

San Diego Doctor Has Been Chosen to Participate in An FDA Approved Breast Implant Study

A study for a new type of breast implant, the Inamed 410 (410) gel implant, has come to San Diego. The Inamed Company is one of the world's leading designers and manufacturers of breast implants. The Inamed 410 is designed to help the problem patient, i.e. one with a poor result from previous implant surgery or the patient with severe deformity from cancer surgery. Past implants have had inherent flaws like rippling, indentations and even cases where the implant could be seen or its edges felt. These flaws are what the 410 is designed to avoid. In the initial FDA study from 2001-2002, only 30 surgeons nationwide were approved to study 960 patients. Recently, however, the FDA has approved the addition of 480 new patients to the study over the next six months and has added an additional surgeon to the study group who is located in San Diego.

This Inamed 410 implant was designed to conceal its own presence and to be resistant to the appearance of ripples and indentations often seen in thinner women. It also has wide application for cancer patients who have received radical mastectomies.

Not only were these implants designed to correct past problems, they were also created to give plastic surgeons another implant option in place of the traditional round one. The Inamed 410 Silicone-Filled Breast Implants come in a variety of height, weight and shape combinations. Therefore the surgeon can decide on the implant best suited to give patients the results they desire.

The Inamed 410 Cohesive gel implant is not new to the surgical world. In fact it has been used in Europe since 1994 and is now Inamed's #1 implant outside the US. The CoheSIL® gel used in the Inamed 410 improves the ability to design and manufacture

shaped breast implants. The CoheSIL® silicone is no different than previous silicone implants; all ingredients are the same. What has changed is the ratio of ingredients in the mix which has created a greater "cross-linkage" among the compounds thus giving the silicone a more solid, natural feel to the gel filler. Along with the improved feel, this "cross linkage" of the implants (the balance between their liquid and solid nature) has also given them a resilient consistency and form. This consistency has been described as that of a "gummy bear" candy. It is thus hard to create folds or indentations and should it ever rupture the gel will not leave the implant shell.

Dr. Gary Manchester, a graduate of Harvard Medical School and a board certified plastic surgeon, is one of those select surgeons in Southern California who has been approved to perform procedures using this implant. His practice, the Manchester Clinic of Plastic Surgery, is located right here in San Diego.

These implants are safer and remove visual defects, explains Dr. Manchester. "Often people with saline implants have rippling, and the implant can be seen through the skin, especially cancer patients who have very thin skin because of surgery. This cohesive silicone gel does not move or reveal its presence. If it were cut it would not leak and it is very soft."

In order to participate in this study, patients must have either had previous breast surgery with a negative outcome, been born with a congenital defect, or undergone cancer surgery. This eligibility can only be determined after a comprehensive patient history and physical examination. The patient must also be willing to participate in the study for 10 years.

The Manchester Clinic of Plastic surgery is now in the process of enrolling patients for this study.
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