



FREEDOM FUNCTION CONTROL

News Release

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Urovalve completes successful feasibility study of critical component of its *Surinate*[®] Bladder Management System

World's first *valved catheter* is designed for men with a urinary retention condition who prefer to be discreet

NEWARK, N.J., Sept. 8, 2009—[Urovalve](#) announced today the successful results of a feasibility study of the Valve component of its [Surinate](#)[®] **Bladder Management System**—designed to improve the quality of life of men who suffer from acute or chronic **urinary retention**, which is an inability to empty the bladder caused by obstruction of the urethra.

The feasibility study was designed to evaluate whether the beta version of the *Surinate*[®] Valve is safe and functional in a real-use situation (i.e., when attached in line with a Foley catheter) and to provide information to guide the design of future clinical studies. This feasibility study was reviewed and approved by an IRB (Investigational Review Board) for each of the investigational sites as a non-significant risk (NSR) study. Therefore, an IDE (Investigational Device Exemption) application did not need to be submitted to, or approved by, the FDA. The target indication for the eventual marketed System will be for controlled urinary drainage in male subjects. However, the purpose of this feasibility study was to assess the performance only of the Valve (which is one component only of the eventual marketed device) and not of the entire System.

“Today, men who have a urinary retention condition must rely on a 50-year-old product called the Foley catheter, *or* intermittent catheterization four to six times *a day*,” said [Harvey D. Homan, Ph.D.](#), President and CEO of Urovalve. “*Surinate*[®] is designed so that the patient is no longer coupled to a urine-collection bag on his leg, which means of course that *no one has to know* that the patient has a urinary retention condition.

“Just as important,” added Dr. Homan, “is the fact that *Surinate*[®] is designed with a magnetized valve inside the catheter that allows the bladder to fill and then empty *only on command of the patient*. In addition, the patient uses an external magnet to open the valve in the *Surinate*[®] catheter to drain the bladder *only when he needs to*. Bottom line? The patient himself has total control over his bladder-emptying process.

“This successful feasibility study has provided valuable information regarding the design and use of the beta version of the *Surinate*[®] Valve, which will be incorporated into future clinical evaluations,” Dr. Homan explained. “The most significant of these findings were: first, that the Valve’s performance exceeded specifications; second, that

encrustation does not appear to be a significant problem affecting the Valve's performance; and third, that leaching of samarium or cobalt does not appear to occur, nor does it pose a significant risk to subjects. With these results, we look forward to announcing commencement of a pilot study of the beta version our of complete *Surinate*[®] system before year-end."

[Urovalve, Inc.](http://www.urovalve.com) (www.urovalve.com) is a privately held company located in the Enterprise Development Center at New Jersey Institute of Technology in Newark, New Jersey. The company develops superior medical devices to address problems associated with urinary flow and control.

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