



For Immediate Release:

## **Physicians, Patient Groups Respond Enthusiastically to FDA Approval of the inFlow™ Device for Women, Vesiflo Announces Market Plan**

REDMOND, WA, October 22, 2014 -- Vesiflo, Inc. today provided a follow-up to last week's announcement that its inFlow Urinary Prosthesis has been approved by the FDA for marketing in the U.S. The inFlow is a non-surgical device that provides a convenient and dignified alternative to urinary catheters. Its target population is women with atonic bladder, a medical condition where patients are unable to spontaneously urinate due to impaired detrusor contractility. Atonic means "no tone" – they cannot generate bladder pressure, so the inFlow *pumps* the urine out. It is an *active* device that replaces *passive* urinary catheters and allows almost normal use of a toilet.

### **Market response to the inFlow**

Kevin Connolly, Vesiflo's CEO, commented, "We have been overwhelmed by the positive response to FDA approval of the inFlow device. We take this as confirmation of the significant unmet that has existed and we promise to do our best to serve the women who can benefit from device use." Responses to device approval include:

- Richard A. Schmidt, M.D., a leading urologist specializing in voiding disorders who was an investigator in the inFlow's pivotal trial, stated, "There are no good alternatives for women who need chronic catheterization. The inFlow device is truly remarkable in its ability to virtually restore the functional behavior of the urinary bladder. No other product, drug, or device can accomplish this to the same degree. The device should be given a high priority consideration for all female patients having difficulty emptying their bladders." Other physicians have commented that the inFlow is "brilliant" and "a winner!"
- Multiple Sclerosis News Today included an article in its Oct. 15 newsletter titled *Urinary Prosthesis Better than Catheterization for Female MS patients*. MS patients often suffer from atonic bladder and are an important part of the target population for the inFlow device.

### **U.S. Product Launch**

Vesiflo is currently planning to launch national marketing of the inFlow at the American Urology Association (AUA) conference in New Orleans May 15-19, 2015. Prior to national launch, the inFlow will be available through certain Centers of Excellence. The Company plans to provide periodic updates via [www.vesiflo.com](http://www.vesiflo.com). Physicians, patients and other interested parties can stay informed about the availability of the inFlow device through this site.

### **About the inFlow**

The inFlow is a non-surgical intraurethral valve-pump in a silicone housing that comes in a variety of sizes. Device sizing and initial insertion is performed by a physician. Thereafter, a new device is inserted every 29 days, typically by a caregiver or spouse. Insertion is similar to that for a urinary catheter. Since the inserted device resides almost entirely in the urethra, only the user knows it's there. To void, the user sits on a toilet, holds a remote control over the lower pelvic area and presses a button. This magnetically activates the miniature internal pump, which drains the bladder at a normal flow rate. When the button is released, the valve is engaged, blocking further urine flow.

### **About Vesiflo**

Vesiflo, Inc. is dedicated to reinventing bladder drainage. Due to their acute need, our initial focus is on improving the lives of women with atonic bladder. We also plan to add related products through internal development and acquisition. Learn more at [www.vesiflo.com](http://www.vesiflo.com).

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