

The Suspension of the Manufacture of Sientra Breast implants

You may have heard that Sientra is temporarily removing its implants from the US market. In recent weeks several steps have been taken to review the technical aspects in the manufacturing of breast implants made in Brazil by Silimed for the European Market and now for Sientra in the US market.

We wish to quickly put to rest any concerns that may arise.

- **No issues about risks to patient health or safety** have been raised.
- The FDA has known of these concerns for months, but there has been **no change to the regulatory status of Sientra's FDA-approved breast implants.**
- We anticipate the **voluntary suspension of Sientra implant usage will be temporary** and will be resolved with the review of manufacturing processes
- **We have every confidence in Sientra and its implants.**

The Technical Background

Silimed has been making breast implants including those for Sientra for 37 years with product approval in 75 countries. Microscopic particulate matter was found on the implants by scientists in Germany inducing them to suspend their use on September 23 until more testing was done. This decision was not based on any evidence that this particulate matter was unusual or harmful.

On October 9, Brazilian regulatory authorities *temporarily* suspended the manufacturing of all medical devices made by Silimed, including products manufactured for Sientra, as they continue to review technical compliance issues related to Good Manufacturing Practices (GMP) at Silimed's manufacturing facility.

Sientra's breast implants, although made by Silimed, are not precisely the same as those made for the European market. They began their clinical trials in the United States in 2000, received their Pre-Market Approval from The FDA and rights to sell the implants in 2012. Their manufacturing processes and facilities are subject to the same inspections and regulations as those of Allergan and Mentor.

Hani Zeini, Founder and Chief Executive Officer Sientra, has *voluntarily* suspended the sale of their implants and requested that plastic surgeons not use those we have in stock until these matters are resolved. Hopefully this will be a matter of weeks.

In the meantime Allergan will be supplying both our saline and silicone implants both smooth and textured, round and shaped.

For those of our patients who have surgery scheduled in the near future minor adjustments will have to be made in your implant selection. Volume and implant

dimensions vary very slightly between the three manufacturers. The change will not affect the final look of your breasts.

If you have concerns please do not hesitate to contact us. We have samples of the Allergan implants if you wish to come in and compare their feel to the Sientra implants.