Title: Accessible Incontinence Control Device

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Problem Statement (Adapted from RERC on AMI project description):
Patients with incontinence are unable to control urine flow due to specific disease pathology, trauma, or other causes. Incontinence affects men and women, occurs more frequently with age, and can cause infection, skin irritation, and embarrassment. It negatively affects quality of life and many incontinent patients avoid activities in public, for instance due to the potential for a spastic bladder to spontaneously cause release of urine without warning.

The aim of the project is to design a device to allow the patient (or caregiver) to control and manage urine flow. It should:
1) Be easily used by a patient with disabilities including sensory-motor, physical and cognitive
2) Allow emptying of the bladder when desired
3) Prevent urine flow when not desired
4) Provide an indication of the status of the bladder
5) Remain indwelling for up to 30 days with no adverse tissue reaction or material degradation

Design Requirements:

1. **Physical and Operational Characteristics**

   a. *Performance requirements*: The device must enable control and management of urine flow by patients with disabilities, be able to be switched on and off, and provide an indication of the status of the bladder. It must also be able to remain indwelling for up to 30 days without adverse patient reaction or material degradation. The design will be based on a traditional Foley catheter design, with several modifications for improved accessibility and performance.

   b. *Safety*: Because the device will be inserted into the urethra and remain indwelling for some time, it must be made of materials that will not cause

a reaction or infection in the patient. Foley catheters are typically made of Latex or silicone. Also, to prevent overpressure and rupture of the bladder, the mechanism used to control flow must have an overpressure safety function where it will release before bladder pressure reaches dangerous levels.

c. *Accuracy and Reliability*: The device will be used to monitor the status of the bladder. This information will be used to assist the patient and caregivers in flow control.

d. *Life in Service*: The device must be able to remain indwelling for up to 30 days before replacement, at which point it will be discarded.

e. *Shelf Life*: The device will be sterilized prior to use and should have a shelf life of 5 years, as this is standard for urinary catheters.

f. *Operating Environment*: During use, the device will be inserted through the urethra and into the bladder. It will be in prolonged contact with urine, with typical pH values varying between 4.5 and 8.0.

g. *Ergonomics*: The device must be accessible for patients with disabilities. The flow control mechanism must be easy to use and the bladder status indication must be simple and clear.

h. *Size and Weight:* Traditional Foley catheters range in size from 8 French (1 French = 0.33 mm) to 24 French. The device should not be obtrusive or interfere with the patient's daily activities.

i. *Materials:* Materials used must not cause any reaction or infection in the patient. Also, the device must be able to remain indwelling for 30 days with no material degradation. Foley catheters are traditionally made of Latex or silicone.

j. *Aesthetics, Appearance, and Finish:* The device should have a smooth and lubricious finish for easy insertion. The control mechanism should be small and the user interface should be simple and easy to operate.

2. Production Characteristics

a. *Quantity:* At this stage, a single prototype device will be designed and produced. Currently according to the Center for Disease Control, at least ten million people are affected by incontinence. This device is not a suitable treatment for all cases of incontinence, but it will be targeted to those suffering who desire a nonsurgical treatment plan. Patients suffering from overflow incontinence will find this a particularly suitable urinary function management strategy.

b. *Target Product Cost:* The total cost to design the device must not exceed $2,000.

3. Miscellaneous

a. *Standards and Specifications:* The device must comply with established industry standards for Foley catheters and other urological medical devices.

b. *Customer:* The device should be simple to use and cater to patients with disabilities such as hearing or vision loss, spinal injuries, or limited movement.

c. *Competition:* Based on our initial research, there are currently no devices on the market that include bladder status monitoring coupled with a patient-controlled valve.