

Orbis Announces Receipt of Health Canada License - April 2024

April 18, 2024. St. Paul, Minnesota. Agitated Solutions, Incorporated (ASI) announced today that it has been issued a Medical Device License (MDL) from Health Canada for its innovative Orbis™ Microbubble Generator that simplifies and streamlines the process of saline agitation and delivery for cardiac bubble studies. Orbis is the first tool to automatically agitate the saline with uniform, small bubbles that endure longer for visibility. Orbis is designed to help save time and resources by requiring only a single operator, allowing ease of delivery and producing clear, reliable diagnostic images.

During a standard echocardiogram, a sterile saline solution is manually mixed with air to produce tiny bubbles that are injected into the patient. The bubbles travel to the right side of the heart where they can be viewed to provide information about blood flow through the heart. The bubbles can detect conditions such as patent foramen ovales (PFO) – holes in the heart that did not properly close after birth. Roughly 25-30% of adults have PFOs¹, often undiagnosed, and in rare cases these PFOs can allow blot clots to travel to the brain and cause a stroke. The standard of care for cardiac bubble studies requires one clinician to conduct the imaging while a second clinician agitates and injects the saline. The process is inefficient and generates inconsistent bubble sizes, volume and longevity. This can subsequently impact timely and consistent patient diagnosis.

Immediately following receipt of the Health Canada license, the first clinical use of Orbis was conducted at University Health Network (UHN) Toronto General Hospital in Toronto, Canada. UHN Toronto General is ranked as the third-best hospital in the world by Newsweek.²

“Our mission is to improve efficiency and take the guesswork out of what should be simply executed diagnostic procedures,” said Morgan Evans, CEO of Agitated Solutions. “Orbis represents the first step in delivering consistency and streamlining resources for a standard cardiac procedure that necessitates ease and clarity. We have received nothing but positive feedback from cardiologists and sonographers and look forward to hearing clinical success stories.”

“Currently there is significant variability and inefficiency in cardiac bubble studies,” said Micah Eimer, MD, Chief Medical Officer and co-inventor of the Orbis device. “Our goal was to develop a tool that would automate the bubble creation process, reduce hospital resources in delivering agitated saline, and produce consistent, long-lasting microbubbles for improved visualization. I’m delighted to see this come to fruition.” Dr. Eimer is also a practicing cardiologist and Associate Medical Director at Northwestern Medicine.

About Agitated Solutions, Inc.

Agitated Solutions is developing a portfolio of products to enhance the use of ultrasound imaging and improve efficiency and clinical outcomes. The Company's platform includes a proprietary ultrasound contrast agent (Orbis), a contrast delivery and maneuver automation system, workflow streamlining accessories, and two AI-enabled software solutions that improve

¹ Hagen PT, et al. Incidence and size of patent foramen ovale during the first 10 decades of life: an autopsy study of 965 normal hearts. *Mayo Clin Proc.* 1984;59(1):17.

² Newsweek: The World's Best Hospitals 2024. Feb 2024.

image quality and enhances diagnostics. For more information, please visit agitatedsolutions.com.

The Orbis™ Microbubble Generator is not available commercially outside of Canada.