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Borvo Medical Announces U.S. FDA 510(k) Clearance for Innovative Surgical Device, Offering a Minimally Invasive Option for Surgical Brain Treatment

Borvo EVAC™ System Provides Advanced Approach for the Growing Number of Patients Requiring Subdural Hematoma (SDH) Drainage Driven by Factors Such as Head Injuries and an Aging Population

Mountain View, CA, October 8, 2024 -- [Borvo Medical](#), a neurointerventional medtech startup, today announced U.S. Food and Drug Administration (FDA) 510(k) clearance of the Borvo (Endoport Vacuum Assisted Collection) EVAC™ system, an advanced alternative to traditional subdural hematoma (SDH) drainage methods. The Company will present its innovative technology later today at the 17th [World Federation of Interventional and Therapeutic Neuroradiology \(WFITN\) Congress](#), taking place in New York from October 6-10, 2024. Designed to address the limitations of existing devices, Borvo EVAC leverages state-of-the-art fabrication techniques, improved materials science, and ergonomic designs to provide a modernized, efficient, and less invasive solution. The EVAC meets the evolving needs of an aging population and individuals requiring SDH drainage due to head injuries and other causes. The EVAC system is anticipated to be available in early 2025.

"Borvo EVAC represents a significant advancement in the approach to treating subdural hematoma. For years, clinicians have relied on traditional devices such as the stainless-steel Subdural Evacuation Port System (SEPS), which, while effective, have not evolved to meet modern demands, including imaging compatibility. Our technology not only addresses the limitations of the current standard-of-care, but also transforms the experience for medical professionals and patients," said Martin Dieck, Founder and CEO of Borvo Medical. "Among other advantages, the patent-pending designs of the EVAC system utilizes a unique geometry which results in more volume and may lead to less clogging as compared to older technologies."

Subdural hematoma (SDH) is a type of bleeding inside the head that can be life threatening, and has become increasingly common due to head injuries, brain atrophy, and the use of blood thinners. Treatment involves drainage to remove blood or fluid buildup on the brain's surface. Traditionally, these procedural options usually include either making an opening in the skull or drilling holes to drain the fluid. With an aging population and the rise in usage of blood thinners, SDH drainage cases are expected to rise exponentially. By 2030, over 60,000 SDH procedures are estimated to be performed annually in

the US alone, with the potential to reach 140,000 cases per year as the population continues to age and medical interventions expand.^{1,2}

Borvo EVAC stands poised to fill these gaps and transform SDH drainage solutions. With advanced technology that reduces artifacts on post-operative CT scans, it delivers clearer, more reliable follow-up imaging for medical teams. Unlike existing options, Borvo EVAC is MRI-compatible, providing a broad range of imaging and monitoring options without performance interference. Additionally, Borvo EVAC employs two unique, patent-pending designs, fabricated with state-of-the-art 3D printed non-ferromagnetic titanium, enabling features and ergonomics, including a significantly larger lumen, previously unattainable with conventional machining and manufacturing.

“It’s clear that the current SDH drainage systems need an upgrade, especially as the demand for better minimally invasive options increases with the rise of middle meningeal artery (MMA) embolization. Borvo presents an opportunity to enhance both safety and effectiveness, which have been limited by the outdated existing options,” said Dr. Adam Arthur, the James T. Robertson Endowed Professor and Chair of the Department of Neurosurgery at the University of Tennessee and Semmes-Murphey Clinic. “As a more efficient, imaging-compatible alternative, I am optimistic that Borvo EVAC holds promise to significantly improve neurosurgical practices for patients.”

About Borvo Medical

Borvo Medical, a NeuroTechnology Investors (NTI) portfolio company, is committed to advancing minimally invasive neurosurgical technology and developing devices that address both clinical and patient needs. Through a focus on safety, innovation and enhanced imaging compatibility, Borvo Medical aims to lead the next generation of subdural hematoma (SDH) treatment solutions.

About NeuroTechnology Investors (NTI)

NeuroTechnology Investors (NTI) is a leading physician investment group dedicated to advancing innovative neurological technologies and other promising advancements in the medical device and digital health sectors. Established in 2016 and headquartered in Palo Alto, California, NTI investors lend their clinical expertise to add value to groundbreaking companies and accelerate access to clinical solutions for patients. To learn more, visit www.themdadvantage.com.

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¹ Balsaer D, et al. J Neurosurg. 2015 Nov;123(5):1209-15

² Demographic Turning Points for the United States: Population Projections for 2020 to 2060; US Census Bureau