

## Restoring Voluntary Control of Bladder and Bowel Function in Spinal Cord Injured and Other Neurologic Individuals

*Imagine if...*

- *You had no idea when your body decided to release urine or feces, regardless of the setting.*
- *The only way to control when urine is released would be to insert a catheter through your urethra into your bladder...4-5 times every day...to drain urine.*
- *Excretion of feces involved digital extraction.*

*You have just imagined...daily routines of many individuals with spinal cord injury.*

After spinal cord injury, messages from the brain to the bladder and bowel are disrupted, resulting in loss of bladder and bowel sensations and the development of involuntary processes for voiding urine and emptying the bowel. Depending on the location of the spinal cord injury, many individuals require a routine that focuses on initiating passage of urine and movement of the bowel on a planned schedule. For most individuals the routine may need to be repeated several times a day to prevent unplanned urination or defecation.

An intermittent catheterization program is commonly used for bladder emptying in spinal cord injured individuals. This program requires passage of a catheter into the urethral opening in the penis or anterior vaginal wall, along the urethra, and into the bladder to facilitate the release of urine. Of course, any time a foreign material is passed from outside to inside the body, there is a danger of introducing pathogens to the urinary tract. To prevent the risk of a urinary tract infection caused by

bacteria entering the urethra, an individual must be careful to maintain a clean catheterization process. When in a public setting, locating a restroom that is compatible with the sanitary standards required for catheterization can be challenging, resulting in a higher risk of a urinary tract infection. Complications from infections of the urinary tract are the most prominent of medical concerns for individuals with spinal cord injuries. Most individuals will experience a urinary tract infection, and 1 in 4 will require hospitalization each year from urinary tract infection complications. Intermittent catheterization is not only a scheduled time commitment but a consistent health risk as well.

Depending on the location of the spinal cord injury, a person may have reflex bowel contractions resulting in an involuntary bowel movement, or he or she may have a flaccid bowel that does not move stool on its own. In either situation, a bowel program that typically lasts 30 to 60 minutes must be established on a routine schedule to ensure the removal of solid waste at socially appropriate times. Programs for inducing reflex bowel movements involve the use of lubricants and stimulants (either chemical or digital), and both reflex and flaccid bowel programs can require manual removal of stool from the rectum. If the spinal cord injured individual is unable to perform the bowel program independently, a family member or hired caregiver must be available to assist with emptying the bowel. Additional factors required to maintain a predictable bowel program include proper nutrition and fluid consumption, a sufficient level of physical activity, and review of medications to determine digestive system effects.

These bladder and bowel programs are burdensome and have a physical and emotional impact on individuals as they adjust to the transition from private, independent restroom visits to a lifetime of time-intensive restroom schedules that may involve the assistance of family members or hired caregivers.

Considering the physical and emotional impact of bladder catheterization and manual extraction of feces from the rectum, imagine the improvement in a spinal cord injured individual's life if they could wheel themselves into a private toilet when it was convenient, take medicine that induced urination and defecation within minutes, and then leave the toilet with their bladder and bowel empty. This type of therapy could provide a remarkable improvement in their daily routine and eliminate or reduce involuntary leakage or incontinent episodes.

Outside of the physical and emotional effects, there is a larger financial impact on all of society. The cost of catheter-associated urinary tract infections and resulting hospitalizations in spinal cord injured individuals has been estimated at over \$300 million dollars each year. In addition, the loss in workplace productivity due to infections and the associated time and financial burden on both individuals and caregivers is enormous. Most medical costs are absorbed by Medicare, Medicaid or managed care organizations and most costs are eventually passed onto U.S. taxpayers. In addition, every workday lost to a urinary tract infection has a negative impact on overall U.S. productivity.

Dignify Therapeutics aims to restore voluntary control of bladder and bowel functions to spinal cord injured individuals, improve their quality of life, and reduce the financial impact on society by providing a rapid-onset, short-acting, safe and effective medicines that would induce bladder and bowel emptying in individuals with spinal cord injury, multiple sclerosis, and other neurological disorders.

(To learn more about bladder management techniques visit <http://www.sci-info-pages.com/bladder.html> and to learn more about bowel management techniques, visit <http://www.sci-info-pages.com/bowel.html>.)

Visit [www.dignifytherapeutics.com](http://www.dignifytherapeutics.com)

*Imagine a drug that ...*

- *Safely and efficiently produces voiding of urine and stool within minutes of administration when and where it was convenient for the spinal injured individual.*
- *Eliminates the need for multiple daily catheterizations and eliminates the need for digital extraction of stools.*
- *Restores voluntary control of the bladder and bowel to a spinal injured individual.*

*You have just imagined...  
Dignify Therapeutics' vision!*