



## Device for Female Bladder Drainage (with remote Activator)

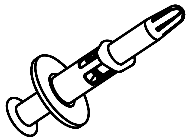
### PHYSICIAN INSTRUCTIONS FOR USE

#### Description and Principles of Operation

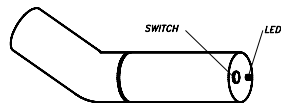
The In-Flow is an advanced intraurethral device designed to permit controlled urine drainage and complete bladder emptying in women who have difficulty voiding naturally.

The In-Flow System consists of four components: (1) the In-Flow Device, a flexible, stent-like insert with an internal valve and pump; (2) the Activator, a small hand-held battery-powered magnetic control unit; (3) Introducer, for inserting the Device; and, (4) Sizing Device, for measuring urethral length.

The Device (**Figure 1**) contains an internal valve and impeller-type pump which is opened, activated, and closed by means of a remote-controlled Activator (**Figure 2**), permitting controlled urine drainage upon demand. The Device is supplied sterile with its Introducer pre-attached, and is intended for a maximum indwelling time of 29 days.



**Figure 1:** In-Flow Device, shown here mounted on Introducer, as provided.



**Figure 2:** The Activator

For the initial insertion, the physician determines the appropriate size by using the In-Flow urethral Sizing Catheter, which is a modified Foley-type catheter with measurement demarcations.

Insertion of the In-Flow Device is conducted in an ambulatory procedure similar to that for indwelling or intermittent catheters. The In-Flow Device is inserted into the urethra until its outer silicone flange (tab) touches the edge of the meatus, preventing proximal migration. By depressing the Introducer, the Device's flexible silicone fins expand in a "flower petal" configuration within the bladder at the bladder neck, preventing migration out of the bladder.

To urinate, the patient places the Activator against her lower abdomen, near the pubic area. The Activator's operating button is depressed to open the Device valve and turn on the urine pump, which actively draws urine out of the bladder at a flow rate similar to that seen in normal urination. When urination is complete, the Activator's button is

released and the Activator is held in place for approximately 5 seconds until the Activator beeps and its LED turns off. This signals that pumping has ceased and the valve has closed, restoring continence until the next desired voided time.

#### Device Size

The In-Flow Device is available in 9 different lengths to match the length of the patient's urethra, which is measured during the initial Catheter insertion procedure. The available lengths and diameter are presented in Table 1 below.

In-Flow Device Diameter	24F
In-Flow Device Lengths (cm)	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0

#### Sterility

The In-Flow Device is provided STERILE (Gamma sterilization). The sterile packaging of the In-Flow Device should be inspected for visible damage prior to use. **Do not use if damage is suspected.**

#### Indications

The In-Flow is indicated for use for urinary bladder drainage only in female patients who are capable of operating the device in accordance with its instructions for use or who have trained caregivers, and for whom normal bladder cycling is not contraindicated.

#### Contraindications

Use of the In-Flow Device is contraindicated in patients with the following conditions:

1. Active urinary tract infection. The In-Flow Catheter can be used once the infection has been treated.
2. Contracted, low-volume bladder (<200 cc bladder pressure).
3. Known vesicoureteral reflux from history, impaired kidney function, recurrent pyelonephritis, or hydronephrosis (moderate to severe).
4. Uninhibited bladder contractions that are not controlled with anticholinergic drugs (as documented by cystometry).
5. Neoplastic or inflammatory processes involving the lower urinary tract, uterus, cervix, or vagina.
6. History of urolithiasis within the last year.
7. Urinary tract fistulas.
8. Bladder diverticulum which cannot be emptied by routine catheterization.
9. Concurrent use of external or internal medical devices with electronic or magnetic components, including pacemakers.
10. Patients undergoing concurrent MRI or radiation therapy. (The Catheter should be removed at the time of investigation or treatment.)
11. Autonomic dysreflexia.
12. Compromised immune system.
13. Patients who are allergic to or cannot take antibiotics.

#### Warnings

- When the protective shield is off, the Activator may attract metal items and may damage magnetic strips (such as those on credit cards) and computer diskettes. Always keep the uncovered Activator at least ½ meter (1½ feet) from such items.
- Do not immerse the Activator in water. Clean with a damp cloth only.

#### Precautions

1. A physician must insert the first In-Flow Device after proper sizing of the urethra, using the Sizing Device. Subsequent insertions may be performed by a nurse, healthcare provider, caregiver or patient who has received appropriate training in device insertion, removal and use.
2. The In-Flow Device is intended for a maximum indwelling time of 29 days.
3. The sterile packaging of the In-Flow Device should be inspected for visible damage prior to use. Do not use if damage is suspected.
4. The In-Flow Device is a single use device and reuse should not be attempted. Do not attempt to reassemble a fully or partially deployed catheter onto the insertion system.
5. Patients (and caregivers, where appropriate) must receive proper education and instruction in the insertion, removal, and use of the device. Specifically, emphasis must be placed on their responsibility to:
  - Keep the Activator available for use at all times;
  - Urinate every three to four hours during waking hours, even if they do not have bladder sensations;
  - Contact their physician if they see blood in their urine, sense irritation or burning when urinating, suspect that the device is not functioning properly, or require MRI or radiation procedures (the device must be removed).
6. The use of the In-Flow Device during pregnancy has not been established. Patients should discontinue use of the device and contact their physician in the event pregnancy is suspected.
7. The In-Flow Sizing Catheter is not intended for dilation.

#### Complications

Possible complications associated with the use of the In-Flow Device are similar to those associated with indwelling or intermittent urinary catheters, and include:

1. Leakage around the Device. (NOTE: Leakage can occur due to encrustation or plug/stone formation, which can prevent the valve mechanism from closing properly. It is not considered an unanti-cipated event and does not signify a device failure.)
2. Incontinence episodes.
3. Urinary tract infections.
4. Asymptomatic bacteriuria.
5. Pyuria.
6. Positive cultures.
7. Pyelonephritis, hydronephrosis, vesicoureteral reflux, upper tract dilatation, and renal failure.
8. Dysuria.
9. Urgency/bladder spasms.

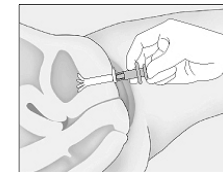
10. Frequency.
11. Urinary retention.
12. Increase in post-void residual volume of urine.
13. Localized perineal or urethral inflammation.
14. Device related discomfort or pain.
15. Localized skin irritation.
16. Adverse cystoscopy findings (urethra and bladder) - mucosal trauma or irritation; stricture(s); diverticula; fistula; abscess; hyperemia/inflammation/edema; erosion/ulcer; severe meatal, urethral or bladder irritation or ulceration; or squamous metaplasia.
17. Urinary calculi.
18. Bleeding or spotting.
19. Hematuria.
20. False passages and perforation.
21. Autonomic dysreflexia.

Possible additional complications include:

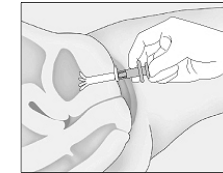
1. Discomfort/device awareness.
2. Device migration or expulsion.
3. Blockage of the internal valve by sediment or stone formation.
4. Device malfunction with resulting urinary retention or urinary leakage (e.g., due to mechanical valve failure or external Activator failure).
5. External Activator failure or battery discharge.

#### Initial Device Sizing

1. With the patient in the lithotomy position, clean the meatal area as for Foley catheter insertion.
2. Insert the In-Flow Sizing Device. This device is a modified In-Flow device in the longest length (7.0 cm) with demarcations and a second, moveable tab:



3. Gently pull the Sizing Device to locate the tabs at the bladder neck:



4. Move the inner, moveable tab **up** the Sizing Device until it touches the meatus.
5. Record the urethral length in this position.
6. Move the inner, moveable tab **down** the Sizing Device until it touches the outer, fixed tab.
7. Instruct the patient to stand.
8. Move the inner, moveable tab **up** the Sizing Device until it touches the meatus
9. Record the urethral length in this position.
10. Repeat this procedure with the patient in a sitting position.
11. Select an In-Flow Device length that is closest to, but not less than the **longest** number recorded in any position (e.g., for a measured length of 3.2 cm, use a 3.5 cm Device).

## Insertion Procedure

1. With the patient in the lithotomy position, clean the meatus area as for Foley catheter insertion.
2. Lubricate the external body of the In-Flow Device with any type of generally accepted medical lubricant.
3. Insert the lubricated In-Flow Device into the urethra until its outer flange touches the edge of the meatus (**Figure 4a**). *The flange should be pointing down, towards the vagina.*

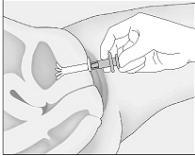


Figure 4a

4. Completely depress the Introducer's pusher (**Figure 4b**) until the device is released (**Figure 4c**). Do not pull out the Introducer until the device is completely released.

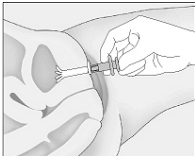


Figure 4b

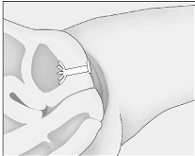


Figure 4c

5. Discard the Introducer.
6. When there is urine in the bladder, check for leakage and for proper device functioning (using the Activator - See "To Urinate").

Many physicians use a topical anesthetic for initial insertion and administer a course of prophylactic antibiotics for the first 5 days of In-Flow Device use.

## Removal Procedure

With the patient in the lithotomy position, gently pull the Device out of the urethra. Due to the flexibility of the silicone fixation system, no damage to the bladder neck or urethra should result.

## To Urinate

1. The patient sits on the toilet as for normal urination.
2. The protective shield is removed from the Activator. NOTE: The Activator will not operate unless the protective shield is removed.
3. The Activator is held close to the pubic area, approximately 4 cm (1 to 2 inches) from the urethral opening (**Figure 5**).



Figure 5

4. The Activator's switch is pressed **continuously** to initiate urination. (The LED will turn on).
5. When urine flow has completely stopped, the switch is released and the Activator is held in place approximately 5 seconds until the Activator **beeps** and the LED shuts off. This signals that pumping has ceased and the valve has closed, completing the urination process.
6. To prevent dislodging of the device, the area should be patted dry, **not** wiped.
7. If necessary, the Activator should be wiped dry.
8. Place protective shield back on the Activator.

## Battery Replacement

The Activator uses two 3-volt lithium batteries (CR123A) which may be purchased wherever camera batteries are sold. The batteries should be replaced every 30 days. Always keep two spare batteries on hand. **When the batteries run low, the Activator will begin to beep and the LED will flash (during use).**

To replace the batteries:

1. Remove the protective shield from Activator.
2. Unscrew the Activator Battery Cover (**Figure 6**).
3. Remove the old batteries. NOTE: Check local laws for possible special disposal requirements. Do not attempt to recharge the original or replacement batteries.
4. Insert the first battery according to the (+) and (-) markings, as shown in **Figure 7**.
5. Insert the second battery on top of the first battery with the (+) marking up, as shown in **Figure 8**, and press into place.
6. Re-screw the two sections of the Activator.
7. Press the **OPEN** switch to check for proper function. (NOTE: The Activator will not operate with the protective shield in place.)
8. Place the protective shield on the Activator.

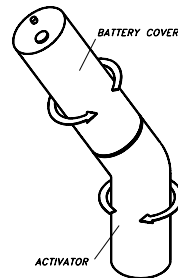


Figure 6

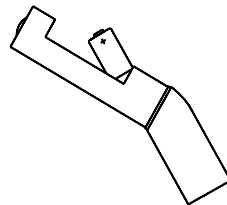


Figure 7

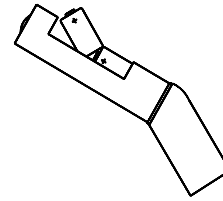


Figure 8

## Suggested Protocol for New Patients

When properly introduced, the In-Flow device can transform the quality of your patient's life. This section suggests a protocol to help new In-Flow patients accommodate to the device and work through any awareness/discomfort that may arise during the initial accommodation period.

Clinical reports indicate that: a) approximately 50% of In-Flow patients report device-related discomfort, typically during the initial accommodation to the device, b) when discomfort occurs it is usually temporary (lasting 3-5 days), c) *the key determinant of treatment success is the motivation of the patient to persevere through the period of device accommodation*, and d) patient counseling and direct nursing support substantially improve patient motivation and (therefore) device acceptance.

Note that other indwelling catheters, such as Foleys, are also known to be uncomfortable for many patients; however, as Foleys are used only when considered medically necessary, they can't be discontinued when uncomfortable. For a patient to continue with an elective procedure despite initial discomfort, it is critical that she be adequately prepared for the fact that she may experience discomfort, that it is likely to be temporary, and that she believe the device's benefits make it worth enduring any initial discomfort.

The recommended clinical protocol for new patients is therefore as follows:

1. Prior to initial insertion, explain that this is a sensitive part of the body and for most patients use of a urethral insert such as the In-Flow Device entails a period of accommodation similar to that required for contact lenses. Let her know that many patients experience discomfort during this accommodation period and instruct her to contact you or your nurse immediately if she is concerned about the level of her discomfort.

Explain that: a) most patients who experience discomfort find that it is only temporary (lasting 3-5 days) and can be palliated with pain relievers and hot baths; and b) if she is unable or unwilling to tolerate the In-Flow, she can easily and safely remove it at any time by simply grasping the meatal tab and pulling the device straight out. (These patients should be instructed to resume their former method of bladder drainage.)

You should then summarize device benefits, to remind your patient of the reasons to persist even if they are uncomfortable. Emphasize the specific ways that the In-Flow will improve her quality of life: 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 patients to void without assistance, increasing self-reliance; and d) it

allows most patients to use a toilet again, a psychologically significant benefit since that is the "normal" way to void.

2. After device insertion, have the patient practice voiding and using the Activator before leaving the office. A supportive nurse is usually the best person to train the patient or caregiver. Patients should also be shown the *In-Flow Patient Video* before leaving the office and be given a printout of the *Guide for New Patients*. (If you or your patient would prefer to have a copy of the video for at-home viewing, please contact MTM.)

3. Provide active nursing support for all patients during the accommodation period and invite patients to call with questions or concerns. Addressing patients' questions and concerns is highly beneficial. Please see *In-Flow Supplemental Instructions* for tips.

Follow-up calls by nurses or continence advisors are crucial to appropriately identify any problems and reassure patients. Suggested points of contact are about 12 hours after the initial insertion, with further phone follow-up again within the first week.

4. If a patient has not accommodated after 3-5 days, consider re-sizing the Device. Correct sizing is critical for patient comfort, as well as for correct device function.

## ENCLOSED PATIENT INSTRUCTIONS FOR USE MUST BE GIVEN TO THE PATIENT UPON EACH DEVICE INSERTION.

In-Flow Device, Cat. No. 203511  
In-Flow Activator, Cat. No. 403507



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Authorized European Representative:

**mtm** medical | technology | marketing

[www.mtm-med.com](http://www.mtm-med.com)

Phone: + 49 0 880 791138

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