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.

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.\(^1\) 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
- Ptsis
- 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.\(^2\)

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

Photograph 2 shows deflation of a 30-year-old woman's left saline-filled breast implant.\(^2\)
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.²

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.

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

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