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Keeping abreast: Are saline implants safer?

By **Carolyn Zinko** | May 13, 2016 | Updated: May 13, 2016 11:54am



Photo: Connor Radnovich, The Chronicle

Dr. Regina Rosenthal, one of the few in the Bay Area who offers the Ideal, holds an Ideal implant (left) and a silicone gel implant in her Campbell office.

It's a Bay Area problem: looking for the healthiest way to live, whether adopting a new workout at the gym, eating organic — or even finding a safer breast implant.

A new, structured saline implant, called the Ideal implant, is finding favor with women concerned about putting chemicals in their bodies. Unlike traditional, balloon-like saline implants or firmer silicone gel varieties, the Ideal implant consists of several stable shells layered atop one another, like nesting Russian dolls, but is filled with saline, not silicone gel.

A decade in the making, the new implant, which hit the market in November, was created by Dr. Robert Hamas of Dallas, a 35-year-veteran of cosmetic plastic surgery, after an airplane flight in which he watched his wife's glass of water splash during turbulence, while his scotch

on the rocks, loaded with ice cubes, spilled nary a drop. His stacked shells provide more structure and less wrinkling under the skin than saline implants can cause — without the fears that ruptures of silicone gel implants can instill.

So far, the device, which is approved by the U.S. Food and Drug Administration, has resonated with women in health-conscious regions like Seattle and the Bay

Area more than with those seeking cosmetic enhancements in cities such as Los Angeles and Miami, where appearance is a bigger priority, Hamas said on a recent Bay Area visit.

Those patients include a 25-year-old technician from Santa Cruz who specifically searched the Internet for a local surgeon using the Ideal implant to rejuvenate her breasts, which changed shape after breastfeeding a son for eight months. She decided on Dr. Regina Rosenthal of Campbell, one of six Bay Area doctors who are using it in their practices.

“I’d say 90 percent of the food I eat is organic, and about the same percentage applies to my beauty and hair products,” said the patient, who asked that her name be withheld to protect her medical privacy. “So there was no way I wanted a synthetic substance leaking into my system, especially as it does so slowly without the patient even knowing it’s ruptured! And since so many synthetic materials are being discovered to cause cancer, I was very uncomfortable with the idea of a synthetic substance circulating in my body.”



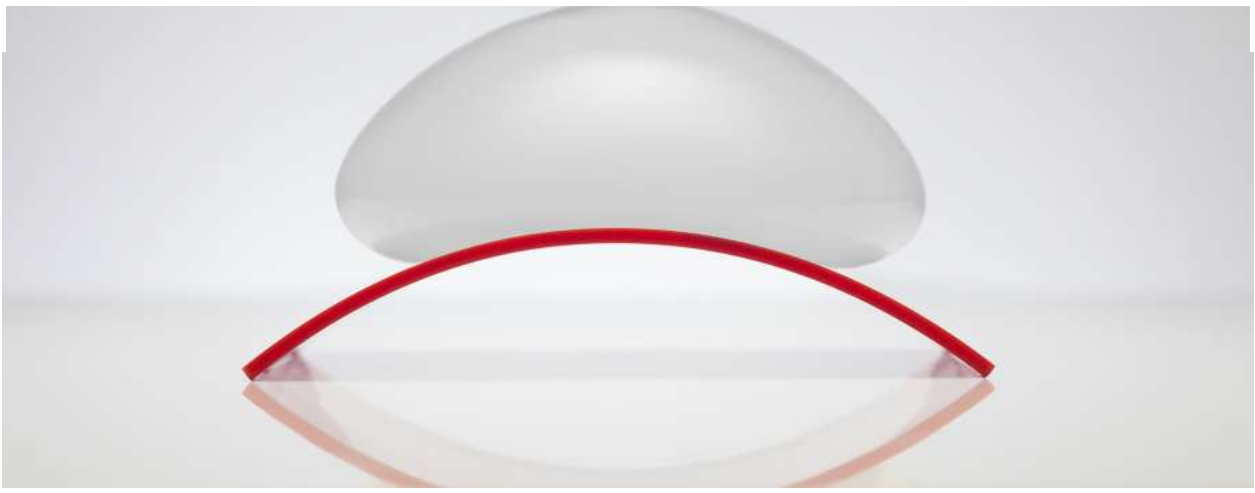


Photo: Courtesy Of Dr. Robert Hamas

IMAGE 1 OF 2

A structured saline implant, called the Ideal implant, made by Dr. Robert Hamas.

There are concerns surrounding saline and gel implants.

In 1992, silicone gel implants were taken off the market after the FDA determined manufacturers had failed to provide enough safety data. They were reintroduced to the market with a thicker formulation of so-called cohesive gel, in 2006, according to the FDA website.

Short-term studies show silicone gel implants to be safe, but no multidecade studies have been conducted, so doctors are unsure of the long-term effects of silicone gel implants in the body.

Ruptures occur in both varieties at a rate of 5.6 percent: When saline implants burst, they deflate like a tire and spread saltwater into the body, but when silicone gel implants rupture, it's virtually impossible to detect. That's why the FDA recommends magnetic resonance imaging, or an MRI, for every woman with silicone gel implants beginning the third year after augmentation and every two years after that, for life. Mammograms are not sensitive enough to detect ruptures.

Each of the doctors interviewed for this story said few, if any, of their patients follow the FDA guidelines, due to the cost: a single MRI can be \$2,000 or more, and insurance doesn't cover it. With the need for an alternative clear, Hamas figured Silicon Valley investors would seed

his startup. He was wrong.

“I made many trips up and down Sand Hill Road and what I got from the people there was, ‘Everybody wants gel,’” he recalled. “I said, ‘I don’t know who you’re talking to. I think women would rather have a saline implant that feels natural than have silicone gel in their body.’ I knew this is what happens when they rupture. They’re a mess.”

So he turned to medical colleagues and funded the company with stocks sales to plastic surgeons and friends.

Of 200 plastic surgeons nationwide using the Ideal implant today, 120 are shareholders in Hamas’ company. In the Bay Area, Rosenthal is an investor, along with Dr. Eric Bachelor of Danville, Dr. Robert Lowen of Mountain View and Dr. Daryl Hoffman of Palo Alto. Two other Ideal implant supporters, Dr. Vivien Teng of Walnut Creek, and Dr. Kimberly Henry of Greenbrae, are not stakeholders.

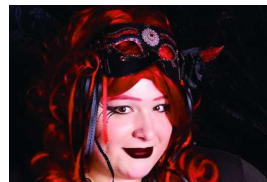
Hoffman, who has performed a dozen procedures with the Ideal implant since December, is unapologetic about recommending it.

“You can’t get insurance to approve an MRI for an asymptomatic patient — someone who doesn’t have any symptoms — and I’ve tried,” he said. “One woman had a mastectomy and reconstruction, and I showed the insurance company the product brochure saying it’s required, and they still wouldn’t approve it.”

Rosenthal, who made a \$5,000 investment, said she believes in the importance of options. Although most of her patients still choose silicone gel implants, 10 have decided upon the Ideal implant “for peace of mind,” she said.

Said Rosenthal’s patient, who recycles and tries to avoid Bisphenol A, a compound in plastics that some contend is toxic, “I will

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totally go eat at a restaurant that I know isn't organic or will happily eat a meal that my boyfriend's mom has cooked for me, but for the most part I try to keep my lifestyle natural and healthy. This is my one body, and I want it to feel the best that it can."



In San Francisco, the art tribes and clans celebrate

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Most common breast implants

Saline implants are filled with a saltwater solution, much like a water balloon and can wrinkle under the skin. When ruptured, they deflate immediately, sending saltwater into the body. They are sold in the U.S. by Mentor and Allergan.

Silicone gel implants are made with a sticky, cohesive silicone gel. When they rupture, they may produce hard lumps over the implant or chest area, and cause pain, or other changes in sensation. Silent ruptures produce no symptoms, so the FDA recommends an MRI the third year after augmentation and every two years afterward. They are sold in the U.S. by Allergan and Sientra.

Structured saline implants are made with a series of internal baffles or shells that hold saline solution in place and create more fullness than traditional saline implants. When ruptured, they deflate immediately. They are sold in the U.S. by Ideal.

Number of augmentations performed in the U.S. in 2015:

279,143 — a 31 percent increase over the year 2000.

Source: FDA.gov, www.plasticsurgery.org

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Features Reporter

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