



June 25, 2019

To IDEAL IMPLANT patients who had to delay or reschedule surgery,

We at Ideal Implant sincerely apologize for the inconvenience caused you by having to delay or reschedule your IDEAL IMPLANT procedure due to our recent limited supply of implants. This was entirely out of your surgeon's control.

Our quality assurance team recently identified a small group of implants that deflated shortly after implantation due to a minute piece of silicone in the valve channel. While these implants met all specifications and posed no threat to patient safety, we recalled those that had not yet been implanted. In addition, we chose to pause production to take a corrective action that improves the manufacturing process. This took longer than expected, and as we extended the timeline, your surgeon had to reschedule your procedure.

We are pleased to announce that our corrective action is now complete and implants have successfully passed a rigorous testing protocol confirming its effectiveness. We have restarted production and are building inventory during the required FDA review period. Approval was anticipated by about July 1st, which would have allowed us to resume sales. Unfortunately, we have just been notified by the FDA that the completion date for their required review before we can resume sales of IDEAL IMPLANT has been extended to the end of September. While no issue has been raised about our implant or manufacturing, this additional delay is entirely out of our control and the approval date depends on the FDA's internal processes.

We hold our product to a very high standard and wish to maintain the superior performance and patient satisfaction rates we have established. IDEAL IMPLANT continues to show significantly lower risk of rupture and capsule contracture over silicone gel alternatives in FDA trial data at eight years. With a beautiful look and natural feel, without the risk of silent rupture, your choice of IDEAL IMPLANT is a choice for long-term satisfaction and peace of mind.

While we regret the inconvenience our supply limitation has caused you, we appreciate your patience as we ensure that women, such as yourself, can confidently choose "Beauty without Compromise" with the IDEAL IMPLANT for decades to come. Your surgeon's office will work with you directly to ensure that you can schedule your procedure as soon as implants are again available.

Sincerely,

Robert S. Hamas, MD
CEO and President

Ideal Implant Incorporated

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