

## Introduction

FDA has produced this brochure to highlight the more common problems that occur in the breast or chest area (local complications), when you choose to have silicone gel-filled or saline-filled breast implants.

For more detailed information and descriptions of diseases that women believe to be related to breast implants, read the FDA Breast Implant Consumer Handbook at <http://www.fda.gov/cdrh/breastimplants/>.

## Institute of Medicine's Independent Review

The Institute of Medicine (IOM) completed its independent review of past and ongoing scientific research of both silicone gel-filled and saline-filled breast implant safety in June 1999.<sup>1</sup> Below are some of the major findings.

Local complications

- are the primary safety issue because they are frequent enough to be a concern
- accumulate over the lifetime of the implant and have not been well studied
- are crucial for women deciding if they want breast implants

## Potential Local Complications and Reoperations

Potential local complications are shown alphabetically below. You may need non-surgical treatments or reoperations (including removal of your implant) to treat any of these. (See the **Glossary** in the Handbook for definitions.)

- Asymmetry
- Breast pain
- Breast tissue atrophy
- Calcification/calcium deposits
- **Capsular contracture**
- Chest wall deformity
- Delayed wound healing
- Extrusion
- Galactorrhea
- Granuloma
- Hematoma
- Iatrogenic injury/damage
- Infection, including Toxic Shock Syndrome
- Inflammation/irritation
- Malposition/displacement
- Necrosis
- Nipple/breast changes
- Palpability/visibility
- Ptosis
- Redness/bruising
- **Rupture/deflation**
- Scarring
- Seroma
- Unsatisfactory style/size
- Wrinkling/rippling

Capsular contracture and rupture/deflation are the most common local complications that occur with both silicone gel-filled and saline-filled breast implants.

## Capsular Contracture

Capsular contracture occurs when the scar tissue or capsule that normally forms around the implant tightens and squeezes the implant. It can happen to one or both of the implants. There are four grades of capsular contracture known as Baker grades.

The Baker grading is as follows

- Grade I** breast is normally soft and looks natural
- Grade II** breast is a little firm but looks normal
- Grade III** breast is firm and looks abnormal
- Grade IV** breast is hard, painful, and looks abnormal

Capsular contracture may require reoperation, usually for Grades III and IV, and it may occur again.

Photograph 1 shows Grade IV capsular contracture in the right breast of a 29 year old woman seven years after sub-glandular placement of silicone gel-filled breast implants.<sup>2</sup>



## Rupture/Deflation

Breast implants do not last a lifetime. Some breast implants may rupture/deflate in the first few months after surgery and some after several years. Others may take 10 or more years to rupture/deflate.

The reasons for rupture are not well understood and are currently being studied. Some possible causes of rupture/deflation include:

- normal aging of the implant
- damage by surgical instruments
- too much handling during surgery
- damage during procedures to the breast, such as biopsies and fluid drainage

- compression during a mammogram
- stresses such as trauma or intense physical pressure
- capsular contracture
- overfilling or underfilling of saline-filled breast implants
- placement through a belly button (umbilical) incision site because it involves too much handling of the implant.

When silicone gel-filled implants rupture, some women may notice decreased breast size, hard knots, uneven appearance of the breasts, pain or tenderness, tingling, swelling, numbness, burning, or changes in sensation. Other women may unknowingly experience a rupture without any symptoms (silent rupture).

Magnetic resonance imaging (MRI) with equipment specifically designed for imaging the breast may be used for evaluating patients with suspected rupture or leakage of their silicone gel-filled implant. Silicone gel may

- escape from the scar tissue capsule around the implant
- migrate away from the breast
- cause lumps, called granulomas, to form in the breast, chest wall, armpit, arm, or abdomen

Plastic surgeons usually recommend removal of the implant if it has ruptured, even if the silicone is still enclosed within the scar tissue capsule, because the silicone gel may eventually leak into surrounding tissues.

When saline-filled breast implants deflate, the saline solution leaks either through an unsealed or damaged valve or through a break in the implant shell. Implant deflation can be immediate or progress over a period of days, months, or years and is noticed by loss of size or shape of the implant. Additional surgery is needed to remove deflated implants. Photograph 2 below shows deflation of a 30-year-old woman's left saline-filled breast implant.<sup>2</sup>



### *Reoperations*

It is likely that you will need to have one or more reoperations over the course of your life because of local complications from breast implants. Reasons for reoperations could include any of the potential local complications above. Multiple reoperations to either improve the appearance of the breasts, to remove ruptured/deflated implants, or both may result in an unsatisfactory cosmetic outcome.

### *Removals*

One type of reoperation is the removal of the implant(s), with or without replacement. Removal involves surgery. You are likely to have your implant removed at some time over the course of your life because of one or more local complications above. Many women decide to have the implants replaced, but some women do not. Women who do not have their implants replaced may have cosmetically undesirable dimpling, puckering, or sagging of the breast following removal of the implant.

Photograph 3 shows the previously pictured 29 year old woman one year after removal of her silicone gel-filled breast implants without replacement.<sup>2</sup>



*To order copies of the Handbook  
or the brochure please contact:*

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### *Key Points to Consider*

- Breast implants will not last a lifetime.
- Either because of rupture or other complications, you will probably need to have the implants removed.
- You are likely to need additional doctor visits, reoperations, or removals because of one or more complications over the course of your life.
- Many of the changes to your breast following implantation may be cosmetically undesirable and cannot be reversed.
- If you later choose to have your implants removed, you may experience unacceptable dimpling, puckering, wrinkling, breast tissue loss, or other undesirable cosmetic changes of the breasts.

<sup>1</sup> *Safety of Silicone Breast Implants*. Institute of Medicine National Academy Press, Washington, D.C. 2000. (IOM Report). Also available through IOM website at [www.iom.edu/report.asp?id=5638](http://www.iom.edu/report.asp?id=5638)

<sup>2</sup> Photographs courtesy of Walter Peters, M.D., Ph.D., F.R.C.S.C., University of Toronto.



# *Breast Implants*



*Potential  
Local Complications  
and  
Reoperations*

*July 2004*