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Major study confirms ClearGuard® HD Antimicrobial Barrier Caps significantly reduce catheter-related bloodstream infection and associated hospitalizations

Results published in the American Journal of Kidney Diseases today represent an important breakthrough for hemodialysis patient care in the United States

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MAPLE GROVE, Minn.--(BUSINESS WIRE)--In a key milestone, Pursuit Vascular announced today that the American Journal of Kidney Diseases (AJKD) has published an Original Investigation entitled, "Dialysis Catheter-Related Bloodstream Infections: a Cluster-Randomized Trial of the ClearGuard HD Antimicrobial Barrier Cap". This trial represents the largest prospective evaluation of a device for preventing catheter-related bloodstream infections (BSIs). In this trial, BSIs were represented by positive blood cultures. Results show the novel ClearGuard HD caps provide a clear and significant benefit to patient health in a real-world setting, and are easy to use without changing procedural workflow.

The 12-month, prospective, multicenter, cluster-randomized trial included 2,470 patients accruing approximately 350,000 treatment-days at 40 dialysis centers across the United States. Participating centers were randomized to either treat patients using ClearGuard HD caps (treatment group) or standard caps (control group and the current standard of care). As reported by the AJKD, trial findings demonstrate sustained use of ClearGuard HD caps resulted in a 69% lower BSI rate ($P = 0.01$), 43% fewer hospital admissions for BSI ($P = 0.04$), and 51% fewer hospitalization-days for BSI ($P = 0.04$). All patients with an appropriate catheter were entered into the study, no patients were excluded, and no device-related adverse events were reported.

Over 15 million catheter-based dialysis procedures are performed annually in the United States, with BSIs serving as a leading cause of hospitalization and death in these patients. According to the Centers for Disease Control and Prevention (CDC), dialysis patients are particularly vulnerable to infection, suffering 37,000 potentially deadly BSIs related to their dialysis treatment every year.

In a call to action, the CDC recently [announced](#) their "*Making Dialysis Safer for Patients Coalition*", a broad syndicate of kidney and dialysis organizations with a goal to significantly reduce catheter-related BSIs using evidence-based best practices and new tools. Additionally, the American Society of Nephrology recently [announced](#) their "*Nephrologists Transforming Dialysis Safety*" through infection prevention initiative, in partnership with the CDC, to improve safety for patients with dialysis catheters. The 3-year, \$2.2 million effort is designed to reduce catheter-related BSIs and strengthen infection control practices in dialysis settings.

"The publication of these groundbreaking results in a leading peer-reviewed journal marks the culmination of a large product development effort and a major turning point in the fight against bloodstream infections," said Doug Killion, President and CEO of Pursuit Vascular. "It's incredibly exciting to announce that the dialysis community now has an evidence-based tool that significantly reduces BSIs. It's also very rewarding to provide a product which dramatically improves patients' lives – to reduce hospitalizations, suffering and death. We look forward to supporting the industry as it looks for effective ways to reduce catheter-related BSIs and improve dialysis patient safety."

About the ClearGuard HD Antimicrobial Barrier Cap

The ClearGuard HD Antimicrobial Barrier Cap is the first and only device cleared for sale in the U.S. that kills infection-causing bacteria inside a long-term hemodialysis catheter, triggering the creation of new Product Code (PEH) by the Food and Drug Administration (FDA). This simple yet revolutionary single-use device is protected by six issued U.S. patents, and several other U.S. and International patent applications are pending. For more information visit www.clearguardhd.com

About Pursuit Vascular

Headquartered in Maple Grove, Minnesota, Pursuit Vascular, Inc. is developing a family of innovative single-use products designed to protect patients from acquiring life-threatening infections associated with long-term catheter and port use, while reducing the cost of healthcare. For more information visit www.pursuitvascular.com

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