InFlow™ intraurethral valve-pump for atonic bladder

The inFlow™ Intraurethral Valve-Pump (the inFlow™ device) developed by Vesiflo is a non-surgical urinary device for women with atonic bladder due to impaired detrusor contractility (IDC). The inflow device allows women with IDC to urinate without the need to catheterise daily or to use an indwelling catheter and urine drainage bag.

The inFlow™ device is designed for temporary use and comprises of three components: 1) a sizing device to measure urethral length, 2) a silicone catheter containing an interval valve and pump mechanism, and 3) a handheld magnetic remote control activator.

A healthcare professional initially sizes the patient for the silicone catheter, which comes in lengths ranging from 3-7cm and in 2 diameters. A disposable inserter is used to introduce the device into the urethra until its outer silicone tab touches the edge of the internal bladder opening. By depressing the introducer, flexible silicone fins extend and expand in a flower petal to hold the valve and pump section of the device in a fixed position at the bladder neck. In the core of the valve and pump mechanism is a small magnet, which is remotely switched by the activator. To urinate, the patient or carer places the activator against the lower abdomen and presses a button to open the device valve and turn on the pump, which actively draws urine out of the bladder. When urination is complete, the patient or carer releases the button and holds the activator in place for approximately 5 seconds until it beeps and its LED turns off. This signals that the pumping has ceased and the valve has closed. The activator comes with a base station for recharging its internal battery.

The inFlow™ device should be replaced every 29 days. The device is removed by pulling the external flange that collapses the fixation system.

The inFlow™ device was approved for use by the FDA and introduced in the USA in
2014/15. The inFlow™ device was CE marked in 2002 and has been available in some European countries (e.g. Germany) for some years.

**POTENTIAL FOR IMPACT**

Atonic bladder is a condition where patients are unable to spontaneously urinate due to insufficient detrusor muscle contraction, which is usually due to neurologic disease or injury to the detrusor muscle. Patients with atonic bladder typically have chronic urinary retention where the bladder is filled and stretched to its maximum, but the patient is unable to urinate, and may experience overflow incontinence. Chronic urinary retention can cause painful and recurrent urinary tract infections (UTIs), which may eventually cause additional damage to the bladder and kidneys. For most women, atonic bladder is secondary to other conditions such as spina bifida, multiple sclerosis, spinal cord injury and diabetic neuropathy. Patients may require assistance from carers to manage their bladder hygiene and urination because of additional disabilities.

Clean intermittent catheterisation (CIC) is currently the most popular management choice for atonic bladder. Self-catheterisation is, however, not suited to all patients with atonic bladder because of symptoms associated with their underlying condition such as a lack of manual dexterity, balance, and vision difficulties and physical flexibility. These patients will need help from carers.

The inFlow™ device may improve quality of life by removing the need to catheterise multiple times daily or to use indwelling catheters with their inevitable increased risk of UTIs. It may also reduce patient dependency on caregivers for their voiding needs, and allow them to avoid the social embarrassment and hygienic issues associated with other management options. Adverse effects of the inFlow™ device include urinary and genital discomfort and pain, urinary leakage, asymptomatic bacteriuria and UTIs.

This technology is predicted to have an impact on the following domains of the NHS Outcomes Framework (www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk):

- Domain 2 Enhancing quality of life for people with long-term conditions;
- Domain 3 Helping people to recover from episodes of ill health or following injury.

**EVIDENCE**

**PUBLISHED PAPERS AND ABSTRACTS**


OTHER INFORMATION


INFORMATION FROM

This Alert is based on information from a time-limited internet search. Limited information was available from the company.

Lay summary

The inFlow™ intraurethral valve-pump is a new device for women with atonic bladder: a condition where women are unable to spontaneously urinate due to poor bladder muscle contraction. The inFlow™ device is placed in the bladder and urethra and uses a magnetic remote control to let urine out of the bladder. Each time the patient wants to urinate, the remote control is placed over the lower abdomen to open the valve, turn on a pump and let urine out. The device needs to be replaced every 29 days. The inFlow™ device allows women with atonic bladder to urinate, without the need to catheterise themselves several times a day or be attached to a urine drainage bag.