



## The inFlow™ Urinary Prosthesis is Approved for Use in Republic of Korea

**REDMOND, WA** - Vesiflo, Inc. today announced that it has received approval from the Korea Food and Drug Administration (KFDA) to market its inFlow™ Urinary Prosthesis in the Republic of Korea. The inFlow is an alternative to urinary catheters for use by women with impaired detrusor contractility (IDC).

Vesiflo's CEO, Kevin M. Connolly, stated "Vesiflo are very pleased to obtain KFDA approval and we look forward to serving the women in South Korea who now require chronic catheterization. This approval is due in large part to the efforts of our Korean partner, Glomedics. We thank them and know they will do the best possible job in delivering this important advance to the women who need it."

### Helping Patients in Acute Need

Impaired detrusor contractility (IDC) is the inability to contract the muscles necessary to push urine out of the bladder. IDC is most often the result of life-altering neurologic disease or injury such as advanced MS, spinal cord injury, pelvic surgery, spina bifida, stroke, or diabetic neuropathies. Due to its neurologic basis, IDC is generally incurable. There are few clinical options and the vast majority of women with IDC must now use urinary catheters to empty their bladders.

Although urinary catheters may be the most commonly used of all medical devices, with chronic use they frequently cause serious problems, notably: 1) urinary tract infections (UTIs) and 2) low quality of life. These problems are acutely heightened for most women with IDC, since they must use urinary catheters every day for the rest of their lives.

The inFlow urinary prosthesis has been shown to address critical catheter-related problems:

- 1) Its 18-site pivotal trial ( $n=273$ ) showed the inFlow to have a lower UTI rate than clean intermittent catheterization (CIC) the current standard of care.
- 2) In published studies, inFlow improved quality of life by 60-80%, due to the following: a) it eliminates the need to self-catheterize multiple times daily; b) it eliminates tubes and bags, improving body image (as well as hygiene); c) it allows most users to void without assistance, increasing self-reliance; and d) it allows use of a toilet, a psychologically significant benefit as that is the "normal" way to void.

The inFlow urinary prosthesis is a system that consists of a silicone-enclosed device with a miniature valve-pump mechanism and a magnetic remote control. Unlike urinary catheters, the device resides almost entirely in the urethra, so that only the user knows it's there. Also unlike urinary catheters, the inFlow mimics normal urination. To void, a woman sits on a toilet and pushes a button on the remote control – this activates the internal pump, which then empties the bladder at a normal flow rate.

### 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 IDC. We also plan to add other innovative bladder-related products through internal development and acquisition. Learn more at [www.vesiflo.com](http://www.vesiflo.com) ###

**Contact:** Susan Robinson, Chief Business Officer  
[srobinson@vesiflo.com](mailto:srobinson@vesiflo.com) or +1 (425) 242-6373