

Caldera Wins FDA Clearance -- Ascend PFR System

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Datamonitor News and Comment

Caldera Medical, a medical device company, has received the FDA's 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 reportedly the latest addition to the Caldera Medical family of products designed to treat female stress urinary incontinence and pelvic organ prolapse.

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, the company said.

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, the company added.

Bryon Merade, CEO of Caldera Medical, said: "We are very excited about Ascend's 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."