework, it remains the responsibility of the individual practitioner to tailor any final documentation to the practice or legislative requirements specific to the local jurisdiction and to make consent decisions appropriate to the circumstances of each patient, in consultation with the patient and, where appropriate, with their guardian or carer.
In providing this guidance as a service to its members, ISAPS accepts no responsibility or liability associated with its subsequent use in clinical practice or in any other context.
ISAPS reserves the right to modify, amend, or update this consent form at any time without prior notice. Users are encouraged to review this form periodically for any changes.*