

## **Medical College Of Wisconsin To Study New Incontinence Device**

BROOKFIELD, Wis./PRNewswire/ -- The Medical College of Wisconsin (MCW) has begun a clinical study of InTone®, a new, FDA-approved medical device that treats female urinary incontinence. The 12-week study will evaluate the effectiveness of InTone in women with stress incontinence, urge incontinence, or mixed (stress AND urge) incontinence.

Stress incontinence is unwanted bladder leakage that can occur after coughing, sneezing, laughing, or exercise. Urge incontinence is a strong, sudden need to urinate due to bladder spasms or contractions. Altogether, urinary incontinence affects up to 25 million, or one in four, adult American women, according to the National Association for Continence (NAFC).

Women who qualify for the study will receive an InTone device and instructions on how to properly use it at home. Study subjects will be evaluated at intervals during the 12-week study period for progress, physical changes and safety factors. Subjects will complete incontinence questionnaires at regular intervals and complete a "bladder diary."

In most cases the root cause of urinary incontinence is poor muscle tone in the pelvic floor muscles – caused by childbirth, lack of exercise, too much high-impact exercise, obesity, trauma, age, or other factors. Most women who "leak" endure their problem in silence. Absorbent pads and diapers, if used, do nothing to treat the condition. Medications, if prescribed, can cause side effects and are not always effective. Surgery, if performed, can be traumatic and painful, and is not always effective. Research has shown that even when properly taught how to perform pelvic floor, or Kegel, exercises, about half of all women do them incorrectly.

InTone is an inserted device that combines mild micro-current stimulation (similar to a TENS unit), exercises and guided biofeedback to strengthen the muscles in the pelvic floor. After prescribing InTone, the physician customizes the settings for InTone and the patient is shown how to properly insert and position the device. A sensor in the unit measures pressure to determine if the patient is doing the exercises properly. The biofeedback unit uses voice-guided instruction to take her through the routine and reports her muscle isolation and strength. Each daily session takes about ten minutes and is done in the privacy of the patient's own home. Data from each session is recorded, and after two weeks or so, the physician analyzes the recorded data and adjusts InTone based on the patient's progress. At-home treatment sessions continue, with additional checkups to evaluate progress. It is anticipated that patients will experience progress in a few weeks, and may experience effective relief in about 90 days.

According to Michael Guralnick, MD, principal investigator for the MCW study, data

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from daily InTone sessions will be collected and analyzed by the study investigators. "This is just as a physician who prescribes InTone would do," said Dr. Guralnick. "In an efficacy study, we aim to determine whether the treatment delivers its intended result - and to what degree it does so. In other words, does it effectively treat urinary incontinence." Secondly, the study will measure improvement in pelvic floor muscle tone, improvement in sexual function based on a questionnaire, and finally, the usability and tolerability of the InTone device.

According to the National Association for Continence:

- Two-thirds of men and women age 30-70 have never discussed bladder health with their doctor.
- On average, women wait 6.5 years from the first time they experience symptoms until they obtain a diagnosis for their bladder control problems.
- Two-thirds of individuals who experience loss of bladder control symptoms do not use any treatment or product to manage their incontinence.

"We want women to know that 'leaking' isn't normal, it could get worse, and it can be effectively treated," said Herschel "Buzz" Peddicord, president and CEO of InControl Medical, LLC, and inventor of InTone. "We encourage women to talk to their doctors about it - and we encourage doctors to ask their patients."

In pre-market testing, 85 percent of test subjects who used InTone reported that their incontinence symptoms disappeared. "Obviously we are excited about that," said Peddicord. "We believe InTone can be the new standard of care for the treatment of female urinary incontinence, or unwanted bladder leakage."

InTone is now available by prescription to patients in the United States. It was developed by InControl Medical, LLC, an FDA-listed company based in Brookfield, Wisconsin providing specialty medical products for women's health, and is sourced and manufactured entirely in the United States. More information on InTone can be found at [www.incontrolmedical.com](http://www.incontrolmedical.com) [1].

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