



SAVE 20%
off Airfare to *Hawaii!* **GO**



Search for

[Back to Home](#) > [Star Telegram](#) >

Tuesday, Aug 12, 2003

Financial Markets
Sponsored by:

Star-Telegram

Posted on Mon, Aug. 11, 2003

Star-Telegram

FDA may approve silicone gel implants

By Jan Jarvis
Star-Telegram Staff Writer

Given a choice, Nicole Cummings would pick silicone over saline. She's not alone.

Despite a ban of more than a decade on silicone gel breast implants caused by concerns about their safety, the Florida-based Web site operator and many other women considering breast augmentation say they prefer silicone because it is softer and more natural than saline.

This year, such women may get what they want. The Food and Drug Administration is reviewing an application from Inamed Corp., based in Santa Barbara, Calif., for approval of its silicone gel-filled implants. A panel of experts will determine whether the product is safe before public meetings are held. Medical professionals predict that a decision could be made this year.

For five years, Cummings has operated Implantinfo.com, a for-profit clearinghouse for breast augmentation information and surgeon listings. She said the FDA's decision can't come soon enough.

"This is the only device on the market that has suffered such a controversy," said Cummings, who had augmentation surgery with saline implants in January 1998 and said she has had no related problems. "They have been studied so much I don't know how much longer any product can be studied."

But it's exactly that -- the length of time the devices have been studied -- that led the National Organization for Women and other advocacy groups to begin campaigns opposing the silicone devices. They say the FDA is only considering two to three years of scientific data -- not enough when implant problems often do not begin for seven to 10 years.

NOW has called for long-term studies of silicone in light of health problems ranging from joint soreness to lupus, a chronic inflammatory disease.

Inamed has enrolled about 1,000 women in three years for clinical trials testing silicone implants. The company follows up with participants within two years of a trial's completion, as per FDA protocols, Inamed spokesman Peter Nicholson said.



Find your match now.

cars.com

CAR SHOPPING JUST GOT FUN™

Star-Telegram.com

- » [Front pages \(.pdf\)](#)
- » [Iraq Coverage](#)
- » [Breaking News](#)
- » [News 2 Use](#)
- » [Fort Worth](#)
- » [Arlington](#)
- » [Northeast Tarrant](#)
- » [Dallas](#)
- » [Texas](#)
- » [Legislature](#)
- » [National](#)
- » [International](#)
- » [Business](#)
- » [Tarrant Business](#)
- » [Sports](#)
- » [Cowboys/NFL](#)
- » [Mavericks/NBA](#)
- » [Rangers/MLB](#)
- » [Stars/NHL](#)
- » [College](#)
- » [Horse Racing](#)
- » [TMS / Motorsports](#)
- » [Golf](#)
- » [Sports Zone](#)
- » [Arts/Entertainment](#)
- » [Life/Living](#)
- » [Food](#)
- » [Travel](#)

Sign up
today!

- » [Books](#)
- » [Home](#)
- » [Faith & Spirit](#)
- » [Star Time](#)
- » [Opinions](#)
- » [Cheers & Jeers](#)
- » [Letters to the editor](#)
- » [Columnists](#)
- » [Special Reports](#)
- » [Weird News](#)
- » [Visitors Guide](#)
- » [Corrections](#)

Resources

- » [Newspaper ads online](#)
- » [Obituary Notices](#)
- » [Weddings & Announcements](#)
- » [Bridal Planner](#)
- » [Automotive](#)
- » [Real Estate](#)
- » [Press Pass](#)
- » [Events](#)
- » [Press Releases](#)
- » [Newspapers in Education](#)
- » [Photo Sales](#)
- » [Employment Opportunities](#)
- » [Reprints & Front Pages](#)
- » [Market Guide](#)
- » [Subscriptions](#)
- » [Subscriber Newsletter](#)

"We believe in the strength of the growing body of scientific evidence that supports silicone," Nicholson said. "We definitely believe in the scientific process that will be used to evaluate the safety of these products."

For the 236,888 women in the United States who had cosmetic breast augmentation in 2002, saline was the only option. The number of elective procedures has increased almost sixfold from 1992 to 2002, according to the American Society of Plastic Surgeons in Arlington Heights, Ill.

An additional 74,090 women had breast reconstruction surgery, which is typically performed after a mastectomy and can include an implant or the patient's own tissue, according to the society.

Studies by the Mayo Clinic, the National Cancer Institute and other health-care agencies show no link between silicone implants and serious health problems.

"The science around silicone gel is one of most well-researched scientific entities there is," said William Adams Jr., an associate plastic surgery professor at the University of Texas Southwestern Medical Center at Dallas. "I know of over 20 studies that looked at whether silicone was causing autoimmune illness, and in every one the answer has been no."

Among the studies is a 1999 report by the Institute of Medicine, a Washington, D.C.-based nonprofit organization whose mission is to provide advice on medicine and health. The institute concluded, based on a review of scientific literature available at the time, that women with silicone implants were no more likely than the rest of the population to develop cancer, neurological disorders or other serious diseases.

The report did, however, warn that the implants commonly lead to complications, such as ruptures, that require surgery. It urged women to consider the risks.

Whether women get saline or silicone implants, both pose risks and must be replaced if they leak or rupture -- which is not uncommon after 10 to 15 years, surgeons said.

"Silicone implants, like every other man-made implant in the world, have a life span of between 13 and 15 years. That's what we tell our patients: Sometime in your life you will need to have your implants replaced," said Rod Rohrich, chairman of UT Southwestern's plastic surgery department and president-elect of the American Society of Plastic Surgeons.

Silicone may leak slowly and silently, but saline ruptures suddenly and deflates, usually requiring immediate removal, a procedure that can cost \$2,000 or more, according to the plastic surgeons' organization.

But Rohrich said the most common problem with such ruptures is a "gel bleed," in which the silicone migrates somewhere in the breast area. It is, however, typically contained near the scar tissue resulting from the original surgery and has "no consequence healthwise," he said.

Other known risks of augmentation include hardening of the breast, loss of nipple sensation and interference with mammography readings, according to the FDA.

Within 18 months of surgery in 1978, Marlene Keeling of Houston said scar tissue developed and her breasts hardened. By the time she had the silicone implants removed in 1994, Keeling was suffering from memory loss, weakness and other health problems, she said.

"Since then, my symptoms have gotten better," Keeling said. "I firmly believe my health problems were connected to the implants."

As a leader of the Houston chapter of United Silicone Survivors of the World, Keeling is working on an e-mail campaign to keep the silicone devices off the market.

"Women need to understand that silicone gel-filled implants have never been approved by the FDA despite years of use because manufacturers have not been able to prove them safe," she said.

The implants were on the market long before the FDA had the authority to regulate any medical devices, said Sharon Snider, an agency spokeswoman. Like any product, they were presumed to be safe and effective until the agency became aware of complications.

Silicone gel implants have not been allowed in the United States except in specific cases, including reconstructive surgery and research, since a ban was implemented in the early 1990s. Yet they have remained popular.

In many markets where saline and silicone are available, silicone is preferred by patients and physicians alike, Nicholson said.

"Silicone has a 90 percent share of the marketing mix in Europe," he said.

Unable to get them in the United States, some women have traveled to Mexico and other countries where the implants are legal, Adams said.

The saline-filled implants have been available in the United States for more than 30 years, though the FDA did not approve them until 2000 after five clinical trials involving 9,000 women.

When the FDA approved saline implants, it was with the requirement that the maker, Inamed, follow the women who participated in the clinical trial for 10 years, Nicholson said. The FDA might require the same follow-up for silicone implants if they are approved, he said.

At the Arlington Cancer Center, doctors recommend that patients use tissue from other parts of their body for reconstruction instead of an implant, said Kim Wagner, a nurse at the center.

"The woman ends up with a remarkably lifelike breast," she said.

In any case, silicone critics and supporters urge women considering implants to research the procedure.

Research prompted Cummings, a former hair stylist, to begin her own Web site. Today, its operation is a full-time job for her and her husband, a former attorney.

"After I had children, I decided to do this, but I couldn't find anything personal about breast augmentation -- you know, not just information from physicians," she said. Cummings' Web site includes message boards, before-and-after photos, and physician listings, for which surgeons pay \$100 to \$200 each.

"Now, it takes up all our time," she said. "It never shuts off."

Staff Writer Kristin Sullivan Contributed to This Report.

ONLINE:

Breast implant information, www.fda.gov

Implantinfo.com

www.plasticsurgery.org

www.inamed.com

Jan Jarvis, (817)548-5423 jjarvis@star-telegram.com