

Breast Implant Safety Update September 2011 Parkland Life

Breast augmentation has remained the most popular cosmetic surgical procedure for 3 consecutive years according to annual statistics from the American Society for Aesthetic Plastic Surgery (ASAPS) . In 2006, the FDA allowed silicone gel implants to be reintroduced for use in cosmetic breast enhancement. Since that time there have been increasing numbers of women opting for the "gel"-filled implants over saline or "salt water"-filled implants. Both are safe and effective options and each individual patient along with their surgeon can decide which is best for them.

Potential silicone gel advantages include a softer, lighter, more natural feel with less rippling possibility than with saline. In 2010, the percentages for implant selection were 38% saline and 62% silicone. With the FDA decision in 2006, recommended guidelines included a minimum age of 22 for women receiving silicone implants and recommendation that MRI examinations be performed periodically beginning 3 years after surgery to monitor the implants.

In January 2011, the FDA issued a statement regarding an extremely rare cancer, anaplastic large cell lymphoma (ALCL) in women with breast implants. There had been 60 reports worldwide out of well over 5 million women. The rare cancer occurred mostly in patients undergoing implant revision surgery presenting with late onset fluid collections around their implants and the prognosis for treatment has been good. A registry was established to track cases.

In June 2011, the FDA issued an update on silicone implants and reiterated that the implants have a "reasonable assurance of safety and effectiveness when used as labeled". Women who receive silicone implants for both reconstructive and cosmetic purposes need to monitor the devices over their lifetime and understand that breast implants are not lifetime devices.