



For Immediate Release:

Vesiflo Introduces the inFlow™ Device and Its Companion Patient Monitoring System

NEW ORLEANS, LA, May 18, 2015 /BusinessWire/ Leveraging the growth of mobile apps, wearables and cloud services, Vesiflo previewed the inFlow™ urinary prosthesis for women and its companion app/information system at the American Urological Association’s annual meeting. Introducing the inFlow to the physician community for the first time since its FDA approval in October 2014, Vesiflo also demonstrated its inFlow Patient Support System (PSS). Vesiflo anticipates full launch of the inFlow device and PSS in the fourth quarter of 2015.

Vesiflo’s stated mission is to “reinvent bladder drainage,” an area they claim has been under-served by technology despite acute patient need. The PSS is part of a broad product plan the company has been rapidly executing since last October, when FDA approved the inFlow urinary prosthesis.

Addressing an Unmet Clinical Need

The target population for the inFlow is women with impaired detrusor contractility (IDC), a medical condition where patients are unable to spontaneously urinate because they cannot generate bladder pressure. IDC is most often the result of life-changing neurologic disease or injury such as multiple sclerosis, stroke, spinal cord injury, Parkinson’s, spina bifida, diabetic neuropathies, etc. IDC is generally incurable and there are few clinical options. Most women with IDC now use urinary catheters on a life-long basis, despite the problems known to be associated with chronic catheterization, notably urinary tract infections (UTIs), encrustation and low quality of life.

The inFlow is intended to address catheter-related problems and, as a prosthetic device, to compensate for a specific anatomic deficiency. Since women with IDC cannot generate bladder pressure, the inFlow *pumps* the urine out. It is an *active* device that replaces *passive* urinary catheters. Its pivotal trial showed the inFlow to have a lower rate of UTIs and higher quality of life than clean intermittent catheterization, the current standard of care. The technology involved is considerable and is the result of extensive development over a 10-plus year period.

“The inFlow restores personal dignity to women in acute need. It mimics normal urination and eliminates the need to catheterize multiple times daily or use tubes and drainage bags” said Vesiflo’s CEO, Kevin M. Connolly. “The PSS builds on the inFlow’s core magnetic transfer technology to monitor the safety of its users and support them in optimizing their bladder health.”

About the inFlow Patient Support System (PSS)

The central component in the PSS is the inFlow’s “smart” remote control, the Activator. Each time an inFlow user voids, the Activator automatically transmits their voiding volume and other clinical event data to its Base Station and/or an iOS app, which in turn sends these data to the cloud. Collecting key clinical data automatically, i.e. without requiring any additional effort by the patient, increases the ability of the PSS to identify unhealthy indicators early, providing the opportunity for early intervention. The PSS can also prompt users to increase hydration and other bladder-healthy behaviors and will generate reports regarding their voiding for clinicians and payers.



About Vesiflo

Vesiflo, Inc. is dedicated to reinventing bladder drainage. Our initial focus is on improving the lives of women with impaired detrusor contractility, a group that has few clinical options currently. Learn more at www.vesiflo.com.

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Contact:

Susan Robinson
Chief Business Officer
425-242-4923