

How the inFlow™ Works

Indication: The inFlow Intraurethral Valve-Pump and Activator is a replaceable **urinary prosthesis** that is intended for use in female patients 18 years of age or older who have incomplete bladder emptying due to **impaired detrusor contractility** of neurologic origin, and who are capable of operating it in accordance with instructions or who have trained caregivers. The device must be replaced every 29 days (or less).

Background: Impaired detrusor contractility (IDC) is the inability to contract the muscles necessary to push urine out of the bladder and IDC of neurologic origin is generally incurable. Most women with IDC must now use urinary catheters every day for the rest of their lives, despite the known problems with chronic catheter use, notably infection and poor quality of life. As a prosthetic device, the inFlow compensates for the inability of women with IDC to generate bladder pressure by pumping the urine out, allowing almost normal use of a toilet. Other benefits of inFlow use include reduced rates of infection and encrustation, as well as improved quality of life.

Description: The inFlow urinary prosthesis is a system with two components:

1. inFlow device – a sterile, single-use urethral insert in a 3-7cm long biocompatible silicone housing, packaged with a disposable introducer (Figure 1-1). Nine sizes are available in order to accommodate individual anatomic variations.
2. Activator – a hand-held magnetic remote control required to operate the internal valve-pump mechanism in the inFlow device. The Activator comes with a Base Station for recharging its internal battery (Figure 1-2).



Figure 1-1: inFlow Device



Figure 1-2: Activator in its Base Station

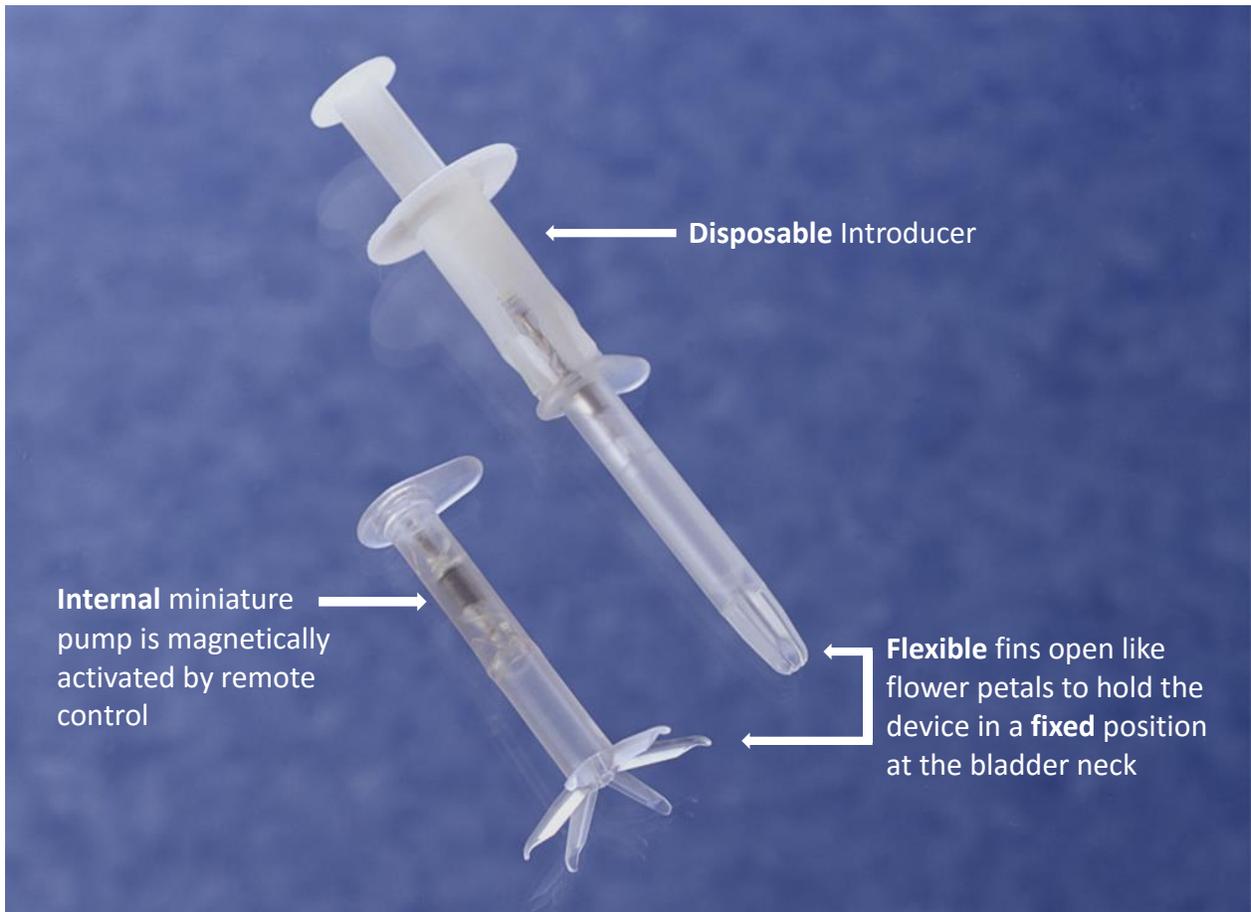
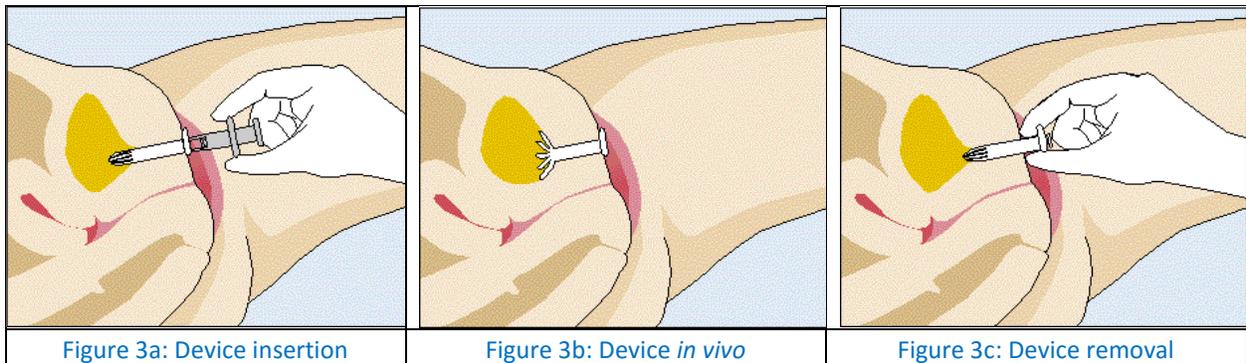


Figure 2: The inFlow with Introducer (top) and after being deployed (bottom)

A physician performs device sizing and initial insertion. Device insertion is similar to that for a urinary catheter (Figure 3a). The inserted device resides almost entirely in the urethra (Figure 3b) so that only the user knows it is there. As with an indwelling (Foley) catheter, the inFlow device should be removed and replaced every 29 days. The device can be easily and safely removed by simply grasping its tab and pulling straight out (Figure 3c). Insertion of replacement devices can often be performed by a trained caregiver or spouse.



Voiding with the inFlow urinary prosthesis mimics normal urination, as shown in Figure 4:

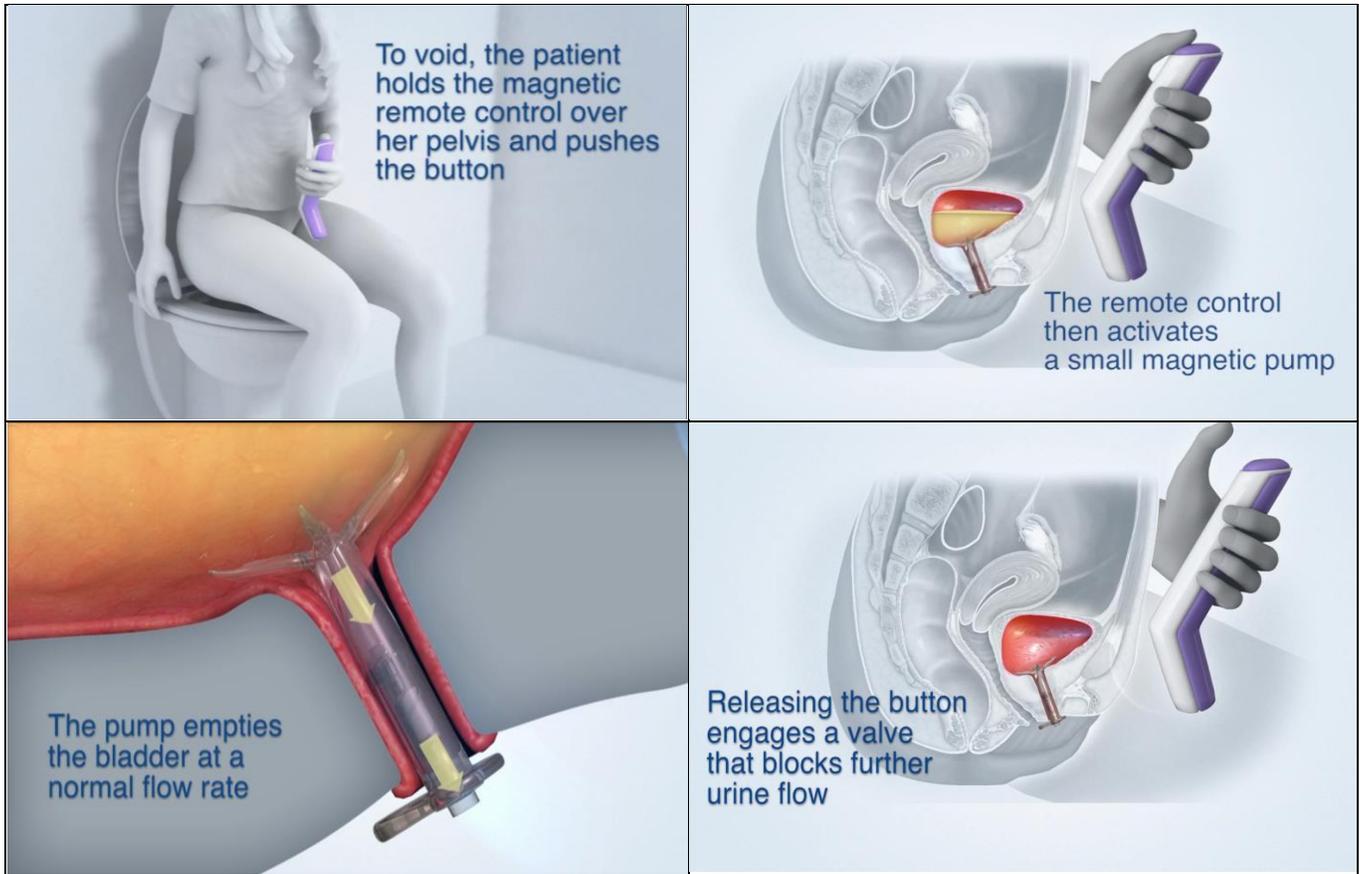


Figure 4: Voiding with the inFlow urinary prosthesis

Summary: As a urinary prosthesis for women with IDC, the inFlow is intended to normalize their toileting to the greatest degree possible. By definition, a prosthetic device compensates for a specific anatomic deficiency. The inFlow prosthetic device’s internal pump compensates for the inability of women with IDC to generate bladder pressure by providing forceful, virtually complete evacuation of urine on demand.