

Aragon Surgical Announces the Expansion of the Lektrafuse Platform of RF Cutting & Sealing Instruments

CAIMAN Received 510(k) Clearance June 24, 2009
TELEO Received 510(k) Clearance January 21, 2010

Palo Alto, Calif. January 27, 2010—Aragon Surgical, Inc., a venture-backed medical device company, announced today that it has received 510(k) clearance for Lektrafuse TELEO, the newest addition to its Lektrafuse platform.

The expansion of the Lektrafuse Platform of radio-frequency (RF) based Tissue Sealing and Cutting Instruments allows surgeons to utilize the unique advantages of the Lektrafuse platform in a broader range of applications. The platform consists of the Lektrafuse RF Generator to be used in conjunction with the Lektrafuse CAIMAN, for laparoscopic surgical procedures, and now the Lektrafuse TELEO, both cleared for sealing vessels up to and including 7mm in diameter. TELEO has a shorter shaft than its predecessor and is therefore ideal for open and minimally invasive procedures where a long shaft is not needed.

Both the CAIMAN and the TELEO are cleared for a broad range of general and gynecologic procedures. Physicians in select sites across the country have been using the CAIMAN instrument for bariatric, gynecologic, and colorectal procedures since its commercialization in September of 2009.

CAIMAN and TELEO offer a number of significant advantages over current RF cutting and sealing devices for surgeons performing laparoscopic or open procedures. The jaw mechanism of these instruments is uniquely engineered with a floating hinge to create durable seals. It precisely grasps the targeted tissue and delivers strong, uniform compression force across the entire electrode surface, from the tip of the jaw to the base, to create optimal conditions for sealing. Compression force in other instruments declines significantly from the proximal to the distal end of the tip, pushing tissue out of the jaws and providing little to no force to tissue near the tip.

The instruments also have the longest jaw sealing length (50 mm) available today, allowing surgeons to seal and divide large volumes and long lengths of tissue to reduce procedure time and surgeon fatigue. Additionally, the need for stapler reloads is greatly reduced in vascular applications.

Another unique aspect of the CAIMAN and TELEO instruments compared to other RF sealing devices is their ability to articulate *and* rotate, giving surgeons excellent maneuverability even in difficult-to-reach areas.

The Lektrafuse RF generator that delivers power to the CAIMAN and TELEO instruments also works to optimize sealing. It uses a sophisticated algorithm to modulate RF energy in response to multiple tissue parameters, delivering a customized seal cycle to each bite of tissue. This customized cycle creates seals with virtually no, tissue adhesion or charring and less than 1 mm of thermal spread.

“Surgeons who are using the CAIMAN instrument have noted the consistently high quality of the seal it produces,” said Roseanne Varner, Aragon Surgical President and CEO. “Procedure time is greatly reduced not only because of the long seal length but also because surgeons do not have to reseat and cauterize due to leaks. CAIMAN and TELEO embody our goal of serving needs that are currently unmet by other RF devices.”

About Aragon Surgical, Inc.

Founded in 2005, Aragon Surgical, Inc. is a venture-backed medical device company headquartered in Palo Alto, CA, USA. Its proprietary Lektrafuse technology and instruments are designed to help general surgeons, gynecologic surgeons and surgical specialists in the performance of both laparoscopic and open procedures. Aragon Surgical is dedicated to Pioneering the utilization of Lektrafuse technology in applications unmet by current RF devices.

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