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Pilot study set for Surinate in treating urinary retention

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A blocked urinary tract – not a big problem, right?

Of course it is, one that means frequent insertions and removals of catheter devices – usually the basic Foley catheter – and offering highly opportunistic possibilities for infections, those infections being a major source of nosocomial infections.

In both cases, the insertion/removal process and frequent infections, the consequences add up to huge healthcare costs and, for the patient, embarrassment and inconvenience to those who suffer from this problem.

Addressing both issues is early-stage firm **Urovalve**, located in the **Enterprise Development Center** at **New Jersey Institute of Technology** (Newark, New Jersey). The company is a developer of remote-controlled fluid valves used for managing the problems of urinary retention and incontinence.

Urovalve has just reported launch of a pilot study of its Surinate Bladder Management System, for controlling the urinary flow in men who suffer from either acute or chronic urinary retention due to obstruction of the urethra.

President/CEO Harvey Homan, PhD, told *Medical Device Daily* that the company hopes to complete the pilot study, of 15 men, by the end of January and then launch a pivotal study, of at least 50 men, which it hopes to complete in six months.

The company has received advice from a consultant at **Quintiles** (Research Triangle Park, North Carolina) for filing of a 510(k) which would allow, in the best case, FDA approval and commercialization by 2010.

As an alternative to the frequent insertions and removals of urinary catheter devices – sometimes multiple times a day – the Surinate system provides for a single insertion in a 28-day cycle, leaving no tubes or other materials outside the body, such as a urine-collection bag, and enabling the individual to void urine from his bladder by using a magnetized valve control.

Besides greatly reducing the chance of urinary infection, the valve system provides for its unobtrusive operation, providing lifestyle normalcy.

The ability to avoid infection, especially of the hospital-related type, is a huge money-saver, putting Urovalve on an important savings wave.

"We think we're in front of the wave," Homan said. "The issue of the health problems associated with catheters is more serious than has been acknowledged."

The system targets both acute and chronic urinary retention, the acute condition often related to prostate problems and treatments, the chronic condition frequently related to spinal cord injury and other conditions causing paralysis.

Homan said that the exact number of patients that might use the system is difficult to calculate exactly. But with millions of men with prostate problems and many thousands with spinal cord injuries, the population that could use the Surinate is potentially in the "hundreds of thousands, if not in the millions . . . We're going to have to understand over time exactly what that number is . . . ."

When the Surinate is inserted, one end is placed in the bladder and expands into a cage, with urine than flowing down through sphincters above and below the prostate toward the control valve.

The valve is operated by a switching magnet. The patient simply moves a thumb-sized magnet close to the scrotum in order to open the valve to permit urine to flow through the urethra and then moves the magnet way to close the valve and stop the flow.

The system is inserted in the urologist's office. Because of a natural buildup of dead cells and other deposits, it must be removed after 28 days and, in the case of chronic obstruction, a new system is then inserted.

The system for inserting the Surinate is withdrawn, leaving nothing outside the body, a key feature of the system helping to avoid infection, Homan noted.

The pilot study is being conducted at four sites: **VA Boston Healthcare System**; **VA New Jersey Healthcare System** (East Orange); **Vanderbilt University Medical Center**, Department of Urologic Surgery (Nashville, Tennessee); and the **Virginia Urology Center** (Richmond).

Eugene Kramolowsky, MD, of the Virginia Urology Center and one of the study's principal investigators, said the Surinate "represents a significant change from conventional catheters, where there is no valve and the patient voids basically into a collection bag, which is very inconvenient and somewhat unsightly. Surinate may

represent a significant advancement for men with a urinary retention condition."

The company did not do initial studies of the system with animals. Because it needed to test the architecture of the design specifically in human anatomy, it performed its first feasibility study in five spinal cord-injured men.

Homan said the system was initially developed by Philip Davis, who had suffered a broken back and thus experienced the many difficulties of the usual handling of urinary obstruction.

He referred to studies indicating that 65% of those having urinary catheters get an infection at least once a year, and that the common difficulties with such catheters result in $2.5 billion dollars in yearly healthcare costs.

Exactly how much the system might reduce such costs, Homan acknowledged, "will require a fairly significant study to be able to accrue enough patients to demonstrate" such savings.

He said that the company may pursue the opportunity to expand the valve system to its use in women and then to other applications, but that initial focus on the firm's five-member team is development of the system for men before pursuing other opportunities.

Homan reported that the company thus far has raised $3.7 million dollars from private investors and other sources, most recently receiving $400,000 from the New Jersey Commission of Science and Technology, and a $740,000 SBIR grant from the National Institutes of Health.

And given the potential clinical and money-saving benefits of the Surinate, he expressed confidence that the company is likely to receive additional NIH grant funding "in the near term." ■