

BREAST AUGMENTATION
A WOMEN'S CHOICE

Saline-Filled
Breast Implants

 **INAMED**
AESTHETICS

YOU'RE CONSIDERING BREAST AUGMENTATION...

Every day, you make decisions that affect the way you live. Some choices depend on the moment, like the clothing, hairstyle and perfume you'll wear today. Other decisions are deeply significant, because they affect how you feel about yourself as a woman, and how others perceive you.

One decision more and more women are making everyday is to have breast augmentation (a procedure to enhance the size of your breasts by using breast implants). Advances in breast implant technology and surgical technique are making breast augmentation a popular option among women of all ages desiring a change in the way they look.

The decision to undergo breast augmentation may result in a more flattering, better proportioned figure, more clothing options, and may enhance your confidence and self-esteem.

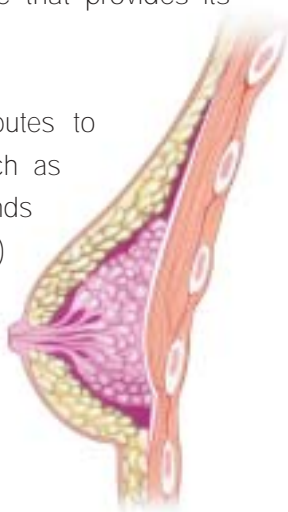
We hope this brochure will assist you in making an informed decision by providing information about your breast augmentation choices with *FDA approved* McGhan® style saline-filled round and shaped breast implants.



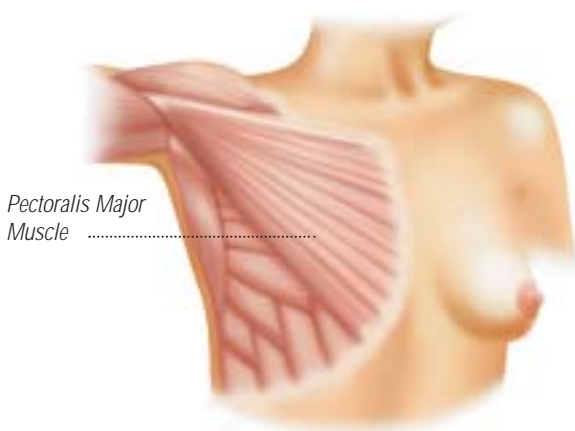
FIRST OF ALL, WHAT GIVES THE BREAST ITS SHAPE?

The breast consists of milk ducts and glands, surrounded by fatty tissue that provides its shape and soft feel.

Skin elasticity also contributes to breast shape. Factors such as pregnancy (when milk glands are temporarily enlarged) and the inevitable effects of gravity as you age combine to stretch the skin, causing the breast to droop or sag.

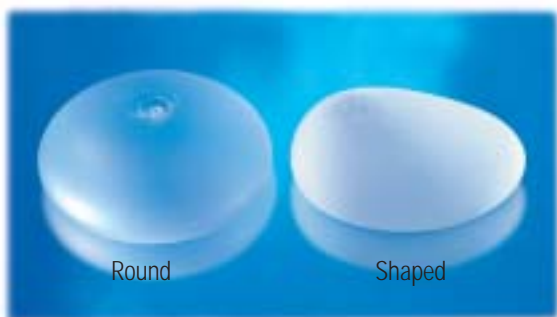


Situated beneath the breast is the pectoralis major muscle. A breast implant can be placed either partially under or over this muscle, depending on the thickness of your breast tissue and its ability to adequately cover the breast implant.



EXACTLY WHAT IS A BREAST IMPLANT?

Virtually all breast implants are made of a round or shaped silicone elastomer (rubber) shell, and are now commonly filled with a saline solution (salt water). Saline solution is used to fill the implant because it is similar to the fluids in your body, and will be absorbed by your body should the implant leak or break.

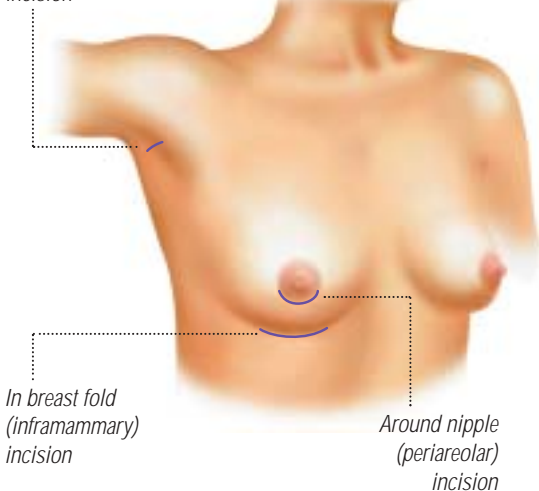


In 1992, the Food & Drug Administration (FDA) greatly restricted the use of breast implants filled with silicone gel pending more information on their physiological effects. INAMED's McGhan® style saline-filled implants are FDA approved, and are available on a prescription basis from a licensed physician. For more information refer to the booklet *Making An Informed Decision; Saline-Filled Breast Implant Surgery*, or the breast implant package insert, available from your physician or INAMED Aesthetics.

HOW DOES A BREAST IMPLANT WORK?

The incision for each implant is made as inconspicuously as possible at one of three typical sites: under the arm, around the nipple, or within the breast fold. If the incision is made under the arm, the surgeon may use a probe fitted with a miniature camera, along with minimally invasive instruments, to create a "pocket" for the breast implant.

*Under arm
(transaxillary)
incision*

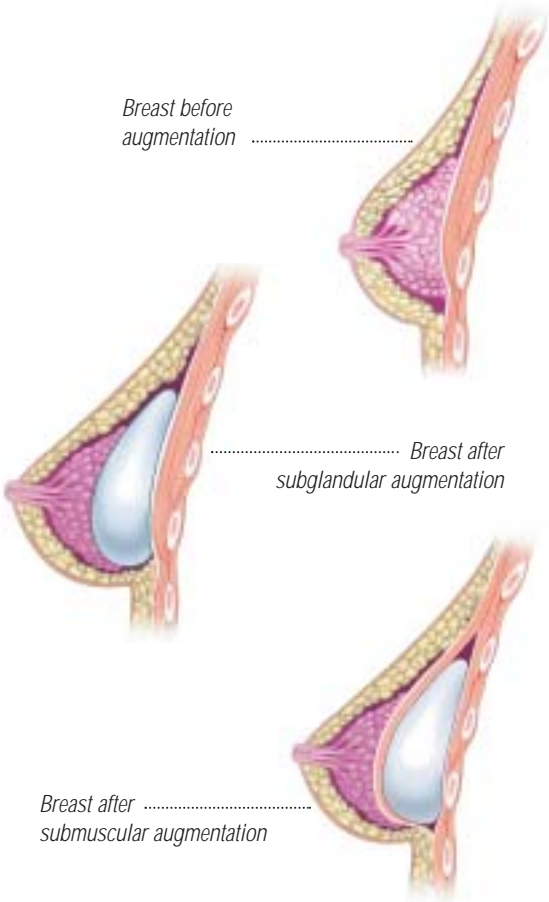


*In breast fold
(inframammary)
incision*

*Around nipple
(periareolar)
incision*

The breast implant is then placed either partially under the pectoralis major muscle (submuscular), or on top of the muscle and under the glands (subglandular).

To permit the smallest possible incision, the implant is typically inserted empty, and then filled with saline. Your surgeon can explain more about the procedures to help you choose the best option for you.



ARE ALL BREAST IMPLANTS CREATED EQUAL?

Generally, all saline-filled breast implants are made of a silicone elastomer shell with a filling valve, for filling with the saline solution. However, to better meet each individual woman's needs, breast implants come in different shapes and sizes.

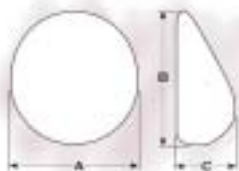
The McGhan® Style 68 and Style 168 Round Breast Implants



are round in design. They enhance breast size, and may produce a more rounded appearance to the upper breast.

The McGhan® Style 468 Shaped Breast Implant

is designed to reflect the slope of a breast. With its upper area gently sloping downward and outward, the McGhan® Style 468 Shaped Breast Implant is more likely to shape the upper part of your breast with a gentle slope. And the McGhan®



BIOCELL® large-pore surface texture may help hold the breast implant in place in some cases.



Though other shaped breast implants exist, they do not provide the overall

height that produces a more gradual transition of the upper breast area.

The McGhan® style round and shaped breast implants are available in a wide variety of sizes to specifically match your body type. Depending on the look you want to achieve, you may prefer one type of breast implant over the other. Be sure to ask your qualified plastic surgeon which breast implant McGhan® style is appropriate for you.



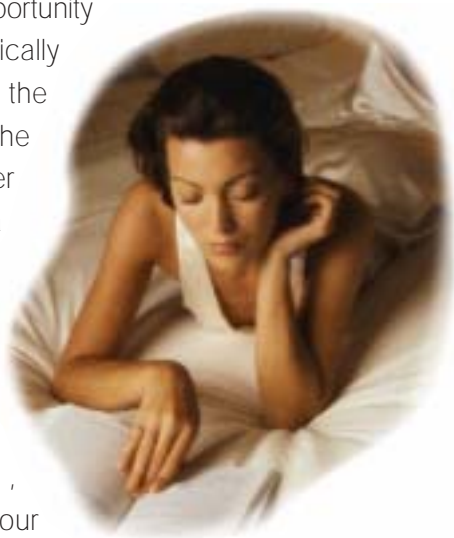
Round breast implants tend to produce a more rounded appearance to the upper breast.



Shaped breast implants are designed to reflect the slope of the breast.

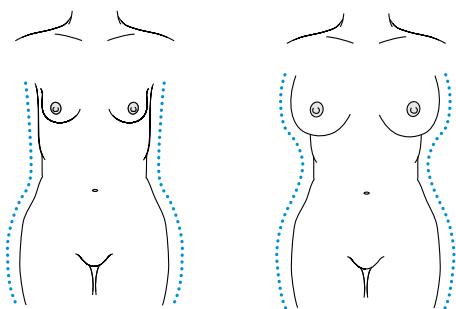
HOW IS IMPLANT SIZE DETERMINED?

Breast augmentation offers a unique opportunity to scientifically "customize" the shape of the breast rather than just bra size. You may want to wear an outfit that reveals more cleavage, change your wardrobe style, or simply create the proper balance between your breasts and hips. Generally, the larger you want your cup size, the larger the breast implant the surgeon will consider (measured in cubic centimeters, or cc's).



The McGhan® BioDIMENSIONAL® Planning System is used with the Style 468 Shaped Breast Implants to help provide more consistent and predictable results. With this unique planning system, you and your surgeon can consider important dimensions like breast width, height and lateral protrusion to establish the ideal implant size and shape to complement your figure. Breast width is significant, because it figures prominently in both cleavage

and lateral (sideways from the body) protrusion. No other system provides such exacting techniques to determine what breast implant will work best for you.



Your surgeon will also evaluate your existing breast tissue to determine whether you have a sufficient amount to cover the breast implant. If you desire a breast implant size too large for your tissue, the doctor may warn you that breast implant edges may be apparent or visible post-operatively. You may even risk surgical complications. Also, excessively large breast implants may not maintain as youthful an appearance over time.

WHAT ABOUT THE SURGERY ITSELF?

Beyond any discussion of breast shape and size, your surgeon will want to evaluate your current physical health and health history before scheduling you for surgery. Breast augmentation is elective surgery. Before you proceed, you and your surgeon will have to decide whether the benefits of breast augmentation surgery outweigh the risks in your particular case.

If you have any condition that could compromise the healing process, or if surgery could jeopardize any pre-existing condition, your surgeon may prefer not to operate until the condition is resolved. Pre-existing infections, a history of poor wound healing, and some medications may be reasons not to operate.

The surgery will be performed in an operating room, either in the surgeon's office, or at a nearby hospital. The surgery is usually performed on an outpatient basis, whereby you will return home the same day. General anesthesia is most commonly used, although local anesthesia may also be an option. Your surgeon can discuss the choice of anesthesia with you in more detail.

The surgery usually lasts one to two hours. Your surgeon will make an incision and create a pocket for the breast implant (see pages 4 and 5 to review these methods). Then, the breast implant will be placed in the pocket, filled, and positioned. Finally, the incision will be closed, usually with stitches, and possibly taped.



A fill kit is used to fill the implant with sterile saline, usually after the breast implant is placed in the surgical pocket.

HOW WILL I FEEL AFTER SURGERY?

You'll probably feel somewhat tired and sore for several days following the operation, and your breasts may remain swollen and sensitive to physical contact for as long as a month. You may also experience a feeling of tightness in the breast area as your skin adjusts to your new breast size. The full results of your augmentation may not be visible until your breast tissue (and muscle, if the implant has been placed submuscularly) adjusts.

If the breast implant is placed submuscularly, you may feel more discomfort for several days longer than if it is placed in the subglandular position. You may also have difficulty raising your arms above your head until you heal, and your surgeon may at first restrict your arm motion. However, submuscular placement may reduce the risk of complications such as severe contraction of the tissue capsule around the breast implant (capsular contracture), visible or palpable implant edges, or interference with mammography.

Post-operative care is usually quite simple, perhaps involving the use of a post-operative bra or jog bra for extra support and positioning while you heal. At your surgeon's recommendation, you will most likely be able to return to work within a few days, although you should avoid any strenuous activities that could raise your pulse and blood pressure for at least a couple of weeks.

Your surgeon can tell you more about the typical recovery process, and may have other specific recommendations based on your individual case. If any unusual symptoms occur after surgery, such as fever or noticeable swelling or redness in one breast, you should contact your surgeon immediately.

WHAT ABOUT COMPLICATIONS?

Undergoing any invasive surgical procedure may involve the risk of complications such as the effects of anesthesia, infection, swelling, bleeding, pain, and delayed healing. In addition, there are potential complications specific to breast implants. These complications include:

- Deflation of the breast implant
- Interference with mammography
- Contraction of the scar tissue capsule around the breast implant (capsular contracture)
- Replacement or revision surgeries
- Calcium deposits in the tissue capsule around the implant
- Changes in nipple and breast sensation
- Shifting of the breast implant

In addition to known complications, there are unanswered questions about whether breast implants could increase your or your child's risk for connective tissue disorders or autoimmune disease. Studies so far have ruled out a large risk for such disorders.

Separate concerns have been raised about the unknown risk of breast implants and cancer. At

this time, there is no scientific evidence to suggest that women with saline-filled breast implants are more susceptible to cancer than other women.

Information on the risks and benefits associated with saline-filled breast implants is available at the back of this brochure, and from INAMED Aesthetics in the booklet *Making An Informed Decision; Saline-Filled Breast Implant Surgery*. You should thoroughly read and understand this information before deciding to proceed with surgery. You can also refer to the McGhan® style breast implant package insert, available from your surgeon or INAMED Aesthetics, for more information.

DOES INAMED AESTHETICS OFFER PATIENT SERVICES?

INAMED Aesthetics' patient services begin with our dedication to providing you, through your surgeon, products that have been designed and manufactured according to the highest quality standards – from the first sketch of an innovative design to the final product inspection before release for shipment.

The INAMED Aesthetics ConfidencePlus™ Breast Implant Limited Warranty Programs offers you lifetime replacement and limited financial reimbursement in the event of loss of product integrity.

Specific program benefits and conditions are described in the ConfidencePlus™ and ConfidencePlus™ Platinum brochure, available from your surgeon or INAMED Aesthetics.

CASE EXAMPLE 1

Choosing McGhan® round breast implants —
This patient had submuscular breast augmentation with the McGhan® Style 68 Round Breast Implant. Her augmentation achieved a noticeable increase in breast size, with a slightly round breast shape.

BEFORE



SIX MONTHS AFTER



CASE EXAMPLE 2

Choosing McGhan® shaped breast implants —
This patient had submuscular breast augmentation with the McGhan® Style 468 Shaped Breast Implant. She also achieved a noticeable increase in breast size, with a more gradually sloping breast shape.

BEFORE

SIX MONTHS AFTER



The cases presented here are only examples to illustrate possible augmentation results with McGhan® shaped and round breast implants. Your results may be different, depending on many factors, including your existing anatomy, personal preferences, and the surgical techniques used. As might be expected, wearing a bra can further “push up” the breasts to create additional cleavage. Your surgeon may be able to provide you with additional examples and insights based on his or her own experience to help you visualize how your augmentation might look, with and without wearing a bra.

What Are Important Factors for You to Consider When Deciding to Have Saline-Filled Implants?

- Whether you are undergoing augmentation or reconstruction, be aware that breast implantation may not be a one time surgery. You are likely to need additional surgery and doctor visits over the course of your life.
- Breast implants are not considered lifetime devices. You will likely undergo implant removal with or without replacement over the course of your life.
- Many of the changes to your breast following implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast.
- Breast implants may affect your ability to produce milk for breast feeding. Also, breast implants will not prevent your breast from sagging after pregnancy.
- With breast implants, routine screening mammography will be more difficult, and you will need to have additional views, which means more time and radiation.
- For patients who have undergone breast implantation either as a cosmetic or a reconstructive procedure, health insurance premiums may increase, coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. You should check with your insurance company regarding these coverage issues.

Augmentation – Insurance does not cover breast augmentation and may not cover reoperation (additional surgery) and additional doctor's visits following augmentation

Are You Eligible for Saline-Filled Breast Implants?

Implants are to be used for females for the following indications:

- Breast Augmentation
This procedure is done to increase the size and proportions of a woman's breasts. **A woman must be at least 18 years old for breast augmentation.**
- Breast Reconstruction
This procedure is done to restore a woman's breast shape after a mastectomy or injury that resulted in either partial or total loss of the breast(s), or to correct a birth defect..

Who is Not Eligible for Breast Implants?

Implants are contraindicated for women with:

- Existing malignant or pre-malignant cancer of your breast without adequate treatment
- Active infection anywhere in your body
- Augmentation in women who are currently pregnant or nursing

What are Contraindications, Warnings, and Precautions for You to Consider?

Surgical practices that are contraindicated in breast implantation:

- Placement of drugs/substances inside the implant other than sterile saline
- Any contact of the implant with povidone-iodine
- Injection through implant shell
- Alteration of the implant
- Stacking of implants: more than one implant per breast per breast pocket

Safety and effectiveness has not been established in patients with the following conditions:

- Autoimmune diseases such as lupus and scleroderma
- Conditions that interfere with wound healing and blood clotting
- A weakened immune system (for example., currently receiving immunosuppressive therapy)
- Reduced blood supply to breast tissue

What Are the Potential Breast Implant Complications?

Undergoing any surgical procedure may involve the risk of complications such as the effects of anesthesia, infection, swelling, redness, bleeding, and pain. In addition, there are potential complications specific to breast implants. These complications include:

• Deflation/Rupture

Breast implants deflate when the saline solution leaks either through an unsealed or damaged valve, or through a break in the implant shell. Implant deflation can occur immediately or progressively over a period of days and is noticed by loss of size or shape of the implant. Some implants deflate (or rupture) in the first few months after being implanted and some deflate after several years. Causes of deflation include damage by surgical instruments during surgery, overfilling or underfilling of the implant with saline solution, capsular contracture, closed capsulotomy, stresses such as trauma or intense physical manipulation, excessive compression during mammographic imaging, umbilical incision placement, and unknown/unexplained reasons. You should also be aware that the breast implant may wear out over time and deflate/rupture. Deflated implants require additional surgery to remove and to possibly replace the implant.

• Capsular Contracture

The scar tissue or capsule that normally forms around the implant may tighten and squeeze the implant and is called capsular contracture. Capsular contracture may be more common following infection, hematoma, and seroma. It is also more common with subglandular placement. Symptoms range from firmness and mild discomfort, to pain, distortion, palpability of the implant, and/or displacement of the implant. Additional surgery is needed in cases where pain and/or firmness is severe. This surgery ranges from removal of the implant capsule tissue to removal and possibly replacement of the implant itself. Capsular contracture may happen again after these additional surgeries.

- **Pain**

Pain of varying intensity and duration may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain associated with nerve entrapment or interference with muscle motion. You should tell your doctor about severe pain.

- **Additional Surgeries**

Women should understand there is a high chance they will need to have additional surgery at some point to replace or remove the implant. Also, problems such as deflation, capsular contracture, infection, shifting, and calcium deposits can require removal of the implants. Many women decide to have the implants replaced, but some women do not. Those who do not may have cosmetically unacceptable dimpling and/or puckering of the breast following removal of the implant.

- **Dissatisfaction with Cosmetic Results**

Dissatisfying results such as wrinkling, asymmetry implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, hypertrophic (irregular, raised scar) scarring, and/or sloughing may occur. Careful surgical planning and technique can minimize but not always prevent such results.

- **Infection**

Infection can occur with any surgery. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. Infections with an implant present are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved. In rare instances, Toxic Shock Syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. A doctor should be seen immediately for diagnosis and treatment.

- **Hematoma/Seroma**

Hematoma is a collection of blood inside a body cavity, and a seroma is a collection of the watery portion of the blood (in this case, around the implant or around the incision). Postoperative hematoma and seroma may contribute to infection and/or capsular contracture. Swelling, pain, and bruising may result. If a hematoma occurs, it will usually be soon after surgery, however this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, large ones will require the placement of surgical drains for proper healing. A small scar can result from surgical draining. Implant deflation/rupture can occur from surgical draining if damage to the implant occurs during the draining procedure.

- **Changes in Nipple and Breast Sensation**

Feeling in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. Changes in feeling can be temporary or permanent and may affect sexual response or the ability to nurse a baby. (See the paragraph on breast feeding below.)

- **Breast Feeding**

At this time it is not known if a small amount of silicone may diffuse (pass through) from the saline-filled breast implant silicone shell and may find its way into breast milk. If this occurs, it is not known what effect it may have on the nursing infant. Although there are no current methods for detecting *silicone* levels in breast milk, a study measuring *silicon* (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone-filled gel implants when compared to women without implants. With respect to the ability to successfully breast feed after breast implantation, one study reported up to 64% of women with implants who were unable to breast feed compared to 7% without implants. The periareolar incision site may significantly reduce the ability to successfully breast feed.

- **Calcium Deposits in the Tissue Around the Implant**

Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery to biopsy and/or removal of the implant to distinguish them from cancer.

- **Delayed Wound Healing**

In some cases, the incision site fails to heal normally.

- **Extrusion**

Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion, which is when the breast implant comes through the skin.

- **Necrosis**

Necrosis is the formation of dead tissue around the implant. This may prevent wound healing and require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis. Factors associated with increased necrosis include infection, use of steroids in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

- **Breast Tissue Atrophy/Chest Wall Deformity**

The pressure of the breast implant may cause the breast tissue to thin and shrink. This can occur while implants are still in place or following implant removal without replacement.

In addition to these complications, there have been concerns with certain systemic diseases, of which you should be aware:

- **Connective Tissue Disease**

Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma, or rheumatoid arthritis, was raised because of cases reported in the literature with small numbers of women with implants. A review of several large epidemiological studies of women with and without implants indicates that these diseases are no more common in women with implants than those in women without implants. However, a lot of women with breast implants believe that their implants caused a connective tissue disease.

- **Cancer**

Published studies indicate that breast cancer is no more common in women with implants than those without implants.

- **Second Generation Effects**

There have been concerns raised regarding potential damaging effects on children born of mothers with implants. A review of the published literature on this issue suggests that the information is insufficient to draw definitive conclusions.

What Are the Risks Based on INAMED's Clinical Studies?

INAMED conducted clinical testing of its McGhan® style saline-filled breast implants to determine the short-term and most common risks of their implants. These were assessed in the following studies:

The Large Simple Trial (LST)

The Large Simple Trial was designed to determine the 1-year risk of capsular contracture, infection, implant leakage/deflation, and implant replacement/removal. There were 2,333 patients enrolled for augmentation, 225 for reconstruction, and 317 for revision (replacement of existing implants). Of these enrolled patients, 62% returned for their 1-year follow-up visit.

What Were the 1-Year Complication Rates from the LST?

Complication	1-Year Complication Rate*		
	Augmentation	Reconstruction	Revision
Capsular Contracture III/IV	7%	13%	12%
Implant Removal	6%	14%	8%
Leakage/Deflation	4%	3%	5%
Infection	2%	6%	3%

*Data on 62% of the 2875 patients enrolled in the study

The 1995 Augmentation Study (A95)

The A95 Study was designed as a 5-year study to assess all complications as well as patient satisfaction, body image, body esteem, and self concept. Patients were followed annually and data through 3 years (with partial 4 year data) were presented to FDA for product approval through the premarket approval (PMA) process. After PMA approval, INAMED switched data collection to a post-approval study. The first phase of this post-approval study consisted of completion of the A95 Study, with collection of all risk/benefit information through 5 years.

What Were the Complication Rates from the A95 Study?

Complications	N = 901 Patients	
	3-Year** Complication Rate	5-Year Complication Rate
Additional Operation (Reoperation)	21%	26%
Breast Pain*	16%	17%
Wrinkling*	11%	14%
Asymmetry*	10%	12%
Implant Palpability/Visibility*	9%	12%
Implant Replacement/Removal for Any Reason	8%	12%
Capsular Contracture	9%	11%
Intense Nipple Sensation*	9%	10%
Loss of Nipple Sensation*	8%	10%
Implant Malposition*	8%	9%
Intense Skin Sensation*	7%	8%
Scarring Complications	6%	7%
Leakage/Deflation	5%	7%
Irritation/Inflammation*	3%	3%
Seroma	3%	3%
Hematoma	2%	2%
Skin Rash	2%	2%
Capsule Calcification*	1%	2%
Delayed Wound Healing*	1%	1%
Infection	<1%	1%

Note: * These complications were assessed with severity ratings. Only the rates for moderate, severe, or very severe (excludes mild and very mild ratings) are shown in this table.

** As reported in original PMA submission.

What Were the Types of Additional Surgical Procedures Performed?

Type of Surgical Procedures	N = 901 Patients	
	Through 4 Years* % (N = 402 Surgical Procedures)	Through 5 Years % (N = 463 Surgical Procedures)
Implant Removal With Replacement**	30%	34%
Capsule Procedure	19%	19%
Adjust Saline Fill Volume	11%	11%
Scar Revision/Wound Repair	9%	9%
Removal of Excess Fluid	7%	6%
Mastopexy	7%	6%
Biopsy/Lump Removal	4%	5%
Reposition Implant	5%	5%
Implant Removal Without Replacement	3%	2%
Removal of Skin Lesion/Cyst	2%	2%
Exploration of Breast Area or Implants	2%	1%
Skin Related Procedure	1%	1%
Nipple Related Procedure (Unplanned)	1%	1%
Total	100%	100%

* As reported in original PMA submission with additional data clarification.

** Some removals were replaced with a McGhan® implant, while others were replaced with a non-McGhan® implant.

What Were the Reasons for Implant Removal?

Primary Reason for Implant Removal	Through 4 Years* % (N = 132 Implants Removed)	Through 5 Years % (N = 166 Implants Removed)
Patient Request for Size/Style Change	43%	43%
Leakage/Deflation	33%	33%**
Capsular Contracture	10%	10%
Wrinkling	5%	4%
Implant Palpability/Visibility	0%	4%
Asymmetry	3%	2%
Breast Pain	2%	2%
Implant Malposition	2%	1%
Infection	1%	1%
Implant Extrusion	1%	1%
Damage to Implant During Surgery	1%	1%
Total	100%	100%

* As reported in original PMA submission with additional data clarification.

** Includes 1 implant removal where the reason for removal is unknown.

What Were the Complication Risk Rates After Implant Replacement?

Complication Following Replacement of Augmentation Implant(s)	2-Year Complication Rate* % (N = 108 Implants)	3-Year Complication Rate % (N = 126 Implants)
Removal/Replacement	5%	18%
Leakage/Deflation	9%	9%
Capsule Contracture III/IV	7%	8%
Infection	1%	3%

* As reported in original PMA submission.

What Were the Breast Disease and CPD Events?

Breast Disease Observation	No. of Patient Reports Through 4 Years*	No. of Patient Reports Through 5 Years
Benign	66	80
Malignant	1	1
Unknown Outcome	7	0

* As reported in original PMA submission with additional data clarification:
Benign includes 22 additional reports and unknown outcome (includes 2 fewer reports).

Connective Tissue Disease	Through 4 Years*		Through 5 Years	
	No. of Confirmed Reports	No. of Unconfirmed Reports	No. of Confirmed Reports	No. of Unconfirmed Reports
Graves' Disease	2	0	3	0
Hyperthyroiditis	1	2**	2	1
Lupus Erythematosus and/or Rheumatoid Arthritis	0	3	0	1
Thyroiditis	0	2	0	4
Chronic Fatigue Syndrome or Fibromyalgia	2	0	2	4
Inflammatory Bowel Disease	0	0	0	1
Raynaud's Phenomenon, Graves' Disease, Hyperthyroiditis, and Rheumatoid Arthritis	0	0	0	1**
Seronegative Spondylarthritis	0	0	0	1
Total	5	7	7	13

* As reported in original PMA submission.

** Patient was recategorized at 5-year timepoint.

For additional information on saline-filled breast implants and complication rates associated with augmentation surgery, contact your surgeon or INAMED Aesthetics for a copy of *Making An Informed Decision; Saline-Filled Breast Implant Surgery*.



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