

## Breast Implants: Silicone or Saline

1. Why the U.S. Food and Drug Administration ban of silicone breast implants? The ban occurred for a number of reasons. Pressure from the media, trial lawyers, and various activist groups was intense after the Connie Chung show in 1990. There was a fear that they were not safe. They were never "approved" by the U.S. Food and Drug Administration to begin with. They were "grandfathered" in 1976 when the U.S. Food and Drug Administration began the process of approval as a formal process. Even though there was a large amount of research including animal data and human data on the safety of these devices, the U.S. Food and Drug Administration elected to take the implants off the market entirely at first and then allowed their use in reconstruction only.

2. Silicon (no "e") is an element that exists nearly everywhere in nature. Silicone is a generic name for a family of silicon-carbon based polymers. Depending on the length or complexity of these polymers, silicone can be liquid, gel, or solid rubber. Silicone does not exist naturally but must be compounded in the chemical laboratory. Saline is a simple solution of salt and water. Normal saline has a concentration of 0.9% and approximates the concentration of human extracellular fluid. Seawater, in contrast, has a concentration of approximately 5% salt in the water.

3. The difference between silicone and saline implants is simply what is contained within the envelope of the implant. All breast implants have the same outer shell that is made from silicone rubber. Most implants are smooth, whereas some implants are textured. The *silicone implant* contains silicone gel and comes prefilled from the factory with a specified amount. The sizes vary in increments of 25 to 30 cc (roughly 1 ounce) depending on the manufacturer. The *saline implant* contains normal saline and the implant is filled to its designed volume in the operating room. The sizes also vary in increments of 25 to 30 cc, but because they are filled during surgery, some additional adjustment can be performed at the discretion of the surgeon for various reasons.

4. As of November 17, 2006, the U.S. Food and Drug Administration has lifted the ban on the use of silicone implants for breast augmentation surgery. That means that women desiring breast augmentation surgery may have the option of choosing a silicone gel-filled implant for her augmentation. This choice will have a number of requirements imposed by the U.S. Food and Drug Administration. The U.S. Food and Drug Administration is requiring magnetic resonance imaging examinations after the first 3 years and every 2 years after that, and the patient must be a minimum of 22 years of age (18 years of age minimum for saline implants).

5. For more information, check out the U.S. Food and Drug Administration web site ([www.fda.gov/cdrh/breastimplants](http://www.fda.gov/cdrh/breastimplants)). This web site has a wealth of information regarding breast implants and is helpful to women trying to make a rational choice about breast augmentation surgery. It also spells out the new requirements for long-term follow-up of silicone gel-filled implants.

6. There are potential complications with either saline or silicone breast implants. Among the potential complications are bleeding, hematoma formation, infection, capsule contracture formation, chronic pain, implant deflation or leakage, implant rupture, changes or loss of sensation, asymmetry, possible interference with breast feeding, possible difficulties with mammography, and the possible causation (none known at this time) of other diseases. Because of the above, it is possible (probable) that a woman undergoing breast augmentation will need additional surgery at some time in the future depending on her age at the time of augmentation.

7. Comparison of breast implants: Saline-filled versus silicone gel-filled

**Saline-filled**

Rippling-palpable/visible  
Less natural feel  
Shape control, negative  
Natural substance  
Adjustable  
Small incision  
Leaks easily detectable  
Initial expense, less

### Silicone gel-filled

Natural feel/minimal rippling  
More natural feel  
Shape control, positive  
Foreign substance  
Not adjustable  
Large incision  
Leak detection requires magnetic resonance  
Imaging examination (expensive)  
Initial expense, more

#### 8. Thoughts on choosing between saline versus silicone:

For women choosing breast augmentation who already have a modest amount of normal breast tissue and subcutaneous fatty tissue, either type of implant will normally be very satisfactory and often almost indistinguishable. This also applies to women desiring a very minimal augmentation.

For women choosing breast augmentation who are relatively thin or have relatively little breast tissue, submuscular placement of the implant can hide or greatly minimize the undesirable properties of the saline implant. This is why submuscular placement is virtually always used in patients who have had mastectomies undergoing reconstruction even with silicone gel-filled implants. For women choosing breast augmentation who are "extremely thin" and with "minimal breast tissue," the silicone gel-filled implant has a number of advantages, particularly when it comes to the issues of rippling and "feel." These implants may be placed submuscularly or under the breast tissue at the discretion of the surgeon.

The majority of my patients seeking breast augmentation prefer saline-filled implants for the following reasons: minimal incision, easily adjustable, natural substance, easy leak detection, and minimal expense. I prefer silicone gel-filled implants for extremely thin patients with minimal breast tissue because they are likely to achieve a better overall result with the silicone-filled implant compared with the saline-filled implant.