



Restore Personal Dignity and Independence

- Safe, convenient and dignified bladder drainage
- Significantly improves quality of life for most users
- Eliminates the need for tubes and collection bags
- Allows patients to use a toilet and provides normal flow rates
- Allows many patients to void without caregiver assistance
- Easily removed at any time, even by patients



In-Flow is a remote-controlled intraurethral valve-pump catheter for women with impaired bladder function

Ordering Information

In-Flow Device – Catalog Number 203511-XX (specify length)
For example, to order 5.0cm, specify Catalog Number IN203510-50

The In-Flow device is available in the following lengths:
3.0cm, 3.5cm, 4.0cm, 4.5cm, 5.0cm, 5.5cm, 6.0cm, 6.5cm, 7.0cm

Activator (Remote Control) – Catalog Number 403507

Sizing Catheter – Catalog Number IN8035000-01



Advanced technology for more natural bladder drainage

CE 0459 The In-Flow device conforms to Council Directive 93/42/EEC and bears the CE mark.

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CAUTION: Not cleared by the FDA for sale in the USA. Investigational device. Limited by US law to investigational use.

U.S. Patent Nos. 5,762,599 and 6,417,750 and related patents worldwide. Additional patents are pending. In-Flow is a trademark of SRS Medical Systems, Inc. Other trademarks are the property of their respective manufacturers.

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For more information: www.srsmedical.com



Finally: A Safe, Convenient and Dignified Alternative to Urinary Catheters

THE IN-FLOW DEVICE is a urethral insert with a remote-controlled valve-pump mechanism that provides bladder drainage for women with atonic or acontractile bladder. It is a temporary prosthetic device (29 day use) and is indicated as an alternative to urinary catheters.

Atonic bladder is a debilitating voiding disorder wherein patients are unable to spontaneously urinate due to neurologic disease or injury. The inability to void is one of life's most discouraging circumstances. It is also a serious medical problem and complications include urinary retention, bacterial colonization, recurrent urinary tract infections, bladder stones, and impaired renal function. Despite their high level of need, these can be challenging patients to provide medical care for. For many, their bladder impairment is secondary to a life-altering condition such as spina bifida, multiple sclerosis, stroke, spinal cord injury, or diabetic neuropathies. Also, many are elderly. Most frustratingly, there is little to be done. There is no cure for atonic bladder; there are no surgical or other remedies. The vast majority of patients rely on urinary catheters to void, although this restricts activity and causes numerous medical problems.

Active urinary flow and more natural voiding patterns

The In-Flow device is designed to provide female atonic bladder patients with a safe, convenient and dignified alternative to urinary catheters. It allows them to use a toilet again and even have a normalized flow-rate. This is a very meaningful benefit, since it is not only a faster way to void, but also the "normal" way, which is psychologically significant. Additional benefits for those using indwelling (Foley) catheters can be even more profound. The In-Flow device: 1) eliminates the need for tubes and collection bags; 2) allows periodic filling and drainage of the bladder, which can promote tone and prevent shrinkage; and 3) virtually eliminates post-void residual, which can otherwise provide a fertile breeding ground for bacteria.

How the In-Flow System Works

THE IN-FLOW SYSTEM consists of two components: the In-Flow device, a stent-like urethral insert with an internal valve and pump mechanism in a soft, silicone housing; and The Activator, a hand-held remote control unit.

The In-Flow device is produced in lengths ranging from 3 to 7 cm (in 0.5 cm increments) and in two diameters: 24Fr and 28Fr. The appropriate length is determined by inserting a graduated Foley catheter. The In-Flow device size used is 0.5 to 1 cm larger than the length measured using this Foley. Patients are typically started on the 24Fr diameter device and are only offered the 28Fr diameter device if

the smaller device does not prevent leakage.

A disposable inserter is used to introduce the In-Flow device into the urethra (Figure 1a). The device is fixed in position by flexible silicone fins that open like flower petals at the level of the bladder neck (Figure 1b) and by a flexible flange at the external urethral meatus (Figure 1c).

The In-Flow device is routinely replaced every 29 days by the caregiver or patient. It is easily removed at any time, even by patients. Prior to removal, its fixation fins can be collapsed by manipulating the flange, however, it can also be removed by simply

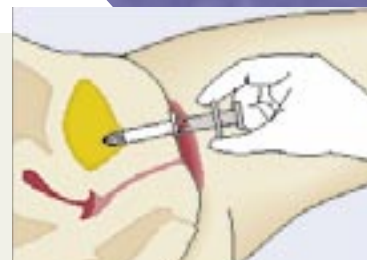


Figure 1a

grasping the flange and pulling straight out. Neither method causes damage to the bladder or urethra due to the flexibility of the silicone.

In order to void, the patient or caregiver positions the Activator against the pubic area and presses its "on" button (Figure 2). This energizes a small magnet in the In-Flow device, causing its valve to open and the miniature rotor in its pump to spin at a speed of 10,000 rpm, and draws urine from the bladder at an average urine flow of 10 to 12 cc per second. When

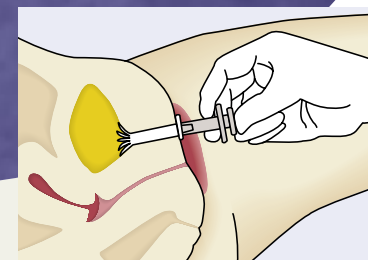


Figure 1b

the urine flow stops, the patient or caregiver releases the "on" button, but continues to hold the Activator in place until it stops beeping. This indicates that the Activator has closed the valve in the In-Flow device, blocking further urine flow.

When not in use, the Activator is stored in its protective shield in order to guard against inadvertent contact with and damage to other electromagnetic components. Its two 3V lithium batteries are replaced every 4 to 6 weeks.

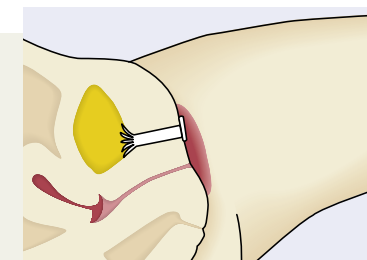
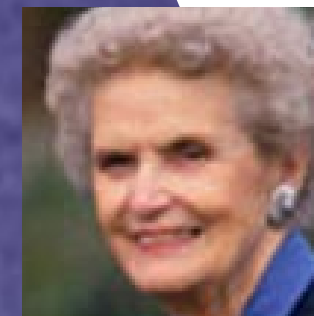
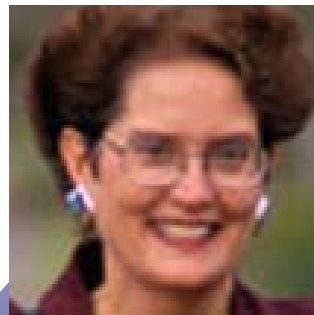


Figure 1c



Figure 2

For additional information, please refer to *Indications for Use*.



NOTE: The In-Flow device should not be confused with other urethral inserts, such as the "UroMed Reliance" and the "Rochester Medical FemSoft". Although the In-Flow device appears similar to these products, it has a different indication for use and is intended for a very different population. Reliance and FemSoft are continence devices, designed to prevent involuntary voiding in otherwise healthy women with stress urinary incontinence. The In-Flow device is essentially the opposite; it is a prosthetic device designed to facilitate voiding for women with impaired bladder function.

The In-Flow device is an entirely new way of providing bladder drainage. Unlike catheters, which rely on gravity to *passively* drain the bladder, the In-Flow device has an advanced turbine pump that spins at 10,000 RPM and *actively* empties urine. The technology involved is considerable and key design aspects, such as the remote magnetic activation and method of bladder fixation, are patented worldwide.

The U.S. IDE clinical study ($n=256$) compared the In-Flow device to the current standard of care, clean intermittent catheterization (CIC), and found that it was comparable to or better than CIC in terms of both post-void residuals (PVR) and rate of urinary tract infection (UTI). In terms of quality of life, however, the In-Flow device was vastly superior. Adverse events were similar, with the exception of discomfort and incontinence, which were more common with the In-Flow device. In general, adverse events associated with In-Flow were of mild severity and were resolved quickly with device removal.

Also, the In-Flow device has been used in Europe, Canada, Australia and Asia since 1997 with no significant adverse events reported to date.

In addition to the U.S. IDE study, the safety and effectiveness of the In-Flow device have been documented in four peer-reviewed clinical studies. (1-4)

IN-FLOW CLINICAL PUBLICATIONS

1. Lynch WJ, Testa GA, Bell D: A study to determine subjective and objective benefits of a remote-controlled intra-urethral device for the management of female acontractile bladder. *Brit J Urol* 2003; (Accepted for publication).
2. Madjar S, Halachmi S, Wald M, Issaq E, Moskovitz B, Beyar M, Nativ O: Long-term follow-up of the In-Flow intraurethral insert for the treatment of women with voiding dysfunction. *Eur Urol* 2000; 38:161-166.
3. Madjar S, Sabo E, Halachmi S, Wald M, Issaq E, Moskovitz B, Beyar M, Nativ O: A remote controlled intraurethral insert for artificial voiding — A new concept for treating women with voiding dysfunction. *J Urol* 1999; 161: 895-898.
4. Surch S, Suter S, Dubs M: Intraurethral sphincter prosthesis to treat hyporeflexic bladders in women — Does it work? *Brit J Urol* 1999; 84:789-794
5. Nativ O, Moskovitz B, Issaq E, Condrea A, Kastin A, Halachmi S, Burbara J, Madjar S, Beyar M: A new intraurethral sphincter prosthesis with a self-contained urinary pump. *ASAIO J* 1997; 43:197-203.