



Are you

*one of the 1.1 million
male urinary
catheter users?*

*Are you interested in a
different option to
manage your bladder?*

*See if the IntelliFlow™
System Study is right
for you.*



Chronic Urinary Catheter Use

Chronic urinary catheter use affects over 1 million men in the United States alone. Most of these men develop chronic Urinary Retention which creates the need for daily catheterization to relieve the bladder.

Common conditions associated with chronic catheter use can impact all types of users. From mobile independent individuals to those dependent on caregivers, the burden of maintaining a safe and practical catheterization practice can be challenging.

Traditional bladder management has seen few changes in the past few decades that address the clinical drawbacks as well as the social and physical challenges of users....Until now.

The IntelliFlow™ Bladder Management System could provide an option for catheter users that would put them back in control of their bladder management.

The Connected Catheter Evaluation Study is a 35-40 day study with a screening period, urinary health assessment, catheter insertion, follow-up appointments, and follow-up phone surveys.

Pre-Screening period

Phone screening, 15-20 minutes
Initial assessment to decide if the study is right for you

Clinic Assessment

1 site visit, 2-3 hours

Initial Device Insertion

1 site visit, 4-5 hours
Your study doctor will insert the device

Catheter Trial Period

5 site visits, 1-1.5 hours each visit
You will have 5 device cycles, up to 7 days each cycle
A cycle is catheter insertion, up to 7 days of catheter use, catheter removal

Follow-Up Period

2 phone surveys, 15-20 minutes, each call
You will be contacted by phone for the surveys



The Connected Catheter Evaluation Study

The Connected Catheter Study is designed to evaluate the safety and performance of the Connected Catheter System in men with chronic Urinary Retention.

In a controlled clinical setting, the study will address both the clinical complications and the quality of life issues that plague all urinary catheter users.

You may be able to participate in the study if you are:

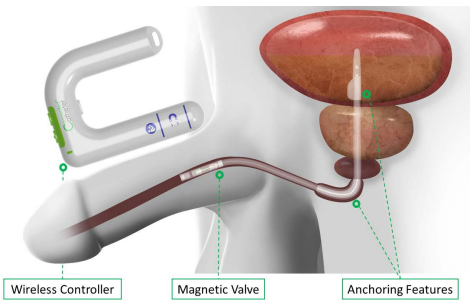
- **Male, 18 years of age or older**
- **Chronic catheter user**
- **Diagnosed with Urinary Retention**

Let your doctor know if you are interested. All qualified candidates will receive compensation and payment for trial participation with no out of pocket cost.



The IntelliFlow™ System

The IntelliFlow™ Catheter is a fully internal, extended use, wirelessly controlled catheter for bladder management.



- **Fully internal to the male anatomy**
- **Extended use (up to 7 days)**
- **Designed to reduce multiple daily catheter insertions**
- **Designed to be quickly removed or inserted by user, caregiver or clinician**

If you are interested in a different
option to manage your bladder,
ask our research team

www.clinicaltrials.gov

CAUTION: The IntelliFlow™ Bladder Management System is an investigational device, limited by federal (United States) law to investigational use only.