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Newly Approved Silicone Implants Have Clear Benefits But Also Some Drawbacks

By David J. Levens, MD, PA, FACS

After years of rigorous scientific review, the U.S. Food and Drug Administration (FDA) last November approved the less restricted use of silicone gel-filled breast implants made by two California companies, Mentor Corp. and Allergan Corp (formerly Inamed).

The announcement was good news for women seeking a more lightweight, supple, natural implant than can be achieved with the saline-filled implants which have been used in most cases since the FDA banned silicone in 1992. Why did it take so long for the FDA to make its decision and what kinds of strings are attached to the ruling?

In 1991, a class action court case claiming the silicone implants caused health problems was resolved with findings that the silicone implants had caused immune system illnesses in patients. A \$7.3 million damage claim had been lodged against Dow Corning, the developer of the silicone gel implant. A number of recipients of silicone breast implants claimed to have developed a wide and divergent set of symptoms ranging from chronic fatigue, to rheumatoid arthritis (and other inflammatory illness of the joints), lupus, damage to the immune system, and scleroderma (a hardening of the skin and internal organs). Many subsequent studies contradicted those claims and silicone implants continued to be widely used in Europe. Last spring, many in the medical community expected the FDA to reverse the ban. But the FDA instead ruled to withhold approval until several ongoing research projects could be completed to demonstrate clearly that silicone gel is not toxic if leaked into the body from an implant rupture.

Finally, after reviewing an extensive amount of data from clinical trials of women studied for up to four years, as well as a wealth of other information to determine the benefits and risks of silicone implants, the studies were concluded and the FDA has decided that: "The extensive body of scientific evidence provides reasonable assurance of the benefits and risks of these devices. This information is available in the product labeling and will enable women and their physicians to make informed decisions."

However, the FDA will continue to monitor silicone implants by requiring both of the approved implant companies to conduct a large post-approval study following about 40,000 women for 10 years after receiving breast implants. The FDA often requires post-market studies to answer important questions that can only be answered once a product is in broader use, such as the incidence of rare adverse events.

Full information about the risks and benefits of the devices can be found in the package and patient labeling mandated by FDA. The patient labeling outlines some of the important factors women should consider when deciding whether to get silicone gel-filled breast implants. Some of these factors are: breast implants are not lifetime devices and a woman will likely need additional surgeries on her breast at least once over her lifetime; many of the changes to a woman's breast following implantation are irreversible; rupture of a silicone gel-filled breast implant is most often silent, which means that usually neither the woman nor her surgeon will know that her implants have ruptured; and a woman will need regular screening MRI examinations over her lifetime to determine if silent rupture has occurred.

The device labeling states that a woman should have her first MRI three years after her initial implant surgery and then every two years thereafter. The cost of MRI screening over a woman's lifetime may exceed the cost of her initial surgery and may not be covered by medical insurance. The labeling also states that if implant rupture is noted on an MRI, the implant should be removed and replaced, if needed.

As for the "strings attached" to the approval: The FDA approved silicone implants for reconstructive breast surgery and for cosmetic augmentations for women over 22. Even during the ban, the FDA had allowed use of silicone implants in special cases, such as breast reconstruction and some lifting procedures where there is very little natural breast tissue to adequately conceal a saline implant. In these cases, patients were enrolled in clinical trials and are carefully monitored for five years after surgery.

While silicone implants have definite advantages over saline implants, the latter is not without its merits. The fill of saline-filled implant can be altered. They come collapsed and are filled at insertion, allowing a smaller incision and fine-tuning volume adjustments. Certain implants allow for volume adjustments after surgery. The fixed fill of silicone implants requires a slightly longer incision and size adjustments require implant replacement.

The bottom line is that while the FDA's action has given patients a new option, an informed decision can only be made after a thorough patient-surgeon discussion about the pros and cons of each choice. #

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