



Supplemental Instructions

*For Physicians, Nurses
and Continence Advisors*



PRE-INSERTION ADVICE

1. Prior to insertion, the patient may wish to view the patient video, brochure and guidelines.
2. It may be desirable for the patient to be shown the device and/ or speak to another user.
3. As with the insertion of any implant into the bladder, a clear mid-stream urine specimen (MSU) should be obtained pre insertion and a course of oral prophylactic antibiotics is recommended.
4. Whilst the In-Flow is designed for acontractile/ atonic bladders, many patients do experience varying degrees of urgency in the initial few weeks. This manifests itself as a “whooshing” sensation where 10mls upwards may be expelled spontaneously. (The patient may better describe volumes in the form of oft used objects e.g. Egg cup, tea cup or glass). Information regarding the management of uninhibited detrusor contraction or sensory urgency should be discussed prior to insertion. The doctor may wish to prescribe anticholinergic (anti-spasm) drugs such as Ditropan or Probanthine. Since the drugs take up to 5 days to work up to full effect, it may be suggested that they commence therapy 5 days prior to initial insertion, or the patient should be informed of this fact if commencing such medication after insertion of In-Flow device. The patient may need to be warned that these drugs have some common side effects, such as blurred vision, dry mouth and constipation. These side effects should be dealt with as required. (Boiled sweets or chewing gum are useful to alleviate a dry mouth if water is not available. Increasing dietary fibre and /or using mild laxatives may manage any constipation).
5. The patient may experience urethral discomfort for up to one week post implantation. They should be reassured that this is normal. Oral analgesics may be required in the first 72 hours. Relief can also be obtained using lubricating creams such as Nystatin around the urethral meatus. Warm baths may help. Should the discomfort be acute, slightly pushing the device towards the bladder and rotating the device slightly may lift the flanges off the bladder trigone.
6. Patients should be encouraged to drink between 1 and 2 litres of fluid per 24 hours, in order to assist the patient in accustoming herself to the In-Flow device and to reduce the risk of infection.
7. A discussion regarding sexual relations (if appropriate) is advisable for sexually active patients in order to outline reasonable expectations. The use of adequate vaginal lubrication and utilising positions that reduce direct friction on the urethral area should be included in any such discussion.
8. It is important to remind the patient that they may experience initial discomfort, but that this discomfort should subside if correctly managed. It may take the patient some time to learn the correct use of the device, but patience and persistence should be rewarded.

INSERTION TECHNIQUES

1. The patient may require local anesthetic gel pre-insertion. Care should be taken to use this sparingly so as not to block the device when used immediately after insertion.
2. The 14Fr sizing catheter (supplied) should be inserted into the bladder using 20cc of saline/ water to inflate the balloon.
3. The bladder should be emptied.
4. Slight tension is applied to the bladder neck and the sizing cylinder is advanced towards the urethral meatus until it is flush against the mucosa. The distal end of the sizing catheter will denote the length of the urethra. An extra 0.3 –0.7mm is added to determine the correct length of In-Flow catheter to be used.
5. The bladder can now be inflated via the sizing catheter with sterile water or saline to 200mls so that the In-Flow catheter operation can be checked. The sizing catheter can now be removed.
6. The In-Flow device is opened in a careful, sterile manner. Lubrication is applied to the proximal circumference avoiding the bladder fins (tip).
7. The device is advanced transurethally until the distal flange is flush with the urethral meatus. Ensure the surgeon is pushing straight on rather than from the side (i.e. does not lean over the patient's leg to insert the device). The patient should be warned of an impending clicking sound as the surgeon advances the Introducer to release the inner valve pump under the outer silicone barrel.
8. Following the release of the device from the Inserter, check to ensure that both inner arms of the "turbine" are fully enclosed by the external silicone flange. If not then the In-Flow device should be aseptically removed and reloaded onto the inserter by tucking the fins of the introducer under the lip of the outer silicone sheath. This needs to be done carefully to avoid tearing the delicate covering, and is best done by gently raising the silicone flap, inserting an arm then rotating the inserter and repeating until all four arms of the white applicator are covered and the inner tube is repositioned.

(This problem will only occur if the clinician performing the insertion is leaning over the patient, so as to cause the catheter to be distorted, or twisted as it is deployed. This may also occur if the patient jumps back at the time of introducer release).
9. The In-Flow catheter is rotated so that the large flap is facing ventral (12 O' clock) or towards the Mons pubis. This is generally the most comfortable position for the flange. There should be enough room for the tip of the finger to be inserted between the meatus and the catheter without discomfort, but no more than 3mm of catheter shaft exposed. Occasionally, certain individuals may need the flange orientated either laterally or dorsally thereby avoiding the clitoris.
10. If the catheter is too short, it will pull on the bladder neck causing urinary urgency and frequency. It may also erode the urethral meatus. If it is too long then it may be easily dislodged, and may be uncomfortable for the patient to sit.
11. Operate the In-Flow device using the battery-operated Activator. When the valve is opened, urine will be released and will stop when the bladder is empty or the valve is closed. Apart from the visible flow of urine it is possible to determine that the valve is opening and closing by looking closely at the lumen of the catheter. When the valve opens it appears to retract higher up the lumen of the device. Upon closure, the valve can be seen to drop and rest against the base of the internal tube, sealing the internal lumen.
12. Ensure that some of the instilled fluid is retained in the bladder in order that the patient may commence training as soon as she has left the treatment room.

POST-INSERTION GUIDELINES

1. The patient should be taken to the bathroom to operate her device as soon as possible. Over a period of time she will establish the best location to operate her Activator. In the first instance, the trainer needs to emphasize the need to hold the short stem of the activator parallel to the In-Flow device i.e. against the pubic bone. This may be more easily achieved by the patient feeling for the anterior rim (front wall) of her vagina and positioning the Activator immediately in front of this, pressing firmly against the pubic bone with the activator.
2. The Activator can be held either towards or away from the patient's abdomen provided the short shaft is against the Mons pubis, and the controls are upper most. (Women with a poor grasp find it easier to hold the whole Activator against them).
3. It is important to stress how to hold the Activator. Operating it upside down or too far away from the patient's body may cause the open/close cycle to be reversed.
4. The patient should be instructed to hold the Activator in place until voiding is completed. They should then release their finger from the button while leaving the Activator in place until a long beep has sounded.

The long beeping sound is an indication that the valve has closed and it is safe to remove the activator *only if the Activator has been kept in the correct position.*

It will still beep even if the Activator has been moved but it will not necessarily mean that the valve has closed.

5. Suggesting to the patient that they double or triple void is advantageous in the early stages to enhance their confidence and ensure complete bladder drainage.
6. Generally, the outer flange should be positioned at the 12 O' clock towards the Mons, but some women find that by turning it to the 3 O' clock, 9 O'clock or even 6 O'clock position it is more comfortable. To do this, the catheter should be pushed upwards towards the bladder and then rotated. Rotating without lifting the flanges off the bladder neck can cause pain. The patient should be specifically instructed on this technique.
7. Patient In-Flow tips are provided and should be detailed thoroughly with the patient by the trainer.
8. Ensure the patient has a completed Patient Medical Alert Card and understands the situations where the device may need to be removed for medical procedures.
9. The patient should be instructed to change the Activator batteries and be aware to carry the Activator at all times.
10. The patient should be instructed how to remove the In-Flow device themselves in an emergency.
11. The patient should be given the contact number of an advisor that they contact out of business hours should they experience problems.

Prepared by: Deborah Bell and Peter Robertson

In-Flow Female Catheter, Cat. No. 203511
In-Flow Activator, Cat. No. 403507



Authorized European Representative:



www.mtm-med.com

mtm medical technology marketing
Waffenschmiedweg, 30A Germany
Phone: + 49 0 880 791138

Manufactured in the U.S.A. by:



www.srsmedical.com

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