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Mentor Statement Regarding FDA Post-Approval Study Warning Letter

Nothing is more important to Mentor than the health and safety of the women who choose our breast implants and Mentor conducts long-term clinical studies to monitor the safety and performance of our products.

Earlier this week, the U.S. Food and Drug Administration (FDA) issued a Warning Letter to Mentor regarding one of our post-approval studies. 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 implant arm of one of our post-approval studies.

Mentor takes our regulatory commitments very seriously and has worked diligently to increase overall study and site enrollment. While we have seen some improvement, we continue to encounter challenges with enrollment in the MemoryShape group, primarily due to low preference for textured devices in the U.S. For context, over 90% of breast implants in the U.S. are smooth surfaced devices. MemoryShape breast implants are offered exclusively with a SILTEX® microtextured[1,2] shell. We are currently collaborating with the FDA to determine the best path forward to meet the post-approval study requirements.

There is extensive long-term clinical and real-world data that supports the safety of MemoryShape breast implants and these studies do not show product safety concerns. 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.

We believe MemoryShape breast implants are an important option for women who are considering breast reconstruction following mastectomy or for those considering augmentation. 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.

Mentor is looking forward to continuing the dialogue at the upcoming FDA General and Plastic Surgery Devices Panel Meeting scheduled for March 25-26, 2019.

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About Mentor Worldwide LLC

Mentor Worldwide LLC, part of Johnson & Johnson Medical Devices Companies, is a leading supplier of breast implants in the global aesthetic market. The company develops, manufactures, and markets innovative, science-based products for surgical and non-surgical medical procedures that allow breast surgery patients to improve their quality of life. The company is focused on two strategic areas: breast reconstruction and breast augmentation. For more information, visit www.mentorwwllc.com

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.