Urinary Catheter System with decreased risk of contamination

Invention Summary
A novel catheter system has been designed to decrease the risk of contamination of urine specimens with peri-urethral bacteria when obtaining urine specimens from patients via bladder catheter.

Medical Need
Urinary tract infection (UTI) is a common clinical problem in infants and young children, and in those under two years of age it has been associated with urinary tract damage. Pediatric UTIs account for 0.7% of physician office visits and 5–14% of emergency department visits by children annually. Accurate diagnosis of UTI has important clinical implications. However, the presenting signs and symptoms of UTI in childhood are often nonspecific and, among infants, definitive testing for UTI involves bladder catheterization.

Urine culture is the criterion standard for diagnosis of UTI, and specimens are commonly obtained via bladder catheterization. Bladder catheterization is the most common method of obtaining urine specimens for culture in infants and young children. Contamination of urine obtained by bladder catheterization can be recognized by the presence of multiple pathogens or nonpathogens on urine culture.

Due to the anatomy of patients under two years of age, specifically girls and uncircumcised boys, when UTI is to be determined using a bacterial culture, it is difficult to obtain a urine specimen that is not contaminated with perimeatal bacteria. The perimeatal bacteria are the bacteria naturally found around the external opening of the urethra. This contamination may lead to a number of false positive results and potentially lead to improper and ineffective medical interventions such as unnecessary antibiotic therapy and diagnostic studies.

Studies have been carried out to investigate rates of contamination, incidences of false positives and patient populations at higher risk of contaminated urine specimens.

- One study involving 185 infants recorded a contamination rate of 14.6%
- Another study analyzed data from 83 infants and showed a high false-positive rate of 71.1%
- Infants younger than 6 months and uncircumcised boys, may be at higher risk of contaminated urine specimens obtained by urethral catheterization

Data
Preliminary patient data using the current prototype suggest that the novel catheter system does reduce the risk of contamination:

- one positive culture in 18 uses
- historical rates would predict approx. 4 positives in an equivalent number of patients.

References