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## **Plastic Surgery: Silicone gel breast implants return to the market**

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**Plastic Surgery**

The Food and Drug Administration announced last month that silicone gel breast implants have been approved for use in breast augmentation. We have been using silicone gel implants for years in breast reconstruction under an investigational protocol, but this new ruling makes the gel implants available for any patient requesting an implant for any indication.

This ruling represents the culmination of a long, bitter fight which has been raging since the early '90s. Silicone gel implants were removed from the market in 1992 when the devices were alleged to cause autoimmune diseases such as arthritis or lupus. Massive lawsuits and general hysteria ensued.

What didn't happen early on was a careful scientific analysis of the situation. Eventually, very large studies (one included 500,000 patients in 30 countries) concluded that there was no association between silicone gel implants and systemic disease of any kind. Certainly women with breast implants get autoimmune-type diseases, but an equal number of women without implants get them, too.

Despite that evidence, the implant manufacturers went through an extremely intensive process of approval involving clinical studies on patients who volunteered to have the implants on an investigational basis. After analyzing the five-year results, the implants were returned to the market.

As one of the investigators in the gel clinical studies, I have used silicone gel implants for some time for breast reconstruction after mastectomy. The new gels are different than the ones from the 1970s and 1980s.

Instead of a liquid inside an envelope, these are semi-solid - kind of like a gummi bear. You can cut them with a knife and they don't leak. This "cohesive" technology reduces the chance of the silicone leaking into the body. Silicone leakage can occur with breakdown or damage to the implant, but it tends to cause local inflammation or lumps, rather than affecting the body as a whole.

So what are the advantages? Saline-filled implants (with a silicone shell, ironically) have served women well for 15 years, so why bother with silicone? Many patients believe the gel implants have a softer, more natural feel. Saline implants can "ripple" as gravity pulls on the shell of the implant, sort of like the ripples you would see if you were holding a zip lock bag full of water.

Gel implants can also be shaped to meet certain needs in patients with different chest or breast shapes. In women with minimal breast tissue, the gels are less likely to be palpable.

Silicone gel implants are about twice the cost of saline implants, so gels add about \$1,000 to the cost of the total procedure. There are some follow-up studies required as well as part of the ongoing FDA study.

Although it has only been a month since approval, I've done two augmentation procedures in patients who have requested gel implants. Both had researched the subject extensively, and they have been delighted with the early results, primarily because of the "natural feel."

Gel implants do require a slightly longer incision because they aren't inflated or deflated.

All implants can have problems. Capsular contracture, or scar tissue, can form around implants in 2 to 5 percent of patients and make the breast firm and unnatural-looking. About 5 percent will deflate after 10 years. Rarely, implants get infected and have to be removed.

Interestingly, a study of women who had had problems with their implants and had to have revisions found that 90 percent were happy with their results, despite the problems.

Breast augmentation can be a useful means of adding proportion to a figure, compensating for lack of breast development or repairing the damage wrought by pregnancy and nursing.

With the release of the silicone gel implants, women have another option.

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