



## CLINICAL EVIDENCE DOSSIER

# Spigot Guard

Catheter-Associated Urinary Tract Infection  
Prevention via the Drainage Spigot

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## SCOPE

This dossier compiles evidence pertaining to the role of the drainage spigot in the pathogenesis of catheter-associated urinary tract infections, drawing from published literature, mechanism studies, and clinical implementation data.

Each section reproduces source materials in their original voice.

*Compiled April 2026 • Spigot Guard LLC*

SECTION 1 • PUBLISHED LITERATURE

## CAUTI Pathogenesis

Foundational study characterizing the routes by which microorganisms gain access to the catheterized urinary tract.

### Source

Tambyah, P. A., Halvorson, K. T., & Maki, D. G. (1999). A Prospective Study of Pathogenesis of Catheter-Associated Urinary Tract Infections. *Mayo Clinic Proceedings*, 74(2), 131–136.

### Study Design

Prospective study of 1,497 newly catheterized patients. Paired quantitative urine cultures were obtained daily from the catheter specimen port and from the collection bag, using a technique capable of detecting 1 colony-forming unit per milliliter. The investigators developed criteria to distinguish extraluminal from intraluminal acquisition based on the timing and relative concentration of organisms appearing in each sample.

### Findings

Among 235 new-onset CAUTIs, the probable mechanism of infection could be determined for 173 cases (69.2%). Of these 173 determinable cases, 115 (66%) were classified as extraluminally acquired, and 58 (34%) were classified as intraluminally acquired.

**Among CAUTIs where the pathogenetic mechanism could be determined (173 of 235 cases), 34% were intraluminally acquired.**

### Authors' Conclusion

The authors concluded that CAUTIs occur by both extraluminal and intraluminal portals of entry. They recommended that strategies for prevention focus on technologies preventing access of organisms by all possible routes.

## SECTION 2 • MECHANISM

# Drainage Spigot Pocket Contamination Study

Preliminary clinical data evaluating the Foley catheter drainage spigot pocket as a potential microbial reservoir.

### Investigator

Kelly Hiatt, MD — Chief Science Officer, ENT Surgeon

### Background

Catheter-associated urinary tract infections (CAUTIs) remain a significant source of healthcare-associated infections. While infection prevention efforts often focus on catheter insertion technique and maintenance, less attention has been given to the Foley catheter drainage spigot and its storage pocket. The drainage spigot pocket may act as a reservoir for microorganisms, creating the potential for contamination of the drainage port during routine urine drainage.

### Purpose

To evaluate whether the Foley catheter drainage spigot pocket contains organisms capable of causing urinary tract infections and to assess the potential for recontamination of the drainage spigot after manual disinfection.

### Methods

Cultures were obtained from the drainage spigot pocket of Foley catheter urine bags in 52 patients. Samples were collected between Day 2 and Day 7 following catheter placement and cultured to identify the presence of organisms associated with urinary tract infections. The presence and frequency of microbial growth were analyzed to determine the extent of contamination within the pocket reservoir.

### Results

Cultures demonstrated that 65% of drainage spigot pocket samples (34 of 52) grew organisms associated with urinary tract infections. These findings indicate that the drainage spigot pocket functions as a microbial reservoir.

**65% of Foley drainage spigot pockets harbored bacteria associated with CAUTI — collected as early as Day 2 post-insertion.**

Notably, contamination was detected as early as Day 2 following catheter insertion — a finding that underscores the importance of protective measures beginning at the time of placement, not after a period of clinical observation. Even when the drainage spigot is manually disinfected prior to urine drainage, reinsertion of the spigot into the contaminated pocket may result in immediate recontamination.

### Conclusion

The Foley catheter drainage spigot pocket represents a previously underrecognized source of contamination. Standard manual disinfection of the drainage spigot prior to and after urine drainage may not be sufficient to maintain sterility if the spigot is subsequently reinserted into a contaminated pocket. The early onset of contamination — identified within the first days of catheter use — indicates that any protective intervention must be applied at the time of insertion to be clinically meaningful.

### Clinical Implications

Because a high percentage of drainage spigot pockets harbor uropathogenic organisms — beginning as early as Day 2 post-insertion — additional protective measures are warranted from the outset of catheter placement. Placement of a Spigot Guard on the drainage spigot at the time of Foley catheter insertion, with replacement after each drainage access, may help protect the spigot from recontamination and potentially reduce the risk of CAUTIs. This approach directly addresses the window of vulnerability identified in this study — the period immediately following insertion during which pocket contamination is already established.

## SECTION 3 • MECHANISM

# Spigot Drain Isolate Profile

Proof-of-concept culture of indwelling-catheter drainage spigots, identifying the organisms recovered from the drain itself.

### Source

Spigot Guard proof-of-concept evaluation. Indwelling-catheter drainage spigots cultured by standard methods, with recovered organisms identified to species.

### Findings

Ten indwelling-catheter drainage spigots were cultured. Every drain grew at least one organism associated with urinary tract infection. Across the ten drains, six distinct uropathogen species were recovered, accounting for nineteen total isolates. Most drains were polymicrobial, carrying more than one species.

**10 of 10 spigot drains (100%) grew recognized CAUTI-causing organisms.**

### Organisms Recovered, by Drain

Spigot drain	Proteus	Klebsiella	E. coli	S. aureus	S. saprophyticus	P. aeruginosa	Species
Drain 1	-	-	-	-	-	✓	1
Drain 2	-	-	-	✓	✓	-	2
Drain 3	✓	-	✓	-	-	-	2
Drain 4	-	✓	-	✓	-	-	2
Drain 5	-	-	✓	-	-	-	1
Drain 6	-	-	-	✓	-	-	1
Drain 7	-	-	-	✓	✓	-	2
Drain 8	-	-	-	✓	✓	✓	3
Drain 9	-	✓	-	-	✓	-	2
Drain 10	✓	-	✓	-	-	✓	3
<b>Drains positive</b>	<b>2</b>	<b>2</b>	<b>3</b>	<b>5</b>	<b>4</b>	<b>3</b>	<b>19</b>

Every organism recovered is a recognized cause of catheter-associated urinary tract infection.

### Clinical Implications

The drainage spigot is not a passive component. In this proof of concept, the spigot of every catheter sampled carried at least one uropathogen, and most carried more than one. A contamination source this consistent and this diverse is structural rather than incidental. This is the intraluminal pathway Spigot Guard is designed to close at the drainage point, with a single-use cap replaced after each access.

## SECTION 4 • SAFETY

# Safety Study with Concurrent CAUTI Observation

Initial 1,000 Foley catheter day evaluation of the Spigot Guard device, with safety as the primary endpoint and CAUTI events recorded as a concurrent observation during the study period.

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### Study Details

**Site:** Community East Hospital, Indianapolis, Indiana, USA

**Principal Investigator:** Kelly Hiatt, MD

**Study Period:** March 1, 2025 – April 30, 2025

**Exposure:** 1,000 Foley catheter days with Spigot Guard in use

### Study Design and Endpoint

The study was designed and conducted as a safety evaluation of the Spigot Guard device across 1,000 Foley catheter days at Community East Hospital. The primary endpoint was the documentation of any adverse events associated with use of the device. The study was not designed or powered as an efficacy trial.

### Safety Outcome

No adverse events were documented during the 1,000 catheter day study period. This finding was confirmed in writing by the Principal Investigator:

*“I am writing to confirm that in our initial 1,000 catheter day study of Spigot Guard, performed at my institution, there were no documented adverse events.”*

— Kelly Hiatt, MD, PhD, July 10, 2025

### Concurrent CAUTI Observation

During the same 1,000 catheter day period in which Spigot Guard was used, no catheter-associated urinary tract infections (CAUTIs) were reported. By comparison, five CAUTI cases occurred during the previous 1,000 Foley catheter day period at the same institution without Spigot Guard use.

The Principal Investigator has noted that this concurrent observation follows a quasi-experimental pre/post intervention design that mirrors the model used by Curo Cap to demonstrate associations with reductions in CLABSI rates.

*Methodology disclosure.* The CAUTI observation reported in this section is concurrent with the safety endpoint, not a primary efficacy endpoint. The study was not randomized, controlled, or blinded. Pre and post intervention periods reflect sequential observation at a single site. The five-case figure for the pre-intervention period reflects events identified during the corresponding prior 1,000 catheter day window at the same institution.

SECTION 5 • REAL-WORLD IMPLEMENTATION

# Thomas Hospital Spigot Guard Evaluation

Quasi-experimental pre/post comparison of urine culture positivity associated with indwelling urinary catheters at Thomas Hospital, before and during the Spigot Guard implementation period.

## Source and Attribution

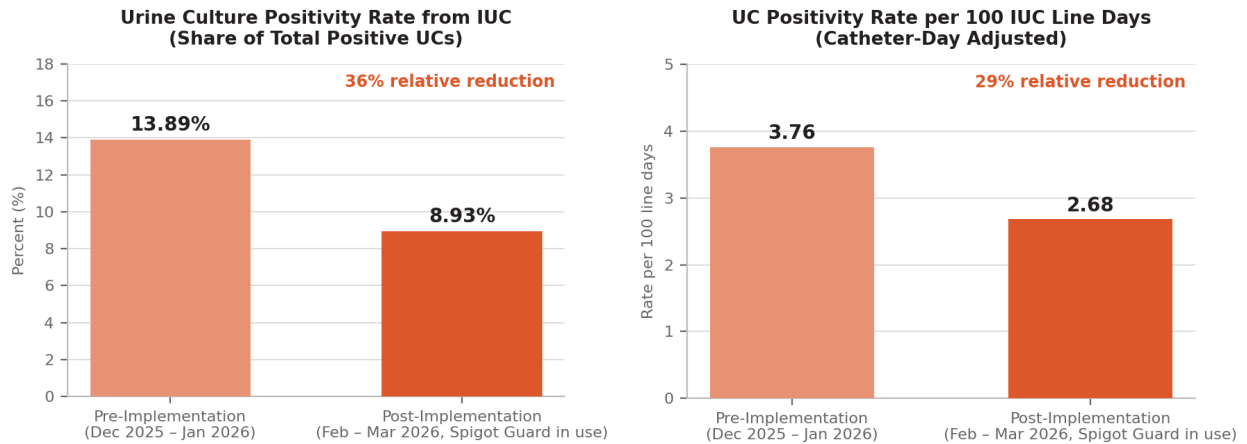
**Source data:** Thomas Hospital internal quality improvement evaluation.

**Pre/post analytical framing and presentation:** Spigot Guard.

**Considerations:** Reproduced verbatim from Thomas Hospital materials.

## Study Periods

- **Pre-Implementation:** December 2025 – January 2026
- **Post-Implementation (Spigot Guard in use):** February – March 2026



Source data: Thomas Hospital. Charts prepared by Spigot Guard.

## SECTION 5 • REAL-WORLD IMPLEMENTATION (CONTINUED)

### Data Table

TH Spigot Guard Evaluation	Pre-Implementation Dec 2025 – Jan 2026	Post-Implementation Feb – Mar 2026 (Spigot Guard in use)
Pos UC from IUC	15	10
Total Pos UC	108	112
<b>Urine Culture Positivity Rate Collected From IUC (%)</b>	<b>13.89</b>	<b>8.93</b>
Total IUC Days	399	373
<b>UC Positivity Rate from IUC per 100 Line Days</b>	<b>3.76</b>	<b>2.68</b>

Source data: Thomas Hospital Spigot Guard Evaluation 2026.

### Observed Reductions

**Urine Culture Positivity Rate from IUC:** 13.89% pre-implementation → 8.93% post-implementation. Absolute reduction of 4.96 percentage points; relative reduction of 36%.

**UC Positivity Rate from IUC per 100 Line Days:** 3.76 pre-implementation → 2.68 post-implementation. Absolute reduction of 1.08; relative reduction of 29%. Indwelling catheter device utilization remained relatively stable across the two periods (399 line days pre vs. 373 line days post).

*Note on denominator:* rates are presented per 100 catheter days to reflect the actual observation period. Both arms accumulated fewer than 1,000 catheter days; per-100 reporting avoids extrapolation beyond the observed window.

### Study Design

Quasi-experimental pre/post implementation observation conducted at Thomas Hospital. Use of the Spigot Guard device was associated with a reduction in positive urine cultures during the implementation period. This study design demonstrates association, not causation.

#### Considerations (reproduced verbatim from Thomas Hospital evaluation materials)

- Small sample size
- No adjustment for patient acuity or culturing practices
- Potential seasonal variation

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REFERENCES

## Source Materials

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1. Tambyah, P. A., Halvorson, K. T., & Maki, D. G. (1999). A Prospective Study of Pathogenesis of Catheter-Associated Urinary Tract Infections. *Mayo Clinic Proceedings*, 74(2), 131–136.
2. Hiatt, K. (2025). Foley Catheter Drainage Spigot Pocket Microbial Contamination Study — Preliminary Clinical Data. Spigot Guard.
3. Spigot Guard. (2025). Spigot Drain Isolate Identification — Proof of Concept. Indwelling-catheter drainage spigot cultures.
4. Hiatt, K. (2025). Spigot Guard Pilot Safety Study, Community East Hospital, Indianapolis, IN. Conducted March 1 – April 30, 2025. Safety attestation correspondence dated July 10, 2025.
5. Thomas Hospital. (2026). Spigot Guard Trial 2026 — Internal Quality Improvement Evaluation.