

THE SILICONE BREAST IMPLANT CONTROVERSY

The health care controversy surrounding silicone breast implants—placed in an estimated 1 million American women—has drawn our attention to glaring weaknesses in women's medical care, FDA regulatory oversights, and alleged abuses by some in the medical device industry.

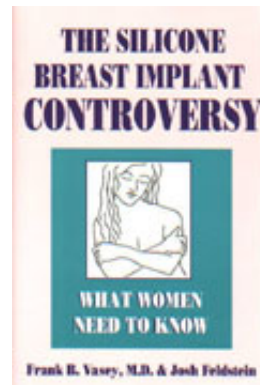
Today, women with breast implants face a critical decision: keep them and risk possible silicone-associated connective tissue disease, or remove them and risk a wide range of other physical and emotional problems.

The Silicone Breast Implant Controversy: What Women Need to Know delivers the vital information all women with implants must have. It is also essential reading for spouses and family members, as well as medical professionals attempting to diagnose and treat women with implants suffering from silicone-induced autoimmune/rheumatic diseases.

Dr. Frank Vasey and Josh Feldstein detail the 30-year history of silicone implants, and offer riveting personal stories of women whose health has been damaged as a result of their immune system's exposure to silicone. They provide a powerful, insightful analysis of the medical, social, governmental, industrial, and emotional aspects of silicone disease, and call for wide-reaching re-evaluation and reform in the field of women's health care.

The Silicone Breast Implant Controversy: What Women Need to Know

by Frank B. Vasey, MD & Josh Feldstein



"Women greatly overestimate society's tastes in breast size," noted Dr. J. Kevin Thompson in a recent psychology study. What's more, "women's beliefs about men's preferences are wrong, and this incorrect belief may be the reason why women opt for breast implants: trying to achieve a cultural ideal they believe others have." Other research, noted Dr. Jennifer Brenner, a Professor of Psychology at Brandeis University, found that "female models are 9% taller and 16% thinner than average women—an unrealistic ideal of beauty to emulate, which contributes to low self-esteem." Another study, noted Kristen Golden, coordinator of a Ms. Foundation for Women effort to promote women's issues, found that "up to age 11, girls are very straightforward and confident. They trust their own experience and say what they think. [But] by age 12, they're beginning to get mixed messages from their families, the media and society that they're supposed to be quiet, nice, thin, and preferably blonde. I think if we stopped lying to our girls, they would be in much better shape."

Clearly, feelings of physical inferiority serve to create a ripe environment for women to embrace "changes" such as breast implantation. A study published several years ago based on research with 2,000 women found that they were less satisfied than men with their appearance and were more critical of their bodies. Another study observed that of 1,100 women queried, 48 percent said they would be more attractive if they lost 20 pounds. The cultural stage has thus been set for women to be unhappy about their physical appearance.

In recent decades, there has been a growing acceptance of high-tech means to alter nature's endowment. But lest anyone think that alteration of a woman's shape to achieve some ideal is new, consider that whalebone corsets of the nineteenth century that forced women into unnatural hourglass shapes, often at the expense of their digestive health (though probably few studies were done to prove it). Consider, too, the breast-lifting, cleavage-forming dresses of centuries past.

The choice to alter one's body is a personal one, and many women are delighted with the results they have achieved through breast augmentation

with silicone and saline implants. It nevertheless remains a strange fact that we live in a society that makes women compare their bodies to a perfect—and often unattainable—ideal, taking their self-worth and self-identity from their appearance only, some going so far as to put themselves through difficult and expensive ordeals to achieve such goals.

In our sexually stereotyped society, it's little wonder, then, that so many women have willingly undergone surgery to achieve the perfect image of femininity. Of over 640,000 cosmetic surgical procedures in 1990, breast augmentation ranked second only to liposuction. Can you imagine the same number of men requesting plastic surgeons to enlarge their penises or to have their buttocks tightened? More important, can you imagine men having to wait nearly 30 years before serious problems affecting their health were finally investigated and brought out into the open?

Frank B. Vasey, M.D., was alerted in the mid-1980's to the possibility that immune response to silicone breast implants could cause rheumatic disease. His opinion was influenced by specific reports from a handful of other rheumatologists, as well as daily interactions with Luis Espinoza, M.D., at the University of South Florida College of Medicine. By 1989, Dr. Vasey's clinical observations of his patients convinced him that an important women's public health issue had been almost completely ignored by medicine, industry, and government: silicone implants could lead to serious health problems in susceptible individuals.

In December 1990, when the late Congressman Ted Weiss (D-NY) requested Vasey's testimony before the Government Operations subcommittee, his medical observations drew widespread press coverage. This media exposure subsequently led hundreds of symptomatic women with silicone implants from around the country to contact Vasey for advice and treatment. To date, he has personally treated nearly 500 women with breast implants who are suffering from rheumatic disease.

This book has been written in an attempt to clarify the complex issues regarding breast implants, the immune system, rheumatic disease, and the governmental, industry-related, and societal elements that have led to this health care debacle. The ultimate decision to have breast implants placed or removed is critical to both a woman's psychological and physiological health. Women making either decision must be as fully informed as possible. This is the book's major concern.

Additionally, this book is intended not only for women who have silicone breast implants—those who feel well, and those who do not—but for their partners, families, and friends as well. It is also for women considering implants. It is the authors' hope that this work will be viewed as a contribution to the medical community as a whole, especially to those health care providers who encounter and attempt to help women suffering from silicone-related medical problems.

At the same time, our book is not intended to resolve the silicone breast implant controversy. Only well-designed, large-scale epidemiologic studies will serve ultimately to convince physicians and, in particular, plastic surgeons of the existence of what we call silicone-associated connective

tissue disease. Nor has this book been written to sensationalize the medical issues or to scare people. The overwhelming majority of the estimated 1 million women with implants will most probably never develop any kind of illness from their prostheses. Exactly what percentage of them will become ill remains to be determined.

Originally, silicone was used in breast implants because silicone itself was believed to be inert when in contact with body tissues. Over the years, silicone devices have included hypodermic needles, cardiac pacemakers, artificial joints, testicular implants, artificial heart valves-and silicone has even been used in a form known as simethicone for over-the-counter (OTC) digestive aids and infant formulas. Considering that 8 of 10 women who have received implants have done so for augmentation, it's no surprise that cosmetic rather than medical factors were primary in the development of the silicone breast implant.

For years, all types of implants were positioned by both implant manufacturers and plastic surgeons as harmless, inert objects. These include silicone gel-filled implants with a smooth or textured outer silicone envelope; inflatable saline-filled implants in silicone envelopes; and double lumen silicone implants, which have a silicone balloon within another silicone balloon, one filled with gel and the other saline. Questions about implant-related side effects-other than capsular contracture (the accumulation of fibrous tissue surrounding the implant)-were very often brushed aside, and most patients were led to believe they wouldn't even know the implants were there. However, the fact-noted in the fine print of some package inserts-that no implant was ever warranted to be a lifelong resident in a woman's body did not seem to be made clear, or clear enough.

The Silicone Breast Implant Controversy is organized to provide the reader in Part I with a complete spectrum of current medical information about silicone-associated connective tissue disease, how the implants affect the body, and the specific clinical manifestations of the illness in the patient and her immune system. Part II offers a historical background-from the early 1960s to the present-regarding the development of the implant controversy, as well as the often complex interactions among the FDA, industry, and the doctors involved. Part III delineates the practical considerations every woman faced with an implantation or explantation decision must know in order for her to make the best possible health care decision. In the appendix, the book provides general information on breast surgery, as well as sources for additional data on silicone disease from numerous support organizations.

Though silicone-associated connective tissue disease has received much attention, the majority of women with implants, as well as their physicians and surgeons, do not yet hold a clear picture of what silicone disease is, how it develops, how to diagnose it, and what to do about it. Worse, the very existence of the disease is still being contested by many physicians. It is our hope that *The Silicone Breast Implant Controversy: What Women Need to Know* will replace confusion with clarity, hopelessness with direction, and fear with reason.

