CALDERA MEDICAL

Dear Patients and Medical Professionals:

Effective April 16th, 2019, the U.S. Food and Drug Administration (FDA) ordered the only two manufacturers of **Transvaginal** Pelvic Organ Prolapse (POP) surgical meshes to stop all sales and distribution in the United States.

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm636114.htm

In our aim to support you in your clinical choices, we want to clarify that Vertessa® Lite is not indicated for transvaginal POP repair and Desara® is not indicated for POP repair. Neither of Caldera Medical products are affected by this FDA decision.

Furthermore, the safety and effectiveness of Abdominal Sarcocolpopexy Meshes used for treatment of POP (Vertessa® Lite) and Mesh Suburethral Slings used for surgical management of female Stress Urinary Incontinence (Desara®) have been well supported and recognized by the FDA.

We want to reinforce our commitment with physician's training and education as they transition to other available options for prolapse repair.

At Caldera Medical, patient safety and healthcare professionals support has always been and will remain our number one priority. On behalf of all Caldera Medical employees, we thank you for your confidence in our products as we work as a team towards our Mission of Improving the Quality of Life for Women.

Sincerely,

Jeffrey S. Hubauer
Chief Operating Officer
Caldera Medical, Inc.

April 17th, 2019

5171 Clareton Drive Agoura Hills, California 91301 TF 866.422.5337 P 818.879.6555 F 818.879.6556