

# sientra®

February 14, 2019

Dear Valued Plastic Surgeon Partner,

There is nothing more important to Sientra than the safety of your patients. We want women to feel confident in FDA-approved Sientra breast implants and in their decision to have breast augmentation or reconstructive surgery. We understand recent media coverage may have created concern for you and your patients. We take these concerns very seriously, and would like to provide you with an update on breast implants and the safety profile of Sientra silicone breast implants.

## **Sientra and the Science**

At Sientra, we are guided by science, and science confirms the long-term safety and effectiveness of all Sientra implants:

- Worldwide, the reported incidence rates of BIA-ALCL vary widely. Due to the distinct differences in each manufacturer's texturing process and outcomes, it is crucial to avoid categorizing all textured implants as one-in-the-same.
- According to FDA, the risk for a woman with textured implants to develop BIA-ALCL is 1:3,817 to 1:30,000.
- Researchers have estimated that the worldwide risk frequency in Sientra textured implants is 1:200,000<sup>(1)</sup>.
- We are so confident in the safety of our implants that we established the Sientra Platinum20™ warranty, which provides an industry-leading 20 years of coverage. This is part of the *Sientra Difference*.

## **Upcoming Food & Drug Administration (FDA) Panel Meeting**

On March 25-26, the FDA will hold a General and Plastic Surgery Devices Panel meeting to ensure patients and healthcare providers have accurate information on breast implants. BIA-ALCL will be one of several topics of discussion at the upcoming meeting. This panel follows a meeting in France of the *Agence Nationale de Sécurité du Médicament (ANSM)* on February 7-8, in which:

- The European Commission's Task Force noted "insufficient scientific evidence to limit the use of textured breast implants as they provide positive clinical and psychological outcomes for patients."
- Recommended against prophylactic removal of Biocell™ – or any textured breast implants.
- Sales of Biocell™ implants remain suspended in CE-mark countries.

Our commitment to board-certified/eligible plastic surgeons remains steadfast – you represent the highest standards, bringing the best training to perform these procedures. We share a fundamental responsibility with you to provide the safest implant options for your patients. I invite you to visit [sientra.com/legacyofsafety/](http://sientra.com/legacyofsafety/) for important safety information and resources and will provide updates as more information becomes available.

I would like to thank you for your continued partnership. We will continue to update you as appropriate. Please do not hesitate to reach out to me or my team with any questions.



Jeffrey Nugent  
Chairman and Chief Executive Officer  
Sientra, Inc.

<sup>(1)</sup> M Bradley Calobrace, Michael R Schwartz, Kamakshi R Zeidler, Troy A Pittman, Robert Cohen, W Grant Stevens; Long-Term Safety of Textured and Smooth Breast Implants, *Aesthetic Surgery Journal*, Volume 38, Issue 1, 1 January 2018, Pages 38–48, <https://doi.org/10.1093/asi/sjx157>