

ClearGuard[™] HD

Antimicrobial Barrier Caps for Hemodialysis Catheters

Clinically proven to reduce the rate of CLABSIs in hemodialysis catheter patients



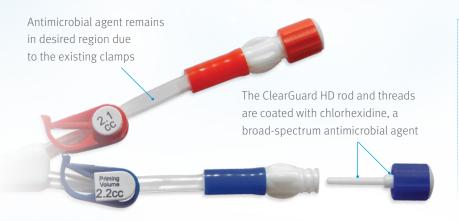
Reduce hemodialysis catheter infections with clinically proven technology

Catheter infections are frequent, costly, and deadly

- > Catheters cause 70% of vascular access-related BSIs and central venous catheters (CVCs) are used in only 19% of all dialysis procedures in the United States¹
- > Central line-associated bloodstream infections (CLABSIs) are a leading cause of hospitalizations and the second leading cause of death in hemodialysis patients^{1,2}
- > CLABSIs are very expensive, with an estimated increase in healthcare costs of approximately \$30,919–\$65,245, with an average of \$45,814 per infection³

Reduce hemodialysis catheter infections by up to 63%

The ClearGuard HD antimicrobial barrier cap is the first and only device for sale designed to kill infection-causing bacteria inside a hemodialysis catheter hub.* ClearGuard HD features a rod that extends into the hemodialysis catheter hub. The rod and cap threads are coated with chlorhexidine, a well-known broad-spectrum antimicrobial agent.



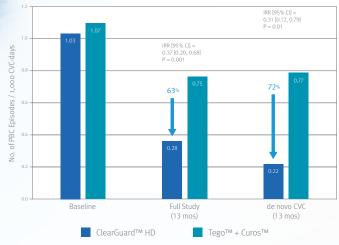
- When the ClearGuard HD cap is inserted into a liquid-filled catheter, chlorhexidine elutes from the rod into the catheter lock solution
- The chlorhexidine coating dissolves to kill microorganisms on the inside and outside of the catheter hub
- > The existing catheter clamp holds the antimicrobial agent inside the catheter hub between treatments
- ClearGuard HD caps are used in place of a standard cap or connector

*Designed to kill microorganisms, not intended to be used for treatment of existing infections.

Clearguard HD antimicrobial barrier caps have been clinically proven to reduce CLABSIs in hemodialysis catheter patients^{4,5}

Multiple large, prospective, cluster-randomized multicenter open-label trials demonstrated a significant reduction in the rate of positive blood cultures (PBCs) and CLABSIs using ClearGuard HD caps versus control groups.





ClearGuard HD Caps vs. Tego[™]+ Curos[™]

Brunelli, SM et al. Cluster-randomized trial of devices to prevent catheter-related bloodstream infection.

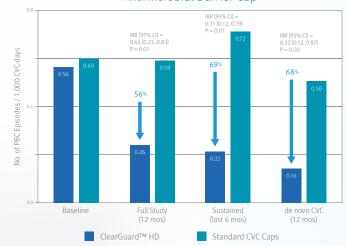
J Am Soc Nephrol 2018 Apr; 29(4):1336-1343.

- 13-month prospective, cluster-randomized multicenter open-label trial
- > 1,671 patients (826 treatment, 845 control) accruing ~183,000 CVC days
- > 40 centers across the US
- > Primary endpoint was PBC rate as an indicator of BSI rate

Results: Use of the ClearGuard HD caps for 13 months was associated with a 63% lower BSI rate vs. use of Tego + Curos.



Dialysis Catheter-Related Bloodstream Infections: A Cluster-Randomized Trial of the ClearGuard HD Antimicrobial Barrier Cap



ClearGuard HD Caps vs. Standard Dialysis Caps

Hymes, JL et al. Dialysis catheter-related bloodstream infections: A cluster-randomized trial of the ClearGuard HD antimicrobial barrier cap. Am J Kidney Dis. 2017; 69(2):220-227.

- 12-month prospective, cluster-randomized, multicenter, open-label comparative effectiveness trial in hemodialysis patients with central venous catheters
- > 2,470 patients (1,245 treatment, 1,225 control) accruing ~350,000 CVC days
- > 40 centers across the US
- > Primary endpoint was PBC rate as an indicator of BSI rate

Results: Use of the ClearGuard HD caps for 12 months was associated with a 56% lower BSI rate vs. use of standard caps. When considering sustained use (defined as 6 months of the study), the intervention vs. control was associated with a 69% lower BSI rate.

ClearGuard HD antimicrobial barrier caps used by leading hospitals and clinics

For years, dialysis staff at hospitals and clinics have focused on educational initiatives to reduce bloodstream infections in hemodialysis patients with limited impact. ClearGuard HD caps succeed in reducing infections by killing bacteria where bloodstream infections start-inside the hemodialysis catheter hub. With over 400 hospitals and over 3,700 outpatient dialysis clinics as customers, ClearGuard HD caps are becoming an increasingly important part of hemodialysis infection control best practices.







These infection control products were evaluated using four criteria: effectiveness, safety (to both patient and healthcare worker), successful real-world implementation, and the stability of the company (to support future implementations).



ClearGuard HD caps recommended in NKF's KDOQI Clinical Practice Guideline for Vascular Access: 2019⁶

21.3 KDOQI considers it reasonable to use an antimicrobial barrier cap to help reduce CRBSI in high-risk patients or facilities; the choice of connector should be based on clinician's discretion and best clinical judgment. (Expert Opinion)



KDOQI

ClearGuard HD caps selected as one of the 100 Infection Control Products to Know for three years in a row

2017 Becker's 105 Infection Control Products to Know, 2018 & 2019 Becker's 100 Infection Control Products to Know



Recommended in the UKs NICE National Guidance for hemodialysis catheter-related bloodstream infections: 2021**

https://www.nice.org.uk/guidance/mtg62/

Product Ordering information

Product Code	Case Quantity	Product Description
CGHD-100	100	ClearGuard™ HD Caps (1 Red, 1 Blue)



1 Nguyen OB, Shugart A, Lines C, Shah AB, Edwards J, Pollock D, Sievert D, Patel PR. National healthcare safety network (NHSN) dialysis event surveillance report for 2014. Clin J Am Soc Nephrol 12(7), 1139-1146, 2017. United States Renal Data System. 2018 USRDS annual report: Epidemiology of kidney disease in the Unites States. National Institutes of Health, Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.

- 3 Zimlichman, E et al. Health care-associated infections: a meta-analysis of costs and financial impact on the US health care system. IAMA Intern Med. 2013;173(22):2039-2046.
- 4 Brunelli, SM et al. Cluster-randomized trial of devices to prevent catheter-related bloodstream infection. J Am Soc Nephrol. 2018 Apr, 29(4):1336-1343.
- 5 Hymes, IL et al. Dialysis catheter-related bloodstream infections: a cluster-randomized trial of the ClearGuard HD antimicrobial barrier cap. Am I Kidney Dis. 2017 Feb:69(2)220-227.
- 6 Lok CE, Huber TS, Lee T, et al; KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019 update. Am J Kidney Dis. 2020;75(4)(suppl 2):S1-S164.

Contact us today to find out how ClearGuard HD can play a large role in your infection control practices. Visit www.icumed.com or call 866.488.6088



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