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An Innovative New System for Urine Specimen Collection

A new, non-invasive device to collect and manage urine for culture for women can expedite diagnosis and treatment while minimizing risk, costs, and the over-prescription of antibiotics.

Obtaining a urine specimen from a female with urinary incontinence using a catheter creates unnecessary risk. Similarly, obtaining a mid-stream or clean catch specimen from a continent female, commonly leads to a contaminated sample. Patient risks and sample contamination can be averted using an innovative system for urine specimen collection.

TillaCare, Ltd. has introduced the patented UriCap Female. Multiple independent, clinical studies of the UriCap Female have demonstrated that the device is safe, effective, accurate, and comfortable.

Females with Urinary Incontinence

The involuntary leakage of urine, urinary incontinence (UI), is common and undertreated. Approximately 50% of adult women suffer from urinary incontinence, but only 25 to 61% of women with symptoms seek professional help.[1, 2]

UTI Frequency & Prevalence

- Urinary tract infections (UTI) are one of the most common diagnoses treated in the US. Approximately 4 million urine tests are made and approximately 1 million UTIs are treated every year in United States emergency departments leading to 100,000 hospitalizations annually.[3, 4, 5]
- One of the challenges in female patients experiencing urinary incontinence is recurrent UTIs. An estimate of 10% of women aged more than 65 years reported UTI in the last 12 months.[6, 7, 8] This number increase to up to 30% in women aged more than 85 years, commonly leading to confusion, kidney infection, and hospitalization if not identified and treated early.[6]
- UTIs have also become one the most common hospital-acquired infections, accounting for as many as 40% of nosocomial infections, noted as the second most common cause of bacteremia in hospitalized patients. [8, 9]

Urine Specimen Collection & Contamination

- Obtaining a representative urine sample and returning a fast, accurate diagnosis are important to minimize both time-to-treatment and excessive use of antibiotics.
- The existing, low risk standard, solution for collecting urine samples in women is a mid-stream clean catch (MSCC). MSSC is non-invasive with negligible risk. MSSC is indicated when the woman can self-collect using an appropriate educational intervention. Contamination rates are high and diagnostic accuracy does not vary significantly in self-collected MSSC with or without prior cleansing. [10, 11]
- Urine specimen contamination commonly skews urine specimen interpretation leading to inaccurate diagnosis and a sequela of care including unnecessary antibiotic use, the potential for adverse drug reactions, and increased risk for additional complications. Contamination also drives increased costs for both the patient and the health care system.
- The higher risk specimen collection method, with narrowly defined indications, is via urinary catheterization, either intermittent, indwelling, or suprapubic are collected under sterile conditions. Catheterizations can cause an infection not already present and are not indicated for routine urine specimen collection or for urinary incontinence.

Solution: An Innovative New System for Urine Specimen Collection

The UriCap Female is an innovative new system for urine specimen collection and management to improve the ease of urine collection and reduce use of catheters in women with urinary incontinence. The UriCap Female is appropriate for across the continuum of care from acute to post-acute care, specialty practice and primary care, including use at home with coverage by Medicare and many insurances.

The UriCap Female

- The UriCap Female system utilizes a small, soft cup made from medical grade silicone which is attached to a short silicone tube and a standard urinary drainage bag.
- The UriCap Female does not require skin adhesives or an external suction source, making it unique from other external urinary collection devices.
- The UriCap Female is applied directly to the skin around the urethra and is designed to stay in its application location using naturally occurring adhesive forces for up to 24 hours.
- Once the UriCap Female is applied, the first urine specimen can be utilized for a clean catch or mid-stream specimen.

Clinical Investigation: Urine Specimen Collection using the UriCap Female

In 2021, the UriCap Female was studied for the purpose of urine specimen collection in a prospective, single-arm, open-label, interventional, pilot clinical investigationIn Carmel hospital (urology department) Haifa, leaded by PI Dr. Friedman Boris

- Thirty-six (n=36) females were recruited for the collection of non-contaminated urine samples for culture in adult female subjects
- Twenty-none (29) subjects enrolled and completed the study with seven (7) subjects failure screening. Safety, performance, and satisfaction were the outcomes of the clinical
- investigation.

- Results for performance and safety demonstrated that out of the 29 urine samples collected using the device and analyzed at the microbiological laboratory of the medical center, only 1 sample was contaminated (1/29, 3.44%), while 28 samples were not contaminated (28/29, 96.55%). Urine contamination was defined as "mixed growth bacteria", with threshold of equal to or greater than (≥) 10,000 Colony-Forming Units per mL (CFU/mL), with 2 or more isolates.
- For the safety outcome, none of the study participants experienced any adverse events (ADEs, SADEs or UADEs) during the clinical investigation.
- For usability, a high 3.55 score was provided for convenience and ease of insertion of the device (1-5) which represent study staff satisfaction levels of between slight to moderate.
- Contamination rates detected using the UriCap Female device were well below the contamination rates reported in several surveys and clinical investigations performed over the years on the same target population, using the same urine collection methods, albeit with different devices.

Conclusion

Urine specimen contamination in women, with and without urinary incontinence, leads to unreliable results, and consequentially misdiagnosis, improper treatments, and an increased cost of care. Compared with other methods, the UriCap Female was shown to shorten time to diagnose and mitigate health care induced infection, preventing empirical over prescription of antibiotics and unnecessary hospitalization. Innovative external female catheters, such as the UriCap Female, can support evidence-based program to reduce urine specimen contamination rates in female urine specimen collections.

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