

# Anuncia Medical Successfully Launches Second Generation Device to Treat Hydrocephalus at Several Leading Neurosurgical Centers Across the United States



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*The ReFlow™ Mini Flusher will Benefit the Lives of Patients in the US and Abroad where Access to Ongoing Advanced Clinical Care can be Limited*

SCOTTSDALE, Ariz., July 26, 2023 /PRNewswire/ -- Anuncia Medical Inc. ("Anuncia" or the "Company"), a Company specializing in advancing innovations for implantable and external cerebrospinal fluid (CSF) management systems and neurocritical care, is pleased to announce the successful U.S. commercial launch of the ReFlow™ Mini Flusher device. Neurosurgeons in the US and soon internationally will now have a new option to reduce the impact of hydrocephalus by providing better access to potentially life-saving therapy for the 30 million patients worldwide suffering from this neurological disorder. Hydrocephalus is a chronic neurological condition in which excess CSF accumulates in the brain, often causing severe symptoms, frequent hospitalizations, and ongoing health concerns, and may be fatal if left untreated.

Data recently published in the Journal of Pediatric Neurosurgery on the first generation ReFlow device suggests that ReFlow prophylactic use, designated as a US FDA Breakthrough Device indication Anuncia intends to further explore in future clinical studies, may reduce the high rate of shunt malfunctions due to catheter occlusions and associated repeat revision brain surgeries. The just launched second-generation ReFlow Mini Flusher is FDA-cleared for use in patients living with hydrocephalus or similar conditions. Its reduced size and profile are designed to better support a broader hydrocephalus patient population, from infants to older adults. Used in line with any shunt system brand, the patented ReFlow Mini Flusher is uniquely designed to flush the patient's CSF back into the ventricular catheter to maintain, restore or increase hydrocephalus shunt flow with just a simple push of the flusher's soft dome located beneath the patient's scalp. Noninvasive flushing with the ReFlow Mini Flusher does not interfere with shunt flow regulation and can be performed in-clinic by trained clinical staff, or anywhere by a trained patient/caregiver, as directed by the treating neurosurgeon.

Since the ReFlow Mini became available earlier this month, multiple leading centers across the country have successfully implanted the technology. Patients are already using the ReFlow Mini to manage their chronic hydrocephalus. Beyond the U.S., Anuncia actively seeks opportunities to assist neurosurgeons in regions where treating the condition remains challenging. Most notably, international news organizations are currently covering a public health crisis in Uganda, highlighting how a bacterial outbreak has led to a new surge in hydrocephalus cases. The Company is currently seeking strategic partners who share the belief that the ReFlow Mini could improve the lives of undermanaged patients.

"Even in developed nations, the need is clear for a device like the ReFlow Mini Flusher that can deliver access to noninvasive therapy wherever the patient is. In my experience with the Gen 1 ReFlow device, this technology may decrease hydrocephalus shunt malfunction due to ventricular catheter occlusion," said Dr. Ramin Eskandari, Chief of Pediatric Neurosurgery at the Medical University of South Carolina. "I'm optimistic that the ReFlow Mini has the potential to do the same in other parts of the world where there is a paucity of neurosurgical care and patients can die within hours to days of having a shunt malfunction. ReFlow prophylactic flushing for shunted patients could be game-changing like the surgical techniques of Endoscopic Third Ventriculostomy (ETV) and Choroid Plexus Cauterization (CPC) pioneered by luminaries like Dr. Benjamin Warf have been to avoid shunting. Armed with new tools like ReFlow, I'm excited to see how we can reduce the hydrocephalus public health crisis globally."

The hydrocephalus crisis in many parts of the world is significant. Patients present with severe hydrocephalus, with high protein and extremely high risk of shunt malfunction and infection. Approximately 70-80% of these patients are treated with ETV/CPC in order to prevent shunting. Unfortunately, the literature reports that about 50% of these will ultimately fail and require shunting. Thus the current risk of shunt malfunction in the middle of rural villages hundreds of miles from any potential surgical hospital remains deadly.

"Hydrocephalus represents a significant global health challenge across various regions. Shunt malfunction, a critical complication, poses a potentially fatal risk, highlighting the importance of exploring viable alternatives, including ETV/CPC, especially in resource-constrained areas situated far from potential surgical facilities. Substantial progress has been achieved in addressing this issue in Uganda and other sub-Saharan African countries. Nonetheless, a considerable task remains ahead, particularly given the recent public health crisis related to hydrocephalus reported in Ethiopia and other African nations," commented Dr. Albert Isaacs, a pediatric neurosurgeon at Nationwide Children's Hospital in Columbus, OH, emphasizing the urgency of ongoing efforts to tackle this challenging medical concern.

"Today is an important milestone as the Company begins to meet the needs of neurosurgeons who have been waiting since the start of the Covid Pandemic for our ReFlow Mini Gen 2 device to become available," shared Elsa Chi Abruzzo, CEO and President of Anuncia Medical. "The tremendous efforts of our entire team have made this moment possible. We share a common mission with leading neurosurgical and hydrocephalus organizations of improving access to better care and quality of life and providing peace of mind to patients. Through continued innovation and perseverance, we believe patients around the world can lead productive lives without constant fear of rehospitalizations or lack of access to lifesaving hydrocephalus care."

### **About Anuncia Medical Inc.**

Anuncia Medical is a neurological device company solving the large unmet needs in cerebrospinal fluid (CSF) management and neurocritical care, through clinically validated, noninvasive, cost-effective, 'breakthrough' technologies that are designed to monitor and treat patients at home, or in clinic. Anuncia aims to empower patients in their care journey and provide peace of mind. Built on a commitment to high-quality standards, evidence-based

medicine, and strong ethical behavior for almost a decade, Anuncia Medical Inc. is a trusted partner for neurosurgeons. For more information, visit [www.AnunciaMedical.com](http://www.AnunciaMedical.com), and follow Anuncia on [LinkedIn](#) and [Twitter](#).

### **About ReFlow™ System Mini and ReFlow™ Mini Flusher**

Available in the U.S. only, the ReFlow™ System Mini represents a platform technology designed to improve the function of CSF management devices in the OR, the ICU, and at-home. The ReFlow™ System Mini and ReFlow™ Mini Flusher are 510(k) cleared by the U.S. FDA for use in the treatment of hydrocephalus as a part of a CSF shunt system. The ReFlow™ System Mini is a small, implanted system consisting of a flushing device and ventricular catheter. When implanted in line with a commercially available shunt, it can be actuated by noninvasively pressing on the flusher dome. It is designed to deliver a small amount of fluid toward the ventricular catheter, for restoration, increase, or maintenance of flow, by clearing catheter flow holes. The implanted ReFlow™ Mini Flusher is meant to be actuated by trained users, in clinical or non-clinical settings, at the personalized direction and supervision of the patient's physician. The ReFlow™ System is a prescription device sold by or on the order of a physician.

Patients are advised to consult with a qualified healthcare professional to determine if this product is right for them. Important Safety Information & Risks: For Indications for Use, Warnings, Precautions, and other safety information, please refer to product labeling.

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