



ClearGuard™ HD

Antimicrobial Barrier Caps for Haemodialysis Catheters

Clinically proven to reduce the rate of bloodstream infections in haemodialysis catheters and recommended in the UK's National Institute for Health and Care Excellence (NICE) Medical Technologies Guidance [MTG62]

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Reduce haemodialysis catheter infections with clinically proven technology

Catheter infections are frequent, costly, and deadly

- › Increased infection rates are associated with use of invasive devices, in particular, central lines, urinary catheters, and ventilators.¹
- › 15-38% of patients receive haemodialysis using a central venous catheter (CVC) in European countries.²
- › CLABSIs are very expensive with an estimated additional length of stay of 4-14 days and *additional* costs per episode of €4200-13 030 in European countries.¹

Reduce haemodialysis catheter infections by up to 63%³

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

Antimicrobial agent remains in desired region due to the existing clamps

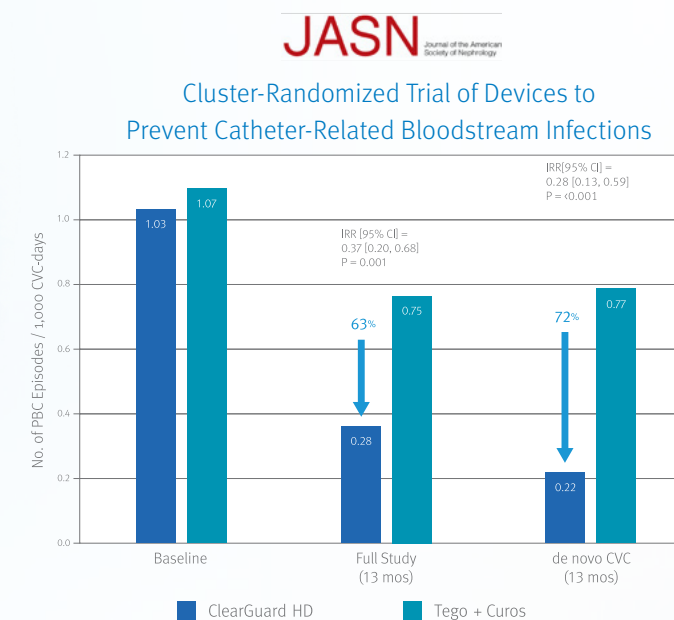
The ClearGuard HD rod and threads are coated with chlorhexidine, a broad-spectrum antimicrobial agent

- › 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 haemodialysis catheter patients^{3,4}

Multiple large, prospective, cluster-randomised 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.

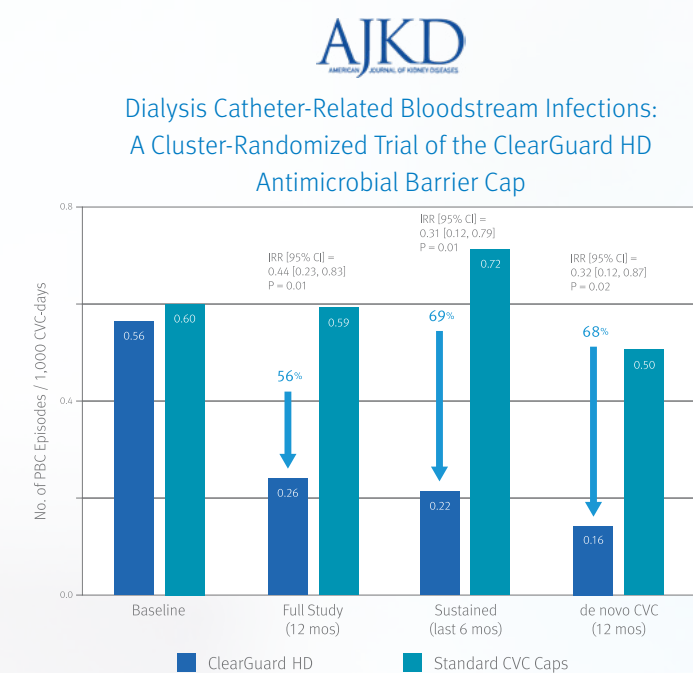


ClearGuard HD Caps vs. Tego™ + Curoc™

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-randomised 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 + Curoc.



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-randomised, multicenter, open-label comparative effectiveness trial in haemodialysis 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 US hospitals and clinics

For years, dialysis staff at hospitals and clinics have focused on educational initiatives to reduce bloodstream infections in haemodialysis patients with limited impact. ClearGuard HD caps succeed in reducing infections by killing bacteria where bloodstream infections start-inside the haemodialysis catheter hub. With over 950 hospitals and over 4,600 outpatient dialysis clinics as customers, ClearGuard HD caps are becoming an increasingly important part of haemodialysis infection control best practices.



Recommended in the UK's NICE National Guidance for preventing haemodialysis catheter-related bloodstream infections: 2021**

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

ClearGuard HD antimicrobial barrier caps recommended by NICE for preventing catheter-related bloodstream infections in people with central venous catheters having haemodialysis.



ClearGuard HD caps named in *Newsweek's* Best Infection Prevention Products two years in a row

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).



National
Kidney
Foundation®

KDOQI®
Kidney Disease
Outcomes Quality Initiative

ClearGuard HD caps recommended in NKF's KDOQI Clinical Practice Guideline for Vascular Access: 2019⁵

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)

Product Ordering information

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



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 +44 (0)203 357 9400

¹ Report on the Burden of Endemic Health Care-Associated Infection Worldwide, World Health Organization. 2011.

² Pisoni, RL et al. Trends in US Vascular Access Use, Patient Preferences, and Related Practices: An Update From the US DOPPS Practice Monitor With International Comparisons. *Am J Kidney Dis.* 2015 Jun;65(6):905-15.

³ 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.

⁴ 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 Feb;69(2):220-227.

⁵ 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.

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