

REF Reorder No. 203134

EC REP

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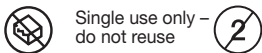
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Manufactured in the U.S.A. by:

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! 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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P/N 203134-SD Rev C - September 2016

inFlow[™]
RESTORING CONTROL[™]

Sizing Device

PHYSICIAN INSTRUCTIONS FOR USE



Device Use
Measures length of female urethra
in order to determine the correct
inFlow device size for patient

Vesiflo[™]
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inFlow Urinary Prosthesis

The inFlow urinary prosthesis is a system with three components:

1. The inFlow Intraurethral Valve-Pump (the “inFlow device”), shown in Figure 1,
2. Activator magnetic remote control, shown in Figure 2, and
3. Sizing Device, shown in Figures 3a and 3b.



Figure 1: The inFlow device as supplied with disposable introducer (top) and without (bottom)



Figure 2: Activator magnetic remote control



Figure 3a: The Sizing Device as supplied with disposable Introducer



Figure 3b: Sizing Device after deployment

Note: The lumen in the Sizing Device is plugged in order to minimize urine leakage.

inFlow Indication

The inFlow urinary prosthesis 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).

For additional information, please see: *inFlow Physician Instructions for Use*

Device Sizes

The inFlow device is available in 9 different lengths to match the length of the patient's urethra as detailed in Table 1 below:

Table 1: The inFlow Device Available Lengths	
Device Lengths (cm)	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0

Prior to initial insertion of the inFlow device, the physician determines the appropriate urethral length by using the inFlow Sizing Device. Correct sizing is critical for patient comfort, as well as for proper device function.

Sterility

The inFlow Sizing Device and its disposable Introducer are provided STERILE (Gamma sterilization). The sterile packaging of the Sizing Device should be inspected for the Gamma sticker (red means sterile) and visible damage prior to use. Do not use if sticker is not red or if damage is suspected.

Device Sizing Procedure

1. With the patient in the lithotomy position, clean the meatal area as for Foley catheter insertion.
2. Lubricate the external body of the Sizing Device with any type of generally accepted medical lubricant.
3. It is normal to also use local anesthetic cream/gel as well as oral analgesics as required.
4. Per Figure 4, ensure that the two tabs are touching, i.e. the inner, moveable tab is in the 7cm position:

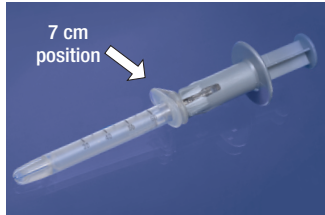


Figure 4: Pre-insertion tab position

5. Per Figure 5, insert the lubricated Sizing Device into the urethra until the inner tab touches the edge of the meatus:

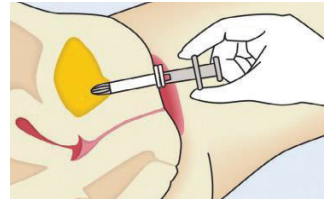


Figure 5: Inserting the Sizing Device

6. Hold the introducer per Figure 6 and completely depress the plunger until you hear a click. This indicates the Sizing Device has been deployed.

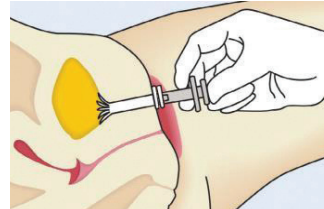


Figure 6: Deploying the Sizing Device

7. Do not pull out the Introducer until the Sizing Device has been deployed.
8. Discard the Introducer.
9. Per Figure 7, gently pull the deployed Sizing Device to ensure that the bladder neck fixation is snugly located:

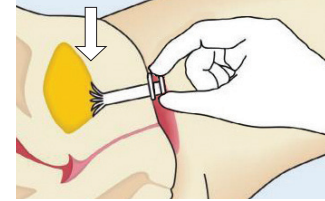


Figure 7: Seating the Sizing Device

10. Move the inner tab in until it touches the meatus
11. Record the urethral length in this position based on the location of the tab.
12. With the device still in place, move the inner tab out, away from the meatus so that it is again in the 7cm position.
13. Instruct the patient to stand.
14. Move the inner tab in until it touches the meatus.
15. Record the urethral length in this position.
16. Repeat this procedure with the patient on a commode or in a squatting position.
17. Remove the Sizing Device.
18. Select an inFlow device length that is closest to, but not less than the largest number recorded (e.g., for a measured length of 3.2 cm, use a 3.5 cm device).