

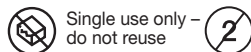


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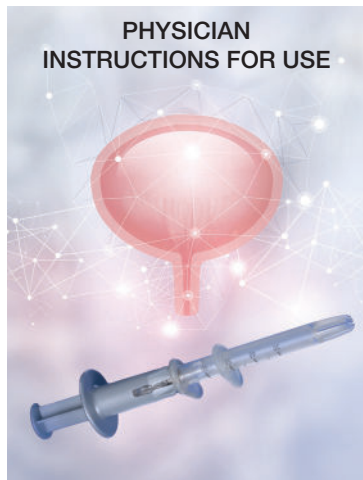
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P/N 203134-SD Rev F - May 2025

inFlow™ VOIDING PROSTHESIS™

Measuring Device



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



inFlow Voiding Prosthesis

The inFlow voiding 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. Measuring 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 Measuring Device as supplied with disposable Introducer



Figure 3b: Measuring Device after deployment

inFlow Indication

The inFlow voiding 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 7 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)	3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5

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

Sterility

The inFlow Measuring Device and its disposable Introducer are provided STERILE (Gamma sterilization). The sterile packaging of the Measuring 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.

Pre-Procedure Prep

1. With the patient in the lithotomy position, clean the meatal area as for Foley catheter insertion.
2. Lubricate the external body of the Measuring 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:

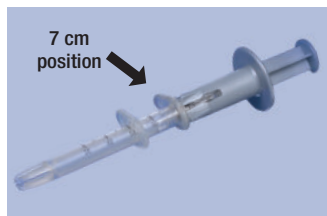


Figure 4: Pre-insertion tab position

Note: The lumen in Measuring Device is plugged to minimize urine leakage.

Procedure

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

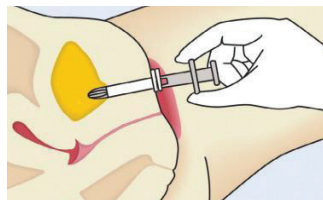


Figure 5: Inserting the Measuring Device

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

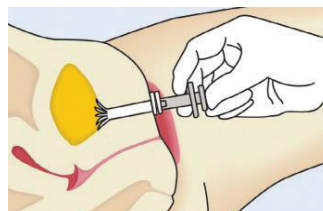


Figure 6: Deploying the Measuring Device

3. Do not pull out the Introducer until the Measuring Device has been deployed.

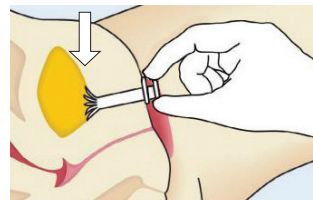


Figure 7: Seating the Measuring Device

4. Discard the Introducer.
5. Per Figure 7, gently pull the deployed Measuring Device to ensure that the bladder neck fixation is snugly located:
6. Move the inner tab in until it touches the meatus
7. Record the urethral length in this position based on the location of the tab.
8. Remove the Measuring Device.
9. 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).