SOMAVAC® Medical Solutions Receives FDA Clearance of Wearable Post-Surgical Pump

Memphis, TN (June 26, 2018) – SOMAVAC® Medical Solutions, Inc. today announced U.S. Food and Drug Administration (FDA) clearance of SOMAVAC® 100 Sustained Vacuum System, a closed suction drain device. The SOMAVAC® 100 is a low-profile, user friendly, wearable medical device that applies sustained vacuum to a closed wound following surgery to remove fluid effectively and reduce the risk of seroma, and is the only patient-centric, value-based alternative to the suction bulbs used in closed suction drains.

SOMAVAC® 100 was designed to replace the legacy technology of using suction bulbs with surgical drains, which has seen little innovation or advancements since the bulbs’ conception in 1970’s. In addition to its health benefits, the drain and pump can be discretely worn under clothing which aids in helping patients return to normal activities while recovering.

“This FDA clearance represents a critical milestone for SOMAVAC® and provides a meaningful advancement in post-surgical care, offering patients the opportunity to recover with dignity at home after major surgeries,” said Esra Roan, PhD, Chief Executive Officer of SOMAVAC® Medical Solutions. “We are excited about receiving our clearance from the FDA for this device so that our technology can begin to improve patients’ recovery after surgeries.”

Continued Roan,” This milestone was achieved with the support of Innova Memphis and MB Venture Partners, both based in Memphis, along with a group of Angel investors, for whom we are incredibly grateful.” SOMAVAC® Medical Solutions was launched in 2016 as it entered, Zeroto510, a medical device accelerator in Memphis, TN.

Of the more than 750,000 U.S. surgical patients annually, approximately 20% experience complicated seromas requiring painful and costly interventions such as aspirations, which add more than a $1 billion burden to the U.S. healthcare system.

The current standard of care is manually operated closed-suction systems, such as Jackson-Pratt (JP) drains or Hemovacs, which are meant to draw fluid out with manual suction generated by a flexible, suction bulb attached to the end of the drain. Surgical drains are worn by patients anywhere from days to several months depending on the self-reported fluid volume. The inability of the flexible suction bulb to generate continuous suction is a major factor in prolonged drain indwelling times which increases opportunities for complications. Bulbs are also fraught with issues such as leakage, clogging and spillage, and patients struggle to follow instructions which may lead to inaccurate use of drains.

The SOMAVAC® 100 is indicated for use in a range of surgeries which lead to large surgical flaps requiring drains, such as abdominal surgery, mastectomy, cosmetic surgery, hernia surgery, orthopedic procedures, etc.

About SOMAVAC Medical Solutions, Inc.
Headquartered in Memphis, TN, SOMAVAC® is a medical device company committed to engineering medical devices that transform healthcare for the benefit of patients. The SOMAVAC® team actively engages and listens to surgeons, patients, caregivers and other healthcare providers to design best-case alternatives to medical devices that enhance patient convenience and compliance. The company recently developed a low-profile, user friendly, wearable medical device that delivers sustained vacuum to remove surgical and bodily fluids and may reduce the risk of seroma. With this device, patients can recover at home with dignity.

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