to hold down the button until you no longer hear or feel a urine stream.

6. **Let go of the button** when you finish voiding, but continue to hold the Activator in position for another 3 seconds. Do not move the Activator away from your body until you hear a loud beep and the LED light changes to **red**. This indicates that the inFlow valve has closed, blocking the flow of urine.

**If you move the Activator before the inFlow valve closes, you will leak.**

If that happens, do this:

a. Sit on the toilet again.

b. Position the Activator so that its bottom section pushes into your body, as described in Step 4 above.

c. Press the button for 10 seconds and then let go.

d. Keep the Activator in position until you hear a loud beep and see the LED light change to red.

When you finish:

- Gently pat the area dry.
- If necessary, wipe the Activator dry with a paper towel or damp cloth. Periodically, use an alcohol wipe to clean its outside surfaces to reduce the chance of bacterial growth.
- Place the Activator back in its Base Station or its magnetic shield.

Some helpful hints:

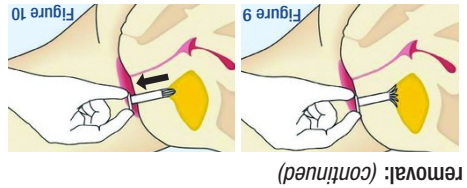
- Urinate every 3-4 hours during waking hours or on the schedule set by your doctor. Follow this schedule even if you do not feel the need (that is, even if your bladder does not feel full).
- Try to drink at least 36 ounces of fluid daily. This should include three 8 oz. glasses of water.
- Avoid drinking three (3) hours before bedtime and always empty your bladder before sleeping.

## 9. How to Clean, Maintain and Store the inFlow and Activator

- The inFlow Device is inserted into the urethra and does not require maintenance or cleaning. After removal of the device, the instructions for Use in Section 7.B should be followed to insert a new device. The used device is disposed of by putting it in a plastic bag and into the garbage after it is removed.
- The Activator should be wiped dry on its outside surfaces with a tissue after every use. Periodically, about once a week, its outside surfaces should be wiped down with an alcohol wipe to discourage bacterial growth.

5. To urinate, **press and hold the button** while keeping the Activator in position. The LED light will turn green and you will hear a whirring sound. This activates the inFlow pump, which will then empty your bladder. Continue

**Device removal:** *(continued)*




If you are replacing the device, insert a new sterile device following the directions above. If you remove the device and do not replace it, tell your doctor. If you are not sure, also ask your doctor what you should do instead for bladder drainage.

## 8. How to Use the Activator to Urinate

To urinate, follow these simple instructions:

1. **Remove** the Activator from its Base Station or magnetic shield.
2. **Sit** on the toilet as you normally would when urinating.
3. **Grasp** the Activator with your dominant hand (**Figure 11**). Your index finger should be in the groove on the back of the Activator and your thumb should be on its button (**Figure 12**).
4. **Hold** the Activator so that its bottom is close to the inFlow tab and press the Activator magnet (the heavy section at the bottom) into your lower public area (**Figure 13**).



**Figure 11**. Grasp the Activator like this and use your thumb to push its button




**Figure 12**. Activator button, LED light and magnet positions

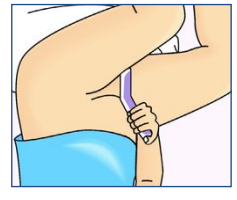


**Figure 13**. Hold Activator in this position to urinate

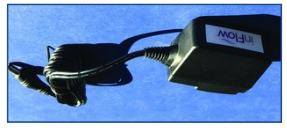
- To maintain the Activator it is important to leave the Activator in its Base Station each night. See Section 11 for signs that the battery is running low.
- The Activator has a strong magnet. Always keep the magnetic cover on when you're not using it. Otherwise, the Activator will attract metal items and could damage magnetic strips (such as those on credit cards). Keep the uncovered Activator at least 1½ ft. from such items.

## 10. Recharging the Activator

The Activator contains a rechargeable lithium battery. If the battery is low, the Activator LED will flash red and you will hear a beep when its button is pushed. To recharge, follow this simple procedure:

1. Insert the Vesiflo-supplied Charger (Figure 14) into the jack in the back of the Base Station (Figure 15).
2. Plug the Charger into an AC outlet.
3. Place the Activator in its Base Station.

**Figure 14**. Charger




The LED light on the Activator will turn red and blink while it is being charged. When the Activator is fully charged, the LED light will change to a solid green.

- Leave the Activator in its Base Station each night so that it will always be fully charged to start the day.
- Always keep the Activator close at hand during the day.
- Remember that the Activator magnet can attract metal objects and damage credit cards when the Activator is not in its Base Station or its magnetic shield is not in place.

**Figure 15**. Charger Input



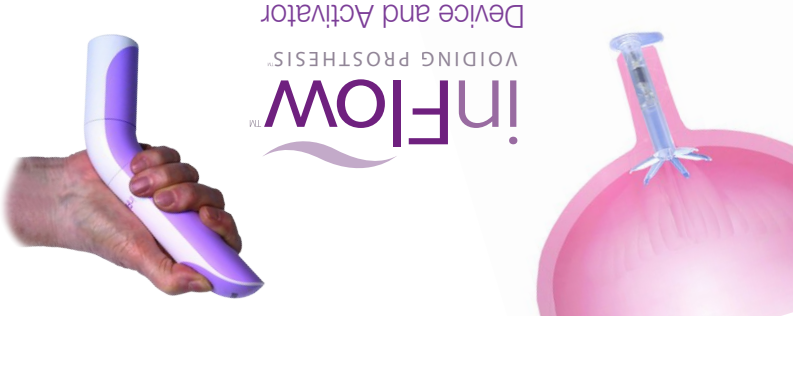
## 11. Travel Considerations

If you plan to travel by plane or through any security clearance process while you are using the inFlow Device, follow the procedures below:

- Since the inFlow and the Activator have metal components, they could trigger electronic security monitors.
- Carry your medical alert card and these instructions with you whenever you travel so that security personnel can see what the device and Activator look like.
- You will be able to show the Activator and explain that it is a magnetic remote control which operates the inserted device.

## 12. What to Do If You Have Problems

| Possible problem: | What to do: |
|---|---|
| **The device falls out** | Call your doctor. Use other means of urine drainage (such as intermittent catheters) until a new device can be inserted. |
| **The device is pushed into your bladder** | Call your doctor to remove the device from the bladder and to discuss what other means of urine drainage should be used until a new device can be inserted. |
| **You leak a lot of urine or leak regularly** | Check to see that the device valve is closed by: 1) sitting on the toilet, 2) using the Activator as normal for voiding and 3) being sure to keep the Activator in place until it beeps. If this does not stop the leaking, consult your doctor. |
| **Signs or Symptoms of urinary tract infection, (pain, irritation, burning, fever)** | Call your doctor. |
| **No urine flows when device is activated, even though your bladder is full** | Call your doctor, remove the device, and use other means of urine drainage (such as intermittent catheters). |
| **Blood in your urine or underclothes** | Call your doctor. |
| **You need to undergo MRI or radiation treatment** | Consult your doctor about device removal. |
| **You may be pregnant** | Consult your doctor. |
| **Activator does not work** | Charge the Activator. If the Activator still does not work then call your doctor to get replacement Activator. |
| **Activator is lost** | Call your doctor. If the replacement Activator is not available in the next several hours, remove the inFlow Device and use other means of bladder drainage (such as intermittent catheters) until the device and Activator can be replaced. |




# Information for Patients and Instructions for Use

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For best results, please read these instructions and keep them for future reference. For brief instructions in larger type, please see the inFlow Activator Supplemental Instructions that came with your Activator. Additional product information and online patient instructions are available at www.inflowdevice.com.

## 13. How the inFlow was Studied

The inFlow Device was evaluated in a U.S. clinical trial of 273 women to compare the use of the inFlow to intermittent catheters. Several different comparisons were made including how well the devices empty the bladder, the frequency of urinary tract infections with both methods, and a quality of life comparison using a standard questionnaire. About half of these women chose to leave the study early because the inFlow was uncomfortable or leaked urine. For those women who completed the trial, the inFlow performed as well or better on the bladder emptying and risk assessment measures. The inFlow provided a significantly higher quality of life compared to intermittent catheter use. In addition to the U.S. clinical trial, more than 200 women have used the device as part of other published studies.

REF

inFlow Device, Cat. No. 203511
inFlow Activator, Cat. No. 403507
Magnetic Shield, Cat. No. 403350

Manufactured in the USA by:

Vesiflo
RESTORING FUNCTION & DIGNITY™


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**T: +1 339 VESIFLO (837 4356)**


LATEX MR unsafe | Do Not Reinsert

**Caution:** Federal (U.S.) law restricts sale or use of this device to the order of a physician or other licensed practitioner.


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U.S. and International patents issued and pending.



P/N 203135 Rev L -June 2026

# PATIENT INSTRUCTIONS

## 1. Purpose of the inFlow Device

Your doctor has prescribed the inFlow Device to help you empty your bladder. The inFlow is intended for women who cannot empty their bladders because of injured nerves. It is for women who are 18 years of age or older. You should use the inFlow only if you can operate it or if you have a caregiver who can operate it. Doctors also prescribe urinary catheters to empty the bladder, such as intermittent catheters and indwelling catheters. Intermittent catheters are hollow tubes that are inserted into the bladder every time you need to urinate. Indwelling catheters are hollow tubes that stay in the bladder for extended periods of time, and drain urine into a bag. Discuss these different bladder drainage methods with your doctor to help you decide which method to use.

## 2. Description of the inFlow Device

The inFlow is actually a system that has two main parts, the inFlow Device (provided on a disposable Introducer) and the Activator. A third part, the inFlow Measuring Device, is used by your doctor to determine which length inFlow Device is right for you.

The inFlow Device is 2-3 inches long and about 1/3 inch in diameter. Its body is made of silicone. (The inFlow is not made with natural rubber latex.) Inside is a miniature valve and pump. The inFlow is supplied with its Introducer attached **(Figure 1)**. The Introducer is used only once. Its first job is to insert the inFlow into the urethra, the tube in the body that carries urine from the bladder to the outside of the body. Its second job is to open the "petals" on one end of the inFlow that hold the device from inside the bladder. **(Figure 2)** A small tab on the other end of the inFlow holds the inFlow in place from outside the urethra. After it is used to insert the inFlow, the Introducer is thrown away. The inFlow can remain in the urethra for 29 days (or less). After the device has remained in the urethra for 29 days it should be removed, discarded and replaced with a new InFlow.

The Activator **(Figure 3)** is a battery-powered remote control you use to operate the inFlow Device. The Activator contains a powerful magnet that "activates" the inFlow's valve and pump.



**Figure 1:** The inFlow Device, shown as supplied with its disposable Introducer (top) and without (bottom)




**Figure 2:** inFlow Device components, including internal valve-pump mechanism



**Figure 3:** Activator magnetic remote control

When the Activator is held over the lower pubic area and turned on, the magnet in the Activator causes the valve in the inFlow to open, and the pump to start which removes urine from the bladder. When the Activator is turned off, the pump stops and the valve closes, stopping urine flow.

When not in use, the Activator should be placed in its Base Station (Figure 4), which recharges it, or its magnetic shield (optional) should be on (Figure 5).

Your doctor or a member of his/her staff will train you in the proper use of the inFlow. You should ask your doctor or his/her staff any questions you have about the use of the inFlow. See Section 7- Instructions for Use for step by step directions on how to insert and remove the inFlow and how to use the Activator to empty your bladder.



**Figure 4:** Activator shown in its Base Station for safe storage and charging



**Figure 5:** Activator with its optional magnetic shield in place

## 3. When should this Device NOT be used?

Your doctor has prescribed the inFlow Device because s/he believes it can help you empty your bladder. Also, s/he has evaluated you to make sure you do not have any conditions that make using this device unsafe. Make sure you always give your doctor complete information regarding your medical history so that they can properly prescribe this device. If you have, or think you have, any of the following conditions you should not use the inFlow and you should talk with your doctor about other ways to empty your bladder. You should not use the inFlow if you have any of the following conditions:

- Untreated urinary tract infection.
- Inability to take oral antibiotics.

## 4. Warnings and Cautions

- Change the inFlow Device every 29 days or less. This minimizes the risk of infection.
- Use the inFlow Device to empty the bladder every 3-4 hours during the day or as instructed by your doctor.
- Always have the Activator on hand. Otherwise, you will not be able to void.
- Some women find the inFlow Device too uncomfortable to tolerate. If you are concerned about the level of your discomfort, contact your doctor. You and your doctor may decide to remove the inFlow and use another type of bladder drainage method. The discomfort should stop following device removal.
- The device must be removed if you need to undergo MRI or radiation treatment. The presence of and use of the inFlow Device during these procedures could cause harm to you and negatively impact the results of the procedures. Consult your doctor about device removal and bladder drainage options.
- The inFlow Device should not be re-inserted once it has been removed from the urethra. Risk of infection or other problems could result if the device is re-inserted.
- Notify your physician immediately if you suspect you may be pregnant. The inFlow has not been tested in pregnant women and so any risks specific to pregnant women, if any, are not known.
- Notify your doctor if you use other medical devices with electronic or magnetic parts, including pacemakers. The inFlow Device and Activator both contain magnets, which may interfere with other medical devices causing malfunctions and harm to you. Consult your doctor to understand what side effects could result if the devices are used at the same time.
- Do not immerse the Activator in water. If it gets wet, the Activator may not work. If the Activator does not work, you will not be able to empty your bladder.
- Always keep the uncovered Activator at least 18 inches from metal objects and magnetic strips (such as those on credit cards). When its magnetic shield is off, the Activator may attract metal items and may damage magnetic strips (such as those on credit cards).
- If you remove the device and do not replace it, talk with your doctor to determine another means of bladder drainage. Without a means to drain your bladder you may experience discomfort or more serious medical problems.
- Keep your Activator charged. The inFlow Device will not drain your bladder if the battery in the Activator loses its charge.
- Keep an alternative means of bladder drainage with you at all times. If the inFlow does not drain your bladder for any reason, remove the inFlow and use an alternative means of bladder drainage

## 5. Risks and Benefits of Using the inFlow

**Risks:** In a U.S. clinical trial of the inFlow Device, no serious or long-lasting side effects (adverse events) were reported. This trial showed that the problems associated with inFlow use were similar to those with intermittent catheters. Eight-five percent (85%) of women experienced at least one problem while using the inFlow. The most common problems that were reported were leaking and discomfort. The rates reported for these and other problems with the inFlow are:

- Leaking/Urinary incontinence (53%)
- Discomfort (31%)
- Urinary tract infection (28%)
- Bladder spasms, increases in frequency and urgency (strong need to urinate) (20%)
- Blood in the urine (11%)
- Other risks - ask your doctor about other risks that have occurred or could occur with the use of the inFlow Device and about the severity of such events if they do occur.

  Note: The percentage after each side effect above shows the percent of people in the U.S. clinical trial that experienced the problem at least once while using the device during the trial.

**Benefits:** A U.S. clinical trial was conducted to compare the use of the inFlow to the use of intermittent catheters. In this clinical trial the inFlow was shown to:

- Empty the bladder as well or better than intermittent catheters;
- Have the same number or fewer urinary tract infections (UTIs); and
- Improve quality-of-life, as measured on a questionnaire.

To find out more about the risks and benefits of the inFlow Device, ask your doctor.

## 6. What to Expect When Using the inFlow

The inFlow can provide women with more comfort and independence associated with bladder emptying. Patients who successfully use the inFlow experience an improved quality of life. Freed from the chores of catheter use, they can sit on a toilet to urinate and feel more in control of their voiding. They take a normal amount of time in the bathroom and do not need special facilities.

If this is the first time you've used the inFlow, your doctor or their nurse will be monitoring your response closely for the first 1-2 weeks. This is considered a trial period. Do not hesitate, because of embarrassment or any other reason, to contact them with your concerns during this trial period or at anytime when you have questions or concerns about the inFlow.

At first, the inFlow may take some getting used to. This reaction is normal. Initially, you may be very aware of the inFlow being there and it may feel uncomfortable. Your doctor or nurse may suggest some helpful ways to reduce unease - such as warm baths, calm walks, or meditation. It is important to create an attitude of acceptance in this time of transition. This can give your body a chance to adapt. Your doctor may prescribe an antibiotic to prevent infection and a vaginal cream to ease your adjustment. "The Guide for New Patients" contains more information to help adapt to the inFlow.

In the U.S. clinical trial which compared the use of the inFlow to the use of intermittent catheters, only about half the women completed the trial. Most of the women who stopped using the device did so in the first couple of weeks because of discomfort or leakage. However, 97% of those who completed the trial chose to continue using the device because of how it improved their quality of life. If you are concerned about the level of your discomfort while using the device, contact your doctor or nurse.

Most women use the Activator every three hours throughout the day and once before going to bed. They set up a daily routine to empty their bladder in a timely, comfortable way. inFlow users find that sexual relations are possible. You and your partner may want to try different positions for sexual relations to determine those that are most comfortable. You may also want to talk with your doctor about sex while using the inFlow.

## 7. Instructions for Use

First time use: Your doctor will determine the correct size of inFlow for you and insert the inFlow the first time. Your doctor or a member of his/her staff will also instruct you and/or your caregiver on insertion and on how to use the Activator to urinate. After you have used the inFlow for at least 90 days, you may want to ask your doctor if your monthly replacements can be done at home.

Device insertion (by you or a caregiver):

1. Lie down on your back and open your legs so that you or your caregiver has access to your urethral opening.
2. Clean the area around the urethral opening with a sterile alcohol wipe, by patting the area from above the urethral opening and then moving back towards the vagina.
3. Open the sterile inFlow Device package (contains the inFlow + Introducer) and hold the Introducer without touching or dropping the inFlow Device to avoid contamination.
4. Lubricate the external body of the inFlow Device with a medical lubricant that is recommended by your doctor.
5. Insert the lubricated inFlow Device into the urethra until its outer tab touches the urethra opening (Figure 6). The tab can be pointed up or down, depending on personal preference. The tab is shown facing up in the following Figures; however, many women find it more comfortable pointing down, towards the vagina.
6. Push the plunger on the Introducer (Figure 7) until the device is released (Figure 8).
7. Dispose of the Introducer. It can go in the trash.
8. Sit on the toilet and practice using the Activator one time. Check to see that you get a continuous flow of urine.

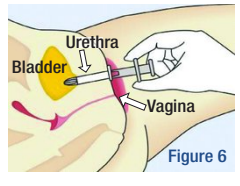



**Figure 6**

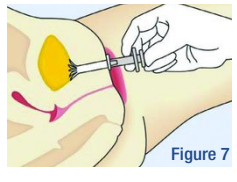


**Figure 7**

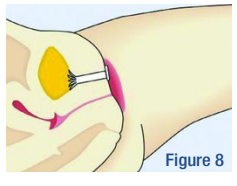


**Figure 8**

**Device removal:** To remove the device, hold it by its outside tab which keeps the device in place inside the bladder, are soft and flexible. Once you start to pull the device out the petals will come together allowing the device to be pulled out without any other tool and without harm. Put the used device in a plastic bag, seal it and dispose of it in the trash.