CAPABILITY STATEMENT

Infection Prevention Solutions for Federal & Healthcare Systems

COMPANY OVERVIEW

Spigot Guard LLC develops practical, FDA-listed infection-prevention solutions designed to improve patient safety and reduce contamination risks associated with catheter drainage systems. Our flagship device, the Spigot Guard Cap, actively disinfects internal and external drain surfaces and provides a protective barrier for catheter drainage spigots — helping healthcare facilities strengthen infection prevention protocols without disrupting clinical workflows. The solution is designed for hospitals, long-term care facilities, and federal healthcare systems including Military Treatment Facilities (MTFs) and Veterans Health Administration Medical Centers.

PROBLEM STATEMENT

Catheter drainage spigots are frequently exposed during routine patient care and become significant points of environmental contamination. The intraluminal pathway through the drainage port accounts for 34% of all CAUTIs — yet standard practice does not disinfect or protect the spigot between drainage events, leaving this pathway completely unaddressed. CAUTIs represent one of the most common and costly healthcare-associated infections, with each event costing an estimated $17,889 (Agency for Healthcare Research and Quality 2017, carried forward to 2025 dollars using the U.S. Bureau of Labor Statistics Medical Care Consumer Price Index), and rising to as much as $29,270 at high-acuity facilities, and CMS no longer reimburses facilities for these preventable complications. Infection prevention teams seek simple, cost-effective tools that actively address this gap.

CORE COMPETENCIES

CAPABILITY	DESCRIPTION
Medical Device Innovation	FDA-listed, 510(k)-exempt Class II device (Product Code: KNX | Reg. 876.5250) that actively disinfects internal and external drain surfaces of the spigot and provides a protective barrier between drainage events
CAUTI Prevention — Dual-Action	Addresses two contamination mechanisms simultaneously: active disinfection of the spigot contact surfaces and physical protection from environmental exposure between uses
Healthcare Workflow Integration	Designed to integrate seamlessly into existing nursing catheter management protocols with minimal training and no meaningful time impact
Government Healthcare Engagement	Active engagement with Defense Health Agency (DHA/OPMED) for MTF product evaluation; outreach to VA Medical Centers nationwide

KEY DIFFERENTIATORS

ADVANTAGE	DESCRIPTION
FDA-Listed Class II Device	510(k)-exempt | Product Code KNX | Regulation 876.5250 | Establishment #1064584 — fully compliant for federal procurement

Dual-Action: Disinfection + Protection	Unlike a standard cap, the Spigot Guard actively disinfects both the internal lumen and external surfaces of the drainage spigot, then seals it against environmental contamination until the next drainage event
Addresses an Overlooked Pathway	The intraluminal pathway through the catheter drainage port accounts for 34% of all CAUTIs. The spigot is routinely exposed and accessed multiple times per day during bag emptying — a documented contamination point not addressed by standard CAUTI prevention bundles
Minimal Workflow Impact	Clinical evaluations confirm device adds less than 1 minute or no additional time to routine catheter care
Visual Compliance Cue	Bright orange color serves as a visible reminder to maintain spigot protection and thorough cleaning protocol
Cost-Effective	Low unit cost with quantifiable downstream savings in CAUTI treatment, CMS penalties, and litigation exposure
Broad Applicability	Hospitals, long-term care, VA medical centers, and Military Treatment Facilities
Patent Pending	U.S. Patent Application No. 63/382,815 — Filed November 8, 2022

FLAGSHIP PRODUCT

PRODUCT DETAIL	INFORMATION
Product Name	Spigot Guard Cap — Urine Collection Bag Drain Cap
Mechanism of Action	Actively disinfects internal and external surfaces of the catheter drainage spigot; provides a sealed protective barrier between drainage events to prevent environmental contamination
Regulatory Status	FDA-listed Class II medical device, 510(k)-exempt
FDA Classification	Collector, Urine (and Accessories) for Indwelling Catheter
Device Class	Class II
Product Code	KNX
Regulation Number	876.5250
Registered Establishment	DemeTech Corp. | Establishment #1064584
SAM.gov Registration	Active

PAST PERFORMANCE

Spigot Guard has completed and is actively building clinical evaluation experience across U.S. healthcare facilities.

Thomas Hospital — Fairhope, Alabama | Outcomes Study + Clinical Evaluation (Med-Surg Unit)

9 Nurse Evaluators | Med-Surg Unit | 1–20 Catheterized Patients Per Evaluator During Trial

100%	of nurses would support continued use of Spigot Guard on their unit
100%	agreed or strongly agreed Spigot Guard is a valuable addition to their CAUTI prevention bundle
100%	agreed or strongly agreed the orange color served as a visual reminder to maintain protection
8 / 10	average likelihood to recommend Spigot Guard to a colleague (scores ranged 5–10)
80%	of nurses observed no issues during use
< 1 min	impact on routine catheter care — majority reported no time added or less than 1 minute

Notable Nurse Comments:

- *"The bright color is a reminder to thoroughly clean the catheter line and spigot."*
- *"More availability" — nurse feedback requesting broader product access*

Pre/post outcomes data (preliminary, unpublished): Quasi-experimental pre/post observation. Pre-implementation (Dec 2025 – Jan 2026): IUC-associated urine culture positivity rate of 13.89%. Post-implementation (Feb – Mar 2026, Spigot Guard in use): 8.93% — a 36% relative reduction. Catheter utilization remained stable across the two periods (399 vs. 373 line days). The cap was the only practice change during the implementation period. Considerations noted by Thomas Hospital: small sample size; no adjustment for patient acuity or culturing practices; potential seasonal variation. Demonstrates association, not causation. Additional active evaluations underway across 11 facilities in 7+ states. First customer conversion: Monadnock Community Hospital, Peterborough, NH.

Foley Catheter Drainage Spigot Pocket Microbial Contamination Study | Kelly Hiatt, MD (Chief Science Officer)

52 Patients | Foley Catheter Drainage Spigot Pocket Cultures | Day 2 to Day 7 Post-Insertion Sampling

Mechanistic data (preliminary, unpublished): Cultures were obtained from the drainage spigot pocket of Foley catheter urine bags in 52 patients, sampled between Day 2 and Day 7 following catheter placement. 65% of pocket samples (34 of 52) grew organisms associated with urinary tract infections — with contamination detected as early as Day 2 post-insertion. The drainage spigot pocket functions as a microbial reservoir; even when the spigot is manually disinfected prior to drainage, reinsertion into the contaminated pocket may result in immediate recontamination. This finding identifies a window of vulnerability that begins at the time of catheter placement and is not addressed by standard manual disinfection of the drainage spigot. Ongoing collection in progress.

GOVERNMENT & FEDERAL ENGAGEMENT

ORGANIZATION	ACTIVITY
Defense Health Agency (DHA/ OPMED)	Active engagement with DHA/OPMED leadership for Spigot Guard product evaluation consideration within Military Treatment Facilities (MTFs)
Veterans Health Administration	Active outreach to VA Medical Centers regarding infection prevention solutions and CAUTI reduction programs
SAM.gov / Federal Procurement	Active registration: UEI SJ7YALTGUNK7 | CAGE 19M12 | NAICS 339113 | PSC 6515

COMPANY INFORMATION

IDENTIFIER	INFORMATION
Company Name	Spigot Guard LLC
Socio-Economic Status	Woman-Owned Small Business (WOSB)
SAM.gov Status	Active Registration
UEI	SJ7YALTGUNK7
CAGE Code	19M12
DUNS Number	12-578-5462
Tax ID (TIN)	92-3481439
NAICS Code	339113 — Surgical Appliance & Supplies Manufacturing
Product Service Code (PSC)	6515 — Medical & Surgical Instruments, Equipment & Supplies
FDA Registration	Establishment #1064584 | Device Class II | Product Code KNX | 510(k)-exempt
Patent Status	Patent Pending — U.S. Application No. 63/382,815 | Filed November 8, 2022

CONTACT INFORMATION

CONTACT DETAIL	INFORMATION
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