Quick Facts about Breast Augmentation with IDEAL IMPLANT® Structured Breast Implants

Important Factors Breast Augmentation Patients Should Consider

August 2015

Caution: Federal law restricts this device to sale by or on the order of a licensed physician.

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About This Brochure

This brochure is intended to provide you with a high level overview of the facts about breast implant surgery with Ideal Implant's Structured Breast Implants. This brochure is not intended to replace consultation with your surgeon. For a complete review of the benefits and risks of breast implant surgery, please read the appropriate Patient Educational Brochure, Making an Informed Decision IDEAL IMPLANT® Structured Breast Implant Surgery, available from your surgeon and posted on idealimplant.com. You may also contact Ideal Implant directly at (214) 492-2500 for a copy of the brochure.

Indications

Ideal Implant's Structured Breast Implants are indicated for women at least 18 years old for:

- Primary breast augmentation to increase the breast size
- Revision augmentation to correct or improve the result of primary breast augmentation surgery.

Contraindications

Breast implant surgery should NOT be performed in:

- Women with active infection anywhere in their bodies,
- Women with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions, and in
- Women who are pregnant or nursing.

Risks Associated With Breast Implants

Undergoing any type of surgery involves risks. There are a number of local complications (problems at or near the breast/surgical incision site) that may occur after your breast implant surgery.

COMPLICATIONS

Table 1 presents the complication rates reported in Ideal Implant's Clinical Study through 2 years.

Table 1 - Complication Rates Reported through 2 Years		
Complication (Includes all levels of severity)	Primary Augmentation (N = 399 patients)	Revision Augmentation (N= 103 patients)
Key Complications		
Any complication or reoperation[1]	42 out of 100 patients (42%)[4]	50 out of 100 patients (50%)[4]
Any breast complication or reoperation[1]	34 out of 100 patients (34%)[4]	45 out of 100 patients (45%)[4]
Reoperation[1]	14 out of 100 patients (14%)	24 out of 100 patients (24%)
Implant removal with or without replacement[1]	8 out of 100 patients (8%)	15 out of 100 patients (15%)
Spontaneous deflation[1]	5 out of 100 patients (5%)	3 out of 100 patients (3%)
Capsule contracture (Baker grade III/IV)	4 out of 100 patients (4%)	8 out of 100 patients (8%)
Other Complications Occurring in 1% or more of Patients[2]		
Breast pain	Less than 1 out of 100 patients (0.3%)	1 out of 100 patients (1%)
Delayed wound healing	1 out of 100 patients (1%)	1 out of 100 patients (1%)
Dissatisfaction with cosmetic result[3]	4 out of 100 patients (4%)	9 out of 100 patients (9%)
Dissatisfaction with size selected	3 out of 100 patients (3%)	4 out of 100 patients (4%)
Hematoma	2 out of 100 patients (2%)	0 out of 100 patients (0%)
Implant extrusion	0 out of 100 patients (0%)	2 out of 100 patients (2%)
Implant malposition	3 out of 100 patients (3%)	1 out of 100 patients (1%)
Infection	1 out of 100 patients (1%)	1 out of 100 patients (1%)
Lesion - benign	2 out of 100 patients (2%)	4 out of 100 patients (4%)
Ptosis	Less than 1 out of 100 patients (0.5%)	4 out of 100 patients (4%)
Scarring	2 out of 100 patients (2%)	4 out of 100 patients (4%)
Seroma	Less than 1 out of 100 patients (0.3%)	3 out of 100 patients (3%)
Wrinkling/scalloping (excludes mild severity)	4 out of 100 patients (4%)	12 out of 100 patients (12%)
Mastopexy Unsatisfactory	2 out of 100 patients (2%)	0 out of 100 patients (0%)
Inadequate Milk Supply	Less than 1 out of 100 patients (0.3%)	1 out of 100 patients (1%)

[1] Rates for Reoperation, Implant removal and Spontaneous deflation are based upon analyses of patients with initial bilateral final design of the implants: N=363 for Primary Augmentation Cohort and N=93 for Revision Augmentation Cohort. The other 36 primary augmentation patients and 10 revision augmentation patients received an early design of the implant which is not being manufactured, and therefore were excluded from the complication rates for these 3 events.

[2] The following complications were reported at a risk rate of 0% in both patient cohorts: capsule calcification and nipple/breast sensitivity change. The following complications were reported at a risk rate of less than 1% in the primary augmentation cohort: lesion-malignant, lymphadenopathy and tissue atrophy/chest wall deformity.

[3] Includes asymmetry, palpability, wrinkling, shape, position, size and capsule contracture.

[4] 151 Primary Augmentation patients and 47 Revision Augmentation patients experienced at least one complication or reoperation through 2 years. 123 Primary Augmentation patients and 42 Revision Augmentation patients experienced at least one breast complication or reoperation through 2 years.

IMPLANT REMOVAL

Breast implants may be removed (with or without replacement) in response to a complication or to improve the cosmetic result. In Ideal Implant's Clinical Study, through 2 years, the most common reasons for implant removal in the primary augmentation cohort were spontaneous deflation and dissatisfaction with implant size (36% and 30% respectively of all implant removals); the most common reasons for implant removal in the revision augmentation cohort were dissatisfaction with implant size and dissatisfaction with cosmetic result (23% of all implant removals).

Figures 1 through 2 below present the reasons for implant removal in Ideal Implant's Clinical Study through 2 years.

Figure 1. Reasons for Implant Removal through 2 Years
Primary Augmentation Cohort (n=44 implants)

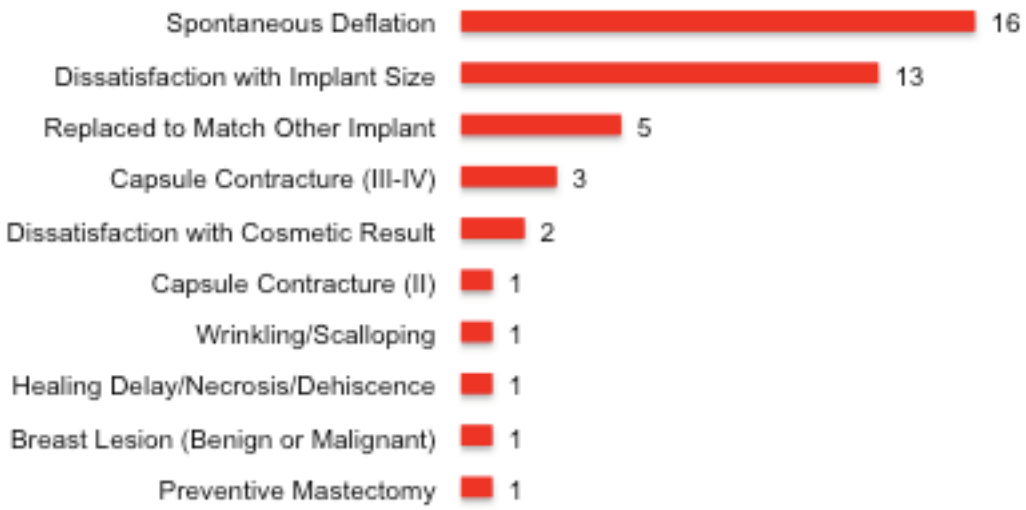
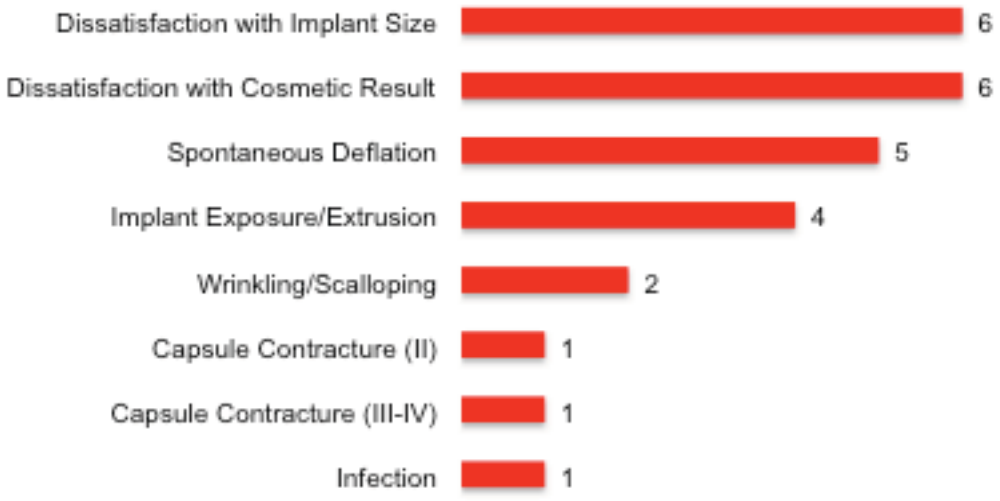


Figure 2. Reasons for Implant Removal through 2 Years
Revision Augmentation Cohort (n=26 implants)



For a more detailed review of potential complications, please refer to Sections 2.2 and 3.2 of the Patient Educational Brochure for breast augmentation with Ideal Implant's Structured Breast Implants.

Important Factors To Consider

Before you have surgery, you should have a detailed conversation with all of your doctors (primary care doctor, surgeon, and any specialists you see) about breast implant surgery in light of your medical history.

PRECAUTIONS

CAUTION: Notify your doctor if you have any of the following conditions as the risks of breast implant surgery may be higher if you have any of these conditions

- An autoimmune disease
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease)
- Conditions that interfere with wound healing and/or blood clotting
- Reduced blood supply to breast tissue
- Planned chemotherapy following breast implant placement
- Planned radiation therapy to the breast following breast implant placement
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. If you have been diagnosed with or treated for depression, an anxiety disorder, or another mental health condition, you should wait until your condition has resolved or stabilized before having breast implant surgery. Discuss any history of mental health disorders with your doctor(s) prior to surgery.

WARNINGS

Below is a list of warnings associated with breast implant surgery. For a more detailed review of warnings, please refer to Section 1.6 of the Ideal Implant Patient Educational Brochure for breast augmentation, Making an Informed Decision IDEAL IMPLANT® Structured Breast Implant Surgery.

- The IDEAL IMPLANT has not been studied for use in breast reconstruction and therefore is not indicated for primary breast reconstruction, revision breast reconstruction or if there will be radiation of the breast.
- Results depend on factors such as your breast shape and position, skin quality, your healing, previous pregnancy or surgery, size of implant and surgeon skill.
- Smoking can make it harder for your body to heal. Do not smoke before your breast implant surgery or while you are recovering.
- Breast implants are not expected to last for the rest of your life, and breast implantation may not be a one-time surgery. Revision procedures have a higher risk of complications than the initial implant procedure.
- Many of the changes to your breasts that may occur as a result of breast implant surgery will be permanent and cannot be undone.
- Breast implants may interfere with your ability to produce milk (lactate) for breast-feeding. Breast implants do not prevent sagging after pregnancy.

- Mammography for detecting breast cancer (or cancer recurrence) may be more difficult with breast implants in place. Be sure to notify the technologist that you have breast implants prior to the procedure.
- Routine self-examination of your breasts may be more difficult with implants. However, you should still perform an examination of your breasts every month for cancer screening.
- After undergoing breast implant surgery, you may experience changes in your healthcare insurance. Be sure to check with your insurance company about potential issues and understand the complete extent of your health coverage before having breast implant surgery.

For a complete review of the risks and benefits please read the Ideal Implant Patient Educational Brochure for breast augmentation, Making an Informed Decision IDEAL IMPLANT® Structured Breast Implant Surgery.

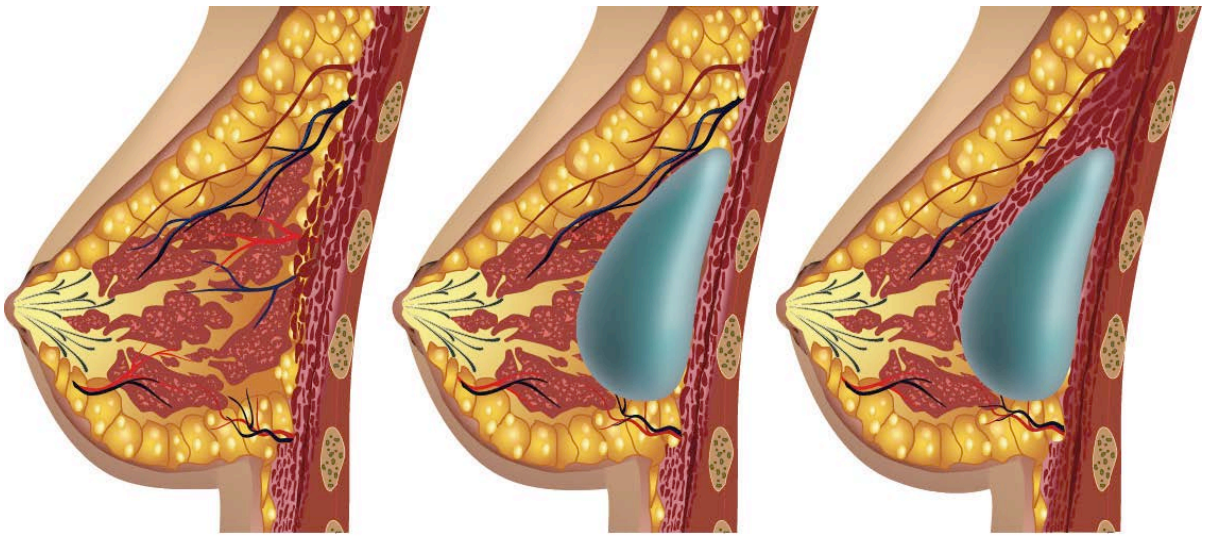
Breast Implant Surgery – Understanding The Procedure

Before your breast implant surgery, you and your plastic surgeon will discuss the implant placement and surgical incision options, as well as your expected postoperative care.

IMPLANT PLACEMENT

Your surgeon will consult with you and suggest where the breast implant is to be placed. Implants are placed beneath your breast tissue, either on top of the chest muscle (subglandular placement) or underneath part or all of the chest muscle (submuscular placement).

Figure 3: Implant Placement

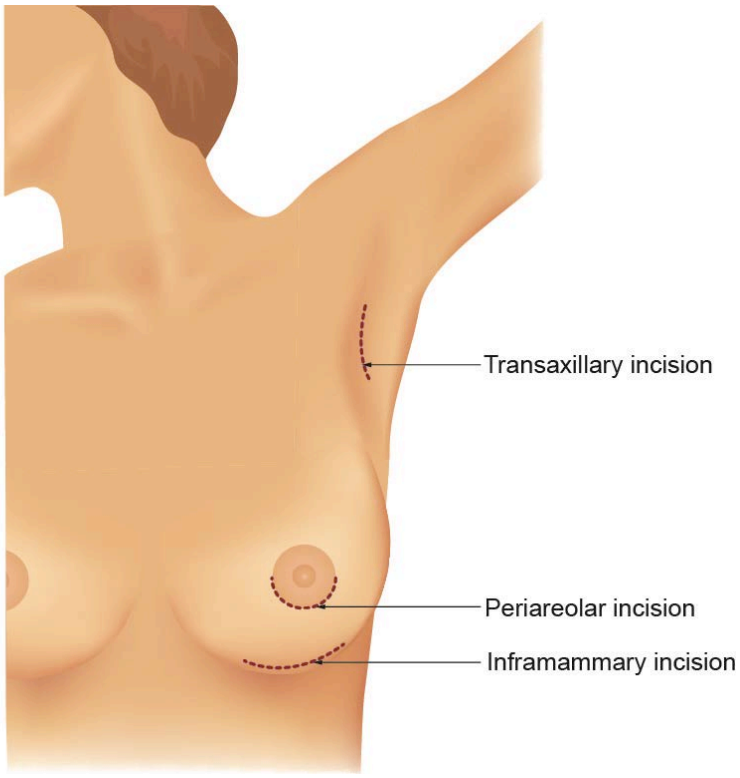


INCISION SITES

Your surgeon will suggest the best incision site option for your particular surgery. There are three common incision sites to consider:

- Inframammary (under the breast at the crease where the breast meets the body)
- Periareolar (around the nipple)
- Transaxillary (in the armpit)

Figure 4: Incision Sites



POSTOPERATIVE CARE

In the weeks after your breast implant surgery, the skin over your breasts may feel tight as it adjusts to your new breast size. After your stitches are removed, your doctor may tell you to massage your incision site(s) with a cream or lotion to keep the skin from drying out; this may make you more comfortable as well. Use the product(s) he or she recommends.

Your doctor may have special directions about avoiding exercise or activities that compress or put pressure on your breasts during the first weeks after surgery. Follow your doctor's directions.

Breast Implants Are Not Lifetime Devices

Breast implants are not expected to last for the rest of your life, and breast implantation may not be a one-time surgery. It is likely that you will need other surgery related to your breast implants over the course of your life. Patients may require a reoperation for a number of reasons, including size and/or style change, implant removal (with or without replacement), capsular contracture procedures, incision and drainage, implant repositioning, scar revision, or to address some of the complications mentioned in Table 1 on page 5.

Additional Information

For additional information or if you have questions regarding Ideal Implant Structured Breast Implants, please visit Ideal Implant's website at idealimplant.com or call Ideal Implant Incorporated at (214) 492-2500.

Additional information about breast implants can be obtained from the United States Food and Drug Administration (FDA) at fda.gov/breastimplants.

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Print date: 8-1-15