

**PETER J. CAPIZZI, M.D.**  
**STILLWATER PLASTIC SURGERY**

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**FDA LIFTS BAN ON SILICONE GEL IMPLANTS**

*Huntersville Plastic Surgeon First In State to Use Latest “Gummy Bear” Silicone Gel Implant*

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HUNTERSVILLE, NC – For women who want more choices in breast implants and the latest in implant technology, a solution. As the FDA lifts the ban on silicone implants, only one doctor in North Carolina certified to use a new kind of implant that seems straight out of science fiction.

Peter J. Capizzi, MD, of Stillwater Plastic Surgery in Huntersville, North Carolina, is among a select group of surgeons selected to participate in an FDA study of the latest style of silicone gel implants called Style 410. The new implants are commonly referred to as a “gummy bear breast implant” due to the cohesive silicone gel it is filled with as opposed to saline. Dr. Capizzi is one of the first physicians in the state of North Carolina chosen to participate in this clinical study and only one of 18 plastic surgeons on the East Coast.

“One of many benefits to the FDA’s decision to lift the ban on silicone implants is that patients will now have more choices,” said Dr. Capizzi. “For example, a new implant that I have been approved to use is part of a clinical study. This is a special type of implant that represents one of many models and we are the first practice in North Carolina allowed to use it under FDA guidelines.” Currently, the implant is used for failed cosmetic saline implants and breast cancer. The findings of the study will serve as the basis for introducing the Style 410 implants to the US market for breast augmentation, reconstruction, and revision patients.

Dr. Capizzi, a double board certified plastic surgeon who received his training at renowned Mayo Clinic, has already had much experience with the implant already, having been a co-investigator with the FDA silicone implant studies since 1998. He has many patients enrolled and says the use of these implants is just an extension of his practice where he specializes in breast surgery, body contouring and facial rejuvenation. Dr. Capizzi is also currently chair of the Plastic Surgery Department at Presbyterian Hospital.



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Inamed Corporation, the leading implant manufacturer, has developed the Style 410. When these implants are cut open they maintain their consistency just as a gummy bear candy would. The implant is a textured, teardrop-shaped implant's filling, called Cohesil® is more like a soft solid which helps the implant maintain its shape. Unlike liquid-filled implants, the Style 410 is less likely to leak, wrinkle, fold or ripple. At this time the only patients undergoing breast reconstruction and those who have experienced problems with saline implants are eligible to participate in the FDA study. The findings of the study will serve as the basis for introducing the Style 410 implants to the US market for breast augmentation, reconstruction, and revision patients.

"Inamed Corporation asked us to participate because we have vast experience in working with silicone gel implants and breast surgery," said Capizzi. "Because I feel that as a practice, it is part of our responsibility to be leaders in the field of breast health overall, I was excited that Stillwater was chosen to participate."

The expanded study will ultimately involve 940 patients at 100 institutions and address all of the clinical requirements of FDA's Breast Implant Guidances. The original feasibility study, which was approved on September 8, 2000, was limited to 25 patients. The new study has included separate patient cohorts for augmentation, reconstruction and revision of existing implants. Upon completion, the pivotal study will serve as the basis for a premarket application (PMA) application to market the Style 410 for augmentation, reconstruction and revision indications in the United States.

"This is our expertise, breast surgery," Capizzi said. "As an experienced plastic surgeon who trained at the Mayo Clinic where one of the country's largest registries is located, I have placed more than one thousand implants, tear drop, round, smooth, textured, saline, and silicone."

Patients have traveled extensively to glean second opinions from Capizzi and have revision surgeries to improve procedures performed by other physicians. The Stillwater breast implant practice has grown over 30% the past two years. Capizzi's office, Stillwater Plastic Surgery, is located in the Doctor's Building in Birkdale Village. Capizzi is a member of the American Society of Plastic Surgeons and the American Society of Aesthetic Plastic Surgeons.

For more information on Stillwater Plastic Surgery or Peter J. Capizzi, MD, contact 704.655.8988 or log onto [StillwaterPlasticSurgery.com](http://StillwaterPlasticSurgery.com) online.

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