

FDA Broadens ClearGuard® HD Antimicrobial Barrier Cap Indications

ClearGuard HD Caps Have Been Shown to Reduce Central Line-Associated Bloodstream Infections in Hemodialysis Patients

Maple Grove, Minn., May 30, 2018 /PRNewswire/ – Pursuit Vascular, Inc., manufacturer of ClearGuard HD Antimicrobial Caps, the leading antimicrobial device for catheter-based dialysis patients, today announced that the U.S. Food and Drug Administration (FDA) granted clearance for a broader indication of the company’s ClearGuard HD caps to include reduction in the incidence of central-line associated bloodstream infection (CLABSI) in hemodialysis patients with central venous catheters (CVCs). The safety and efficacy of the ClearGuard technology is well established, and ClearGuard HD caps were first cleared for use with hemodialysis catheters in 2013. The expanded clearance was based on post-market clinical surveillance data.

Bloodstream infection is the leading cause for hospitalizations and the second leading cause of death in hemodialysis patients, and catheters cause 70% of these infections. The ClearGuard HD cap is the first and only device cleared for sale in the U.S. that kills infection-causing bacteria inside a long-term catheter. The caps are simple to use, yet highly effective and clinically shown to reduce bloodstream infection.

The expanded clinical indications are a result of a recent study published in the April 2018 *Journal of the American Society of Nephrology*. The study, conducted by DaVita® Clinical Research, demonstrated that use of ClearGuard caps vs. Tego Connector plus Curoc caps, lowered the rate of BSIs in hemodialysis patients using CVCs. The study builds on prior research conducted by Frenova® Renal Research (Fresenius Kidney Care), published in 2017 in the *American Journal of Kidney Diseases*, demonstrating that use of ClearGuard HD caps vs. standard CVC caps lowered the rate of BSIs in hemodialysis patients using CVCs.

“Bloodstream infections can have a devastating effect on patients and contribute significantly to health care costs for insurers and patients,” said Doug Killion, President and CEO of Pursuit Vascular. “Dialysis patients are particularly vulnerable to infections, and ClearGuard HD caps represent a lifesaving tool that have a real impact on these patients’ lives.”

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. The caps are simple to use and clinically shown to reduce central line-associated bloodstream infection. This simple, yet revolutionary single-use device is protected by 7 issued U.S. patents, and several other U.S. patents pending. Foreign patents issued and pending. For more information, visit www.clearguardhd.com

About Pursuit Vascular

Headquartered in Maple Grove, Minnesota, Pursuit Vascular, Inc. (www.pursuitvascular.com) is developing a family of innovative products designed to protect patients from acquiring life-threatening infections associated with long-term catheter and port use, while reducing the costs of health care.

Connect with us at www.pursuitvascular.com and on Twitter at @ClearGuardHD.

Source: Pursuit Vascular, Inc.

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