MENTOR®
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Dear Customer,

Earlier this week, the U.S. Food and Drug Administration (FDA) issued a Warning Letter to MENTOR® related to an ongoing post-approval study. It's important to note that the Warning Letter did not raise any specific safety or quality concerns, but cites the fact that we have not met the study requirements for the number of patients enrolled in the MemoryShape® breast implants arm of one of our post-approval studies. The Warning Letter doesn't affect the regulatory status or availability of MemoryShape® in the U.S. or any other market in the world.

MENTOR® takes its regulatory commitments very seriously and has continuously implemented additional approaches which have resulted in a significant increase in overall study and site enrollment. We have continued to encounter challenges with enrollment in the MemoryShape® device group. A contributing factor is a low preference for textured devices in the U.S., as compared to markets outside of the U.S. where texture is preferred and used in approximately 80% of cases. For context, over 90% of the implants in the U.S. are smooth devices. MemoryShape® breast implants are offered exclusively with a SILTEX® microtextured[1,2] shell.

MENTOR® is currently collaborating with the FDA to determine the best path forward to meet post-approval study requirements.

There is extensive long-term clinical and real-world data that supports the safety of MemoryShape® breast implants and there have been no safety signals observed to-date in studies of the product. Specifically, the safety and effectiveness of MemoryShape® breast implants have been evaluated in two open-label, multicenter prospective clinical studies which followed nearly 3,000 patients implanted with MemoryShape® breast implants. These include the 10-Year Mentor MemoryShape® Post-Approval Cohort Study and the MemoryShape® Continued Access prospective study.

Nothing is more important to Mentor than the health and safety of the women who choose our breast implants. We are aligned with the FDA in the belief that an important part of ensuring patient safety is through ongoing surveillance of our products through post-approval studies.

We look forward to continuing the dialogue at the FDA's General and Plastic Surgery Devices Panel meeting scheduled for March 25-26, 2019.

If you have any medical, scientific, or technical questions or would like to discuss anything further please don't hesitate to reach out to one of us to discuss. Medical Information Requests (MIR) can also be submitted to our official MIR website.

Regards,

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1 Atlan M, Nuti G, Wang H, Decker S, Perry T. Breast implant surface texture impacts host tissue response. J Mech Behav Biomed Mater. 2018 Dec;88:377-385
2 Derby BM, Codner MA. Textured silicone breast implant use in primary augmentation: core data update and review. Plast Reconstr Surg. 2015 Jan;135(1):113-24
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