

Caldera Medical Announces FDA Clearance of Novel Treatment for Pelvic Organ Prolapse

Ascend® enables treatment of both anterior and apical prolapse in a single procedure

AGOURA HILLS, CA, June 23, 2009 – Caldera Medical, Inc. announced today that it has received FDA clearance and CE Mark certification for the Ascend Pelvic Floor Repair System with Apical Support, a novel treatment for female pelvic organ prolapse Ascend[®] is the latest addition to the Caldera Medical family of products designed to treat female stress urinary incontinence (SUI) and pelvic organ prolapse (POP). Caldera's product line includes the Desara[®] Sling System, a universal sling that allows surgeons their choice of multiple surgical approaches by utilizing reusable instrumentation. Caldera is the only U.S. company offering this unique solution, which benefits surgeons, hospitals, and the environment.

Pelvic Organ Prolapse is one of the most common quality of life conditions facing women. In fact, nearly 50% of women who have given birth vaginally will develop this condition. Furthermore, a woman's lifetime probability for undergoing a surgical treatment to correct POP is approximately 11%, and approximately 29% of surgically managed patients require reoperation due to reoccurrence of the condition. Patients with POP often present with a dual diagnosis of stress urinary incontinence, and Caldera's SUI offering, Desara, can be used together in the same surgical procedure as Ascend.

Ascend introduces several key differentiators to the market. Notably, Ascend provides apical support from the anterior compartment through unique implant geometry utilizing CentraSoft™ mesh technology and a patented surgical method that is designed to both reduce invasiveness and enhance patient outcomes. CentraSoft™ mesh technology provides a thin, lightweight central mesh designed to conform to the patient's anatomy with stronger lateral arms for support. For patients with both anterior and apical defects, Ascend offers the ability to treat both defects with one surgical implant, reducing the potential for complications and the cost to the healthcare system. Bryon L. Merade, CEO, commented, "We are very excited about Ascend's cutting edge technology and the option it provides surgeons to treat their patients with minimally invasive techniques utilizing the fewest number of implants possible. Ascend underscores our commitment to improving women's health."

Tomas Antonini, M.D. of Round Rock, TX, one of the nation's leading urogynecologists, said, "Ascend fulfils a need surgeons have had for years for an implant that can treat both anterior compartment and apical prolapse at the same time and in the same procedure. The ability to treat these two defects with a single implant will address a common cause of failures seen in these types of repairs. Caldera has once again brought a unique technology to market in an effort to improve the treatment of pelvic organ prolapse and stress urinary incontinence."

About Caldera Medical



Caldera Medical is dedicated to bringing innovative medical devices to the marketplace. Caldera focuses exclusively on differentiated, high-impact products across the gynecology, urology and urogynecology specialties.

Caldera Medical is a privately held company located in Agoura Hills, California. For more information, visit Caldera's Web site at www.calderamedical.com.

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