Patient Identification Tips for Bladder Control

The following patient remarks could be cues to identify patients with symptoms of overactive bladder and urinary retention. These patient remarks may also correspond with a related urodynamic testing diagnosis.

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<th>Urodynamic Diagnosis</th>
<th>Patient Remarks</th>
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| **Detrusor Instability** (wet or dry) | - When the urge hits, I have to cross my legs until it passes.  
- When the urge hits, I’d better be near a bathroom or I’ll leak.  
- I have to know where every bathroom is.  
- When I turn the water on, I usually leak. |
| **Mixed Incontinence** (urge incontinence is primary concern) | - I leak when I cough and with urge, but the urge leak bothers me the most.  
- I can handle the leaking when I run, but it is the leak with urge that I can’t handle. |
| **“Low” normal UDS** | - I don’t empty well.  
- I have a small bladder.  
- I have a shy bladder.  
- I go to the bathroom every hour.  
- I can’t travel because I have to stop so often.  
- I always feel like I have to go, even if I just went.  
- I only go very small amounts when I go. |
| **Retention** | - I have to cath myself every 3-4 hours and I usually get a lot out. |

What do patients say that may indicate they are seeking alternative treatment?

- I’m really constipated all the time.  
- My eyes are so dry that I had to buy eye drops.  
- My mouth is so dry that I have to drink more liquids.  
- The side effects are almost as bad as my bladder problems.  
- I seem to have a lot of side effects.  
- None of these medications seem to work.  
- The medications work a little bit, but I still have a lot of problems.  
- I wish I could find something that works better.  
- I have to take so many pills already. Isn’t there something else I can try?  
- Is this the only option that I have?
Patient Identification Tips for Bowel Control

The following patient remarks could be cues to identify patients with symptoms of fecal incontinence.

- I thought I was going to pass gas, but I had a bowel movement.
- I just forget to wipe well.
- I have loose stools and then I take a medication to constipate myself.
- I have to carry a change of clothing with me in case I leak.
- I have to avoid certain foods the day of an activity I want to attend.
- I feel like I smell all the time.
- I have pellets of stool fall out without knowing it.
- I soil my clothing even though I’m wearing pads.
- I always have a brown smear on my underwear.
- I spend so much time in the bathroom.
- I have accidents without warning.
- I have to keep wiping myself. I never seem to get clean.

Indications for Use:
InterStim® Therapy for Urinary Control is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency–frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.

The following Warning applies only to InterStim Therapy for Urinary Control:

**Warning:** This therapy is not intended for patients with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture.

InterStim® Therapy for Bowel Control is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.

Contraindications for Urinary Control and for Bowel Control: Diathermy. Patients who have not demonstrated an appropriate response to test stimulation or are unable to operate the neurostimulator.

Warnings/Precautions/Adverse Events:
For Urinary Control: Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 16; or for patients with neurological disease origins such as multiple sclerosis.

For Bowel Control: Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 18; or for patients with progressive, systemic neurological diseases.

For Urinary Control and for Bowel Control: The system may be affected by or adversely affect cardiac devices, electrocautery, defibrillators, ultrasonic equipment, radiation therapy, MRI, theft detectors/screening devices. Adverse events include pain at the implant sites, new pain, lead migration, infection, technical or device problems, adverse change in bowel or voiding function, and undesirable stimulation or sensations, including jolting or shock sensations. Patients should be assessed preoperatively for the risk of increased bleeding. For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic’s website at www.medtronic.com. Product technical manual must be reviewed prior to use for detailed disclosure.

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