Background

Women who laugh & leak want the comfort, convenience and cost savings of the Floelle™ device, replaced yearly, over replacing pads ten times/day, a survey of 80 such women showed. This “Stress Incontinence” significantly impacts quality of life for 1 in 8 women, costing billions in palliative measures and surgery. Floelle™, a safe & effective medical device inserted into the urethra in minutes in any doctor's office, reduces or eliminates leakage. Its $1,000 cost is much lower than pads or surgery and its convenience is thousands of times higher. A European launch with easier CE mark into receptive countries will generate sufficient revenue to fund approval & launch in the US.

Salient Features*

The Floelle™ device in a stress incontinent woman’s mid-urethra (where she has little sensation) acts like a normally open valve most of the time, allowing normal urination. But the rise in abdominal pressure from a laugh, cough, sneeze, etc. is transmitted to the urethra, squeezing it against the Floelle™ device and closing the valve to prevent urine loss. An antimicrobial compound is mixed into the plastics from which the device is formed in order to kill any microbes that try to attach themselves to any part of the device to form a biofilm. With no live bacteria on the device, there is no biofilm; and since the biofilm attracts protein and mineral precipitates from urine to occasionally produce incrustation, with no biofilm there’s no incrustation, thus eliminating the problems that have plagued other medical devices in the urinary tract for long periods.

Market Potential*

52 million women in the US and Europe need the Floelle™ device right now, and more will need it as the population ages and becomes more obese. The potential world market is 430 million incontinent women, but many of those are without access to healthcare. A conservative sales model built on precisely how a medical device salesperson sells was used to forecast sales. Once sales start after regulatory approval in Year 3 they will grow to gross sales of about $75 million in Year 5 and continue upwards to the $500 million level in Europe and the same in the US.

Current Status with M2D2

- Tied for third place in M2D2’s 2012 New Venture Competition
- Working with UMass Lowell Plastics engineering department

IP Status

“Apparatus and Method for Inhibiting Stress Urinary Incontinence” International Patent filed 4/2/2012 by the inventors listed above and assigned to Floelle Inc.

*These are the inventors claims and do not necessarily represent the opinions of the Massachusetts Medical Device Development Center