



Medicare Announces Coverage of Vesiflo's inFlow™ Device

June 15, Redmond WA: The Centers for Medicare & Medicaid Services (CMS) announced that effective July 26, Medicare will provide coverage of the inFlow device as an alternative to intermittent catheterization for adult women with neurologically impaired bladder function.

Vesiflo's CEO, Kevin M. Connolly, stated "The inFlow device can restore function and dignity to women who need urinary catheters. It's been a long and challenging path to U.S. commercialization and now we have to expand our business quickly, but we are eager to bring this practice-changing device to some of Medicare's most fragile beneficiaries."

Jerry Stringham, President of Medical Technology Partners, Vesiflo's reimbursement strategy partner, said "Securing national coverage from Medicare represents a huge achievement for Vesiflo and the inFlow device. I am excited this important technology will now be accessible to the many women who so acutely need it."

The inFlow device is a replaceable voiding prosthesis. Unlike catheters, which are tubes that *passively* drain urine, the inFlow is an *active* device that provides forceful, virtually complete evacuation of urine on demand. inFlow use mimics natural bladder function and allows almost normal use of a toilet or commode. Its pivotal trial compared the inFlow device to intermittent catheterization (CIC), the current standard of care, and showed the inFlow to empty the bladder as well as CIC, while significantly improving quality of life and reducing UTI rate.

Laurie Steinbach, who has MS and has used the inFlow for over four years, said "inFlow has restored my independence and self-esteem in terms of being able to complete the simple process of urination on my own (and it) has significantly improved my quality of life."

Dr. Richard Schmidt, a recognized expert in neurourology and co-inventor of Medtronic InterStim® added "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."

About Vesiflo: Vesiflo, Inc. is a privately-held, FDA registered and ISO 13485:2016 certified medical device manufacturer located in Redmond WA. The inFlow device is a magnetically-coupled intraurethral valve-pump that is FDA approved for 29 day use by adult women. For more information, see www.vesiflo.com/videos.

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